

## UR 1: Utilization Review Policy

Department: KPNW Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Kathy Fazio, RN

Number: UR 1  
Issued: 10/03  
Reviewed: 10/03, 12/04, 12/05, 12/06, 1/08, 1/09, 3/10, 3/11, 10/11,  
10/12, 3/13, 3/14, 3/16, 3/17, 3/18  
Revised: 4/10, 3/11, 10/11, 10/12, 3/15  
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**PURPOSE**

To ensure that all criteria used to evaluate the necessity of medical and behavioral healthcare services are developed, adopted and applied according to national and community standards, as applicable, and are compliant with external and internal regulatory standards.

**POLICY**

- A. Written, objective, evidence-based criteria will guide Utilization Review (UR) clinical determinations of medical necessity within KPNW. The Regional Operations Quality Group (ROQG) has the ultimate authority and responsibility for the criteria used within the region. Responsibility for implementation of the regional UR program, including the criteria development and adoption process, is delegated to the UR Associate Medical Director with the assistance of the UR Oversight Committee (UROC).
- B. The UR Department is charged with working with clinical departments to develop, evaluate, and implement the UR decision-making criteria for targeted services. Criteria are available to all practitioners upon request and can also be accessed via the UM website on the KPNW intranet. Notification of the availability of criteria and how to obtain criteria is provided to internal providers and external contracted providers via the annually-distributed QM/RS Provider Bulletin.
- C. Unless nationally-recognized criteria exist, the need to develop criteria will be evaluated when:
  1. A service contractually requires health plan prior-authorization for coverage;
  2. Care, service, procedure, admission, or equipment is a higher cost than other acceptable alternatives;
  3. There is evidence that care, service, procedure, admission, or equipment has been over- utilized;
  4. There is evidence that care, service, procedure, admission, or equipment has been mis-utilized;
- D. In the process of development or adoption of medical necessity criteria, the UROC committee will ensure the following:
  1. Criteria are based on sound medical evidence, on a consensus of relevant health professionals and/or on community standards, or are imposed by a funding source such as Medicare.
  2. Criteria are objective.
  3. Criteria are developed with input from and approval by practitioners with professional knowledge or clinical expertise in the area of medical care reviewed. This includes, but is not limited to primary care and specialty care practitioners, psychologists, behavioral health specialists, addiction medicine specialists, social workers, clinical nurse specialists, pharmacists and podiatrists. Staff assures alignment with current Clinical Practice Guidelines (CPGs) and medical evidence. When criteria are reviewed or updated it is the practice of Kaiser Permanente to review the most current clinical practice guidelines during the review/revision process to ensure alignment. In addition, criteria will be updated when there are mid-cycle changes to CPGs that are prompted by new medical evidence or guidelines.

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4. Criteria are typically designed for uncomplicated patients and for use within a comprehensive delivery system, therefore, criteria application by the physician reviewers must also include consideration of the member's individual needs and the availability of services within the local delivery system.
  - a. At a minimum, consideration must include:
    - i. Age
    - ii. Co-morbidities
    - iii. Complications
    - iv. Home environment, as appropriate
    - v. Progress of -treatment
    - vi. Psychosocial situation
  - b. Consideration is given to the characteristics of the local delivery system available for specific patients, for example:
    - i. the availability of inpatient beds, skilled or sub-acute care, post hospital discharge care or home care,
    - ii. coverage of benefits for skilled nursing facilities, sub-acute care facilities or home care where needed,
    - iii. local hospitals' ability to provide all recommended services within the estimated length of stay.

When criteria aren't met, it's the responsibility of the physician reviewers to determine if UM guidelines and criteria are appropriate for a specific complex case and/or when the local delivery system may be inadequate to meet the patient's needs. When factors indicate that criteria are not appropriate, reviewers will consult with clinical experts, including UM physician reviewers and/or board-certified physician consultants, as appropriate.

5. Criteria are reviewed and updated annually and as necessary by practitioners with professional knowledge or clinical expertise in the area of medical care reviewed.  
Please see [UR 4: Medical Necessity Determinations](#) for additional requirements.
6. Criteria are to be used by trained physician and non-physician staff.  
Please see [UR 4: Medical Necessity Determinations](#) for additional requirements.
7. Only a Northwest Permanente (NWP) physician (MD or DO) can make a decision to deny a service based on medical necessity for Oregon or Washington Kaiser Permanente health plan members. Exceptions: Chiropractic denial determinations for Washington members are performed by a physician or a chiropractor;  
Partial or fully adverse determinations for Medicare members are performed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, with a current and unrestricted license to practice within the scope of his or her profession.

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8. There is no incentive for staff and physicians involved in utilization review processes and medical necessity determinations to deny, limit, or discontinue medical care/services. Please see [UR 3: Appropriate Care and Services, KPNW Affirmation of Incentive Policy](#) for additional information.
9. Criteria are applied in a consistent manner between reviewers. Please see [UR 35: Consistency of UR Application \(Inter-rater Reliability\)](#) for additional information.
10. There are appeal processes for members and/or practitioners who disagree with a medical necessity determination resulting in a denied service. Please see [UR 26: Appeals of Adverse Determinations](#), for additional information. In addition, the treating/requesting practitioner is notified of the reviewing physician's availability to discuss UM denial decisions via the provider denial notification as well as the annually-distributed QM/RS Provider Bulletin.
11. There are timeliness standards that support utilization decisions to accommodate the clinical urgency of the situation. Please see [UR 4: Medical Necessity Determinations](#).
12. Non-plan, non-emergent inpatient referred services are subject to pre-authorization processes. Please see [UR 28: Onsite Utilization Review Process](#) for additional information.
13. Utilization Review Care Coordinators (e.g., SNF Coordinators, et al) and/or Physician Advisors will assist the attending physician and other health care team members in optimal utilization of acute care resources by concurrently reviewing and assessing the individual member's medical condition and health care needs and by formulating recommendations for appropriate options or alternative care settings, if any, with the attending physician, utilizing reference guidelines/criteria (including sources such as MCG, CMS regulations, benchmark data, and expert knowledge of available resources in various care settings).
14. If a member has a continued need (meets criteria) for health care services when their benefit ends, the service department that is providing or overseeing the care of the member will assist the member's transition of care by providing educational information on accessing alternative sources of continued care. Please see [UR 2: Transition To Other Care After Benefit Ends](#), for additional information.
15. Emergency services are covered when necessary to screen and stabilize members without prior approval in cases where a prudent layperson, acting reasonably, would have believed that an emergency medical condition existed. KPNW also covers emergency services if an authorized representative, acting for the organization, authorized the provision of emergency services. Although KPNW may review clinical cases to identify opportunities for member and provider education regarding the appropriate use of the Emergency Department, emergency services will not be retrospectively denied based on medical necessity.

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**DEFINITIONS**

Prudent layperson- a person without medical training who draws on his or her practical experience when making a decision regarding whether medical emergency treatment is needed. A prudent layperson is considered to have acted reasonably if other similarly situated laypersons would have believed, on the basis of observation of the medical symptoms at hand, that emergency medical treatment was necessary. Severe pain and other symptoms may constitute such emergency cases.

Authorized representative- an employee or contractor of KPNW who directs the member to seek services, for example, an advice nurse, network physician or customer service representative. (An ED practitioner is not considered an authorized representative of the organization unless they participate in the organization's practitioner network).

**RESPONSIBILITIES****Determining the need for development of new medical necessity criteria**

Requests for Medical Necessity Criteria development may come from many sources including, but not limited to, the Inter-regional New Technology Committee (INTC), Regional Benefits Committee (RBC), and Service/Specialty areas based on grievance and appeals data, changes in regulations, and identified Health Plan population-based needs of the Northwest region.

UR staff will:

1. Identify criteria to be reviewed.
2. Identify the subject matter experts (appropriate specialty practitioners) involved in the development and annual review of the criteria.
3. Identify any required regulatory standards for determinations, including Washington, Oregon, CMS and NCQA regulations or guidelines.
4. Identify any required Evidence of Coverage: i.e., benefits or other contractual requirements.
5. Perform benchmark search (including but not limited to other Kaiser regions, other insurance companies, and MCG).
6. Present findings and recommendations to the UROC for review and recommendation for further development or determination that new criteria are not needed.
7. Reviewed/revised criteria are posted to the UR website two weeks after UROC approval.

**Assuring the annual review of medical necessity criteria**

During the annual review process and when a request for medical necessity criteria is received, UR department staff may review utilization data, which could include volume, cost, denials and appeal overturn decisions.

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**SPECIAL GROUP CONSIDERATIONS**

None

**REFERENCES****NCQA**

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

**CMS**

Code of Federal Regulations (CFR), Title 42, Chapter IV, Subchapter B, Part 422:

**WASHINGTON**

WAC 284-43-410 & RCW 48.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

**OREGON**

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans



## UR 2 TRANSITION TO OTHER CARE AFTER BENEFIT END

Department: Social Work  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Aimee Guardado, Program Manager for Quality Improvement

Number: UR 2  
Effective: Issued 04/02  
Reviewed and/or Revised: 02/02, 02/03, 02/04, 4/05, 6/06, 08/07, 8/08, 8/09, 8/11, 8/13, 8/14, 8/15, 9/17  
Last Revised:  
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### PURPOSE

To describe the policy for educating the Member/Member’s representative regarding alternatives for continuing care and how to obtain care when benefit coverage ends, for approved medically necessary care.

### POLICY

The organization offers qualified members assistance in transition to other care when benefits end. This policy applies to members who are receiving approved services but whose benefit coverage will end while the members still need the medically necessary care.

### DEFINITIONS

None

### PROCEDURES

- A. Service Departments identify qualified members through service extension requests for previously-approved care and assess the member’s need for continued medically necessary care when benefits end, including but not limited to the following types of coverage:
  - 1. Specific benefit exhaustion
    - a. Skilled Nursing Facility
    - b. Durable medical equipment (DME)
    - c. Physical Therapy, Occupational Therapy and Speech Therapy
    - d. Chiropractic treatments
  - 2. Lifetime, annual, other maximum is reached
  - 3. Member loses insurance coverage: Please see **Non-member policy**
  
- B. Service Departments identify available resources within the local community and offer to provide the Member/Member’s representative with information to make an informed decision about obtaining needed healthcare.  
Alternative resources may include but are not limited to:
  - 1. Financial alternatives within Kaiser Permanente (such as dues subsidy programs or charitable care)
  - 2. External funding programs
    - a. Federal Medicaid, SSI, Public Health Department
    - b. State Subsidized Medicaid, or basic health insurance, FHIAP (Family Health Insurance Assistance Program) which is available in all states; Washington DSHS (Department of Social and Health Services), state maternity support services/infant case management; Oregon DHS (Department of Health and Human Services); OMAP (Office of Medical Assistance Program); OHP (Oregon Health Plan)
    - c. Locally funded programs/health clinics



**UR 2 TRANSITION TO OTHER CARE AFTER  
BENEFIT END**

Department: Social Work  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Aimee Guardado, Program Manager for  
Quality Improvement

Number: UR 2  
Effective: Issued 04/02  
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- 3. Other community Providers
  - a. Shriners Hospital for orthopedic care
  - b. Doernbecher Children's Hospital for childhood cancers
  - c. Vendors for DME
- 4. National or Community Associations
  - a. Lion's Club for eyewear
  - b. Diagnosis-specific associations such as the American Diabetes Association
- 5. **www.211info.org** : *211info* is a nonprofit information and referral service for health and human services that connects people in need to services. All information is also included in print directories and on the *211info* website. This listing is provided free for community agencies, non-profits, and government agencies.

**SPECIAL GROUP CONSIDERATIONS**

None

**REFERENCE**

**NCQA**

NCQA Standards and Guidelines are updated annually and available by contacting Quality Resource Management at 503-813-3850. NCQA 2017: QI 8, Element D

**WASHINGTON**

RCW 284-43-410 & RCW 483.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

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ORS 743.804: Requirements to provide criteria and information about utilization management

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## UR 3: Appropriate Care and Services, KPNW Affirmation of Non-Incentives Policy

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Department: Utilization Review

Number: UR 3

Applies to: KPNW Region

Issued: 5/00

Review Responsibility: Kathy Fazio, RN

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### PURPOSE

Kaiser Permanente Northwest (KPNW) adjudicates all requests, claims and appeals in a manner designed to ensure the independence and impartiality of the people involved in making coverage determinations. Utilization Management decision making is based only on the appropriateness of care and service and the existence of coverage. KPNW does not specifically hire, reward, compensate, terminate or promote practitioners or other individuals for issuing denials of coverage or care nor do financial incentives for UM decision makers encourage decisions that result in under-utilization.

### POLICY

- A. Care and services for Kaiser Foundation Health Plan of the Northwest are provided based on the appropriateness of the care and service for individual health care needs and coverage under the member's medical plan.
- B. Appropriate care is achieved by optimizing resource use in the provision of patient care. Inappropriate care occurs when there is over-utilization, under-utilization and/or mis-utilization of resources. The Health Plan objective is to appropriately provide for the health care needs of individual members and the membership at large through judicious use of available resources and use of an organized and effective approach to identify and minimize over-, under-, or mis-utilization.
- C. KPNW does not make payments or offer other financial incentives (i.e. base compensation or bonuses on measures that would encourage denial or withholding of care) to encourage providers or physicians and staff involved in utilization management (UM) decisions to deny or withhold care or services from our members or that would encourage under-, over-, or mis-utilization.
- D. The Utilization Review Oversight Committee (UROC) ensures that communication of affirmation statements regarding incentives is provided on an annual basis to all members, and to all practitioners, providers and employees who make UM decisions.
- E. KPNW is required under state and federal law to provide information to our Commercial, Medicaid, and Medicare members related to any risk-sharing arrangements with physicians and other practitioners and to explain any compensation arrangements designed to encourage practitioners to withhold services or avoid referrals. In addition, KPNW is required to provide members with summary information on how decisions are made regarding coverage and payment for treatment or services, including a general description of prior authorization and utilization review requirements that affect payment or coverage. This information is provided through annual reports submitted to our regulators and is contained in other member collaterals including the KPNW *Medical Directory* and the member's *Evidence of Coverage*.
- F. This policy does not preclude the use of appropriate incentives for fostering efficient and appropriate care.

### DEFINITIONS: None



**UR 3: Appropriate Care and Services, KPNW  
Affirmation of Non-Incentives Policy**

Department: Utilization Review

Number: UR 3

Applies to: KPNW Region

Issued: 5/00

Review Responsibility: Kathy Fazio, RN

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**RESPONSIBILITIES**

KPNW will communicate this affirmation statement regarding incentives:

- to all members through the annual provision of the Medical Directory;
- to internal and external/contracted practitioners and providers through the annual distribution of the QM/RS Provider Bulletin; and
- to staff who make UM decisions through an email sent at least every other year.

**SPECIAL GROUP CONSIDERATIONS**

Medicare	None
Washington Medicaid	None
Oregon Medicaid	None
Feds	None
PEBB	None

**REFERENCES****NCQA**

UM Standard 4.G: Affirmative Statement about Incentives

**Washington**

RCW 48.43.510 2 (d) &amp; (e), WAC 284-43-410: Utilization Review

**Oregon**

ORS 743.804 6(d): Requirements for insurer offering health benefit plan

**CMS (Medicare)**

42 CFR Chapter IV § 438.210: Managed Care

42 CFR Chapter IV § 438.6: Managed Care

## UR 4: Utilization Management Medical Necessity Determinations

Department: Member Relations

Number: UR 4

Applies to: KPNW Region

Issued: 3/95

Review Responsibility: UROC

Reviewed: 3/96, 3/97, 6/99, 3/00, 6/02, 1/03, 1/04, 7/04, 4/05,

SME: Kathy Fazio, RN

5/06, 9/06, 11/07, 11/08, 1/09, 5/09, 9/09, 10/10, 10/12, 9/13, 9/15, 9/16

Last Revised: 10/11, 9/14, 2/16, 11/16, 3/17, 10/17

### PURPOSE

To define standards, accountabilities, and processes for departments who are responsible for reviewing requests from clinicians, members or their designated representatives for initial medical necessity review determination for specific items, services or care requiring medical necessity review.

### DEFINITIONS AND ABBREVIATIONS

CIDARS: Customer Information Documentation and Reporting System.

Concurrent Review: any review for an extension of a previously approved, ongoing course of treatment (typically associated with inpatient care or ongoing ambulatory care).

DO: Doctor of Osteopathy.

ERISA: Employee Retirement Income Security Act (of 1974).

NCQA: National Committee for Quality Assurance

Urgent Care Request: any request for medical care or treatment (pre-service or concurrent) with respect to which the application of time periods for making nonurgent care determinations:

- i. could seriously jeopardize the life or health of the member, the life or health of a fetus, or the member's ability to regain maximum function, based on a prudent layperson's judgment, **or**
- ii. in the opinion of a practitioner with knowledge of the member's medical condition, would subject the member to severe pain that cannot be adequately managed without the care or treatment that is the subject of the request.

Admissions, continued stays or other health care services for a member who received emergency services but has not been discharged from a facility will also be considered urgent requests.

### POLICY

- A. Departments who respond to clinicians', members' or their designated representatives' requests for items, services or care based on medical necessity, make decisions in a consistent, equitable, timely manner in accordance with the applicable criteria.
- B. When a pre-service request procedure is not followed, for example, a request is directed to the wrong person or department, the member (or provider if applicable) is notified and informed of the correct procedure to follow in order to initiate the request. This notice is provided as soon as possible, not to exceed 24 hours for urgent requests and two days for non-urgent requests. The notification can be verbal unless the member requests it in writing.
- C. All requests for services subject to a utilization review process for medical necessity determinations will have established regional policies and procedures applied outlining the accountabilities, timeliness, processes, and documentation of same, which are consistent with all regulatory requirements and accrediting standards and have been approved by the Utilization Review Oversight Committee.

## UR 4: Utilization Management Medical Necessity Determinations

Department: Member Relations

Number: UR 4

Applies to: KPNW Region

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Review Responsibility: UROC

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SME: Kathy Fazio, RN

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## D. Medical necessity determinations include:

- Decisions about covered medical benefits;
- Decisions about care or services that could be considered either covered or not covered, depending on the circumstances;
- Dental services and procedures that may be covered under the medical benefit;
- Out-of-network services that are only covered in clinically appropriate situations (e.g. when covered, medically necessary services are not available in-network);
- Authorizations for pharmaceuticals requiring prerequisite drug(s) for a step therapy program;
- Requests for known or potential “experimental” or “investigational” services.

## E. Benefit determinations include:

- Services that are specifically excluded in the member’s benefits plan;
- An extension of services in the member’s benefits plan that are limited by number, duration or frequency;
- Care that does not depend on any circumstances.

## F. Appropriate reviewing personnel include:

1. For Approvals: Licensed healthcare professionals, including designated pharmacists, physician assistants, nurse practitioners, nurses, PhDs, and mental health counselors, make UM decisions that require clinical judgment (e.g. assessing if a member’s reported condition meets medical necessity criteria for treatment and determining appropriate level and intensity of care). Staff members who are not qualified healthcare professionals may collect data for preauthorization and concurrent review under the supervision of appropriately licensed health professionals and may also have the authority to approve (but not to deny) services for which there are explicit criteria.
2. For Denials: Initial Medical Necessity denials are completed by one of the following (MD or DO):
  - a. a Utilization Management physician;
  - b. the Doctor-of-the-Day (a locums physician); or
  - c. an appropriate specialist;whose education, training or professional experience is appropriate, and who is practicing with a current, unrestricted license.  
Exception: Chiropractic denial determinations for Washington Commercial and Medicare members may be performed by a chiropractor.

Licensed physicians oversee UM decisions pertaining to behavioral healthcare and non-behavioral healthcare to ensure consistent medical necessity decision-making and to provide high-level involvement in complex cases. The Regional Referral Center (RRC) provides specifically trained and designated nursing professionals who are responsible for selected pre-service, concurrent, and retrospective review activities, and screening of cases through the use of published and organizationally-developed criteria. The RRC is supervised by a Registered Nurse who ensures consistent criteria application, participates in staff training

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and monitors documentation adequacy. The supervisor has day-to-day involvement in UM activities and is consistently available onsite.

- G. Staff and physicians involved in approval or denial processes will review appropriate clinical information for the individual patient involved, for example, the clinical information sent with the request, by accessing the patient's electronic record, and/or by consultation with the ordering clinician. Information may include but is not limited to lab results, consultations, history and physical examination reports, medication history and imaging reports. Physicians involved in medical necessity determinations will utilize clinical expertise, knowledge of availability of resources/services in the local delivery system, and supporting clinical information related to the patient's individual needs and safety (age, co-morbidity, complications, and progress of treatment, psychosocial and home environment, as applicable). The organization will consult with board-certified specialists, when appropriate, for assistance with UM decision making. A list of board-certified specialists is maintained within the Regional Referral Center. Verification of board-certification occurs annually and as the specialists accept the consultant role.
- H. Members are notified via the annually-distributed Medical Directory of the availability of free language interpretation services. In addition, each non-Medicare denial notice (initial and appeal) will include an offer of non-English language assistance. Medicare requirements are met via the annually-distributed Medical Directory and a 5% threshold determined from our service area on a yearly basis by CMS further assessment. The language interpretation services will be provided, upon request and free of charge, in a linguistically and culturally appropriate manner by a professional interpreter service.
- I. Written denial notification to members contain:
- information sufficient to identify the claim/request, including (when applicable) the date of service, the provider, and the claim amount;
  - the specific reason and complete explanation of the grounds for the denial (also called the "discussion of the decision") communicated in plain, easily understandable language that does not include abbreviations or acronyms nor defined or healthcare procedure codes that are not explained.
  - a reference to or the complete criteria, benefit provision, guideline or protocol on which the denial decision was based, specific to the member's condition or to the requested service(s) . When complete criteria are not provided, notification is provided that the member can obtain upon request and free of charge, a copy of the actual benefit provision, guideline, protocol or other similar criterion on which the decision was based;
  - denial codes and their meaning, when applicable;
  - an offer to provide diagnosis and procedure codes, as well as their meanings, to members upon request;
  - disclosure of the availability of, and contact information for, the applicable office of health insurance consumer assistance to assist people with the appeals and external review processes;
  - the state-specific or product-specific Appeal Brochure, which includes: (also see UR 26, Appeals Policy)
    - the available internal appeal process, including the expedited appeal process for urgent pre-service and urgent concurrent services, how to initiate an appeal, the timeframes that appeals

## UR 4: Utilization Management Medical Necessity Determinations

Department: Member Relations

Number: UR 4

Applies to: KPNW Region

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SME: Kathy Fazio, RN

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will be resolved, and the timelines in which to file an appeal (NOTE: the timeline in which to file an appeal varies by line of business, for example, commercial members are provided 185 days to file an appeal while Medicare Advantage members are provided 60 days.

- the right of members to appoint a representative to act on their behalf at all levels of appeal (this must be in a signed, written statement granting specific permission);
- the right to submit written comments, documents, or other information relevant to the appeal and the right to telephonically present evidence and testimony as part of the internal claims and appeals process;
- the right to review and/or receive a free copy of the appeal file, upon request;
- the provision of continued coverage pending the outcome of an appeal in urgent and concurrent care situations;
- the requirement to participate in one internal appeal before a member can take legal action or before a member's appeal can be considered for external review. Exceptions:
  - Claimants must first exhaust the internal appeals process unless the health plan failed to comply with appeal rules whereby causing prejudice or harm to the claimant's right to external review;
  - Individuals who qualify for an expedited appeal review (urgent care situations and individuals receiving an ongoing course of treatment) will be allowed, upon request, to proceed simultaneously with an expedited external review while pursuing the internal appeal process.

When members request a copy of the benefit provision, guideline, protocol or other similar criterion on which the denial decision was based, the information will be mailed to the member within five business days of receipt of the request. The provision of the information will be documented in a CIDARS addendum with a reference to the specific information provided (name of the specific document is sufficient) and the date it was mailed.

In addition to receiving a copy of the member's initial denial notification, the ordering practitioner's denial notification contains a description of how to contact the reviewing physician to discuss the medical necessity denial determination.

- J. Kaiser Permanente strives to comply with all regulations related to timelines for UM decision-making, notification and extensions, however, due to conflicting requirements put forth by the states (Oregon and Washington), federal regulators and accrediting agencies, the most stringent timelines are applied. Although NCQA allows extensions to pursue additional clinical information when necessary to make UM decisions, the following turn-around time requirements for provider requests are strictly adhered to and efforts to obtain necessary information will be made within these timeframes (see "I" below for exception related to Medicare):

## UR 4: Utilization Management Medical Necessity Determinations

Department: Member Relations

Number: UR 4

Applies to: KPNW Region

Issued: 3/95

Review Responsibility: UROC

Reviewed: 3/96, 3/97, 6/99, 3/00, 6/02, 1/03, 1/04, 7/04, 4/05,

SME: Kathy Fazio, RN

5/06, 9/06, 11/07, 11/08, 1/09, 5/09, 9/09, 10/10, 10/12, 9/13, 9/15, 9/16

Last Revised: 10/11, 9/14, 2/16, 11/16, 3/17, 10/17

### COMMERCIAL

- Routine Pre-service Oregon: decision and notification within two (2) business days from receipt of request.
- Routine Pre-service Washington: decision and notification within five (5) calendar days from receipt of necessary information.
- Urgent Pre-service Oregon: decision and verbal notification within two (2) business days, not to exceed 72 hours, unless the claimant fails to provide sufficient information to determine whether, or to what extent, a service should be covered. An additional three (3) calendar days is allowed to issue written notification of the decision.
- Urgent Pre-service Washington: decision and verbal notification within 48 hours, unless the claimant fails to provide sufficient information to determine whether, or to what extent, a service should be covered. An additional three (3) calendar days is allowed to issue written notification of the decision.
- Immediate Request Situations Washington: decision and verbal notification within 1 business day when the lack of treatment may result in an emergency visit or emergency admission. An additional three (3) calendar days is allowed to issue written notification of the decision.
- Retrospective Oregon and Washington: decision and notification within 30 calendar days.

### MEDICARE

- Part C Routine Pre-service and Retrospective Pre-Claim: decision and notification within 14 calendar days from receipt of request (may extend an additional 14 calendar days to obtain necessary information).
- Part C Urgent Pre-service: decision and notification within 72 hours.
- Part D Standard: Decision and notification within 72 hours.
- Part D Urgent: Decision and notification within 24 hours.

### ALL

- Urgent Concurrent: decision and notification within 24 hours from receipt of request. An additional three (3) calendar days is allowed to issue written notification of the decision.

In situations when extensions are allowed, the member will be notified of the delay as well as the information needed, in writing within the applicable decision-making time frame; the extension will be in the best interest of the member; and will be utilized to request additional clinical information needed to make a determination. The request may be denied if the additional information is not received within the applicable extension time frame, at which point the member may request an appeal.

The Organization's intent is to review and respond with a determination to the ordering clinician and the member in writing as soon as possible to accommodate the clinical urgency of the situation, not to exceed

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 5/06, 9/06, 11/07, 11/08, 1/09, 5/09, 9/09, 10/10, 10/12, 9/13, 9/15, 9/16  
 Last Revised: 10/11, 9/14, 2/16, 11/16, 3/17, 10/17

the turn-around time requirements established by state and federal regulators and accrediting agencies.

Other considerations:

1. Members' insurance benefits and eligibility are to be checked prior to review of request
  2. If a pre-service or concurrent request is approved, the item or service is ordered/scheduled. If a post-service request is approved, the item or service is authorized and appropriate payment is made to the provider or reimbursement made to the member.
  3. Denials (member letter and provider notification) are documented in CIDARS.
- K. Medicare requires diligent efforts be undertaken to obtain medical records and other pertinent documentation from a member's provider when processing coverage decisions. This is defined as a minimum of three outreach attempts (if the first two are unsuccessful) to request supporting clinical documentation. These outreach attempts will be conducted by the clinical and/or non-clinical staff involved in preparing the case for the reviewing physician or by the reviewing physician him/herself. Outreach to contracted providers who are unresponsive will be done by the reviewing physician.

Below is a summary of Medicare guidance related to outreach attempts:

<u>Case Type</u>	<u>Date of 1<sup>st</sup> Attempt</u>	<u>Subsequent Attempts</u>	<u>Allowable Contact Methods</u>
<b>Medicare Part C</b>			
Standard Organization Determinations	Within 2 calendar days of receipt of request	Subsequent request should be made in a manner that increases likelihood of making contact (consideration given to whether the Plan used multiple methods of communication)	Phone, fax, email, and/or <u>standard or overnight</u> mail with certified return receipt
Expedited Organization Determinations	Upon receipt of request	Same as above	Phone, fax, email, and/or <u>overnight</u> mail with certified return receipt

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 5/06, 9/06, 11/07, 11/08, 1/09, 5/09, 9/09, 10/10, 10/12, 9/13, 9/15, 9/16  
 Last Revised: 10/11, 9/14, 2/16, 11/16, 3/17, 10/17

Medicare Part D			
Coverage Determinations – Requests for Payment	No specific guidance on when first attempt should be made	Same as above	Phone, fax, email, and/or <u>standard or overnight</u> mail with certified return receipt
Standard Coverage Determinations	Within 24 hours of receipt of request	Same as above	Phone, fax, email, and/or <u>overnight</u> mail with certified return receipt
Expedited Coverage Determinations	Upon receipt of request	Same as above	Phone, fax, and/or email. <u>No mail</u>

**L. Urgent Concurrent requests**

- If a request to extend a course of treatment beyond the period of time or number of treatments previously approved by the organization does not meet the definition of urgent care, the request may be handled as a new request and decided within the appropriate pre-service timeframe.
- Concurrent review of specific items, services or care for acute care/skilled nursing facility care (regardless of whether previously approved), intensive outpatient and/or residential behavioral care, or previously approved service deemed urgent in nature after physician review, is reviewed and acted upon within 24 hours of receipt of the request to continue or extend coverage.
- Any request to extend a course of treatment deemed urgent in nature after physician review beyond the period of time or number of treatments shall be decided as soon as possible, not to exceed 24 hours after receipt of the request if the request was made at least 24 hours prior to the expiration of the prescribed period of time or number of treatments. If the request is received after the 24 hour timeframe, the determination must be made as soon as possible, not to exceed two business days or 72 hours”. [29 CFR §2560.503-1]

**M. Retrospective requests** are reviewed only in emergent situations when extenuating circumstances prevent a member or provider from obtaining pre-authorization. In these situations, if the provider contacts the health plan to explain the extenuating circumstance prior to submitting the claim and the services are determined to be medically necessary, the claim will not be automatically denied for lack of pre-authorization. Emergent services don't require pre-authorization, however post-stabilization care is subject to the same pre-authorization requirements that apply to all non-emergent services. (Also see UR 53 ER and Post-Stabilization Care Policy)



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5/06, 9/06, 11/07, 11/08, 1/09, 5/09, 9/09, 10/10, 10/12, 9/13, 9/15, 9/16

Last Revised: 10/11, 9/14, 2/16, 11/16, 3/17, 10/17

### SPECIAL GROUP CONSIDERATIONS:

Oregon Health Plan (OHP) members, see “OHP Dispute Resolution Policy for Handling OHP Grievances; Complaints; Actions and Appeals” for complete requirements and timeframes.

WA State Health Care Authority Healthy Options, see policy for handling “DSHS Actions and Appeals” for complete requirements and timeframes.

### REFERENCES

**NCQA:** NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Mgmt at 503-813-3850.

### WASHINGTON

*WAC 284-43-410. Utilization Review Generally*

*RCW 284-43-410 & RCW 483.43.520:* Requirement to maintain a documented utilization review program description and written utilization review criteria.

### OREGON

*OR Senate Bill 89*

*ORS 743.804:* Requirements to provide criteria and information about utilization management

*ORS 743.806:* Utilization review requirements for medical services contracts to which insurer not party

*ORS 743.807:* Utilization review requirements for insurers offering health benefit plans

*ORS 743.837:* Prior authorization requirements

### FEDERAL

*29 CFR 2560.503-1*

*Patient Protection and Affordable Care Act (PPACA), Act 1001(5) (section 2719 of the Public Health Services Act), 1004, 1251, 10101(g), 10103(d)/Reconciliation 2301(a)/Interim Final Regulations/CFR 43330/Last Revised 072211.*

## UR 5: ROUTINE FOOT CARE MEDICAL NECESSITY CRITERIA

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Department: Podiatry	Number: UR 5
Applies to: KPNW Region	Issued: 12/01
Review Responsibility: Dan Granville, DPM; Medicare Compliance	Reviewed: 12/01, 02/02, 02/03, 02/04, 07/02, 12/03, 12/04, 12/05, 12/06, 02/06, 04/07, 07/07, 07/08, 02/09, 2/10, 1/11, 1/12, 1/13, 1/14, 2/16, 1/17 Last Revised: 1/15, 1/18

### MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR ROUTINE FOOT CARE

Routine Foot Care, regardless of the provider rendering the service, involves: 1) the cutting or removal of corns and calluses; 2) the clipping, trimming, or debridement of nails; 3) shaving, paring, cutting or removal of keratoma, tyloma, and heloma; and 4) non-definitive, simple palliative treatments like shaving or paring of plantar warts which do not require thermal or chemical cautery and curettage; 5) other hygienic and preventive maintenance care in the realm of self-care, such as cleaning and soaking the feet and the use of skin creams to maintain skin tone of both ambulatory and bedridden patients, and any other service performed in the absence of localized illness, injury, or symptoms involving the foot.

### DEFINITIONS

Severe circulatory embarrassment: severe impairment or insufficiency of the circulation of the blood through arteries and veins.

Peripheral vascular disease (PVD): any abnormal condition affecting the blood vessels outside of the heart and lymphatic vessels, characterized by signs and symptoms such as numbness, pain, pallor, elevated blood pressure and impaired peripheral pulsations. Examples of PVD include arteriosclerosis and atherosclerosis.

### CRITERIA

- A. Referral to Foot Care may be covered when systemic condition(s) result in circulatory embarrassment or areas of diminished sensation in the member's legs or feet and routine foot care by a nonprofessional may pose a hazard.<sup>4</sup>
- B. Qualifying Diagnoses include:
  - 1. Foot ulcer, wounds or infection when:
    - a. Foot care is documented as a necessary and integral part of the services ordinarily covered for ulcers, wounds, or infection, and
    - b. Foot care is part of the diagnosis and treatment for ulcers, wounds, or infection.

Note: A Podiatry referral is required if documentation does not reflect that a) and b) above are met or present.
  - 2. \*\*Systemic conditions (see list) such as: Metabolic, neurologic, or peripheral vascular disease requiring scrupulous foot care by a professional and these systemic conditions have resulted in:
    - a. Severe circulatory embarrassment, or
    - b. Areas of diminished sensation in the individual's legs or feet, and

## UR 5: ROUTINE FOOT CARE MEDICAL NECESSITY CRITERIA

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Department: Podiatry	Number: UR 5
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Review Responsibility: Dan Granville, DPM; Medicare Compliance	Reviewed: 12/01, 02/02, 02/03, 02/04, 07/02, 12/03, 12/04, 12/05, 12/06, 02/06, 04/07, 07/07, 07/08, 02/09, 2/10, 1/11, 1/12, 1/13, 1/14, 2/16, 1/17 Last Revised: 1/15, 1/18

c. Specific documentation substantiates severe peripheral involvement.

Examples of the specific documentation in the medical record **(must have either 1) the Class A finding OR 2) two Class B findings OR 3) one Class B finding in addition to two Class C findings)**:

- *Class A Finding*
  - Non-Traumatic amputation of foot, or integral skeletal portion thereof or,
- *Class B Finding*
  - Absent posterior tibial pulse,
  - Three advanced topical changes required – such as: hair growth (decrease or absence of), nail changes (thickening), pigmentary changes (discoloration), skin texture (thin, shiny), skin color (rubor or redness),
  - Absent dorsalis pedis pulse,
- *Class C Findings*
  - Claudication (cramping or pain in leg muscles, related to peripheral vascular disease),
  - Temperature changes (e.g. cold feet),
  - Edema,
  - Paresthesias (abnormal spontaneous sensations in the feet),
  - Burning

3. Diabetic sensory neuropathy with documented loss of protective (LOP) sensation to the feet.

NOTE: In the absence of a systemic condition, treatment of mycotic nails may be covered. The treatment of mycotic nails for an ambulatory patient is covered only when the physician attending the patient's mycotic condition documents that (1) there is clinical evidence of mycosis of the toenail, and (2) the patient has marked limitation of ambulation, pain, or secondary infection resulting from the thickening and dystrophy of the infected toenail plate. The treatment of mycotic nails for a nonambulatory patient is covered only when the physician attending the patient's mycotic condition documents that (1) there is clinical evidence of mycosis of the toenail, and (2) the patient suffers from pain or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.

NOTE: The treatment of warts (including plantar warts) on the foot is covered to the same extent as services provided for the treatment of warts located elsewhere on the body.



## UR 5: ROUTINE FOOT CARE MEDICAL NECESSITY CRITERIA

Department: Podiatry	Number: UR 5
Applies to: KPNW Region	Issued: 12/01
Review Responsibility: Dan Granville, DPM; Medicare Compliance	Reviewed: 12/01, 02/02, 02/03, 02/04, 07/02, 12/03, 12/04, 12/05, 12/06, 02/06, 04/07, 07/07, 07/08, 02/09, 2/10, 1/11, 1/12, 1/13, 1/14, 2/16, 1/17 Last Revised: 1/15, 1/18

\*\*The diagnoses listed below represent systemic conditions that may result in the need for routine foot care (this list is not exhaustive):

Amyotrophic Lateral Sclerosis (ALS)

Arteriosclerosis obliterans (ASO, arteriosclerosis of the extremities, occlusive peripheral arteriosclerosis)

Arteritis of the feet

Buerger’s disease (thromboangiitis obliterans)

Chronic indurated cellulitis

Chronic thrombophlebitis

Chronic venous insufficiency

Diabetes mellitus

Intractable edema secondary to a specific disease, e.g. congestive heart failure, kidney disease, hypothyroidism)

Lymphedema secondary to a specific disease, e.g. Milroy’s disease, malignancy)

Peripheral neuropathies involving the feet:

- Associated with malnutrition and vitamin deficiency
  - Malnutrition (general, pellagra)
  - Alcoholism
  - Malabsorption (celiac disease, tropical sprue)
  - Pernicious anemia
  - Associated with
- Associated with carcinoma
- Associated with diabetes mellitus
- Associated with drugs and toxins
- Associated with multiple sclerosis
- Associated with uremia (chronic kidney disease)
- Associated with traumatic injury
- Associated with leprosy or neurosyphilis
- Associated with hereditary disorders
- Associated with hereditary sensory radicular neuropathy
- Associated with angiokeratoma corporis diffusum (Fabry’s)
- Associated with amyloid neuropathy

Peripheral vascular disease

Raynaud’s disease

These criteria do not imply or guarantee approval. Please check your plan to ensure coverage. Preauthorization requirements are only valid for the month published. They may have changed from previous months, and may change in future months. JULY-18



## UR 5: ROUTINE FOOT CARE MEDICAL NECESSITY CRITERIA

Department: Podiatry	Number: UR 5
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### SPECIAL GROUP CONSIDERATIONS

**Individual and Commercial group (including Feds and PEBB):** See individual member’s summary of benefits for specific coverage information. Procedures and/or services may be excluded by coverage under the member’s medical plan. In all instances, medical necessity must be established for the procedure to be a covered benefit.

**Medicare:** No special considerations

**Oregon Medicaid:** Check Linefinder/Prioritized List

**Washington Medicaid:** No special considerations

### REFERENCES

#### CLINICAL

1. CMS/NCD for Services Provided for the Diagnosis and Treatment of Diabetic Sensory Neuropathy with Loss of Protective Sensation (70.2.1)
2. CMS/LCD for Routine Foot Care (L14940), (L27486, last revised 12/2014)
3. Noridian last revision 10/2017, related to mycotic nails and plantar warts

#### BEAM Policy

<https://sites.sp.kp.org/teams/nwreg/NWHP/MABACARE/bp/beampolicy/Pages/BeamPolicyIndex.aspx>

UR 7 Skilled Nursing Facility  
Medical Necessity Criteria

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Department: Continuing Care

Section: Skilled Nursing

Applies to: KPNW Region

Review Responsibility: UROC

SME: Preston Peterson, MD & CCS Medical Director;  
Anne Mooney, Senior Manager SNF

Number: UR 7

Effective: 2/04

Reviewed: 6/07; 3/05; 4/06; 8/08; 8/09; 8/10;

8/11; 8/12; 8/13; 8/15; 9/16, 10/17, 03/18

Last Revised: 8/14, 10/17, 03/18

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**MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR SKILLED NURSING FACILITY CARE FOR COMMERCIAL, MEDICAID, AND MEDICARE BUSINESS-see Special Group Considerations for Medicare Washington Medicaid specific information**

**DEFINITIONS**

**Definitions of Skilled Nursing Facility**

1. An institution or distinct part of an institution that is primarily engaged in providing skilled nursing care and related services for the rehabilitation of injured, disabled or sick persons, and meets the requirements for participation in # 1819 of the Social Security Act and in regulations 42CFR part 483.
2. For Medicare purposes, the term SNF does not include any institutions that are primarily for the care of mental disease or tuberculosis.

**Definition of Benefit for Skilled Services**

1. Post-hospital extended care services furnished to inpatients of a skilled nursing facility are covered under the Part A hospital insurance program, commercial plans, and under Oregon and Washington Medicaid benefits.
2. Patients with hospital insurance coverage are entitled to have payment made on their behalf for the reasonable cost of covered extended care services furnished by a skilled nursing facility, or by a hospital with which the facility has a transfer agreement.
3. Part A covers up to 100 days of skilled nursing facility services per each benefit period. Oregon Medicaid Health Plan (OHP) covers up to 20 days of skilled nursing services per each benefit period. Commercial plans have various benefits periods. A benefit period begins with the first day of a Medicare covered inpatient skilled nursing stay, and ends with the close of a period of 60 consecutive days during which the member was neither an inpatient of a hospital or a SNF. As long as the beneficiary continues to be entitled to Part A, or OHP, there is no limit on the number of benefit period(s) he/she may have. There is no limit to the amount of skilled benefit days for Washington Medicaid members as long as they meet medically necessary criteria.
4. Beginning the benefit period: A benefit period begins upon admission to a qualified SNF for skilled care, even though payment for the services cannot be made because the prior hospitalization or transfer requirement has not been met.
5. See Waiver of a Three Day Stay Admission Criteria below for details on the waiver of a three-day qualifying stay.

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Department: Continuing Care

Section: Skilled Nursing

Applies to: KPNW Region

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6. Prolonging a benefit period: Beneficiaries who continue to require skilled care after exhausting their 100 days of covered Part A coverage until the close of a period of 60 consecutive days during which the beneficiary was neither an inpatient of a hospital or a SNF at a skilled level of care.

### Covered Skilled Services

1. Skilled nursing care.
2. Bed and board.
3. Physical Therapy (PT), Occupational Therapy (OT), Speech Therapy (ST).
4. Respiratory services (RT).
5. Medical/Social Services
6. Drugs and biologicals. (See below)
7. Medical services of interns and residents (see regulations for details).
8. Other health services necessary to the health of patients as are generally provided by SNFs (e.g., labs, x-ray, routine personal hygiene items and services).
9. Medical equipment, both standard and complex.
10. Medically necessary ambulance services.

### Covered Drugs and Biologicals

1. During a covered skilled stay, prescribed drugs and biologicals that are ordinarily furnished by the facility are covered. Three requirements for coverage are:
  - a. Must represent a cost to the institution, AND
  - b. Must be included in the US Pharmacopoeia, the National Formulary, or the US Homeopathic Pharmacopoeia; or, except for those unfavorably evaluated, in AMA Drug Evaluations Accepted, AND
  - c. Must be reasonable and necessary.
2. Drugs not included in the compendia are nevertheless covered if such a drug:
  - a. Was furnished during the patient's prior hospitalization, AND
  - b. Was approved by the hospital's drug therapeutic committee, AND
  - c. Is required for the continued treatment in the SNF.

UR 7 Skilled Nursing Facility  
Medical Necessity Criteria

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Department: Continuing Care

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3. Drugs used outside the facility:

- a. If the drug or biological is deemed medically necessary to permit the patient's departure from the facility, and a supply is required until he/she can obtain a continuous supply, the drugs or biologicals would be covered as an extended care service of the SNF.

### CRITERIA

Extenuating circumstances around pre-authorization and admission notification is based on the Best Practice Recommendations (BPR) put forth by the Washington Healthcare Forum operated by OneHealthPort, but are applicable to all lines of business in Oregon and Washington. Please see associated Regional UM Policy: UR Policy 70: Extenuating Circumstances Policy at <http://internal.or.kp.org/utilization/>.

### Pre-Admission Qualifying Criteria (Medicare Part A and Commercial)

- A. Entitlement to Part A Medicare or Commercial Kaiser Permanente Health Plan coverage.
- B. SNF day(s) available.
- C. Care is reasonable and necessary.
- D. The need for skilled services is certified/re-certified by a physician (MD), nurse practitioner (NP) or Clinical Nurse Specialist (CNS) (see Timing of Certifications and Re-certifications for frequency).
- E. Prior hospitalization: Part A - The patient must have been an inpatient of a hospital for a medically necessary stay of at least three consecutive days. (See Waiver of a Three Day Stay Admission Criteria regarding waiver of this and associated requirements).
- F. In addition, the patient must have been either:
  - a. transferred to a participating SNF within 30 days after discharge from the hospital (the day of discharge is not counted); or
  - b. if period of more than 30 days has elapsed, and the patient's condition makes it medically inappropriate to begin and achieve a course of treatment within 30 days after hospital discharge AND it is medically predictable at the time of hospital discharge that such care will be required within a pre-determinable time period.
- G. The care is related to prior hospitalization (NOTE: "related to" means the condition requiring skilled care was treated during the hospitalization). Or
- H. The patient has been evaluated by a physician within the last 7 days in a clinic, emergency room, or in Home Health ) and skilled care is required to prevent hospitalization.
- I. Skilled services (nursing or rehabilitation) must be needed and provided on a "daily basis" i.e., on essentially a 7-day-a-week basis, a patient whose inpatient stay is based solely on the need for skilled rehabilitation services would meet the daily basis requirement when services are needed and received on at least 5 days per week.



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Section: Skilled Nursing

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8/11; 8/12; 8/13; 8/15; 9/16, 10/17, 03/18

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### Waiver of Three Day Stay Admission Criteria (Medicare Part A)

- A. A number of Kaiser Foundation Health Plans have elected to waive the 3-day qualifying stay requirement allowing patients to be directly admitted to a SNF when medically appropriate
- B. This waiver means that a SNF stay not preceded by a qualifying stay for the 1876 Cost member must be billed to KFHP not Medicare.
- C. Medicare Advantage member admissions are always billed to KFHP.
- D. If the Kaiser Permanente (KP) SNF benefit waives the qualifying stay, the 30-day transfer rule and the requirement for the SNF care to be related to the preceding hospital care is also waived.

### Pre-Admission Qualifying Criteria (Washington Medicaid)

- A. Entitlement with Medicaid managed care organization (MCO).
- B. Washington Medicaid covers costs when the patient is not covered by Medicare, another primary insurance, or third party insurance. Medicaid is the payor of last resort.
- C. All members are required to have a Preadmission Screening and Resident Review Level I screening (PASRR). This screening looks for indicators of an intellectual disability or a serious mental illness.
- D. Care is reasonable and necessary. Covered when the Plan determines that nursing facility care is more appropriate than acute hospital care.
- E. The need for skilled services is certified/re-certified by a physician (MD), nurse practitioner (NP) or Clinical Nurse Specialist (CNS) (see Timing of Certifications and Re-certifications for frequency).
- F. Skilled services (nursing or rehabilitation) must be needed and provided on a “daily basis” i.e., on essentially a 7-day-a-week basis, a patient whose inpatient stay is based solely on the need for skilled rehabilitation services would meet the daily basis requirement when services are needed and received on at least 5 days per week.
- G. Services are not covered by DSHS Aging and Long Term Supports Administration.
- H. Services are not covered if it is determined to not be medically necessary for rehabilitation.
- I. The Plan shall coordinate with the Skilled Nursing facility to provide prescription medications, durable medical equipment, therapies, intravenous medications, and any other medically necessary service or product.

### Pre-Admission Qualifying Criteria (Oregon Medicaid)

- A. The post hospital extended care benefit must be authorized by pre-admission screening for individuals not enrolled in managed care.
- B. SNF days available.
- C. Must be receiving Oregon Health Plan benefits and not Medicare eligible.

UR 7 Skilled Nursing Facility  
Medical Necessity Criteria

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Department: Continuing Care

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- D. Have a medically necessary, qualifying hospital stay, not including a hold bed, observation bed, or emergency room bed. The stay must consist of three or more consecutive days, not counting the day of discharge.
- E. Transfer to a nursing facility within 30 days of discharge from the hospital.
- F. Need skilled nursing or rehabilitation services on a daily basis meeting Medicare skilled criteria that may be provided only in a nursing facility.
- G. All members are required to have a Preadmission Screening and Resident Review Level I screening (PASRR). This screening looks for indicators of an intellectual disability or a serious mental illness.

**Criteria for Skilled Care under Medicare Part A, Commercial and Oregon and Washington Medicaid**

## A. Skilled means:

1. The patient requires skilled nursing or skilled rehabilitation services (PT, OT, ST).
2. These services require the skills of technical or professional personnel and are furnished directly by, or under the supervision of such personnel.
3. These services are required on a daily basis (skilled nursing 7 days per week; skilled therapies at least 5 days per week).
4. As a practical matter, considering economy and efficiency, the daily skilled services can only be provided on an inpatient basis in a SNF.

## B. Specific categories of skilled services are:

1. Direct care.
2. Management and evaluation of a patient's care plan.
3. Observation and assessment of a patient's condition.
4. Teaching and training services.

**OTHER CLINICAL REQUIREMENTS****Physician Services in SNF**

- A. A physician must approve, in writing, a recommendation that an individual be admitted to a facility.
- B. Each resident must remain under the care of the physician.
- C. Visits: Physician must:
  1. Review the total program of care at each visit.
  2. Write, sign and date progress notes at each visit.
  3. Sign and date all orders.
  4. Frequency: Beneficiary must be seen once every 30 days for the first 90 days after admission and at least once every 60 days thereafter. The visits must be timely which means the visit occurs no later than 10 days after the required visit date.

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Department: Continuing Care

Section: Skilled Nursing

Applies to: KPNW Region

Review Responsibility: UROC

SME: Preston Peterson, MD & CCS Medical Director;  
Anne Mooney, Senior Manager SNF

Number: UR 7

Effective: 2/04

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8/11; 8/12; 8/13; 8/15; 9/16, 10/17, 03/18

Last Revised: 8/14, 10/17, 03/18

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- D. The physician must make the initial visit. Thereafter he/she may elect to alternate between personal visits and visits by a Physician Assistant (PA), Nurse Practitioner (NP), or Clinical Nurse Specialist (CNS) as permitted by State Law.
- E. Physician must be available for emergency care.
- F. Physician must certify and/or re-certify to the skilled level of care (also see Physician Delegation below).

#### Physician Delegation of Tasks in SNF

All required physician visits must be made by the physician personally except at the option of the State, the physician may delegate these tasks/visits to a NP, CNS, or PA who is not an employee of the facility, but who is working in collaboration/association with the physician, and is acting within their scope of practice.

Note: A Physician Assistant is not permitted to sign certifications/re-certifications.

#### Discharge Planning

1. The resident must have a discharge summary that includes a post-discharge plan of care that is developed with the participation of the resident and his/her family, and that will assist the resident to adjust to his or her new living environment.
2. DME may be delivered to a facility that does not qualify as the patient's home, up to 2 days prior to discharge for the purposes of fitting or training. However, suppliers may only bill from date of discharge.

#### OTHER ADMINISTRATIVE REQUIREMENTS

##### Certification General Requirements

- A. A physician must approve in writing a recommendation that an individual be admitted to a facility.
- B. Each resident must remain under the care of a physician.
- C. Certification: A physician must certify in writing that:
  1. The beneficiary needs daily skilled nursing or rehabilitation services which can only be provided in a SNF on an inpatient basis for either the condition for which he/she received inpatient hospital services, or for a condition which arose after transfer while in the SNF for treatment of a condition for which he/she received inpatient hospital services, OR
  2. The individual has been correctly assigned to one of the RUGs designated as representing the required level of care (Part A).

##### Re-Certification General Requirements

- A. Re-certification: The physician must recertify to:

These criteria do not imply or guarantee approval. Please check your plan to ensure coverage. Preauthorization requirements are only valid for the month published. They may have changed from previous months, and may change in future months. JULY-18

UR 7 Skilled Nursing Facility  
Medical Necessity Criteria

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Department: Continuing Care

Section: Skilled Nursing

Applies to: KPNW Region

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1. The reasons for the continued need for post-hospital SNF care.
  2. The estimated time the individual will need to remain in the SNF.
  3. Plan for home care, if any.
  4. If appropriate, that continued services are needed for a condition that arose after admission to the SNF and while the individual was still under treatment for the condition for which he/she had received inpatient hospital services.
- B. There is no requirement for a specific procedure or form as long as the approach permits verification that the certification and re-certification requirement is met. They may be entered in forms, notes, or other records that a physician normally signs in caring for the patient, or on a separate form.

**Certification and Re-certification:**

- A. The attending physician or a physician on the staff who has knowledge of the case signs certifications and re-certifications.
- B. The physician may delegate certification/re-certification to a nurse practitioner or clinical nurse specialist who does not have a direct or indirect employment relationship with the facility, but is working in collaboration with the physician.

Note: Per regulation, Physician Assistants may not sign certifications/re-certifications.

**Timing of Certifications and Re-certifications**

- A. Certification: First certification must be made at the time of admission or as soon thereafter as is reasonable and practical.
- B. Re-certifications: No later than the 14<sup>th</sup> day of post-hospital SNF care. Subsequent recertification must be made at intervals not exceeding 30 days.

**Change From Skilled to Custodial Level or Exhausted Benefit**

- A. Beneficiaries who are in a skilled Medicare Part A covered SNF stay, whose physician determines that they no longer require skilled care must be notified in writing via a Medicare Notice of Non-Coverage (NOMNC) prior to discharge to the non-skilled level (Form CMS 10123-NOMNC).
- B. Beneficiaries who exhaust their Medicare Part A 100-day benefit and continue to require skilled care are not considered custodial, and must receive a Medicare Notice of Denial of Medical Coverage (CMS-10003-NDMCP).
- C. Beneficiaries who are in a skilled commercial covered SNF stay, whose physician determines that they no longer require skilled care or who have exhausted their benefit must be notified in writing via a Concurrent Care Claim Denial Notice.

UR 7 Skilled Nursing Facility  
Medical Necessity Criteria

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Department: Continuing Care

Section: Skilled Nursing

Applies to: KPNW Region

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- D. Beneficiaries who are in a Washington Medicaid skilled covered SNF stay, whose physician determines that they no longer require skilled care must be notified in writing via a Notice of Denial of Services (Notice 16-2429).
- E. Beneficiaries who are in an Oregon Medicaid skilled covered SNF stay, whose physician determines that they no longer require skilled care or have exhausted their 20-day benefit, must be notified in writing via a Notice of Action.

**Minimum Data Set (MDS)/Resident Assessment (Part A)**

- A. The Balanced Budget Act (BBA) of 1997 established the Prospective Payment System (PPS) for SNFs. Under the PPS, SNFs are paid a per diem rate by Medicare based on a case-mix using a resident classification system that accounts for the relative resource utilization of different patient types. This classification system, called Resource Utilization Group-III (RUG), assigns beneficiaries to one of 44 RUG groups using assessment data from the Minimum Data Set (MDS).
- B. The SNF is required to complete a MDS according to Medicare assessment schedule if they are billing Medicare directly. If the SNF is billing Kaiser Foundation Health Plan, Inc., the first MDS is not due until the 14<sup>th</sup> day of SNF stay.

**Billing Rules (Medicare Part A)**

- A. Care must be ordered and directed by a physician, AND
- B. The care must be furnished for a condition for which the beneficiary received inpatient hospital care, or which arose while receiving inpatient hospital care (see Waiver of Three Day Stay).
- C. Under the Prospective Payment System, when the SNF bills Medicare directly, the clinical criteria for covered skilled care must include documentation per the Minimum Data Set assessment (see aspect S1.0 on MDS) and assignment to a payable RUG category.
- D. Patients assigned to one of the top 26 RUG categories are PRESUMED to be receiving daily skilled services.
- E. Services which are not included in the SNF PPS and for which separate Part B payment must be made:
  - 1. Cardiac catheterization
  - 2. CT (computerized tomography)
  - 3. MRI (magnetic resonance imaging)
  - 4. Ambulatory surgery
  - 5. Emergency services
  - 6. Radiation therapy
  - 7. Angioplasty
  - 8. Lymphedema and venous insufficiency
  - 9. Physician services

UR 7 Skilled Nursing Facility  
Medical Necessity Criteria

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F. Medicare Advantage Contract billing requirements:

1. SNFs bill KFHP
2. Payment based on contract terms
3. MDS not required until the 14<sup>th</sup> day

G. #1876 Cost Contract billing requirements:

1. SNFs bill Medicare directly
2. SNFs must abide by Medicare PPS and consolidated billing rules, i.e., MDS assessment schedule and RUG assignment.

**Contracts (Medicare Part A and Commercial)** KFHP must use a Medicare-certified provider. The SNF must have an active state license.

**(Oregon and Washington Medicaid)** KFHP must use a Medicaid-certified provider.

#### SPECIAL GROUP CONSIDERATIONS, WHEN GROUP HAS A SNF BENEFIT

Commercial, FEDs, Oregon Medicaid: None;

Medicare: January 2014 revisions to the Medicare Benefit Policy Manual related to Skilled Nursing facility, Home Health and Outpatient skilled care clarified that a beneficiary's lack of restoration potential cannot serve as the basis for denying coverage in this context. Rather, such coverage depends upon an individualized assessment of the beneficiary's medical condition and the reasonableness and necessity of the treatment, care, or services in question. Moreover, when the individualized assessment demonstrates that skilled care is, in fact, needed in order to safely and effectively maintain the beneficiary at his or her maximum practicable level of function, such care is covered (assuming all other applicable requirements are met). Conversely, coverage in this context would not be available in a situation where the beneficiary's maintenance care needs can be addressed safely and effectively through the use of *nonskilled* personnel.

Washington Medicaid: Skilled Nursing care is covered for members that meet Milliman Care Guidelines (MCG) for skilled nursing care instead of Medicare criteria. There is no limit to the number of days in a benefit period. The coverage of skilled care will continue as long as the care is medically necessary.

#### REFERENCES

##### NCQA

NCQA Standards and Guidelines are updated annually and available by contacting Quality Resource Management at 503-813-3819.

UR 7 Skilled Nursing Facility  
Medical Necessity Criteria

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Section: Skilled Nursing

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**WASHINGTON**

Molina Healthcare of Washington (MHW) Benefits Index: Skilled Nursing Facilities.

RCW 284-43-410 & RCW 483.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

Washington State Health Care Authority: Nursing Facilities Billing Guide January 1, 2017.

**OREGON**

OAR 411-070-0033: Post Hospital Extended Care Benefit

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

ORS 743.837: Prior authorization requirements

**MEDICARE**

Criteria are based on Medicare Standards: SNF Manual CMS Publication 12, Chapter 2, Sections 214 - 214.5.

Medicare Benefit Policy Manual, Chapter 8, Coverage of SNF Services (Rev. 10/13/16).

Note: Kaiser Foundation Health Plan (KFHP) of the Northwest does not require a 3-day hospital stay prior to admission to a Skilled Nursing Facility (SNF).

## UR 7: Skilled Nursing Facility Preauthorization and Concurrent Review Policy

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Department: Continuing Care Services

Section Skilled Nursing Facility

Applies to: KPNW Region

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### POLICY:

- I. A SNF (Skilled Nursing Facility) denial notice is issued to a member within required timeframes whenever the Plan denies, delays, or modifies a pre-service or concurrent care service/item requested by a practitioner based on medical necessity, benefit exhaustion/exclusion or eligibility. The denial notice contents include the specific information about the reason for the denial and describe the appropriate appeal process according to the membership type.
- II. All medical necessity decisions are made by the SNF Medical Director or physician designee.
- III. Kaiser Permanente Health Plan will clearly track and monitor all skilled nursing facility appeals and the reasons for each overturn. This information will be reported quarterly to the Senior Manager in Continuing Care Services and no less than yearly to the Utilization Review Oversight Committee (UROC).

### PURPOSE:

- I. To provide guidance on processing SNF denials for pre-service medical necessity and benefits.
- II. To provide processes for the management and tracking of appeals and Medicare QIO decisions for SNF continued stay, benefit, medical necessity and expedited/fast track appeals.

### A. CRITERIA

1. Skilled Nursing Facility (SNF) requests/referrals must be medically necessary and meet Medicare criteria (SNF Manual CMS Publication 12, Chapter 2 Sections 214 through 214.5) or MCG in order to qualify for health plan coverage. Revisions in criteria are reviewed/adopted as revisions are made by Medicare, Medicaid and MCG.
2. The criteria are located on the Kaiser Foundation Health Plan of the Northwest internal website at ([http://internal.or.kp.org/utilization/criteria/SNF\\_Criteria.pdf](http://internal.or.kp.org/utilization/criteria/SNF_Criteria.pdf)) and [www.mcg.com](http://www.mcg.com).
3. Written criteria are available to all clinicians upon request from the Continuing Care Services Department.
4. The process of applying the review criteria is overseen by the Administrator of Continuing Care Services (CCS), the SNF Operations Manager, and the Chief of Geriatric Long Term Care (GLTC). Consistency in application is evaluated by:
  - a. A centralized referral process;



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- b. SNF RN Care Coordinators, SNF RN Placement Care Coordinators, Kaiser SNF Operations Manager, and Department Administrators for the North, South, East and West will complete the Medicare Advantage: Grievances, Organization Determinations, and Appeals yearly on KP Learn. Copies of the transcripts will be maintained by the SNF Operations Manager and Compliance;
  - c. The SNF Department will conduct yearly IRR Review, with all physicians, nurse practitioners, RN case managers, and CCS department administrators. The reviews will be conducted individually on the three same random cases. The SNF Operations Manager will tally the results and report at the SNF All Staff meeting. Areas of significant differences in the denial or approval recommendations will also be discussed at the SNF All Staff meeting for purposes of instruction and education;
  - d. The SNF Operations Manager in conjunction with the CCS department administrators will provide ongoing education and training to the RN Care Coordinators no less than twice a year. Evidence of the education, including sign in sheets will be maintained by the SNF Operations Manager and a copy sent to Compliance;
  - e. day to day oversight by supervisory staff.
5. The Centers for Medicare and Medicaid Services (CMS) SNF Manual Publication 12, Chapter 2, is used as a procedural reference for application of criteria for Medicare, Commercial and Oregon Health Plan members.
  6. MCG are used to apply medically necessary criteria for Washington Medicaid members.

### B. DENIALS:

Commercial members: Please see associated Regional UM Policy:

- [UR Policy 4](#): UM Medical Necessity Denials
1. All denial letters/notices will be approved by compliance and stored on K drive within Skilled Nursing Department within CCS. Staff will only use letters/notices that have been approved and are on the K drive within CCS. All notices/letters are required to meet the following:
    - a. The date on the letter is the actual date that the letter is issued (electronically, mailed or faxed) to the member and, as applicable, to the facility and provider.
    - b. The basic template language in the letters (excluding the denial reason statement), including the appeal language and notice requirements, must not be altered.

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- c. The written notification includes the specific reason for the denial, including reference to the specific criteria upon which the decision was made, as they related to the covered person's medical circumstances.
- d. The denial notice must be written to be accurate, in an easy to comprehend, and written no higher than a sixth grade reading level (42 CFR 438.10(b)(1)).
- e. The date the member becomes financially responsible is the issuance date of the denial. The exception is for Medicaid members. They cannot be held financially responsible for any denial of service, or refusal to transfer.
- f. Denial notices are issued to members according to their membership type.

### C. Types of Denials

1. Medical Necessity- All modifications, delays or denials based on the lack of clinical criteria for skilled care must be reviewed and the determination made by a physician.
2. Benefit-Modifications, delays, or denials based on Benefit exclusion or exhaustion of benefits are made by the Health Plan and do not require physician review. EXCEPTION: All benefit denials for Medicaid members must be reviewed by a physician.

### D. Pre-Service Denial for SNF

1. Skilled nursing care is covered for patients that meet Medicare guidelines and/or MCG guidelines for skilled nursing care.
2. RN Placement Coordinators will screen referrals for skilled care requirements. The patient should be screened within three days of the actual admission date so that criteria are based on the patient's current condition.
3. Referrals that are authorized will have the approval documented in the Tapestry referral and written notification will be sent to the vendor facility, provider and patient.
4. Referrals for skilled care that do not meet Medicare and/or MCG guidelines will be referred to the Medical Director or physician designee for review.
5. The Medical Director or physician designee will make the final determination to approve or modify, delay or deny service/care. The physician will document via email to the RN Placement Coordinator or directly into the Tapestry referral any denials. The RN Placement Coordinator will copy and paste the physician review into the Tapestry Referral.

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6. The RN Placement Coordinator will complete the appropriate Pre-service denial for KPSA/Medicare, Commercial or Medicaid members. The RN Placement Care Coordinator will discuss the medical necessity decision with the hospital care coordinator or clinic RN.
7. The hospital Care Coordinator and or clinic RN will review the denial and appeal process with the member or authorized representative.
8. A copy of the pre-service denial will be mailed to the member and the physician that ordered skilled nursing care.
9. Referrals that are not authorized will have the denial documented in the Tapestry referral and written notification will be sent to the vendor facility, provider and patient.
10. A copy of the pre-service denial will be filed in the SNF Desk office and maintained for 10 years.
11. If the enrollee disagrees with the denial, he/she can request a “fast track” or expedited appeal.
12. Extenuating circumstances around pre-authorization and admission notification is based on the Best Practice Recommendations (BPR) put forth by the Washington Healthcare Forum operated by OneHealthPort, but are applicable to all lines of business in Oregon and Washington. Please see associated Regional UM Policy: UR Policy 70: Extenuating Circumstances Policy at <http://internal.or.kp.org/utilization/>.

### **E. Concurrent Service Denial and Appeals Process for SNF for Senior Advantage Medicare**

#### **Notice of Medicare Non-Coverage**

1. The Notice of Medicare Non-Coverage (NOMNC) is required when coverage of a pre-approved course of SNF skilled care will end. The notice may be issued as early as admission, but no less than 2 days in advance of termination of services.
2. A NOMNC should be issued when the attending physician makes a determination, based on clinical information, that continued stay or change in level of care does not meet clinical criteria for skilled level of care.
3. The “effective date” to be listed on the letter is the last covered day.

## UR 7: Skilled Nursing Facility Preauthorization and Concurrent Review Policy

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4. The NOMNC must be signed by the patient or Durable Power of Attorney for Health Care (DPOAHC) on the day the NOMNC is issued. If the patient is not competent and the DPOAHC/designated family member is not available in person, the RN Care Coordinator and/or designee must notify the DPOAHC via phone. The RN care coordinator will then document the phone call on the Attestation Form (Attachment A). Leaving a voice mail does not meet the requirement of notification. The letter will then be mailed to the DPOAHC on the same day as the NOMNC was given via phone.
5. If the RN care coordinator or designee is unable to reach the DPOAHC after three attempts, the NOMNC will be sent to the patient's address via certified mail on the same day that the NOMNC is issued. A certified mail receipt will be retained. A signed return receipt will be requested.
6. If the enrollee disagrees with the denial, he/she may request a "fast track" appeal. A Quality Improvement Organization (QIO) will process the fast track appeals. In Oregon and Washington, the QIO is Livanta.
7. Livanta is available to process appeals whenever they are filed.
8. The member must contact the QIO in writing or by phone by noon of the day **before the effective date**.
9. The IRE will notify KFHP SNF Desk and the SNF facility of the appeal. The SNF desk LTC Assistant will notify the Care Coordinator, Physician and Nurse Practitioner.
11. The Kaiser SNF care coordinator will issue a Detailed Explanation of Non Coverage (DENC) to the member and prepare a case file for submission to the QIO Monday through Friday by 4:30pm. On weekends, the SNF facility will provide the documentation directly to Livanta.
13. A copy of the NOMNC and DENC denial will be filed in the SNF Desk office for two years and archived for 8 years.

### F. Detailed Explanation of Non-coverage (DENC) for Part A.

1. The DENC is required if the member appeals by noon of the day after receipt of the NOMNC.

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2. The DENC notice must contain the following:
  - a. Specific detailed information as to why KFHP will no longer cover services.
  - b. Citation of pertinent Medicare coverage criteria.
3. The case file should be sent to Livanta no later than 5:00pm of the date of notification by Livanta that the member has appealed. The only exception is if the member requests an appeal on the same day of receipt of the NOMNC, then KFHP will have until the close of business day before the effective date to provide Livanta with the DENC and case file.
4. The case file sent to Livanta must contain:
  - a. Admission history and physical
  - b. All therapy notes including long and short term goals
  - c. Nurses notes for previous two weeks
  - d. Physician progress notes
  - e. Physician orders
  - f. Medication administration record
  - g. Treatment sheets if applicable
  - h. Notes of plan of care/discharge
  - i. Notes from wound care nurse if applicable
5. Livanta must render decisions as soon as possible, generally no later than the effective date of the NOMNC.
6. If Livanta is unable to make a decision, the member will not be financially liable until a denial decision is made.
7. If KFHP's denial is overturned by Livanta, KFHP must issue a new NOMNC if the discharge date is not determined by Livanta.
8. If the enrollee misses the deadline for a fast-track appeal, he/she may appeal under the expedited appeal process available through KFHP Member Relations Dept.

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### G. KP Commercial/ Federal Members/ Medicare Members that Missed Deadline –SNF Concurrent Denial and Appeals Process

1. Skilled nursing/rehabilitation care is covered for patients that meet Medicare guidelines for skilled care.
2. The Claim Denial Notice is required when coverage of a pre-approved course of SNF skilled care will end. The notice may be issued as early as admission, but at least 2 days in advance of termination of services.
3. A Claim Denial Notice should be issued when the attending physician, makes a determination, based on clinical information that continued stay or change in level of care does not meet clinical criteria for skilled level of care.
4. The “effective date” to be listed on the letter is the last covered day.
5. If the enrollee disagrees with the denial, he/she may request a “fast track” appeal, as applicable. Member Relations will process the fast track appeals.
6. The member must contact Member Relations or the SNF desk **before the effective date**.
7. The SNF desk will notify Member Relations of any patient calls regarding filing an appeal.
8. If the person calling to initiate the appeal is not the patient or Power of Attorney, the SNF desk staff will fax a copy of the Appointment of representative and Authorization to Use/Disclose Protected Health Information to facility. Both the patient and the caller must complete the form and fax back to SNF desk.
9. The SNF desk will verify the patient’s benefits and contact the SNF to fax the patient’s chart.
10. The SNF Desk Staff will contact the SNF Physician of the Day or Medical Director to review the chart. The Physician doing the review cannot have rounded on the patient during the current SNF stay.

## UR 7: Skilled Nursing Facility Preauthorization and Concurrent Review Policy

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Department: Continuing Care Services

Section Skilled Nursing Facility

Applies to: KPNW Region

Review Responsibility: UROC

SME: SME: Preston Peterson, MD & CCS Medical Director;

Mynell Harper, RN

Number: UR 7

Issued: 3/95

Reviewed: 5/96, 6/97, 1/00, 1/01, 2/02, 2/03, 2/04,  
3/05, 4/06; 8/08, 8/09; 8/10; 8/11; 8/12; 8/13; 8/15

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11. The SNF Desk Staff will contact the SNF social worker to have the chart faxed to the reviewing physician for determination of medical necessity.
12. The reviewing physician will complete a Physician Review Report (See Attachment B) that demonstrates that the patient does or does not require skilled SNF care. This will be faxed or emailed to the Senior Grievance and Appeal Administrator (SGAA).
13. The decision to deny or allow continued care services to be made within 24 hours of receipt of request.
14. The SNF desk will notify the attending physician, the care coordinator, and the SNF staff of the appeals decision. The SGAA will notify the member of the decision.
15. The date the member becomes financially responsible is the issuance date of the denial notice. Exception: Medicaid members cannot be held financially responsible for any denial of service or refusal to transfer.

### H. KP Oregon HealthShare Plan/ Medicaid –SNF Concurrent Denial and Appeals Process

1. Skilled nursing care is covered for patients that meet Medicare guidelines for Oregon Medicaid.
2. The Denial Notice is required when coverage of a pre-approved course of SNF skilled care will end. The notice may be issued as early as admission, but at least 2 days in advance of termination of services.
3. A Notice of Denial of Services/Notice of Action should be issued when the attending physician makes a determination, based on clinical information, that continued stay or change in level of care does not meet clinical criteria for skilled level of care.
4. The “effective date” to be listed on the letter is the last covered day.

## UR 7: Skilled Nursing Facility Preauthorization and Concurrent Review Policy

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Department: Continuing Care Services

Section Skilled Nursing Facility

Applies to: KPNW Region

Review Responsibility: UROC

SME: SME: Preston Peterson, MD & CCS Medical Director;

Mynell Harper, RN

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3/05, 4/06; 8/08, 8/09; 8/10; 8/11; 8/12; 8/13; 8/15

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5. If the enrollee disagrees with the denial, he/she may request an Appeal, a Hearing, or both. An enrollee may also request “fast track” appeal. Member Relations will process the fast track appeals.
6. The member must contact Member Relations within 10 days from the effective date.
7. A qualified physician reviews all denials (medical necessity and benefit) requests for Medicaid managed care services requiring pre-authorization and concurrent review.
8. The SNF desk will notify Member Relations of any patient calls regarding filing an appeal.
9. If the person calling to initiate the appeal is not the patient or Power of Attorney, the SNF desk staff will fax a copy of the Appointment of representative and Authorization to Use/Disclose Protected Health Information to facility. Both the patient and the caller must complete the form and fax back to SNF desk.
10. The SNF desk will verify the patient’s benefits and contact the SNF to fax the patient’s chart. The SNF Desk Staff will contact the SNF Physician of the Day or Medical Director to review the chart. The Physician doing the review cannot have rounded on the patient during the current SNF stay.
11. The decision to deny or allow continued care services to be made within 24 hours of receipt of request.
12. The SNF desk will notify the attending physician, the care coordinator, and the SNF staff of the appeals decision. Member Relations will contact the patient.

### **I. KP Molina Health Care/ Washington HealthCare Authority/ Medicaid –SNF Concurrent Denial and Appeals Process**

1. Skilled nursing care is covered for patients that meet MCG guidelines for skilled nursing care.



## UR 7: Skilled Nursing Facility Preauthorization and Concurrent Review Policy

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Department: Continuing Care Services

Section Skilled Nursing Facility

Applies to: KPNW Region

Review Responsibility: UROC

SME: SME: Preston Peterson, MD & CCS Medical Director;

Mynell Harper, RN

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3/05, 4/06; 8/08, 8/09; 8/10; 8/11; 8/12; 8/13; 8/15

Revised: 10/13, 10/17

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2. The Notice of Denial of Services is required when coverage of a pre-approved course of SNF skilled care will end. The notice may be issued as early as admission, but no less than 2 days in advance of termination of services.
3. A Notice of Denial of Services/Notice of Action should be issued when the attending physician makes a determination, based on clinical information, that continued stay or change in level of care does not meet clinical criteria for skilled level of care.
4. The “effective date” to be listed on the letter is the last covered day.
5. If the enrollee disagrees with the denial, he/she may request an appeal from Molina Healthcare.
6. The member must contact Molina Healthcare within 10 days from the date of the denial letter.
7. A qualified physician reviews all denials (medical necessity and benefit) requests for Medicaid managed care services requiring pre-authorization and concurrent review.
8. If the person calling to initiate the appeal is not the patient or Power of Attorney, the SNF desk staff will fax a copy of the Appointment of representative and Authorization to Use/Disclose Protected Health Information to facility. Both the patient and the caller must complete the form and fax back to SNF desk.
9. The SNF desk will verify the patient’s benefits and contact the SNF to fax the patient’s chart. The SNF Desk Staff will contact the SNF Physician of the Day or Medical Director to review the chart. The Physician doing the review cannot have rounded on the patient during the current SNF stay.
10. The decision to deny or allow continued care services to be made within 24 hours of receipt of request.

## UR 7: Skilled Nursing Facility Preauthorization and Concurrent Review Policy

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Department: Continuing Care Services

Section Skilled Nursing Facility

Applies to: KPNW Region

Review Responsibility: UROC

SME: SME: Preston Peterson, MD & CCS Medical Director;

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Number: UR 7

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3/05, 4/06; 8/08, 8/09; 8/10; 8/11; 8/12; 8/13; 8/15

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### J. Denial Notice Retention and Reporting

1. A complete copy of the denial notice and supporting documentation or criteria relied on in issuing the denial, evidence of discussions with the family and all return receipts must be kept in SNF Appeal Files.
2. The files will be kept onsite in the SNF Department for (2) years and then offsite for an additional period of (8) years.
3. The SNF Administrative staff are responsible for keeping an ongoing electronic log with specific required information of all denial notices issued, appeals and QIO decisions.
4. The Denial log will be reviewed quarterly by the SNF Operations Manager for trends and emerging issues. Any identified trends or issues will be escalated to the SNF/HH Director and the Medical Director of CCS.
5. The report will be reviewed quarterly in CCS QI meetings.
6. The report will be reviewed yearly in Regional QI committee.

### C. APPEALS:

Please see associated Regional UM Policies:

- [UR Policy 26](#): Appeals of Adverse Determinations for OR and WA Commercial Members

Note: For Medicare Advantage Members: After receiving the Medicare Notice of Non-Coverage (MNONC), members have the right to appeal directly to the Quality Improvement Organization (QIO) until noon, the day before the last covered day. If an appeal is done through the QIO, the review will be done by a QIO physician, and the member will receive a response by noon, the last covered day. If the member misses the deadline for an appeal to the QIO, they may appeal to KPNW directly as an expedited appeal.

To define standards, accountabilities, and processes of pre-authorizations and concurrent review of Skilled Nursing Facility services.

### UR 7: Skilled Nursing Facility Preauthorization and Concurrent Review Policy

Department: Continuing Care Services

Section Skilled Nursing Facility

Applies to: KPNW Region

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3/05, 4/06; 8/08, 8/09; 8/10; 8/11; 8/12; 8/13; 8/15

Revised: 10/13, 10/17

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#### RESPONSIBILITIES

Primary Responsibility	Action
RN Discharge Planners, SNF Coordinators, NP, SNF Placement Coordinator	<ol style="list-style-type: none"> <li>1. Review and approve all requests/referrals for benefit coverage and medical necessity, based on approved criteria.</li> <li>2. If the admission doesn't appear to meet medical necessity criteria, the nurse reviews the case with the attending physician and the patient and recommends alternative resources.</li> <li>3. In the event that either the physician or patient disputes the decision, the nurse requests a case review by the Medical Director CCS or designee within two (2) days. (Or urgently, as clinically appropriate.)</li> </ol>
Geriatric Skilled Nursing Care Physician	<ol style="list-style-type: none"> <li>1. The reviewing physician, based on clinical expertise, knowledge of available resources/services in the local delivery system, and utilizing supporting clinical information related to the patient's individual needs (age, co-morbidities, complications, progress of treatment, psychosocial, and home environment, as applicable), will make a determination of medical necessity. Clinical information may be accessed via the electronic clinical information systems and/or conversation with the ordering clinician, and/or consultation with a board certified specialist.</li> </ol>
Continuing Care Services Administrator or Designee	<ol style="list-style-type: none"> <li>4. Will monitor processes to ensure that all review processes, including physician review, will be completed and documented within the timelines outlined above, depending upon the clinical urgency of the request.</li> <li>5. Is responsible to ensure that denial notices include all required documentation and that the denial is recorded in Tapestry beginning October 2017.</li> </ol>

## UR 7: Skilled Nursing Facility Preauthorization and Concurrent Review Policy

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Department: Continuing Care Services

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3/05, 4/06; 8/08, 8/09; 8/10; 8/11; 8/12; 8/13; 8/15

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### SPECIAL GROUP CONSIDERATIONS, WHEN BENEFIT IS AVAILABLE

Commercial: No special considerations

Medicare: No special considerations

Washington Medicaid: Check CM or EPIC

Oregon Medicaid: Check CM or EPIC

FEDS: No special considerations

PEBB: No special considerations

### REFERENCES

#### NCQA

NCQA Standards and Guidelines are updated annually and available by contacting Quality Resource Management at 503-813-3850.

#### WASHINGTON

RCW 284-43-410 & RCW 483.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

Washington State Health Care Authority : Nursing Facilities Billing Guide January 1, 2017.

#### OREGON

OAR 411-070-0033: Post Hospital Extended Care Benefit

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

ORS 743.837: Prior authorization requirements

## UR 7: Skilled Nursing Facility Preauthorization and Concurrent Review Policy

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### MEDICARE

Policy is based on Medicare Standards (SNF Manual CMS Publication 12, Chapter 2, Sections 214 through 214.5) and Medicare Benefit Policy Manual Chapter 8, Coverage of SNF Services (Rev. 10/13/16).

Kaiser Foundation Health Plan (KFHP) of the Northwest does not, however, require a 3-day hospital stay prior to admission to a Skilled Nursing Facility (SNF)

## UR 8 Home Health Admission Medical Necessity Criteria

Department: Continuing Care

Section: Home Health

Applies to: KPNW Region

Review Responsibility: UROC

SME: Preston Peterson, MD & CCS Medical Director;  
Joclyn Tosch, RN

Number: UR 8

Effective: 8/97

Reviewed: 1/00, 12/01, 2/02, 6/02, 12/03, 2/03, 10/04,  
9/05, 9/06, 08/08, 9/09, 8/10, 8/11, 8/12, 8/13, 8/15, 9/16

Last Revised: 8/14, 9/17

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### MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR HOME HEALTH ADMISSION

#### CRITERIA-See Special Group Considerations for Medicare-specific information

- A. Patients must require skilled and intermittent care which can be safely provided in the home setting with reasonable expectation of clinical improvement.

Skilled care includes care services such as physical and occupational therapy, speech language therapy, medical and social services. "Skilled care" is care that must be provided by a Registered Nurse (RN), licensed physical or occupational therapist or speech and language pathologist, which is primarily rehabilitative in nature.

"Intermittent care" in general is not performed on a daily basis. In some cases, where daily care is required, it may be provided only for a period of short duration (weeks versus months).

- B. Patient is homebound.

For purposes of the statute, an individual shall be considered "confined to the home" (homebound) if the following two criteria are met:

1. Criteria One: The patient must either:

- a. Because of illness or injury - need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave their place of residence.

OR

- b. Have a condition such that leaving his or her home is medically contraindicated.

If the patient meets Criteria-One conditions, then the patient must ALSO meet two additional requirements defined below:

2. Criteria Two:

- a. There must exist a normal inability to leave home;

AND

- b. Leaving home must require a considerable and taxing effort.

If the patient does in fact leave the home, the patient may nevertheless be considered homebound if the absences from the home are infrequent or for periods of relatively short duration, or are attributable to the need to receive health care treatment. Absences attributable to the need to receive health care treatment include, but are not limited to:

UR 8 Home Health Admission Medical Necessity  
Criteria

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9/05, 9/06, 08/08, 9/09, 8/10, 8/11, 8/12, 8/13, 8/15, 9/16

Last Revised: 8/14, 9/17

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- Attendance at adult day centers to receive medical care;
- Ongoing receipt of outpatient kidney dialysis; or
- The receipt of outpatient chemotherapy or radiation therapy.

Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited to furnish adult day-care services in a State, shall not disqualify an individual from being considered to be confined to his home. Any other absence of an individual from the home shall not so disqualify an individual if the absence is of an infrequent or of relatively short duration.

For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. It is expected that in most instances, absences from the home that occur will be for the purpose of receiving health care treatment. However, occasional absences from the home for nonmedical purposes, e.g., an occasional trip to the barber, a walk around the block or a drive, attendance at a family reunion, funeral, graduation, or other infrequent or unique event would not necessitate a finding that the patient is not homebound if the absences are undertaken on an infrequent basis or are of relatively short duration and do not indicate that the patient has the capacity to obtain the health care provided outside rather than in the home.

**OTHER REQUIREMENTS**

Decisions for accepting patients for care by the Home Health Department are based on medical, nursing, therapy, and social information provided by the physician responsible for the patient's care and is determined after assessing the member's unique medical condition. Decisions are made by institutional personnel and staff of the Home Health Program.

*Considerations Prior to Acceptance of patient for Home Health Services*

- There are adequate and suitable department personnel and resources to provide the services required by the patient.
- Attitudes of patient and his family toward his care at home.
- There is a benefit to the patient's health to receive care at home as distinguished from care in a hospital, long-term care facility, or medical office setting.

**UR 8 Home Health Admission Medical Necessity Criteria**

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- There is a reasonable expectation that patient's medical, nursing, therapy and social needs can be met adequately and safely in his residence, including the availability of a plan to meet medical emergencies.
- There are adequate physical facilities and equipment in the patient's residence for safe care.
- There is an assessment whether there is the availability of family or other caregiver in the home, with the ability and willingness to participate in the care and if it is required to assure the patient's safety and adequacy of care.
- There is an assessment of the degree of patient and family awareness of their rights and responsibilities.
- How recently the patient has had contact with the ordering physician.
- Assurance that services can be effectively coordinated through liaison with other organizations and individuals also providing care to the patient.
- Acceptance of any patient by Home Health is at the discretion of Continuing Care Services (CCS), which exists to provide home health services to members of the Kaiser Foundation Health Plan. Medical necessity denials are made by a MD or DO.

**CONTRAINDICATIONS**

None

**SPECIAL GROUP CONSIDERATIONS**

See individual member's summary of benefits for specific coverage information. Procedures and/or services may be excluded under certain service agreements and/or employer group and individual contracts. In all instances, medical necessity must be established for the procedure to be a covered health benefit.

Commercial: None

Medicare: January 2014 revisions to the Medicare Benefit Policy Manual related to Skilled Nursing facility, Home Health and Outpatient skilled care clarified that a beneficiary's lack of restoration potential cannot serve as the basis for denying coverage in this context. Rather, such coverage depends upon an individualized assessment of the beneficiary's medical condition and the reasonableness and necessity of the treatment, care, or services in question. Moreover, when the individualized assessment demonstrates that skilled care is, in fact, needed in order to safely and effectively maintain the beneficiary at his or her maximum practicable level of



**UR 8 Home Health Admission Medical Necessity  
Criteria**

Department: Continuing Care

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Number: UR 8

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Reviewed: 1/00, 12/01, 2/02, 6/02, 12/03, 2/03, 10/04,  
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function, such care is covered (assuming all other applicable requirements are met). Conversely, coverage in this context would not be available in a situation where the beneficiary's maintenance care needs can be addressed safely and effectively through the use of *nonskilled* personnel.

Washington Medicaid: Check CM or EPIC

Oregon Medicaid: Check CM or EPIC

FEDS: No special considerations

PEBB: No special considerations

**REFERENCES****NCQA**

NCQA Standards and Guidelines are updated annually and available by contacting Quality Resource Management at 503-813-3819.

**WASHINGTON**

RCW 284-43-410 & RCW 483.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

WAC 246-855-010 Definition of Acupuncture.

**OREGON**

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

ORS 743.837: Prior authorization requirements

**CLINICAL**

Criteria Based: Medicare Regulations. CMS Publication 11 – Home Health Manual, Chapter 2. Coverage of Services.



UR 8 Home Health Admission Medical Necessity Criteria

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9/05, 9/06, 08/08, 9/09, 8/10, 8/11, 8/12, 8/13, 8/15, 9/16

Last Revised: 8/14, 9/17

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Medicare Benefit Policy Manual, chapter 7, Home Health Services, section 30.1.1 (Patient Confined to the Home), effective 2/24/17.

**Revision History**

Medicare Criteria: Oct, 1999, Reviewed upon issue of revisions by HCFA (now CMS)

Home Health/Hospice Acceptance of Patients - September, 2003

October 2004, Home Health and Hospice policies separated

August 2014, revised definition of “confined to the home”



## UR 9 MEDICALLY NECESSARY SCHEDULED AMBULANCE TRANSPORTATION POLICY

Department: Medical Transportation

Number: UR 09

Applies to: KPNW Region

Effective: 03/00

Review Responsibility: Christen Lake, RTMC;  
UROC

Reviewed and/or Revised: 2/02, 2/03, 2/04, 4/05, 8/05, 8/06,  
10/07, 10/08, 10/09, 10/10, 10/12, 10/14

Last Revised: 1/17

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### PURPOSE

To define standards, accountabilities, and processes of scheduled non-emergent MEDICALLY NECESSARY AMBULANCE Medical Transportation.

### POLICY

- A. To qualify for health plan coverage, scheduled medical transportation requests/referrals must meet specific level of service and medical necessity protocols.
- B. *Medically Necessary Transportation* is a transportation service that, in the judgement of a Northwest Permanente physician, is needed to prevent, diagnose, or treat a medical condition. The transportation service is necessary only if a Northwest Permanente physician determines that without transportation, there would be an adverse effect on the health and wellbeing of the member.
- C. Scheduled non-911 transportation is requested via calling the local contracted ambulance vendor's call center.
- D. Performance reports are reviewed by the contracted ambulance vendor, the local Kaiser Steering Committee and the national Kaiser Steering Committee.

### DEFINITIONS

- A. Call Protocols: the protocols and procedures developed and implemented by the contracted ambulance vendor, as approved by each applicable Kaiser Medical Group, for determining in response to each call received (1) the medical necessity of each request for medical transportation services, and (2) the appropriate level of medical transportation services.
- B. Level of Urgency and Type of Service: the appropriate medical transportation services, determined in accord with the Call Protocols. The Levels of Urgency and Type of Service include:

VRT LEVEL	VEHICLE RESPONSE TIME STANDARD
Level 1	30 minutes or less
Level 2	45 minutes or less
Level 3	60 minutes or less
Level 4	1-4 hours
Level 5	Greater than 4 hours

## UR 9 MEDICALLY NECESSARY SCHEDULED AMBULANCE TRANSPORTATION POLICY

Department: Medical Transportation

Number: UR 09

Applies to: KPNW Region

Effective: 03/00

 Review Responsibility: Christen Lake, RTMC;  
UROC

 Reviewed and/or Revised: 2/02, 2/03, 2/04, 4/05, 8/05, 8/06,  
10/07, 10/08, 10/09, 10/10, 10/12, 10/14

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TYPE OF SERVICE	
Advanced Life Support Services (ALS)	ALS personnel provide: intravenous therapy, endotracheal airway, anti-shock, cardiac monitor, cardiac defibrillator, drugs, relief of pneumothorax or other invasive procedures and services.
Basic Life Support Services (BLS)	Medical transportation services limited to transportation, first aid, and any needed administration of oxygen.
Critical Care Transportation (CCT)	Paramedic crew plus a Critical Care RN providing advanced life support and specialized monitoring for high risk patients needing higher level care.
Other levels or types of service	Such levels or types of service include but are not limited to wheelchair services and may be appropriate in certain situations.

- C. **Leakage:** during the process of transferring a patient, due to controlled or uncontrolled conditions, the transfer falls outside the agreed upon guidelines resulting in inappropriate use, delay in or complete lack of patient transfer. In general, such trips are initiated from within KPNW. When this occurs a penalty fee is assessed.
- D. **Medically Necessary:** medical transportation services that are covered as basic covered benefits under the applicable Membership Agreement and are appropriate and necessary for the symptoms or treatment of a medical condition.
- E. **Scheduled Services:** non-emergent medical transportation.

### RESPONSIBILITIES

- A. Designated Kaiser Facility Staff (including contracted facilities) request scheduled non-911 ambulance by following the guidelines described in the following procedures (click on the following link):  
<http://internal.or.kp.org/Commtrans/mednec-ksmc.html#NON911>
- B. NWP Emergency MD oversees ambulance protocols
- C. Resource Stewardship will retrospectively audit routine inter-facility transports for leakage
- D. Operations Manager for Medical Transportation will monitor to ensure that all review processes will be completed and documented

### SPECIAL GROUP CONSIDERATIONS

None

### REFERENCES

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.



## UR 9 MEDICALLY NECESSARY SCHEDULED AMBULANCE TRANSPORTATION POLICY

Department: Medical Transportation

Number: UR 09

Applies to: KPNW Region

Effective: 03/00

Review Responsibility: Christen Lake, RTMC;  
UROC

Reviewed and/or Revised: 2/02, 2/03, 2/04, 4/05, 8/05, 8/06,  
10/07, 10/08, 10/09, 10/10, 10/12, 10/14

Last Revised: 1/17

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### WASHINGTON

WAC 388-531-0200 Physician-related services requiring prior authorization

RCW 284-43-410 & RCW 483.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria

### OREGON

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

ORS 743.837: Prior authorization requirements

### CLINICAL

*Ambulance TPA Manual* Final Approved April 2003, pgs 34-39

*Amended and Restated National Medical Transportation and Management Services Agreement*, document number 023.205521.15

***KPNW Medical Transportation Claims Adjudication Business Rules for EMI, revised April 2005***



UR 10.A Bariatric Surgery Medical Necessity Criteria for Commercial, OEBB and PEBB

Table with 2 columns: Department/Section/Applies to/Review Responsibility and Number/Effective/Reviewed and/or revised/Revised. Row 1: Department: Surgery, Section: KPNW Region, Applies to: Bariatric Surgery, Review Responsibility: Dr. Andre Leger & Dr Nathan Bronson, Bariatric Surgery; Terri Graven, RN. Row 2: Number: UR 10.A, Effective: 3/2000, Reviewed and/or revised: 12/01, 6/02, 2/03, 12/04, 3/05, 3/06, 05/07, 10/07, 01/08, 10/08, 7/09; 11/09; 10/10; 7/11; 7/12; 7/14; 7/15, Revised 7/11; 7/13; 7/16; 7/17.

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR THE BARIATRIC SURGERY PREPARATION PROGRAM (NOTE: admission into the Program, also known as the Severe Obesity Program, is required prior to consideration of bariatric surgery) FOR COMMERCIAL LINES OF BUSINESS

CRITERIA

Patients will be eligible to participate in the preparation process and may be a candidate for bariatric (obesity) surgery if:

- 1. Body Mass Index (BMI)<sup>1</sup> is ≥ 35 Kg/m2 with one or more serious co-morbid (co-existing conditions that can be life-threatening) conditions in the following categories:
a. Sleep apnea<sup>2</sup> requiring treatment with Continuous Positive Airway Pressure (CPAP)<sup>3</sup> or inability to use CPAP with an Apnea/Hypopnea Index (AHI)<sup>4</sup> > 15 on sleep study or inability to use CPAP with an AHI > 5 and documentation of excessive daytime sleepiness, impaired cognition (ability to think clearly), mood disorders or insomnia, hypertension, ischemic<sup>5</sup> heart disease, or history of stroke
b. Congestive heart failure (CHF) or cardiomyopathy<sup>6</sup> with a NW Permanente Cardiologist recommendation for bariatric surgery
c. Obesity hypoventilation and PCO2 ≥45<sup>7</sup> and a NW Permanente Pulmonologist recommendation for bariatric surgery
d. Diabetes mellitus requiring medical therapy that includes insulin or an insulin sensitizing oral agent i.e. metformin or pioglitazone (or documented intolerance to insulin or insulin sensitizing oral agents) or > 15 pound weight gain within 2 years of starting insulin therapy or endocrinologist recommendation for bariatric surgery.
e. Severe hypertriglyceridemia (> 1000 mg/dl)<sup>9</sup> requiring medical therapy, which includes fibrate<sup>10</sup> drugs and therapeutic doses of omega-3 fatty acid (6 grams daily), or a NW Permanente Endocrinologist recommendation for bariatric surgery

<sup>1</sup> BMI or Body Mass Index- a way of calculating the degree of obesity.
<sup>2</sup> Sleep apnea- temporary absence of breathing while asleep.
<sup>3</sup> CPAP or Continuous Positive Air Pressure- a prescribed machine that is worn while asleep to keep the airway open.
<sup>4</sup> AHI or Apnea/Hypopnea Index- the number of times per hour the patient has temporarily stopped breathing or gets insufficient oxygen, as determined during a monitored sleep study evaluation.
<sup>5</sup> Ischemic- a local and sometimes temporary deficiency of blood flow through a blood vessel due to an obstruction.
<sup>6</sup> Cardiomyopathy-a condition affecting the strength of the heart muscle
<sup>7</sup> PCO2- the concentration of carbon dioxide in the blood. Normal PCO2 is 35-45.
<sup>9</sup> Hypertriglyceridemia- a condition characterized by a high level of triglycerides (a fatty acid) in the blood. Normal value is 40-150.
<sup>10</sup> Fibrate- a specific type of drug used to lower cholesterol or triglycerides or both.



UR 10.A Bariatric Surgery Medical Necessity Criteria for Commercial, OEBC and PEBB

Table with 2 columns: Department/Section/Review Responsibility and Number/Effective/Reviewed and/or revised dates.

- f. Hypertension (high blood pressure) with blood pressure >140/90...
g. Extremity edema with ulceration...
h. Gastroesophageal reflux requiring prolonged medical management...
i. Stress incontinence related to obesity...
j. Pseudotumor cerebri documented by a NW Permanente Neurologist;

OR

- 2. BMI is >= 40 Kg/m2 with no co-morbid condition

AND

- 3. Be >=18 years old and general health adequate to tolerate surgery;

AND,

- 4. Have documentation in the medical record or referral that the member has been previously unsuccessful with medical treatment for obesity.

Practitioner documentation in the medical record of one of the following must occur:

- a. Minimum of 6 month participation (does not need to be continuous or uninterrupted for 6 months) in a recognized commercial behavioral weight management program.

11 Refractory extremity edema- swelling of the legs and feet that is resistant to treatment.

12 Gastroesophageal reflux – a backflow of contents of the stomach into the esophagus (also known as GERD).

14 Incontinence- the inability to control urination.

15 Pseudotumor cerebri- a non-cancerous condition characterized by increased pressure in the brain causing headache, vomiting and swelling of eyes.



**UR 10.A Bariatric Surgery Medical Necessity  
Criteria for Commercial, OEBB and PEBB**

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Department: Surgery	Number: UR 10.A
Section: KPNW Region	Effective: 3/2000
Applies to: Bariatric Surgery	Reviewed and/or revised: 12/01, 6/02, 2/03, 12/04, 3/05, 3/06,
Review Responsibility: Dr. Andre Leger &	05/07, 10/07, 01/08, 10/08, 7/09; 11/09; 10/10; 7/11; 7/12;
Dr Nathan Bronson, Bariatric Surgery;	7/14; 7/15
Terri Graven, RN	Revised 7/11; 7/13; 7/16; 7/17

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Nutrisystem, and/or Jenny Craig. Non-commercial, book-based programs, such as Atkins and Dr. Phil, do not qualify.

b. Minimum of 6 month participation in a Physician, Nurse Practitioner, Physician Assistant, Registered Dietician, or Licensed Behavioral Therapist supervised weight loss program, with or without obesity pharmacotherapy (drug therapy).

c. Three or more primary care visits over a minimum of 6 months with weight management treatment and follow-up plan, in the progress note.

d. Participation and completion of at least an 8 week Kaiser Permanente NW (KPNW) health education weight management program.

**OTHER REQUIREMENTS**

After the bariatric surgery referral, but prior to bariatric surgery, the member must sign and understand the document, "Severe Obesity Evaluation and Management Program Contract for Participation" and complete **all** program requirements. Surgical clearance must be received.

**OTHER CONSIDERATIONS**

1. Surgical risk determinations: Individuals with BMI >60 and/or age >60 years are at higher surgical risk. Decisions regarding the appropriateness of surgery will be made individually based on rehabilitation potential and the physician and surgeon’s judgment regarding surgical risk and likelihood of benefit.

2. Revisional bariatric surgery.  
Patients who have previously had bariatric surgery requesting re-operation for weight loss or severe reflux will be managed individually but will need to meet BMI and co-morbidity requirements. There is no evidence suggesting that performing more aggressive bariatric procedures is indicated for weight regain after procedures with both restrictive and malabsorptive components or impaired absorption of nutrients, such as roux-en-y gastric bypass (a type of bariatric surgery).

3. Because the most common reason for surgical failure (weight regain) is inappropriate eating behaviors and lack of physical activity, patients will need to have their current behaviors carefully assessed and surgery will not be recommended unless current behaviors are conducive to appropriate for post-operative success.





UR 10.A Bariatric Surgery Medical Necessity Criteria for Commercial, OEBC and PEBB

Table with 2 columns: Department/Section/Review Responsibility and Number/Effective/Reviewed and/or revised. Includes details for Surgery, KPNW Region, and review dates from 2000 to 2017.

CONTRAINDICATIONS

- 1. Current pregnancy or desire for pregnancy in the next 18 months
2. Alcohol or substance abuse within the last year
3. Uncontrolled major psychiatric disorder. If you suspect the presence of uncontrolled depression, suicidal ideation (thoughts), paranoid ideation, psychotic disorder, multiple personality disorder or active/untreated eating disorder i.e. bulimia, a NW Permanente Psychiatrist must be consulted pre-referral to ascertain control.
4. Endogenous (originating within the body) reasons for obesity i.e. Cushing's disease, a disease characterized by increased secretion of steroids within the body
5. Clinical cirrhosis or advanced liver disease is a contraindication to bariatric surgery due to excessive operative mortality (death). Patients with hepatitis C or chronic active hepatitis B, prior jejunoileal bypass (obesity surgery), or chronically abnormal liver tests of any cause should be evaluated with further testing including transaminase levels, tests of hepatic synthetic function (albumin and PT/INR), CBC, and abdominal ultrasound with doppler.
6. Other conditions which the primary care provider, bariatric surgeon, KPNW consultant, or Severe Obesity Team member feels would raise the risk of surgery to unacceptable levels.

SPECIAL GROUP CONSIDERATIONS-

Commercial (UR10A): Applies to all commercial groups, including Federal, OEBC and PEBB members
Medicare: See UR 10B Medicare MNC for bariatric surgery
Washington Medicaid: Not covered
Oregon Medicaid: See UR 10C OHP MNC

NOTE

Patients requesting repeat bariatric procedures need to have their prior operative records obtained to define post-surgical anatomy. If this is not possible, an upper GI x-ray may be useful. If metabolic, renal,



UR 10.A Bariatric Surgery Medical Necessity Criteria for Commercial, OEBC and PEBB

Department: Surgery	Number: UR 10.A
Section: KPNW Region	Effective: 3/2000
Applies to: Bariatric Surgery	Reviewed and/or revised: 12/01, 6/02, 2/03, 12/04, 3/05, 3/06, 05/07, 10/07, 01/08, 10/08, 7/09; 11/09; 10/10; 7/11; 7/12; 7/14; 7/15
Review Responsibility: Dr. Andre Leger & Dr Nathan Bronson, Bariatric Surgery; Terri Graven, RN	Revised 7/11; 7/13; 7/16; 7/17

or hepatic complications are present from prior jejunoileal bypass, general surgery referral is recommended regardless of the BMI status to discuss revision of this operation unless clinical cirrhosis or other conditions are present that would increase operative risk to unacceptable levels.

Patients with mechanical complications stemming from previous bariatric surgeries (i.e. vomiting, obstruction) should be referred to general surgery or gastroenterology for further evaluation.

Patients with intact post bariatric surgical anatomy from previous procedures with both malabsorbptive and restrictive components will not be offered revisional operative procedures (ie stomal narrowing, band over bypass or pouch reductions) because of inadequate weight loss or weight regain. Those whose operative anatomy have broken down (ie gastric-gastric fistulae) will be considered for revisions as indicated by risk/benefit ratios.

REFERENCES

NCQA; Washington; Oregon: See UR 10 Bariatric Surgery Commercial Policy

CLINICAL

1. CMS NCD 100.1 *Bariatric Surgery for Treatment of Morbid Obesity*
2. Maggard MA, Shugarman LR, Suttrop M, et al. Meta-analysis: surgical treatment of obesity. *Ann Intern Med* 2005;142:547-559
3. Milliman Care Guidelines On-line: <http://www.careguidelines.com>
4. NIH consensus conference document: [http://consensus.nih.gov/1991/1991GI\\_SurgeryObesity084html.htm](http://consensus.nih.gov/1991/1991GI_SurgeryObesity084html.htm)
5. Sjostrom L, Lindroos AK, Peltonen M, et al. Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery. *N Engl J Med* 2004;351:2683-2693  
Snow V, Barry P, Fitterman N, et al. Pharmacological and surgical management of obesity in primary care: a clinical practice guideline from the American College of Physicians. *Ann Intern Med* 2005;142:525-531

## UR 10 B Bariatric Surgery Medical Necessity Criteria- Medicare

Department: Surgery	Number: UR 10B
Section: KPNW Region	Effective: 3/2000
Applies to: Bariatric Surgery	Reviewed: 12/01, 2/02, 6/02, 2/03, 2/04, 6/02, 2/03, 12/04,
Review Responsibility: UROC;	3/05, 3/06, 5/06, 7/06, 1/07, 2/07, 3/07, 4/07, 05/07, 10/07,
CMS Compliance Director	01/08, 4/08, 10/08, 4/09, 7/09, 11/09, 10/10; 7/11; 7/12;
Author: CMS Medicare	7/14, 7/16, 7/17
	Revised :7/11 (clarified); 7/13, 8/15

### MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR BARIATRIC SURGERY PROGRAM MEDICARE LINE OF BUSINESS (FFS and Senior Advantage)

#### DEFINITIONS

- A. **Biliopancreatic bypass with duodenal switch:** A variant of the biliopancreatic bypass. Instead of performing a distal gastrectomy, a "sleeve" gastrectomy is performed along the vertical axis of the stomach. The sleeve gastrectomy decreases the volume of the stomach and the parietal cell mass.
- B. **Gastric bypass using the Roux-en-Y anastomosis:** A procedure which restricts the size of the stomach by stapling shut 90% of the lower stomach. The proximal intestinal anatomy is re-arranged, thereby bypassing the duodenum.
- C. **Gastric banding:** A procedure which involves placing a gastric band around the outside of the stomach. The stomach is not entered.
- D. **Sleeve gastrectomy** is an irreversible surgical removal of a large portion of the stomach along the greater curvature in which the stomach is reduced to about 25% of its original size.

#### MEDICAL NECESSITY CRITERIA

Patients will be eligible to participate in the preparation process and may qualify for bariatric (obesity) surgery if:

Therapeutic measures prior to referral: Failed trial of medical treatment for obesity (see medical necessity criteria, C.)

Bariatric surgery for Medicare beneficiaries is considered reasonable and necessary for those who:

- A. Have a body-mass index (BMI)  $\geq 35$  kg/m<sup>2</sup>, and
- B. Have at least one co-morbidity related to obesity<sup>3</sup>
  - Medical management options for co-morbidities must be exhaustively considered prior to bariatric surgery referral by both patient and physician<sup>1</sup>, **and**
- C. Have documentation in the medical record or referral that the member has been previously unsuccessful with medical treatment for obesity (i.e., demonstrate the failure of reasonable non-invasive treatments for obesity).

Member must meet one of the following:

1. Minimum of 6 month participation in a recognized commercial behavioral weight

## UR 10 B Bariatric Surgery Medical Necessity Criteria- Medicare

Department: Surgery	Number: UR 10B
Section: KPNW Region	Effective: 3/2000
Applies to: Bariatric Surgery	Reviewed: 12/01, 2/02, 6/02, 2/03, 2/04,6/02, 2/03, 12/04,
Review Responsibility: UROC; CMS Compliance Director	3/05, 3/06, 5/06, 7/06, 1/07, 2/07, 3/07, 4/07, 05/07, 10/07, 01/08, 4/08, 10/08, 4/09, 7/09, 11/09, 10/10; 7/11; 7/12;
Author: CMS Medicare	7/14, 7/16, 7/17
	Revised :7/11 (clarified); 7/13, 8/15

management program. The treatment program must include hypocaloric (low calorie) diet changes, nutrition education, physical activity, and behavior change strategies. Acceptable programs include but are not limited to: Weight Watchers or similar behavioral-based programs such as Medifast, Nutrisystem, and/or Jenny Craig. Non-commercial, book-based programs, such as Atkins and Dr. Phil, do not qualify.

2. Minimum of 6 month participation in a Physician, Nurse Practitioner, Physician Assistant, Registered Dietician, or Licensed Behavioral Therapist supervised weight loss program, with or without obesity pharmacotherapy (drug therapy).
3. Three or more primary care visits over a minimum of 6 months with weight management treatment and follow-up plan, in the progress notes.
4. Participation and completion of at least an 8 week Kaiser Permanente NW (KPNW) health education weight management program.

- D. Have a diagnosis that appears on the Medicare list of co-morbid conditions supporting medical necessity for bariatric surgery procedures which includes but is not limited to diabetes, hypertension, cardiac and/or respiratory diseases. Co-morbid conditions, to qualify, must have other (nonsurgical) treatment options exhaustively considered and exercised. The co-morbidity may be controlled or uncontrolled. A controlled comorbidity will not make an individual ineligible for the bariatric surgery program if all other criteria are met.

Note: For a complete list of qualifying diagnoses (co-morbidities) for medically necessary bariatric surgery, please contact the Member Relations Department at (503) 813-4480, Monday through Friday, 8:00 am-5:00 pm.

Providers: see the following Medicare website for a complete list of ICD9 codes associated with qualifying diagnoses for medically necessary bariatric surgery:

[https://www.noridianmedicare.com/provider/updates/docs/bariatric\\_surgery\\_coverage.pdf](https://www.noridianmedicare.com/provider/updates/docs/bariatric_surgery_coverage.pdf)

## UR 10 B Bariatric Surgery Medical Necessity Criteria- Medicare

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Department: Surgery	Number: UR 10B
Section: KPNW Region	Effective: 3/2000
Applies to: Bariatric Surgery	Reviewed: 12/01, 2/02, 6/02, 2/03, 2/04,6/02, 2/03, 12/04,
Review Responsibility: UROC;	3/05, 3/06, 5/06, 7/06, 1/07, 2/07, 3/07, 4/07, 05/07, 10/07,
CMS Compliance Director	01/08, 4/08, 10/08, 4/09, 7/09, 11/09, 10/10; 7/11; 7/12;
Author: CMS Medicare	7/14, 7/16, 7/17
	Revised :7/11 (clarified); 7/13, 8/15

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### **Bariatric surgery complications.**

Procedures that might be billed for treatment of complications potentially include those on the CMS Update of 10/24/08 list. Per Medicare requirements these approvals will be done on an individual consideration basis. Requirements of 10M 100-02, Medicare Benefit Policy Manual, Ch 1, Section 120 discussing “Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare” must be met.

### **OTHER REQUIREMENTS**

CMS no longer requires that covered bariatric surgery procedures be performed in facilities that are certified Centers of Excellence.

Individual Senior Advantage or Group Senior Advantage members may be referred to KSMC for bariatric surgery if all of the following conditions are met:

1. KPNW provides a notice of choice to the member between KSMC and another facility in writing.
2. KSMC and other facilities’ Medicare certification status are provided in the Notice of Choice document.
3. Member signs and dates the Notice of Choice. Refer to: Notice of Choice document.
4. Documentation of the notice and the member's signature is kept in the KSMC outpatient record a minimum of ten years after surgery is performed.

### **CONTRAINDICATIONS**

- a. Current pregnancy or desire for pregnancy in the next 18 months.
- b. Alcohol or substance abuse within the last year.
- c. Uncontrolled major psychiatric disorder. If the presence of uncontrolled depression, suicidal ideation, paranoid ideation, psychotic disorder, multiple personality disorder or active/untreated eating disorder i.e. bulimia is suspected, a NWP Psychiatrist must be consulted pre-referral to ascertain control.
- d. Endogenous reasons for obesity i.e. Cushing’s disease.
- e. Clinical cirrhosis or advanced liver disease is a contraindication to bariatric surgery due to excessive operative mortality. Patients with hepatitis C or chronic active hepatitis B, prior jejunal-ileal bypass, or chronically abnormal liver tests of any cause should be evaluated with further testing including transaminase levels, tests of hepatic synthetic function (albumin and PT/INR), CBC, and abdominal ultrasound with Doppler. If significant abnormalities are found (i.e., ascites, hepatofugal blood flow, splenomegaly, thrombocytopenia, albumin < 3, coagulopathy despite vitamin K replacement) referral



UR 10 B Bariatric Surgery Medical Necessity Criteria- Medicare

Department: Surgery	Number: UR 10B
Section: KPNW Region	Effective: 3/2000
Applies to: Bariatric Surgery	Reviewed: 12/01, 2/02, 6/02, 2/03, 2/04,6/02, 2/03, 12/04,
Review Responsibility: UROC;	3/05, 3/06, 5/06, 7/06, 1/07, 2/07, 3/07, 4/07, 05/07, 10/07,
CMS Compliance Director	01/08, 4/08, 10/08, 4/09, 7/09, 11/09, 10/10; 7/11; 7/12;
Author: CMS Medicare	7/14, 7/16, 7/17
	Revised :7/11 (clarified); 7/13, 8/15

to gastroenterology is recommended for further evaluation prior to consideration of bariatric surgery. Although fatty infiltration of the liver and NASH (non- alcoholic steatohepatitis) are the most common causes of abnormal transaminase levels in severely obese patients, persistently abnormal liver tests should have serologic evaluation for chronic viral hepatitis as well as other causes of transaminase elevation.

- f. Other conditions which the primary care provider, bariatric surgeon, KPNW consultant, or Severe Obesity Team member feels would raise the risk of surgery to unacceptable levels.
- g. Procedures determined by CMS to be non-covered because evidence of “reasonable and necessary” is not adequate for coverage:
  1. Open adjustable gastric banding\*
  2. Open sleeve gastrectomy;
  3. Laparoscopic sleeve gastrectomy (not covered prior to June 27, 2012)
  4. Open and laparoscopic vertical banded gastroplasty
  5. Intestinal bypass surgery; and,
  6. Gastric balloon for treatment of obesity

Summary: Medicare provides coverage for the laparoscopic gastric sleeve procedures, not the open gastric sleeve, for the conditions listed (diagnoses) that support medical necessity.

SPECIAL GROUP CONSIDERATIONS

The Centers for Medicare & Medicaid Services (CMS) bariatric service benefit became effective as of 02/21/06.

Services which are covered for Medicare beneficiaries, who meet Medicare’s medical necessity criteria (see section IX) include:

1. Open and laparoscopic Roux-en-Y gastric bypass (RYGBP). This is the only operative procedure presently performed at Kaiser Sunnyside Medical Center.
2. Laparoscopic adjustable gastric banding (LAGB)
3. Open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS)
 

(Note: While BPD/DS is covered by Medicare, it is not clinically recommended by KPNW).
4. Laparoscopic Sleeve Gastrectomy (age restrictions were removed for any lap gastric sleeve procedures performed post 1/1/2015).

REFERENCES

## UR 10 B Bariatric Surgery Medical Necessity Criteria- Medicare

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Department: Surgery	Number: UR 10B
Section: KPNW Region	Effective: 3/2000
Applies to: Bariatric Surgery	Reviewed: 12/01, 2/02, 6/02, 2/03, 2/04,6/02, 2/03, 12/04,
Review Responsibility: UROC; CMS Compliance Director	3/05, 3/06, 5/06, 7/06, 1/07, 2/07, 3/07, 4/07, 05/07, 10/07, 01/08, 4/08, 10/08, 4/09, 7/09, 11/09, 10/10; 7/11; 7/12;
Author: CMS Medicare	7/14, 7/16, 7/17
	Revised :7/11 (clarified); 7/13, 8/15

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**NCQA:** NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

### **MEDICARE:**

CMS Decision Memo for Bariatric Surgery for the Treatment of Morbid Obesity  
(CAG- 00250R)

National Coverage Determination for **BARIATRIC** Surgery for Treatment of Morbid Obesity 100.1  
effective 9/24/13 (National Coverage Determination Manual (NCDM))

Noridian:

<https://med.noridianmedicare.com/documents/10546/7933826/Bariatric+Surgery+Coverage+L+CD/33e2be08-1adc-42cb-b16c-d9076c11cf92>

## UR 10 C Bariatric Surgery Medical Necessity Criteria- Oregon Health Plan (OHP)/ Medicaid Product

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Department: Surgery	Number: UR 10C
Section: KPNW Region	Effective: 1/2008
Applies to: Bariatric Surgery	Reviewed and/or revised: 4/08, 1/09, 4,09, 11/09,
Review Responsibility: UROC	10/10; 7/11; 7/12; 7/13, 7/14; 7/15; 7/16; 7/17
Authors: State of Oregon	Revised: 2/15; 9/16
Reviewers: Terri Graven, RN	

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### MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR THE BARIATRIC SURGERY PROGRAM OHP LINE OF BUSINESS

Oregon Health Plan only covers Roux-en-Y gastric bypass, laparoscopic adjustable gastric banding and sleeve gastrectomy.

#### MEDICAL NECESSITY CRITERIA

Patients will be eligible to participate in the preparation process and may qualify for bariatric (obesity) surgery when the diagnoses and services are funded as determined by the Oregon Prioritized List and when the following criteria are met:

- A) Age  $\geq$  18
- B) The patient has:
  - 1) a BMI  $\geq$  35 with co-morbid \*type II diabetes (covered on OHP Line 30, TYPE II DIABETES MELLITUS); **OR**
  - 2) BMI  $\geq$  35 with at least one significant co-morbidity other than type II diabetes, for example, obstructive sleep apnea, hyperlipidemia, hypertension (covered only when OHP Line 589 is funded) **OR**
  - 3) BMI  $\geq$  40 without a significant co-morbidity (covered only when OHP Line 589 is funded)

**\*Type II diabetes is considered a co-morbidity of obesity. Type I diabetes is not a co-morbidity and does not pair with bariatric surgery on the prioritized list.**

#### OTHER REQUIREMENTS

All qualified bariatric procedures that are covered, including the evaluation, are to be performed at a center of excellence for bariatric surgery as recognized by Medicare.

**THE FOLLOWING WILL OCCUR AT OREGON HEALTH AND SCIENCES UNIVERSITY** (as part of their Center of Excellence protocol) and are therefore not required to be done prior to admission into OHSU's Bariatric Program.

- A) Verify no prior history of Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding, unless they resulted in failure due to complications of the original surgery.
- B) Patient will participate in the following four evaluations and meet criteria as described.





UR 10 C Bariatric Surgery Medical Necessity Criteria- Oregon Health Plan (OHP)/ Medicaid Product

Department: Surgery
Section: KPNW Region
Applies to: Bariatric Surgery
Review Responsibility: UROC
Authors: State of Oregon
Reviewers: Terri Graven, RN

Number: UR 10C
Effective: 1/2008
Reviewed and/or revised: 4/08, 1/09, 4,09, 11/09, 10/10; 7/11; 7/12; 7/13, 7/14; 7/15; 7/16; 7/17
Revised: 2/15; 9/16

- 1) Psychosocial evaluation: (Conducted by a licensed mental health professional)
a) Evaluation to assess potential compliance with post-operative requirements.
b) Must remain free of abuse of or dependence on alcohol during the six-month period immediately preceding surgery.
c) No mental or behavioral disorder that may interfere with postoperative outcomes.
d) Patient with previous psychiatric illness must be stable for at least 6 months.
2) Medical evaluation: (Conducted by OHP primary care provider)
a) Pre-operative physical condition and mortality risk assessed with patient found to be an appropriate candidate.
b) Optimize medical control of diabetes, hypertension, or other co-morbid conditions.
c) Female patient not currently pregnant with no plans for pregnancy for at least 2 years post-surgery.
3) Surgical evaluation: (Conducted by a licensed bariatric surgeon associated with Program)
a) Patient found to be an appropriate candidate for surgery at initial evaluation and throughout period leading to surgery while continuously enrolled on OHP.
b) Received counseling by a credentialed expert on the team regarding the risks and benefits of the procedure and understands the many potential complications of the surgery.
4) Dietician evaluation: (Conducted by licensed dietician)
a) Evaluation of adequacy of prior dietary efforts to lose weight.
b) Counseling in dietary lifestyle changes.

C) Participate in additional evaluations:

- 1) Post-surgical attention to lifestyle, an exercise program and dietary changes and

## UR 10 C Bariatric Surgery Medical Necessity Criteria- Oregon Health Plan (OHP)/ Medicaid Product

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Department: Surgery	Number: UR 10C
Section: KPNW Region	Effective: 1/2008
Applies to: Bariatric Surgery	Reviewed and/or revised: 4/08, 1/09, 4/09, 11/09, 10/10; 7/11; 7/12; 7/13, 7/14; 7/15; 7/16; 7/17
Review Responsibility: UROC	Revised: 2/15; 9/16
Authors: State of Oregon	
Reviewers: Terri Graven, RN	

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understands the need for post-surgical follow-up with all applicable professionals (e.g. nutritionist, psychologist/psychiatrist, exercise physiologist or physical therapist, support group participation, regularly scheduled physician follow-up visits).

### SPECIAL GROUP CONSIDERATIONS

This MNC is applicable for Oregon Medicaid (Oregon Health Plan, OHP) only. OHP members can not opt out of participation with a Bariatric Surgery Center of Excellence.

### REFERENCES

#### NCQA

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3819.

#### MEDICAID

Oregon Prioritized List, Guideline Note 8.

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<sup>i</sup> Many patients (>50%) have depression as a co-morbid diagnosis that, if treated, would not preclude their participation in the bariatric surgery program.

## UR 11: Preauthorization of Durable Medical Equipment Policy

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Department: Durable Medical Equipment

Number: UR 11

Applies to: KPNW Region

Issued: 3/95

Review Responsibility: UROC

Reviewed: 5/96, 1/99, 2/00, 11/00, 2/01, 2/02, 2/03, 2/04, 2/05,  
3/06, 02/07, 05/07, 4/08, 4/09, 4/10, 4/12; 4/14SME: Jamie Flores, Shyla Bierner,  
Sam Prochovnic

Revised: 4/11, 5/16

Page: 1 of 3

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### PURPOSE

To define standards, accountabilities, and processes for preauthorization review of Durable Medical Equipment (DME) requests.

### POLICY

DME requests must meet established Medicare, Medicaid, and/or Kaiser Permanente Northwest (KPNW) medical necessity criteria (MNC) in order to qualify for coverage. The review/development/adoption of these criteria is the responsibility of the DME Advisory Committee. Oversight of the criteria is by the Utilization Review Oversight Committee (UROC).

The criteria are based on sound clinical evidence and are reviewed and/or updated annually, with a board certified physician as an active participant in the review process. The DME Advisory Committee and UROC minutes reflect the annual review of the criteria.

DME items specifically excluded by the coverage under a member's medical plan are a benefit denial. Some members, including Medicaid and self-funded group members, have different review processes.

Approved Medical Necessity Criteria (MNC) are DME equipment/supply-specific and are used in conjunction with assessment of individual patient circumstances to make the determination of medical necessity. Documentation of co-morbidities, functional limitations, duration and course of condition, rehabilitation potential, response to prior treatment, test results and physical examination findings, as these relate to the DME MNC, are considered in making a medical necessity determination. Written criteria are available to all clinicians upon request. The criteria are located in the Durable Medical Equipment (DME) department, the [KPNW–DME Formulary website](#), the [Oregon Medicaid DME Rulebook website](#) and the [Washington Medicaid DME website](#):  
(<http://apps.leg.wa.gov/WAC/default.aspx?cite=182-543>)

The DME Sharepoint now has the most up to date criteria at:

<https://sites.sp.kp.org/teams/nwreg/Admin/Finance/HME/SitePages/Home.aspx>

Denial Determinations and Appeals: Please see the associated Regional UR Policy:

**[UR 4: Utilization Management Medical Necessity Determinations](#)**

**[UR 26: Appeals of Adverse Determination](#)**

**[OHP Dispute Resolution: Policy for Handling OHP Complaints, Grievances, and Appeals](#)**

## UR 11: Preauthorization of Durable Medical Equipment Policy

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Department: Durable Medical Equipment	Number: UR 11
Applies to: KPNW Region	Issued: 3/95
Review Responsibility: UROC	Reviewed: 5/96, 1/99, 2/00, 11/00, 2/01, 2/02, 2/03, 2/04, 2/05, 3/06, 02/07, 05/07, 4/08, 4/09, 4/10, 4/12; 4/14
SME: Jamie Flores, Shyla Bierner, Sam Prochovnic	Revised: 4/11, 5/16
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### RESPONSIBILITIES

The DME Supervisor oversees the process of applying the review criteria for HME. Consistency in application of criteria is assessed at least annually for all participating physicians and staff. The DME manager partners with Utilization Review (UR) for opportunity actions regarding criteria application and a compliant referral process.

#### HME Coordinator-Initial Review

- Reviews and approves, if appropriate, Oregon Medicaid Member referrals applying Linefinder:
  - If above the line, applies appropriate MNC
  - If below the line, forwards to Regional Referral Center (RRC) RN to determine if member has a qualifying co-morbid condition:
    - RRC notifies Member Relations if no co-morbidity exists and request is denied;
    - RRC notifies DME Coordinator if member has a qualifying co-morbidity and DME Coordinator applies appropriate MNC
- Reviews and approves, if appropriate, all other referrals applying KPNW MNC (see UR 4: Utilization Management Medical Necessity Determinations)
- If the clinical information does not appear to meet medical necessity requirements, the ordering clinician may be asked to provide additional documentation.
- If medical necessity criteria are not met, the referral and all supporting clinical information are forwarded to the Utilization Management Physician Reviewer.
- Documents determination in Kaiser Permanente Health Connect Referral Management System and updates the Health Connect authorization status appropriately.

#### Utilization Management (UM) Physician

- Reviews and determines medical necessity based on MNC provided by DME.
- Notifies DME Coordinator (Cc DME pool) of the medical necessity determination.
- Please see associated Regional Policy: **UR 4: Utilization Management Medical Necessity Determinations**

#### DME Coordinator-Post UM Physician Review

- Receives determination from UM Physician reviewer.
- Documents determination in Kaiser Permanente Health Connect Referral-Management System and updates the Health Connect authorization status appropriately.
- Generates preauthorization if medical criteria are met or medical exception is necessary.
- Notifies Member Relations of any denial determination, along with the complete criteria and member specific medical necessity denial reason.

## UR 11: Preauthorization of Durable Medical Equipment Policy

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Department: Durable Medical Equipment

Number: UR 11

Applies to: KPNW Region

Issued: 3/95

Review Responsibility: UROC

Reviewed: 5/96, 1/99, 2/00, 11/00, 2/01, 2/02, 2/03, 2/04, 2/05, 3/06, 02/07, 05/07, 4/08, 4/09, 4/10, 4/12; 4/14

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Sam Prochovnic

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### Supervisor, DME department

- Monitors processes to ensure that all review processes, including physician review, will be completed and documented within the regulatory timelines, depending upon the clinical urgency of the request (see UR 4 Utilization Management Medical Necessity Determinations, and OHP Dispute Resolution: Policy for Handling OHP Complaints, Grievances, and Appeals).
- Is responsible to ensure that medical necessity determinations include all required documentation in the HealthConnect Referral Management System.
- Ensures that formulary guidelines and medical necessity criteria are updated with the most current information for Medicare, Medicaid, etc.

### UR Administrator and Project Manager

- Partner with DME supervisor or accountable stakeholders to ensure medical necessity criteria are based upon current federal and state regulatory requirements, accrediting body performance standard requirements, objective medical evidence coverage under the member's medical plan, Kaiser insurance products and organizational need.
- Audit for consistent criteria application and determination documentation (see UR 35 Consistency of UM Application-IRR Policy).

### **SPECIAL GROUP CONSIDERATIONS**

Commercial Groups (including Feds, PEBB): This policy applies.

Medicare: This policy applies to Medicare; "Check Medicare Updates Maintained by DME Department"

Washington Medicaid: TBD

Oregon Medicaid: Must be on Medicaid formulary; "Check Medicaid Updates Maintained by DME Dept"

### **REFERENCES**

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

### **WASHINGTON**

RCW 284-43-410 & RCW 483.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

### **OREGON**

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

ORS 743.837: Prior authorization requirements

### UR 12: Preauthorization Policy for Outside Referrals

Department: KPNW Utilization Review

Number: UR 12

Section: Regional Referral Center

Issued: 3/95

Applies to: KPNW Region

Reviewed: 11/98, 1/99, 12/01, 2/02, 3/03, 12/04, 12/05

Review Responsibility: UROC

Revised: 1/00, 12/01, 6/02, 11/06, 1/08, 1/10, 1/12, 1/14, 5/16, 4/18

Subject Matter Expert: Cynthia Rubio, RN

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#### PURPOSE

To define standards, accountabilities, and processes for preauthorization of requests for Outside Medical Care when either a) services are not available from Kaiser Permanente providers or facilities; or, b) services are of a type, nature, or scope that a Permanente provider is making a referral for the care to be provided outside of Kaiser Permanente facilities.

#### POLICY

Referral requests for medically necessary care outside of Kaiser Permanente facilities or to a provider outside of Kaiser Permanente must be authorized by the appropriate UM department in order to qualify for health plan coverage (HMO members). Denials of requests for outside care are reviewed by Utilization Review MDs or DOs or actively practicing clinicians from the appropriate specialty area, responsible for determining if the requested services are available, in a timely manner, within Kaiser Permanente. The process of reviewing Outside Referrals is overseen by the Director of Referral Services.

#### RESPONSIBILITIES

- A. Denials. See associated UR Policy: UR 4-Utilization Management Medical Necessity Determinations
- B. Appeals. See associated UR Policy: UR 26-Appeals of Adverse Determinations Policy
- C. Primary Action Responsibility

Referral Services Staff	<ol style="list-style-type: none"> <li>1. Review and approve or deny requests/referrals based on benefit coverage, or approve requests/referrals based on medical necessity criteria, or coordinate a physician medical necessity review, when necessary.</li> <li>2. If the clinical information does not appear to meet medical necessity requirements, the request/referral with all supporting information is forwarded to the Utilization Review (UR) doctor of the day or the MD designated to review requests for the specialty department.</li> <li>3. Monitors processes to ensure that all reviews, including physician reviews, are completed and documented within regulatory timelines, depending upon the clinical urgency of the request.</li> <li>4. Is responsible to ensure information provided to the denial letter processors is complete, accurate and timely.</li> </ol>
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### UR 12: Preauthorization Policy for Outside Referrals

Department: KPNW Utilization Review

Number: UR 12

Section: Regional Referral Center

Issued: 3/95

Applies to: KPNW Region

Reviewed: 11/98, 1/99, 12/01, 2/02, 3/03, 12/04, 12/05

Review Responsibility: UROC

Revised: 1/00, 12/01, 6/02, 11/06, 1/08, 1/10, 1/12, 1/14, 5/16, 4/18

Subject Matter Expert: Cynthia Rubio, RN

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Physician Advisor	<ol style="list-style-type: none"> <li>The reviewing physician, based on clinical expertise, knowledge of available resources/services in the local delivery system, and utilizing supporting clinical information related to the patient's individual needs (age, co-morbidities, complications, progress of treatment, psychosocial, and home environment, as applicable), will make a determination of medical necessity. Clinical information may be accessed via the electronic clinical information systems, medical records submitted by a non-Kaiser Permanente practitioner, and/or a conversation with the ordering clinician. Appropriate board-certified specialists will be consulted as necessary to determine medical necessity.</li> </ol>
RRC Manager/ RRC Associate Director	<ol style="list-style-type: none"> <li>Monitors compliance with applicable quality and regulatory guidelines.</li> <li>Designs and implements corrective action based on ongoing monitoring.</li> </ol>

#### **SPECIAL GROUP CONSIDERATIONS**

Added Choice/POS- members may directly access non-KP providers under their Tier 2 and Tier 3 benefits, without prior-authorization, for office visits that do not include a procedure. Procedures and levels of care other than office visits require prior-authorization.

#### **REFERENCES**

##### **NCQA**

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

##### **WASHINGTON**

RCW 284-43-410 & RCW 483.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

WAC 388-531-0200 Physician-related services requiring prior authorization

##### **OREGON**

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

ORS 743.837: Prior authorization requirements

## UR 12.1: Cardiac Rehabilitation Medical Necessity Criteria

Department: KPNW Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Tim Jacobson, MD (Cardiology)

Number: UR 12.1  
Issued: 04/03  
Reviewed: 3/05, 7/05, 11/05, 4/06, 7/06, 09/07, 10/07,  
10/08, 7/09, 05/10, 5/11, 7/12, 4/13, 4/14, 4/18  
Revised: 5/11, 4/13, 5/15, 5/16, 9/16, 03/17  
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Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

Requests from KP clinicians for Cardiac Rehabilitation Programs and Intensive Cardiac Rehabilitation Programs are submitted through the HealthConnect referral process for non-Kaiser services.

### DEFINITIONS

Cardiac Rehabilitation is a coordinated sum of interventions required to ensure the best physical, psychological, and social conditions so that patients with chronic or post acute cardiovascular disease may, by their own efforts, preserve or resume optimal functioning in society and, through improved health behaviors, slow or reverse progression of disease. It is a complex, individualized program intended to modify cardiac risk factors through prescribed exercise, education, counseling, and behavioral intervention.

### MEDICAL NECESSITY CRITERIA

Members will have been diagnosed with ONE of the following cardiac diagnoses or had ONE of the following cardiac procedures:

- a. coronary artery bypass surgery
- b. stable, chronic heart failure with left ventricular ejection fraction of  $\leq 45$  and New York Heart Association Class II to IV symptoms (including patients with a ventricular assist device) despite being on optimal heart failure therapy  $\geq 6$  weeks. Stable patients are defined as those who have not had recent ( $\leq 6$  weeks) or planned ( $\leq 6$  months) major cardiovascular hospitalizations or procedures.
- c. acute myocardial infarction (MI) within the preceeding 12 months
- d. current stable angina pectoris
- e. heart valve repair or replacement
- f. percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting
- g. heart or heart-lung transplant

### OTHER REQUIREMENTS

Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Programs must include the following components:

- a. Physician-prescribed exercise each day cardiac rehabilitation items and services are furnished;
- b. Cardiac risk factor modification, including education, counseling, and behavioral intervention at least once during the program, tailored to patients' individual needs;
- c. Psychosocial assessment;
- d. Outcomes assessment; and
- e. An individualized treatment plan detailing how components are utilized for each patient.



## UR 12.1: Cardiac Rehabilitation Medical Necessity Criteria

Department: KPNW Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Tim Jacobson, MD (Cardiology)

Number: UR 12.1  
Issued: 04/03  
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10/08, 7/09, 05/10, 5/11, 7/12, 4/13, 4/14, 4/18  
Revised: 5/11, 4/13, 5/15, 5/16, 9/16, 03/17  
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Cardiac rehabilitation and intensive cardiac rehabilitation items and services must be furnished in a physician's office or a hospital outpatient setting. All settings must have a physician immediately available and accessible for medical consultations and emergencies at all times during which items and services are being furnished under the program.

- a. Unmonitored exercise programs are not considered to be medically indicated and are not authorized.
- b. The program must be a graded exercise program, incorporating some educational components and monitored by a healthcare professional.
- c. The facility meets the definition of a hospital outpatient department or a physician directed clinic i.e., a physician is on the premises available to perform medical duties at all times the facility is open, and each patient is under the care of a hospital or clinic physician.
- d. The facility has available for immediate use the necessary cardio-pulmonary, emergency, diagnostic and therapeutic life saving equipment accepted by the medical community as medically necessary, e.g., oxygen, cardiopulmonary resuscitation equipment, or defibrillator.
- e. The program is conducted in an area set aside for the exclusive use of the program while it is in session.
- f. The program is staffed by personnel necessary to conduct the program safely and effectively, who are trained in both basic and advanced life support techniques and in exercise therapy for coronary (heart) disease. Services of non-physician personnel must be furnished under the direct supervision of a physician. Direct supervision means that a physician must be in the exercise program area and immediately available and accessible for an emergency at all times the exercise program is conducted.

### **CONTRAINDICATIONS (THESE ARE NOT MEDICARE APPROVED, APPLY TO COMMERCIAL MEMBERS ONLY)**

Cardiac rehabilitation should not be used when the following conditions exist (Commercial members only):

**NOTE:** Coverage for cardiac rehabilitation can not be denied for a **Medicare** member based on the existence of a contraindicated condition. When medical necessity criteria and the facility/program requirements are met, coverage must be authorized. It is up to the prescribing practitioner to determine if a co-existing condition contraindicates the provision of cardiac rehabilitation.

- a. unstable angina
- b. uncontrolled hypertension:
  - resting systolic blood pressure  $\geq 200$  mm Hg
  - resting diastolic blood pressure  $\geq 110$  mm Hg
- c. symptomatic aortic stenosis
- d. acute systemic illness or fever
- e. uncontrolled atrial or ventricular arrhythmias
- f. uncontrolled sinus tachycardia ( $>120$  bpm)
- g. atrial fibrillation or flutter with onset (new onset or recurrence)  $\leq 7$  days
- h. uncompensated heart failure

**UR 12.1: Cardiac Rehabilitation Medical Necessity Criteria**

Department: KPNW Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Tim Jacobson, MD (Cardiology)

Number: UR 12.1  
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Revised: 5/11, 4/13, 5/15, 5/16, 9/16, 03/17  
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- i. third degree atrioventricular block (without a functioning pacemaker)
- j. active pericarditis or myocarditis
- k. recent venous thromboembolism (< 3 months)
- l. resting ST displacement (> 2mm)
- m. orthopedic condition that would prohibit exercise

**SPECIAL GROUP CONSIDERATIONS****Medicare:**

As specified at 42 CFR 410.49(f)(1), cardiac rehabilitation program sessions are limited to a maximum of two 1-hour sessions per day for up to 36 sessions over or up to 36 weeks, with the option for an additional 36 sessions over an extended period of time if approved by the Medicare contractor.

Intensive cardiac rehabilitation programs must be approved by Medicare. In order to be approved, a program must demonstrate through peer-reviewed published research that it has accomplished one or more of the following for its patients:

- Positively affected the progression of coronary heart disease;
- Reduced the need for coronary bypass surgery; and/or
- Reduced the need for percutaneous coronary interventions.

An intensive cardiac rehabilitation program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in 5 or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services:

- Low density lipoprotein;
- Triglycerides;
- Body mass index;
- Systolic blood pressure;
- Diastolic blood pressure; and
- The need for cholesterol, blood pressure, and diabetes medications.

**CLINICAL**

1. Pub 100-04, Medicare Claims Processing Manual; Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Programs Furnished On or After January 1, 2010.
2. MCG; Ambulatory Care- Cardiac Rehabilitation (contraindications) 21st Edition.
3. Medicare Decision memo for Cardiac Rehabilitation (CR) Programs- Chronic Heart Failure (CAG-00437N), February 18, 2014.
4. LVEF threshold of  $\leq 45\%$  is based on the Heart Failure Reduced Ejection Fraction used by the American College of Cardiology and the American Heart Association.

## UR 12.2: Pulmonary Rehabilitation Medical Necessity Criteria

Department: KPNW Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Dr Jonathan Rettmann and  
Dr Holly Vanni (Pulmonology)

Number: UR 12.2  
Issued: 11/03  
Reviewed: 2/04; 3/06; 2/05; 4/07; 4/08, 4/09, 5/10, 5/11, 5/12,  
7/12, 5/13, 5/15, 5/16  
Revised: 5/11; 8/12; 5/13; 4/14, 6/17, 3/18  
Page: 1 of 2

### DEFINITIONS

Pulmonary Rehabilitation is a multidisciplinary program of care for patients with chronic respiratory impairment that is individually tailored and designed to optimize physical and social performance and independence.

### MEDICAL NECESSITY CRITERIA

- A. Diagnosis of moderate to very severe chronic obstructive pulmonary disease (COPD), defined as GOLD classification II, III and IV, when referred by the physician treating the chronic respiratory disease; or,
- B. Preoperative or postoperative for lung transplant or resection
- C. Interstitial lung diseases (especially idiopathic pulmonary fibrosis)
- D. Bronchiectasis
- E. Pulmonary arterial hypertension
- F. For other diagnoses for which pulmonary rehab may be indicated, the pulmonologist will provide evidence-based references supporting its approval.

### OTHER REQUIREMENTS:

Pulmonary Rehabilitation Programs must include the following components:

- a. Physician-prescribed exercise. Some aerobic exercise must be included in each pulmonary rehabilitation session (Respiratory Therapists who see patients under case management may order Pulmonary Rehab under the Pulmonology doctor-of-the-day);
- b. Education or training closely and clearly related to the individual's care and treatment which is tailored to the individual's needs, including information on respiratory problem management and, if appropriate, brief smoking cessation counseling;
- c. Psychosocial assessment;
- d. Outcomes assessment; and
- e. An individualized treatment plan detailing how components are utilized for each patient.

Pulmonary rehabilitation items and services must be furnished in a physician's office or a hospital outpatient setting. All settings must have a physician immediately available and accessible for medical consultations and emergencies at all times during which items and services are being furnished under the program.

## UR 12.2: Pulmonary Rehabilitation Medical Necessity Criteria

Department: KPNW Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Dr Jonathan Rettmann and  
Dr Holly Vanni (Pulmonology)

Number: UR 12.2  
Issued: 11/03  
Reviewed: 2/04; 3/06; 2/05; 4/07; 4/08, 4/09, 5/10, 5/11, 5/12,  
7/12, 5/13, 5/15, 5/16  
Revised: 5/11; 8/12; 5/13; 4/14, 6/17, 3/18  
Page: 2 of 2

### CONTRAINDICATIONS (THESE ARE NOT MEDICARE APPROVED, APPLY TO COMMERCIAL MEMBERS ONLY)

**NOTE:** Coverage for pulmonary rehabilitation cannot be denied for a **Medicare** member based on the existence of a contraindicated situation/condition. When medical necessity criteria and the facility/program requirements are met, coverage for Medicare members must be authorized. It is up to the prescribing practitioner to determine if a co-existing condition contraindicates the provision of pulmonary rehabilitation.

- The patient has not quit smoking or will not participate in smoking cessation activities prior to or during the course of pulmonary rehabilitation services (including tobacco, marijuana and vaping);
- The patient is not physically able, motivated or willing to participate;
- There is no expectation of measurable improvement in a reasonable and predictable time frame;
- Presence of unstable cardiac disease;
- Presence of active pulmonary infection (excludes COPD exacerbation).

### SPECIAL GROUP CONSIDERATIONS

Medicare: As specified at 42 CFR 410.47(f), pulmonary rehabilitation program sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions, with the option for an additional 36 sessions if medically necessary. Contractors shall accept the inclusion of the KX modifier on the claim lines as an attestation by the provider of the service that documentation is on file verifying that further treatment beyond the 36 sessions is medically necessary up to a total of 72 sessions for that beneficiary.

### CLINICAL REFERENCES:

- Pub 100-02 Medicare Benefit Policy; Pulmonary Rehabilitation Program Services Furnished On or After January 1, 2010.
- MCG; Ambulatory Care- Pulmonary Rehabilitation (contraindications) 21st Edition.

For NCQA; Washington and Oregon references, please see Pulmonary Rehabilitation Policy

Title: Formulary Exception Process and  
Excluded Drug Review

Department: Pharmacy Services  
Applies to: KPNW Region  
Review Responsibility: RFTC  
SME: Emily Thomas, PharmD

Number: UR 13a  
Issued: 7/96  
RFTC Review: 4/01, 6/01, 6/02, 8/04, 10/04, 12/05, 4/06, 10/07, 4/09,  
6/10, 7/11, 6/12, 6/13, 7/14, 7/16, 6/17  
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5/09, 7/10, 7/11, 7/12, 7/13, 7/14, 7/15, 9/16, 7/17  
Last Revised: 9/16, 2/17  
Page: 1 of 6

**PURPOSE**

To define the standards, accountabilities, and processes for the Clinician exception process for Therapeutic Equivalent drugs (TE) and drugs with generic equivalents on the Formularies.

To provide an objective, evidence-based, consistent review of each individual case in collaboration with a member's clinician. The Regional Formulary and Therapeutics Committee (RFTC) determines what situations require the exception process in accordance with the management of the Formularies and organizational guidelines.

Examples include, but are not limited to:

1. A physician or member requests coverage under the member's pharmacy co-payment or coinsurance (after the deductible is met, if applicable) of a non-formulary drug(s) as medically necessary.
2. A physician or member requests coverage under the member's pharmacy co-payment or coinsurance (after the deductible is met, if applicable) of a brand name drug when a generic is the preferred formulary product.

**DEFINITIONS**

- A. Therapeutic Equivalent (TE) Drugs: Therapeutic Equivalent drugs (TE) produce essentially the same therapeutic outcome and have similar toxicity profiles. Usually these drugs are within the same pharmacological class or are different dosage forms of the same drug (e.g. tablet instead of a capsule, half-tablet for a full tablet of lesser strength, etc.).
- B. Generic Equivalents (as defined by the FDA): According to the U.S. Food and Drug Administration (FDA), a generic drug is a copy that is identical to a brand-name drug in dosage, safety, strength, how it is taken, quality, performance and intended use.

**POLICY**

- A. Requests for Coverage
  1. Requests for coverage must meet exception criteria in order to qualify for pharmacy benefit coverage.
- B. Criteria Review/Revision Timelines:
  1. Criteria will be reviewed/revised by the staff of the Regional Formulary and Therapeutics Committee (RFTC) minimally every 12 months with no greater than 14 months between reviews. Updated criteria will be distributed to Committee members and are available on the Kaiser Permanente Intranet Home page.

Title: Formulary Exception Process and  
Excluded Drug Review

Department: Pharmacy Services  
Applies to: KPNW Region  
Review Responsibility: RFTC  
SME: Emily Thomas, PharmD

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6/10, 7/11, 6/12, 6/13, 7/14, 7/16, 6/17  
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5/09, 7/10, 7/11, 7/12, 7/13, 7/14, 7/15, 9/16, 7/17  
Last Revised: 9/16, 2/17  
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C. Criteria for Non-Formulary Drug Exception Request:

1. Exception Criteria

- a. Documented/substantiated intolerance to the Formulary alternative(s).
- b. Documented/substantiated allergy to the formulary alternative(s).
- c. Documented/substantiated treatment failure with the formulary alternative.

2. Other factors of consideration when applying the non-formulary exception criteria may include but are not limited to:

- a. Age
- b. Progress of treatment
- c. Co-morbidity
- d. Psychosocial status
- e. Home environment when applicable
- f. Complications

**NON-FORMULARY EXCEPTION REVIEW PROCEDURE –Initial Reviews**

A. Review Process for New Members: Transition of New Members

1. The New Member Pharmacy Services staff will conduct a phone consultation for new members requesting prescription refills within Kaiser Permanente.
2. New Member Pharmacy Services staff will obtain a medication history while helping the member transition their medications into Kaiser Permanente.
3. In consultation with the appointed clinician or designee (DOD or Doctor of the Day) selected by the new member, the clinical pharmacist will help new members maximize their pharmacy benefit and will forward all data to their appointed clinician for future reference.
4. Members may receive authorization for up to a 30-day supply of medication to last until their scheduled appointment.
5. If patient does not go through the New Member Pharmacy Services program, then the review process is the same as for existing members in section B. below.

B. Review Process for Existing Members: Clinician Requests. All medications have exception codes. If the clinician applies an exception code at the time of prescribing, the medication is automatically approved (unless it is an excluded medication or a Criteria-Based Consultation (CBC) medication and FAST does not do any review of the medication).

C. Clinician Review Process for Existing Members: Member Requests to Member Relations

Title: Formulary Exception Process and  
Excluded Drug Review

Department: Pharmacy Services  
Applies to: KPNW Region  
Review Responsibility: RFTC  
SME: Emily Thomas, PharmD

Number: UR 13a  
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5/09, 7/10, 7/11, 7/12, 7/13, 7/14, 7/15, 9/16, 7/17  
Last Revised: 9/16, 2/17  
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1. Member Relations process will be completed within regulatory timeframes for Commercial; Medicare; and Medicaid business: See Attachment 1.
2. Clinician will review the request using the exception criteria.
3. Documents or systems reviewed may include but are not limited to:
  - a. KPNW Health Connect chart notes
  - b. Pharmacy computer-notes
  - c. Information given directly from the patient
  - d. Consultation with prescribing clinician
  - e. Consultation with a Clinical Pharmacist
4. Medical necessity approvals may be made by the prescribing clinician.
5. Medical necessity denial determinations are made by the prescribing clinician or a covering physician.
6. Patient is notified of review outcome in writing.
  - a. Denial letters are sent from Member Relations with appropriate denial reason and appeal information. (See *UM Policy 4: Medical Necessity Determinations*.)
7. When a standard exception request is granted, the non-formulary drug must be provided to the member for the duration of the prescription, including refills, unless an addition review is conducted.

When an expedited exception request is granted, the non-formulary drug must be provided to the member for the duration of the exigency precipitating the expedited request.

On occasion, members will arrive at the pharmacy and verbally request a brand name (non-Formulary) after their clinician had ordered the Formulary drug. When this occurs, patient is directed to Membership Services (to start the review process with Member Relations) if the issue could not be resolved by pharmacy contacting clinician for an alternate medication or convincing patient to try an alternative medication.

**Exception Review process for Appeals - Department Specific Procedural Information.**

- A. After FAST is notified by Member Relations of appeal receipt, FAST will submit appeal and applicable documentation to RFTC physician, if the member states s/he does meet the exception criteria.
- B. RFTC Physician makes a coverage decision based on member chart review, in conjunction with prescribing clinician as needed, and then, notifies FAST of decision.

Title: Formulary Exception Process and  
Excluded Drug Review

Department: Pharmacy Services  
Applies to: KPNW Region  
Review Responsibility: RFTC  
SME: Emily Thomas, PharmD

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Last Revised: 9/16, 2/17  
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- C. RFTC Physician decisions shall include a specific denial or approval reason (i.e. what criteria the member does meet for approval or what criteria the member does not meet for a denial).

**EXCLUDED DRUG REVIEW PROCEDURE**

- A. If a drug whose primary indication is excluded from coverage is prescribed for another indication which is not excluded from coverage, that drug may be reviewed for a Pharmacy benefit exception on a patient specific basis. Review process will be completed within two business days of the clinician's request.
1. The following criteria should be considered for such reviews:
    - a. Request for coverage is from a Clinician.
    - b. Specialty provider is consulted and approves of treatment plan.
    - c. There is documented evidence in the scientific literature that the drug is effective and safe for prescribed indication.
    - d. Member has history of treatment failure with, or is inappropriate candidate for, formulary alternatives.
    - e. RFTC staff must be contacted prior to initiating therapy.
  2. The following process should occur when a request of this nature is considered:
    - a. Clinician contacts RFTC staff, discusses specific case and previous therapies with Clinical Pharmacist.
    - b. Clinical Pharmacist:
      - i. Performs a review of scientific literature to evaluate safety and efficacy of proposed drug therapy
      - ii. Performs review of patient medical record
      - iii. Determines that formulary therapies will not achieve therapeutic goal
      - iv. Consults with clinician specialist
      - v. Discusses case with RFTC Chair
    - c. If approved, the Pharmacist will contact the prescribing clinician to establish guidelines for use and process for ordering the medication to facilitate smooth access and coverage of the drug therapy throughout the system.
- B. Drugs used for indications excluded from coverage by contract language are not eligible for a Pharmacy benefit exception review.



## Title: Formulary Exception Process and Excluded Drug Review

Department: Pharmacy Services  
 Applies to: KPNW Region  
 Review Responsibility: RFTC  
 SME: Emily Thomas, PharmD

Number: UR 13a  
 Issued: 7/96  
 RFTC Review: 4/01, 6/01, 6/02, 8/04, 10/04, 12/05, 4/06, 10/07, 4/09,  
 6/10, 7/11, 6/12, 6/13, 7/14, 7/16, 6/17  
 Reviewed by UROC: 2/03, 1/04, 11/04, 12/05, 6/06, 8/07, 11/07, 11/08,  
 5/09, 7/10, 7/11, 7/12, 7/13, 7/14, 7/15, 9/16, 7/17  
 Last Revised: 9/16, 2/17  
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### Attachment 1: NW TURN-AROUND TIMES INITIAL DETERMINATION/ NOTIFICATION/ EXTENSION

BD= business days

CD= calendar days

H= hours

	OR CO	OR Medicaid	WA CO	WA Medicaid	Medicare part D	On Exchange OR and WA Ind. & SBG	On/Off Exchange WA Ind. & SBG
Pre-service Routine  (provider requests)	Decision and Notification-  <b>2 BD</b> from receipt of request	Decision and Notification- <b>14 CD</b> from receipt of request	Decision and Notification-  <b>5 CD</b> from receipt of necessary information	Decision-  <b>5 CD</b> from receipt of necessary information	Decision and Notification - <b>72 H</b> from receipt of request  If request is for an exception without prescriber supporting documentation, must wait an additional <b>24H</b> before denying (total of <b>96H</b> ) to obtain needed information.	For formulary exception process, Decision and Notification - <b>72 H</b> from receipt of request	For formulary exception process, Decision and Notification - <b>72 H</b> from receipt of request
Pre-service Urgent/ Expedited	Decision and Notification-  <b>2 BD</b> from receipt of request  (Per NCQA, not to exceed <b>72 H</b> )	Decision and Notification-  <b>3 BD</b> from receipt of request- includes alcohol and drug services & care required while in a SNF; may extend <b>14 CD</b>	Decision and Notification-  <b>48 H</b> from receipt of necessary information	Decision and Notification-  <b>48 H</b> from receipt of necessary information	Decision and Notification-  <b>72 H</b> from receipt of request  <u>Part D:</u>  Decision and verbal Notification- <b>24 H</b> from receipt  (additional 3 CD for written notification)	For urgent formulary exception process, Decision and Verbal Notification-  <b>24 H</b> from receipt of request	For urgent formulary exception process, Decision and Verbal Notification-  <b>24 H</b> from receipt of request
Concurrent	When urgent, Decision and Verbal Notification- <b>24H</b> from receipt of request  (additional <b>3 CD</b> for written notification)	Decision and Notification-  <b>10 CD</b> prior to termination of previously authorized service	When urgent, Decision and Verbal Notification-  <b>24H</b> from receipt of request  (additional <b>24 H</b> for written notification)	Decision and Notification-  <b>10 CD</b> prior to termination of previously authorized service	Decision and Verbal Notification- <b>24H</b> from receipt of request  (additional <b>3 CD</b> for written notification)	For urgent formulary exception process, Decision and Verbal Notification-  <b>24H</b> from receipt of request	For urgent formulary exception process, Decision and Verbal Notification-  <b>24H</b> from receipt of request

## Title: Formulary Exception Process and Excluded Drug Review

Department: Pharmacy Services  
 Applies to: KPNW Region  
 Review Responsibility: RFTC  
 SME: Emily Thomas, PharmD

Number: UR 13a  
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 RFTC Review: 4/01, 6/01, 6/02, 8/04, 10/04, 12/05, 4/06, 10/07, 4/09,  
 6/10, 7/11, 6/12, 6/13, 7/14, 7/16, 6/17  
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 5/09, 7/10, 7/11, 7/12, 7/13, 7/14, 7/15, 9/16, 7/17  
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	OR CO	OR Medicaid	WA CO	WA Medicaid	Medicare part D	On Exchange OR and WA Ind. & SBG	On/Off Exchange WA Ind. & SBG
Post-Service	Decision and Notification-  <b>30 CD</b> from receipt of necessary information	Decision and Notification-  <b>30 CD</b> from receipt of necessary information	Decision and Notification-  <b>30 CD</b> from receipt of necessary information	Decision and Notification-  <b>30 CD</b> from receipt of necessary information	Decision and Notification-  <b>14 CD</b> from receipt of necessary information	See applicable line of business	See applicable line of business
Member Requests (pre-service routine)	<u>NON-ERISA ONLY:</u> Decision and Notification-  <b>2 BD</b> from receipt of request	Decision and Notification-  <b>14 CD</b> from receipt of request	<u>NON-ERISA ONLY:</u> Decision and Notification-  <b>5 CD</b> from receipt of necessary information	Decision and Notification-  <b>5 CD</b> from receipt of necessary information	Decision and Notification –  <b>72 H</b> from receipt of request  If request is for an exception without supporting documentation, may extend to total of <b>96H</b> to obtain needed information	For formulary exception process, Decision and Notification –  <b>72 H</b> from receipt of request	For formulary exception process, Decision and Notification –  <b>72 H</b> from receipt of request

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Department: Pharmacy Administration	Number: UR 13b
Applies to: KPNW Region	Issued: 10/03
Review Responsibility: RFTC	RFTC Review: 10/05, 4/06, 6/07, 10/07, 4/09, 5/10, 7/11, 6/12, 6/13, 7/14, 7/15, 8/15, 12/15, 7/16, 6/17
SME: Emily Thomas, PharmD	UROC Review: 02/04, 04/05, 10/05, 11/05, 6/06, 8/07, 11/07, 11/08, 5/09, 5/10, 7/11, 7/12, 7/13, 7/14, 7/15, 7/16, 7/17
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### Purpose

The Formulary process is intended to enhance the quality of patient care by ensuring that available drugs meet established quality standards by providing information for safe and effective use and by limiting the availability of drugs that are unsafe, less effective, and ineffective or have high potential for toxicity or abuse.

Formularies provide a vehicle for educating practitioners on the relative safety, medical appropriateness and cost-benefit of various drug therapies. It promotes use of effective but less costly therapeutic equivalents, reduces the number of therapeutically redundant drugs, maximizes leverage through the drug purchasing and bid process, and optimizes pharmacy management of drug inventories.

There are four outpatient drug formularies for the Kaiser Permanente Northwest Region: the Commercial Formulary, the National Medicare Part D (MPD) Formulary, the Oregon Marketplace Formulary, and the Washington Marketplace Formulary. (For additional policy related to the National MPD Formulary, refer to the National MPD Formulary Policies).

### Policy

The Kaiser Permanente Drug Formularies are a compilation of drugs and drug supplies approved by the Regional Formulary and Therapeutics Committee (RFTC) for general use. The RFTC (refer to the *Constitution of the Regional Formulary and Therapeutics Committee*), with expert guidance from various specialists, evaluates, appraises and selects from available drugs those considered to be the most appropriate for patient care and general use within the Northwest region. The Formularies are published under authority of the RFTC.

### Procedure

#### A. Formulary Drugs

1. Formulary drugs are drugs and biologic agents that have been reviewed by the RFTC and placed on the Formulary.
2. Non-formulary drugs are drugs which have not yet been reviewed or which were reviewed but not accepted for inclusion in the Formulary.
3. Therapeutic Equivalent drugs (TE) produce essentially the same therapeutic outcome and have similar toxicity profiles. Usually these drugs are within the same pharmacological class or are different dosage forms of the same drug (i.e. tablet for capsule or half-tablet for full tablet of lesser strength).
4. KPNW does not employ incentives or penalties in order to influence clinician prescribing. KPNW does employee formulary education to encourage and support formulary prescribing.

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Department: Pharmacy Administration	Number: UR 13b
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SME: Emily Thomas, PharmD	UROC Review: 02/04, 04/05, 10/05, 11/05, 6/06, 8/07, 11/07, 11/08, 5/09, 5/10, 7/11, 7/12, 7/13, 7/14, 7/15, 7/16, 7/17
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5. Some drugs are restricted to use by one or more specialty physician groups or for use within the framework of a specific guideline. Restricted drugs are identified as such in the electronic medical record “medication orders” screen. Therapeutic messaging instructs the prescriber about the specific restriction.

- a. Criteria for restriction may include:
  - i. High potential for abuse.
  - ii. High potential for adverse effects (significant side-effect profile).
  - iii. High cost to benefit ratio in conjunction with other clinical concerns.
- b. KPNW employs Criteria-Based Consultation Prescribing. (*See UM Policy 13e: Criteria-Based Consultation Prescribing* for more information).

#### B. Drug Selection

1. Drugs are chosen for formulary review based on one or all of the following:
  - a. A practitioner requests review of a certain drug via *form 11.7* “Drug Formulary Change Request Form.”
  - b. The drug represents a therapeutic class of drugs reviewed during an annual review of all formulary drugs.
  - c. The drug becomes generically available.
  - d. High rate of non-formulary use.
  - e. New information is available to support a change in current formulary.
  - f. NOTE: To assess post-marketing safety and effectiveness data, the committee may wait a few months after market entry to review a drug.
2. Drug selection decisions are made primarily based on safety and effectiveness. Safety and effectiveness are determined by a thorough review of pertinent medical evidence, incorporating expert opinion and relevant findings from appropriate external organizations (e.g., Centers for Disease Control, National Institutes of Health, American Academy of Pediatrics, etc.). After safety and effectiveness are investigated, cost is considered.
  - a. Medical evidence can include peer reviewed journal articles obtained through library searches and on-line search engines, as well as Kaiser Permanente Drug Information Services in other Kaiser Permanente regions. Medical evidence provides insight into the following:
    - i. Documentation of effectiveness
    - ii. Results and extent of clinical investigation
    - iii. Severity and incidence of toxicity and side effects
  - b. Expert opinion is obtained from practitioners who serve as consultants to the RFTC. Consultants may be invited to an RFTC meeting to present their opinions regarding the inclusion of certain

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SME: Emily Thomas, PharmD	UROC Review: 02/04, 04/05, 10/05, 11/05, 6/06, 8/07, 11/07, 11/08, 5/09, 5/10, 7/11, 7/12, 7/13, 7/14, 7/15, 7/16, 7/17
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medications on the formulary, or they may present their opinions in writing or verbally communicate with a RFTC member.

- c. Relevant findings of appropriate external organizations are included in the monographs presented to the RFTC for consideration. Information is usually obtained via reliable sites on the internet or from peer reviewed journals.
- d. Additional information considered in making decisions include:
  - i. Availability of current formulary drugs to meet the therapeutic need
  - ii. Reliability and quality control of the drug manufacturer
  - iii. Current utilization of the drug by practitioners within the program
  - iv. Comparative cost of alternative equivalent therapy
  - v. Utilization of the Non-Formulary Exception Process (See Section D below).
  - vi. Other unique attributes which may warrant inclusion of the drug.

3. After the RFTC has reviewed the clinical evidence, expert opinion and other relevant information, a motion is made to add the drug to the Formulary, not add to the Formulary, to defer the decision awaiting further clinical information or, if applicable, to delete a drug from the Formulary. The decision is carried forth via parliamentary procedure and simple majority vote of the RFTC. Changes to the Formulary are not effective until they are posted on the internet the second Tuesday of the month following the meeting, unless otherwise specified.

### C. Formulary Reviews

1. All therapeutic classes of medications are reviewed on an annual basis. Throughout the year, the RFTC periodically selects specific classes of drugs for review (e.g., antibiotics, antihypertensives, etc.). The review includes current Formulary products, existing non-Formulary alternatives and drugs which have recently been introduced into the market.
2. On an annual basis, the Medicare Formulary and the Marketplace Formularies are reviewed and approved in conjunction with the Commercial Formulary.
3. Any KPNW practitioner, pharmacist or member may request that a drug or dosage form be added to or deleted from the Formulary. Practitioner and pharmacist requests may be submitted in writing via form 11.7, "Drug Formulary Change Request Form" or via verbal communication to an RFTC member. Members requesting a formulary change will be directed to the Member Relations Department to submit a formal request that will be reviewed through the medical necessity determination process and, if approved, through the RFTC review process.
4. The RFTC evaluates the medical and pharmaceutical literature, discusses use of the drug with experts in the appropriate area of specialty, and may contact the requesting practitioner or

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pharmacist for additional information before discussing data and recommendations at the RFTC meeting.

5. The RFTC Staff communicates the committee's decision to the requesting practitioner or pharmacist within thirty days after the decision is made (See Section-E., below regarding communication).
6. The internal RFTC Actions document specifies effective dates for all formulary changes. This document generates changes to KP HealthConnect, ePIMS, Lexicomp, and the PBMs.

**NOTE:** Member requests are evaluated by their physician for medical appropriateness and may be prescribed via the Non-Formulary Drug Review Process. Should the physician deem a formulary exception is necessary, Section D., Non-Formulary Drug Exception Process is followed.

D. Non-Formulary Drug Exception Process

1. Drugs not on the KPNW Formulary list are considered non-formulary, and are not covered by the drug plan co-pay or co-insurance, unless the prescribing clinician has determined the non-Formulary medication to be medically necessary.
2. The KPNW Regional Formulary and Therapeutics Committee sanctions the Non-Formulary Drug review process. The process is initiated by clinicians, pharmacy staff or members, and is overseen by Clinical Pharmacists, the RFTC Physician Chairman, and Pharmacy Department managers. (See *UM Policy 13a: Formulary Exception Process and Excluded Drug Review*, for additional information on the exception process).
3. The Non-Formulary Drug review process does not apply to drugs used for indications excluded by contract, drugs used for non-covered services, or drugs with criteria (see *UM Policy 13e: Criteria Based Consultation Prescribing & Step Therapy*).
4. The New Member Pharmacy Services Staff will conduct a telephone consultation for new members requesting prescription refills. New Member Pharmacy Services staff will obtain a medication history while helping members transition their medications into Kaiser Permanente. In consultation with the PCP selected by the member, the clinical pharmacist will help members maximize their pharmacy benefit and forward all data to the new PCP for future reference. Members may receive authorization for up to a 30 day supply of medication to last until their scheduled PCP appointment. The PCP appointment date is determined by individual patient requirements.

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#### E. Availability of Formulary to Practitioners

1. The KPNW Drug Formularies are available to all clinicians and Health Plan staff via the internal KPNW Pharmacy Department website. Contract providers can access the Formularies via the kp.org website.
2. Physicians and Allied Health Plan staff are provided with information about the drug Formulary process upon employment. The New Clinician Packet also includes information about Therapeutic Equivalency interchange and authorization, and other materials pertinent to the Pharmacy Department Formulary Management procedures.
3. A copy of the monthly RFTC meeting minutes, which includes drug summary rationale of formulary decisions, is distributed to all KPNW physicians and Allied Health Plan staff. The RFTC meeting minutes are also sent to all pharmacy department staff via electronic mail distribution.
4. The Formulary postings on the internal website (for employee use) and externally on kp.org are derived from the same system (Lexicomp) and are updated monthly to reflect changes made by the RFTC, including new drugs that are made available. Changes to the Formularies become effective the second Tuesday of the month following the meeting.
5. Updates are mailed to non-Northwest Permanente network clinicians/providers when substantive changes are made to processes and information not posted on the internet, and no less frequently than once per year.

#### F. Communication to Members

1. Both existing and prospective members are informed about the Kaiser Permanente Formulary Process via the Formulary process document, which includes information about how drugs are evaluated for formulary addition, and the criteria and process used to make those decisions. Members may access the Formulary on the internet via kp.org, or request a paper copy of the Formulary list from a KPNW pharmacy or have a paper copy mailed.
2. Coverage determination of formulary or non-formulary medications or the extent of coverage is communicated to members.
  - a. Prospective members are informed through their enrollment materials and/or in-services provided by the sales and marketing representatives.
  - b. Existing members are informed through their Human Resources Department, or by calling Pharmacy Services. Also, verbal information about the Non-Formulary Exception Process is provided at the time a non-formulary medication request is initiated.

#### G. Applying the Formulary

These criteria do not imply or guarantee approval. Please check your plan to ensure coverage. Preauthorization requirements are only valid for the month published. They may have changed from previous months, and may change in future months. JULY-18

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Department: Pharmacy Administration      Number: UR 13b  
Applies to: KPNW Region                      Issued: 10/03  
Review Responsibility: RFTC                  RFTC Review: 10/05, 4/06, 6/07, 10/07, 4/09, 5/10, 7/11, 6/12, 6/13,  
SME: Emily Thomas, PharmD                7/14, 7/15, 8/15, 12/15, 7/16, 6/17  
UROC Review: 02/04, 04/05, 10/05, 11/05, 6/06, 8/07, 11/07, 11/08,  
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1. Practitioners
  - a. All KPNW Physicians and Allied Health providers who are licensed to prescribe pharmaceuticals in the state of Oregon or Washington may prescribe Formulary drugs without restriction.
  - b. Restricted medications are labeled as such in the Formulary and may be prescribed only by clinicians in certain specialties as designated in the Formulary.
    - i. Clinicians within the specialty may prescribe the restricted product without special authorization.
    - ii. Clinicians outside the designated specialty may only prescribe the restricted medication after consultation with a designated specialist. Upon specialist's approval, the prescribing clinician orders the restricted drug and documents the specialist's recommendations in the Electronic Medical Record.
2. Members
  - a. Formulary Drugs are covered under the prescription drug benefit and are available to members according to their specific plan co-pay or coinsurance (after the deductible is met, if applicable). See the section under *Procedure: A. Formulary Drugs* above for additional clarification.
  - b. Non-Formulary drugs are not covered under the prescription drug benefit. Members are required to pay full price for non-formulary medications unless the prescribing clinician deems the non-formulary drug to be medically necessary using the exception process (see *UM Policy 13a: Formulary Exception Process and Excluded Drug Review*).
  - c. Medically necessary non-formulary drugs are covered under the normal prescription drug benefit.
  - d. Tiered co-pay plans for brand/generic products are employed by KPNW. Co-pays for brand/generic drugs apply as defined by the specific plan. Generally, brand drugs on the Formulary are covered at the brand co-pay or coinsurance (after the deductible is met, if applicable) and generic drugs on the formulary are covered at the generic co-pay or coinsurance (after the deductible is met, if applicable). Exceptions to the brand co-pay or coinsurance rule are determined by RFTC and occur when our purchasing contract allows the bulk price savings be passed on to our KPNW members.
  - e. Standard prescription quantities are as defined by the drug benefit: a 30-day supply or unit of use per co-payment or coinsurance (after the deductible is met, if applicable) at the clinic level, or a 90 day supply of maintenance medication for two (2) co-payments from the mail order pharmacy as defined by the plan. There are no limits on the number of prescriptions, which may be prescribed per member, or number of refills other than those delineated by state and federal laws or per RFTC recognized therapeutic guidelines established by the FDA.
3. Pharmacists
  - a. Pharmacists adjudicate each prescription based on its formulary status and adherence to the prescription drug benefit.



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- b. Upon receipt, all prescriptions are entered into the computer system and evaluated for correctness by a pharmacist as required by law. The pharmacist verifies the drug, dose, strength, and directions for use and formulary status.
  - c. If the medication is on the Formulary, the prescription is filled and pharmacy staff collects the appropriate co-pay or coinsurance amount, as appropriate.
  - d. If the prescription is for a non-Formulary drug, the member may purchase the non-Formulary medication at the retail price. If the patient disagrees with being charged the full retail price, the pharmacist may:
    - i. Contact the prescribing clinician to suggest using an appropriate Formulary alternative. If the prescribing clinician agrees to convert the non-Formulary medication to the Formulary alternative, the pharmacist makes the change and fills the prescription, charging the member the regular co-payment or co-insurance, as appropriate; or
    - ii. Member may file grievance/request appeal through Member Relations. If the medication is denied because it was found not to be medically necessary by the prescribing clinician, the medication is dispensed to the member at the retail price. (For additional information on the Exception Process, see *UM Policy 13a: Formulary Exception Process and Excluded Drug Review*).
4. Generic Substitutions
- a. As drugs become available in generic form, they are reviewed by the RFTC based on bioequivalence data provided by the Food and Drug Administration (FDA). Clinicians may deem a non-Formulary branded drug to be medically necessary using the non-Formulary exception review process. If found to be medically necessary, the branded non-Formulary drug is covered at the branded co-pay or co-insurance (after the deductible is met, if applicable) as described in *UM-13a, "Formulary Exception Process and Excluded Drug Review"*.
    - i. Members demanding non-Formulary branded products will pay the retail cost of the drug unless medically necessary as determined through the Criteria-Based Consultation Prescribing review process. (See *UM Policy 13e: Criteria-Based Consultation Prescribing*).
    - ii. Single-sourced branded formulary drugs are covered under the member's branded co-payment or co-insurance as defined in Section-G. 2. d, above.
    - iii. Pharmacists administer generic substitution as outlined by the state Board of Pharmacy laws.
      1. Oregon State Pharmacy Statutes, Chapter 689. 689.515 Regulation of generic drugs; substitutions; rules.  
[https://www.oregonlegislature.gov/bills\\_laws/lawsstatutes/2013ors689.html](https://www.oregonlegislature.gov/bills_laws/lawsstatutes/2013ors689.html)
      2. Washington 69.41.130: Savings in price to be passed on to purchaser:  
<http://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/Pharmacist/Laws>  
Unless the brand name drug is requested by the patient or the patient's representative, the pharmacist shall substitute an equivalent drug product which he or she has in stock

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if its wholesale price to the pharmacist is less than the wholesale price of the prescribed drug product.

## Kaiser Permanente Northwest Pharmacy System

### PHARMACY PROGRAM DESCRIPTION

*(RFTC Review/Approval: 4/09, 6/10, 7/11, 6/12, 6/13, 7/14; 7/15, 7/16, 6/17*

*UROC Review: 5/09, 7/10, 7/11, 7/12, 7/13, 7/14, 7/15, 7/16, 7/17*

*Last Revised 7/16, 7/17*

The Regional Pharmacy Department uses an integrated, electronic delivery system to serve the Kaiser Permanente Northwest (KPNW) region from Eugene, Oregon to Longview, Washington, with 30 pharmacy locations available to serve over 500,000 members and fill more than 5 million prescriptions annually.

Medication safety, efficacy and cost are the core values of the KPNW Pharmacy Department. These values are applied at monthly meetings of the Regional Formulary and Therapeutics Committee (RFTC) through “evidence-based” decision making. These decisions are implemented by the Clinical Pharmacy Services department with operations staff assistance down to the clinic pharmacy level. Formulary decisions, drug initiative strategies, and Pharmacy Department policies & procedures are made available to all pharmacy, health plan and medical staff via several communication methods, including postings on the Pharmacy Department internal website and electronic mail distributions. As a result, the pharmacy program and all elements of pharmacy service delivery support the mission of Kaiser Permanente.

The RFTC maintains policies and procedures for pharmaceutical management as a framework to guide safe, effective and cost-conscious medication management in each therapeutic area. KPNW regional clinical targets help shape the development of pharmaceutical management procedures. The use and development of policies ensure consistent application of the procedures and support contractual obligations to KPNW members. The review of pharmacy policies and procedures is an ongoing process, with all policies reviewed at least annually and updated as appropriate.

To facilitate consistent application of the RFTC’s formulary decisions and drug initiative strategies, approved criteria and therapeutic messaging is programmed into the electronic medical record and pharmacy computer system. These electronic systems are used by all clinicians, pharmacy and medical staff of KPNW. This enhances patient safety by allowing for real time communication between medical staff and pharmacy staff.

### Pharmacy Oversight & Administration

Responsibility for the development and review of pharmaceutical management policies is delegated to RFTC by the KPNW Regional Operations Quality Group (ROQG).

The RFTC membership is broad-based and includes practicing primary care physicians, hospitalists, pharmacist experts, and consulting specialty physicians.

The RFTC meets monthly and implements the formulary process to support the successful attainment of Kaiser Permanente goals for rational, safe, effective and economical drug therapy in the Northwest Region.

## Management of Pharmaceutical Policies & Procedures

The RFTC sponsors several subcommittees. Among them are the Regional Antibiotic Subcommittee, the Natural Products Advisory Committee, and the Immunization Practice Committee. The membership of these subcommittees includes physicians, pharmacists and other health care professionals [all subject matter experts in their given specialty area]. These subcommittees forward their recommendations to the RFTC for consideration. Approval and adoption follows the process described above.

The RFTC utilizes many medical expert resources to establish recommendations for safe and effective drug use within Kaiser Permanente. The regional Pharmacy Department functions independently but is interactive with other Kaiser Permanente regions. Examples of interregional cooperation include the sharing and development of drug monographs used by RFTC to make evidence-based medication determinations.

## KPNW Formulary Process

The major responsibilities of the RFTC are the development of the KPNW Drug Formularies and the Therapeutic Equivalencies, as well as approval of medication related clinical content in the electronic medical record and any guideline that includes pharmaceutical agents. In developing the Formularies, the RFTC and the specialists evaluate, appraise and select from all available drugs those considered to be *most* appropriate for patient care and general use in the KPNW region.

The Formularies are reviewed at least annually by the RFTC and updated as appropriate.

The RFTC promotes the use of the Formulary and therapeutic equivalencies utilizing direct communication and education to encourage and support clinician use of preferred drugs. The Pharmacy Department acknowledges the use of non-formulary drugs when deemed medically necessary by the prescribing clinician or when prescribing criteria is met. Non-formulary drugs excluded by contract are not covered, but may be ordered.

When KPNW clinicians order a non-formulary drug that is not a criteria-based medication, there is a process to determine coverage, however this is not a requirement of the Utilization Management program. Ultimately, if a physician determines a non-formulary drug that is not criteria-based to be medically necessary and it is not excluded by contract, the clinician may order it for the member. If the non-formulary drug is determined to be medically necessary, the drug will be covered as specified by the member's pharmacy benefit.

When KPNW clinicians order a non-formulary, criteria-based medication, there is a specific process to determine coverage [see *UM Policy 13e: Criteria-Based Consultation Prescribing*].

## Pharmacy Communication to Clinicians and Members

All changes to the Formularies and Pharmaceutical Management policy or procedure are communicated to clinicians and members. This communication includes restrictions and preferred pharmaceuticals, an explanation of limits or quotas when applicable, how to use the pharmaceutical management procedures, the formulary exception process, how the prescribing clinician must support or provide information in support of a formulary exception request, and the processes for generic substitution, therapeutic interchange and step-therapy.

KPNW clinicians are routinely notified via the Pharmacy Department website, electronic mail distributions and the electronic medical record. The Pharmacy Department website is an official communication channel and clinicians are notified what the website contains and how to access

the site in their new hire packets. The Utilization Management department physician survey confirms clinician use of this communication method. External contracted clinicians are notified via a direct mailing annually and when changes are made to pharmaceutical management procedures. External contracted clinicians have access to the KPNW Formularies via the community provider portal and the KPNW member website, kp.org, and are notified of criteria-based consultation medication changes when they occur via direct mailing.

Members are notified via the annually-distributed Evidence of Coverage (member contract) and the annually-distributed Medical Directory on how to obtain or electronically access information regarding the prescription drug formulary process and the current Formularies. Members are notified via a member mailing if substantive changes are made to pharmacy procedures that affect their prescription drug benefit that were not included in their Evidence of Coverage.

### **Review of Management Policies, Procedures and Drugs**

The RFTC is also accountable to oversee the ongoing review of Pharmaceutical Management policies and procedures and the evaluation of drugs for inclusion or removal from the drug Formularies. This monthly review includes but is not limited to:

- Annual review of existing formulary drugs
- Process of adding a drug to a formulary
- Process of deleting a drug from a formulary
- Process of communicating policies and procedures to practitioners annually and/or when a formulary is changed

### **Criteria used for Policy Development**

Criteria for inclusion of a drug to the Formularies include, but are not limited to: demonstrated safety, measurable effectiveness, and affordability. Varied mechanisms and processes are used to execute these criteria.

#### **Safety**

- The RFTC process of evaluating medications allows for NOT adding medications that have high side effect profiles with risks that outweigh benefit.
- Safety alerts which occur at the time of dispense, allowing for immediate clinician notification.
- Known drug interactions and drug contraindications are monitored with the use of computer software programs that are continually updated.
- Ongoing review and monitoring of many pharmaceutical resources, including the FDA website for new or updated drug information including FDA directed withdrawals due to safety, contamination, manufacturing errors and mislabeling.
- Electronic Medical Record drug orders and individualized prescription histories are kept on electronic file and allow for member specific notification in the case of national drug withdrawals or other formulary process changes that would affect the member.

### **Efficacy**

Efficacy is the demonstrated effectiveness of the drug in question for the indication for which it is prescribed. Effectiveness is determined by a thorough review of pertinent medical evidence, incorporating expert opinion and relevant findings from appropriate external organizations (e.g., Centers for Disease Control, National Institutes of Health, American Academy of Pediatrics, etc.).

- Medical evidence can include peer reviewed journal articles obtained through library searches and on-line search engines, as well as Kaiser Permanente Drug Information Services in other Kaiser Permanente regions.
- Expert opinion is obtained from practitioners who serve as consultants to the RFTC. Consultants may be invited to an RFTC meeting to present their opinions regarding the inclusion of certain medications on the Formularies, or they may present their opinions in writing or verbally communicate with a RFTC member.
- Relevant findings of appropriate external organizations are included in the monographs presented to the RFTC for consideration. Information is usually obtained via reliable sites on the internet or from peer reviewed journals.

### **Cost**

Since effective use of the membership dollar is a primary Pharmacy Department value, the RFTC works with both Kaiser Permanente Regional and National Drug Purchasing departments to ensure Formulary drugs are not only safe and effective, but cost competitive. Methods of ensuring this include:

- Community based pricing strategies, allowing the KPNW Purchasing Department to monitor the pulse of retail community pharmacies to ensure we are within predefined limits.
- National contract and volume purchasing, allowing all Kaiser Permanente regions to optimize the health plan's ability to purchase large volumes of any given medication at a set price per unit for a determined contract period.

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Department: Pharmacy Services	Number: UR13e
Applies to: KPNW region	Effective: 3/01/04
Review Responsibility: RFTC	Last Revised: 8/13/15
SME: Emily Thomas, PharmD	Reviewed RFTC: 10/04, 10/05, 4/06, 6/07, 10/07, 4/09, 6/11, 6/12, 6/13, 7/14, 7/15, 8/15, 7/16, 6/17
	Reviewed UROC: 4/05, 11/05, 6/06, 8/07, 11/07, 11/08, 5/09; 5/10, 7/11, 7/12, 7/13, 7/14, 7/15, 7/16, 7/17
	Last Revised: 7/16
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## PURPOSE

The Kaiser Permanente Northwest Regional Formulary and Therapeutics Committee (RFTC) has developed prescribing criteria to apply to selected medications. Medications classified as criteria-based or step therapy are usually second- or third-line medications for the treatment of a specific disease state. The RFTC uses both internal and external resources, including Specialty Department input, Food and Drug Administration recommendations, and clinical trials published in the medical literature to guide them in the creation of prescribing criteria. This process is a cornerstone of the KPNW Formulary Process.

## DEFINITIONS

- A. Step Therapy: RFTC may recommend that certain drugs be chosen as second- or third-line medications in the treatment of specific disease states. If the first- or second-line agents are ineffective or not tolerated, clinicians may prescribe drugs that are designated as step therapy. First- and second-line agents are selected after careful review of medical literature, manufacturer product information, and consultation with formulary consultants and department chiefs. A clinician may also request an exception to step therapy if he or she determines that the first- and second-line medication options are not appropriate for a specific patient.
- B. Second-line or third-line medications: Treatment that is given when initial (first-line therapy) or subsequent (second-line therapy) treatment is contraindicated, not tolerated (including allergy), or not effective.
- C. Criteria Based Consultation (CBC) medications: drugs that have specific criteria for use.

## POLICY

- A. Criteria
  1. Development:
    - a. Prescribing criteria are established for specific drugs by the RFTC.
    - b. A pharmacist reviews the available information, including the prescribing information, independent studies, and other recognized authoritative compendia and creates criteria for review with assistance of Specialty Departments. The physician specialist provides input regarding the appropriate use of a specific drug.
    - c. RFTC approves the final criteria.
    - d. Criteria are reviewed at least annually or when changes are made.
  2. Clinicians requesting a CBC drug will evaluate and document as required:
    - a. Use of one or more alternatives.

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	Reviewed UROC: 4/05, 11/05, 6/06, 8/07, 11/07, 11/08, 5/09; 5/10, 7/11, 7/12, 7/13, 7/14, 7/15, 7/16, 7/17
	Last Revised: 7/16
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- b. Contraindication, treatment failure, intolerance, or allergy to one or more alternatives.
- c. Diagnosis of any approved indication.
- d. Specialist consult or recommendation.
- e. Laboratory monitoring.
- f. Age appropriateness.
- g. Lab values.
- h. Prescribing program enrollment for clinicians or members.
- i. Any other criteria required to support evidence-based use.

3. Criteria are available upon request to members or clinicians.

#### B. Criteria Based Consultation Drugs

1. Criteria Based Consultation drugs are available for the member's co-pay when medically necessary and the member meets the established criteria.
2. No incentives are employed to influence prescribing decisions by clinicians who select Criteria Based Consultation drugs.
3. Use of Criteria Based Consultation drugs may be restricted to one or more specialty groups. This restriction may be due to:
  - a. Potential for significant safety concerns.
  - b. High potential for adverse effects.
  - c. High cost-to-benefit ratio in conjunction with other clinical concerns.
  - d. High potential for abuse.
4. For additional information, see the [Criteria Based Consultation Prescribing Website](#), which includes a listing of criteria-based drugs.

#### PROCEDURE for CBC Drugs

- A. The ordering clinician will determine appropriate medication therapy based on current regional treatment guidelines, the member's known drug history, and documented diagnosis.
- B. If a criteria-based medication is selected, the completed form is transmitted electronically to and processed by the Formulary Application Services Team (FAST).
  1. A pharmacist will review the patient's chart to determine if criteria are met.
  2. If criteria are not met, a note will be sent to the prescriber, and he or she is given the opportunity to update to a preferred alternative. If a preferred alternative is not ordered, the request is forwarded to a reviewing physician for determination of approval or denial.



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Department: Pharmacy Services	Number: UR13e
Applies to: KPNW region	Effective: 3/01/04
Review Responsibility: RFTC	Last Revised: 8/13/15
SME: Emily Thomas, PharmD	Reviewed RFTC: 10/04, 10/05, 4/06, 6/07, 10/07, 4/09, 6/11, 6/12, 6/13, 7/14, 7/15, 8/15, 7/16, 6/17
	Reviewed UROC: 4/05, 11/05, 6/06, 8/07, 11/07, 11/08, 5/09; 5/10, 7/11, 7/12, 7/13, 7/14, 7/15, 7/16, 7/17
	Last Revised: 7/16
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3. Member is notified of approval or denial in writing within regulatory guidelines (see UM - 4, [Utilization Management Medical Necessity Determinations](#) and UM-26, [Appeals of Adverse Determination](#)). Member Relations will issue a formal denial letter if medication is denied.
- C. When all criteria are met, the drug will be covered by the member's pharmacy co-pay or coinsurance (after the deductible is met, if applicable). When criteria are not met, the drug will not be covered under the member's pharmacy co-pay or coinsurance.
1. Member Relations will generate a denial letter with appropriate appeal information (see UM - 4, [Utilization Management Medical Necessity Determinations](#)).
  2. At any time, a member may choose to purchase a Criteria Based Consultation drug that has been deemed not medically necessary by paying full price for the drug.
- D. For the member appeal process, refer to UM-26, [Appeals of Adverse Determination](#).



## UR 14 A- Mental Health Medical Necessity Criteria

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Department: Mental Health	Number: UR 14 A
Section: Referrals; Preauthorization; Concurrent Review	Effective: Jan 2001
Applies to: KPNW Region	Reviewed: 1/01, 3/02, 1/04, 2/05, 3/06, 10/06,
Review Responsibility: UROC	5/07, 8/08, 8/09, 8/10, 9/11, 10/12, 8/13, 8/14,
SMEs: Jay Roberts, MSW; John Custer, LCSW;	9/16
Julie Peterson, MA	Revised: 9/12, 8/14, 8/15, 9/17

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**POLICY:**

The purpose of this policy is to provide a guide for the consistent application of plan mental health benefits through the use of formal medical necessity criteria. The Utilization Management Department is responsible for the application of benefits as the health plan representative. All mental Health UR medical necessity criteria are applied no more restrictively than those for medical/surgical care in accordance with the Mental Health Parity and Addiction Equity Act (MHPEA).

**CRITERIA UTILIZED:**

KPNW will utilize the most recent approved edition of the nationally recognized and researched MCG Health Care Guidelines for all levels of care. Medical necessity criteria will be applied to all benefit requests in the absence of a contracted benefit exclusion. Medical necessity criteria must be reviewed and approved annually by the Regional Utilization Review Oversight Committee (UROC).

**GENERAL CRITERIA FOR THE AUTHORIZATION OF THE MENTAL HEALTH BENEFIT**

1. Authorization of payment for treatment must be for a recognized diagnosis as defined in the most current edition of the Diagnostic and Statistical Manual (DSM) of Mental Disorders. The disorder must be serious and disabling in some area of life as opposed to a mild or time-limited disorder. Symptoms and functional impairment must be documented and support the DSM diagnosis.
2. The treatment is not for “problems of living” or to establish goals such as self-understanding, vocational assessments, social support, vocational rehabilitation, social networking, personality restructuring or other supportive services that may be considered psychosocially necessary but are not medically necessary.
3. Authorization of treatment is not for the convenience of the member or the clinician.
4. The services must be the most clinically appropriate and cost-effective means of treating members or to prevent further deterioration. The member must be able to participate in treatment that is designed to reduce acuity and severity of symptoms and/or improve functional impairments. Treatment goals are formulated in collaboration with the member and are specific, measurable, goal-oriented, and reasonable for the level of care provided.
5. Only treatment interventions that have been reviewed and approved by KPNW can be authorized. Services that are considered experimental, investigational or lacking in scientific evidence for outcomes must be reviewed as set forth in policy UR 19, “Evaluation of New Medical Technologies for Inclusion in Benefit Package Policy.”



## UR 14 A- Mental Health Medical Necessity Criteria

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Applies to: KPNW Region	Reviewed: 1/01, 3/02, 1/04, 2/05, 3/06, 10/06, 5/07, 8/08, 8/09, 8/10, 9/11, 10/12, 8/13, 8/14, 9/16
Review Responsibility: UROC	Revised: 9/12, 8/14, 8/15, 9/17
SMEs: Jay Roberts, MSW; John Custer, LCSW; Julie Peterson, MA	

6. If the requested authorization is primarily for a personality disorder, the specific targeted symptoms must be addressed as the treatment focus to be considered medically necessary.
7. In applying the medical necessity criteria for children and adolescents, behaviors must be thoroughly evaluated for cause. Behaviors that are not stemming from a DSM diagnosis cannot be considered for payment under the benefit.
8. In applying the medical necessity criteria to geriatric clients with a diagnosis of dementia, delirium must be clearly ruled out in order to apply the mental health benefit.
9. A thorough medical evaluation is recommended for members seeking mental health care in order to rule out any underlying medical issues that may mimic mental health symptoms. Coordination between medical and mental health providers early in the patient’s treatment is encouraged to aid in the development of the most appropriate and comprehensive plan of care. Programs offering higher levels of care (inpatient, residential, PHP, IOP) generally require a medical evaluation to have taken place within 30 days prior to admission.
10. For adults and geriatric members, when considering voluntary inpatient hospitalizations, the Kaiser Permanente Brookside Treatment Facility must be considered first.

### LEVEL OF CARE DEFINITIONS:

**Inpatient care** is the behavioral health level of care that offers the highest level of physical security and most intensive psychiatric and nursing intervention. Inpatient psychiatric units, whether they are located in general hospitals or freestanding behavioral health facilities, are generally locked, equipped to restrain or seclude patients if necessary, and staffed by nurses around the clock. Attending physicians typically round at least 5 days per week, and a covering physician is always available to see a patient on site. (KP Benefit: Inpatient)

**Residential care** is intended for patients who need around-the-clock behavioral care but do not need the high level of physical security and frequency of psychiatric and nursing interventions that are available on an inpatient unit. Patients admitted to residential care are usually voluntary and unlikely to need physical restraint or extensive nursing care. Psychiatrists typically round less often, and nurses are generally on site for fewer hours each day than at an inpatient unit. However, the treatment team is generally composed of the same mix of professionals as on an inpatient unit. Although it is sometimes assumed that residential care implies a longer length of stay than inpatient care, randomized controlled trials (RCTs) have shown that



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Applies to: KPNW Region	Reviewed: 1/01, 3/02, 1/04, 2/05, 3/06, 10/06, 5/07, 8/08, 8/09, 8/10, 9/11, 10/12, 8/13, 8/14, 9/16
Review Responsibility: UROC	Revised: 9/12, 8/14, 8/15, 9/17
SMEs: Jay Roberts, MSW; John Custer, LCSW; Julie Peterson, MA	

residential care is an efficacious short-term alternative to inpatient care for voluntary patients with urgent behavioral health conditions. (KP Benefit: Residential)

- **Partial hospital programs (PHPs)** provide multidisciplinary behavioral care for typically 6 to 8 hours per day, 5 to 7 days per week, and are staffed similarly to the day shift of an inpatient unit. Like residential care, treatment in PHPs generally is conducted by the same mix of behavioral health professionals as inpatient care. For voluntary patients with urgent behavioral health conditions who have sufficient community support and do not require around-the-clock behavioral care, PHPs represent a less restrictive alternative to inpatient care, and their efficacy has been supported in randomized controlled trials (RCTs). For almost all the behavioral health diagnosis categories, the term PHP refers only to programs that are tasked primarily with the treatment of acute behavioral health conditions (as opposed to day treatment programs, which provide a mix of psychosocial treatment, education, and recreational activities to patients with nonurgent behavioral health conditions). (KP Benefit: Residential)
- **Intensive outpatient programs (IOPs)** typically provide 3 to 4 hours of psychosocial treatment, 1 to 4 days per week (generally for 6 to 12 hours a week), mostly by using a group format, and are intended for circumstances when a patient needs a type or frequency of psychosocial treatment that is not available in a standard outpatient setting. An IOP may or may not provide pharmacotherapy or nursing care. (KP Benefit: Intensive Outpatient)
- **Acute outpatient care** consists of pharmacologic and psychosocial treatment services, provided in office or clinic settings, for managing acute or sub-acute manifestations of behavioral health disorders. Visit frequencies are flexible based on each patients’ needs. (KP Benefit: Outpatient)
- **Observation care** is undertaken for short-term evaluation and treatment with the anticipation that it generally will last about 12 hours (average length) and not more than 24 hours (although in some situations it may be appropriate to continue for a longer period of time) using a psychiatric emergency services unit, holding unit, or other facility-based setting. (KP Benefit: Emergency)
- **Maintenance outpatient care** consists of pharmacologic and psychosocial treatment services provided in office or clinic settings for preventing relapse or exacerbation of remitted or stable behavioral health disorders. Visit frequencies are generally much lower than in acute outpatient care (eg, 4 to 8 visits per year). (KP Benefit: Outpatient)
- **Assertive community treatment (ACT)** is a long-term form of multidisciplinary, multifactorial outpatient care that targets individual patients with refractory, severe mental illness (especially



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Review Responsibility: UROC	5/07, 8/08, 8/09, 8/10, 9/11, 10/12, 8/13, 8/14,
SMEs: Jay Roberts, MSW; John Custer, LCSW;	9/16
Julie Peterson, MA	Revised: 9/12, 8/14, 8/15, 9/17

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schizophrenia), who have had poor engagement with psychiatric services leading to medication and other treatment nonadherence, recurrent hospitalization, and social breakdown (eg, social withdrawal, chronic homelessness) ACT helps optimize overall functioning within the community by comprehensively addressing patient needs, including symptom stabilization, medication adherence, management of comorbid medical conditions and substance-related disorders, stabilization of living environment, development of personal care and social skills, and vocational support. ACT services may overlap and share commonalities with other types of case management services, including intensive case management, and may in part be distinguished from other interventions by patient-specific characteristics (eg, symptom severity, intensity and volume of psychiatric service utilization, chronic homelessness), differences in program delivery (ACT is delivered by a multidisciplinary team, whereas case management services may be coordinated by a single case manager or delivered in a team approach), and differences in programmatic emphasis (eg, ACT often has a greater focus on increasing medication adherence as a goal of treatment than is typical of intensive case management). (KP benefit: ACT)

### NEUROPSYCHOLOGICAL TESTING

Neuropsychological testing, also known as psychological testing, can only be delivered by a licensed psychologist, or a resident under the direct supervision of a licensed psychologist. Neuropsychological testing is considered medically necessary under the following conditions:

1. When a diagnosis cannot be completed through the usual diagnostic methods such as, intake assessment or diagnostic interview, AND it would affect the prescribed treatment interventions; OR
2. If multiple treatment interventions have been tried without response, psychological testing may help determine an alternate course of intervention.

Neuropsychological testing should be completed by a KPNW psychologist when possible.

### PSYCHIATRIC DURABLE MEDICAL EQUIPMENT

Psychiatric durable medical equipment can only be considered for payment if it is included in the member’s benefits. Any equipment included in a member’s benefit description must be authorized by the UM physician.



## UR 14 A- Mental Health Medical Necessity Criteria

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Department: Mental Health	Number: UR 14 A
Section: Referrals; Preauthorization; Concurrent Review	Effective: Jan 2001
Applies to: KPNW Region	Reviewed: 1/01, 3/02, 1/04, 2/05, 3/06, 10/06,
Review Responsibility: UROC	5/07, 8/08, 8/09, 8/10, 9/11, 10/12, 8/13, 8/14,
SMEs: Jay Roberts, MSW; John Custer, LCSW;	9/16
Julie Peterson, MA	Revised: 9/12, 8/14, 8/15, 9/17

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### SPECIAL GROUP CONSIDERATIONS

Benefit packages differ. Refer to member-specific benefit to clarify limitations, such as type of treatment facilities covered.

Commercial: This policy applies

Medicare: This policy applies

Washington Medicaid: When MH services are a covered benefit, this applies

Oregon Medicaid: This policy does not apply. Kaiser Permanente does not provide Mental Health services for Oregon Medicaid

FEDS: This policy applies

### REFERENCES

#### NCQA

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

#### WASHINGTON

RCW 284-43-410 & RCW 483.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

#### OREGON

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

ORS 743.837: Prior authorization requirements

#### CLINICAL

Diagnostic and Statistical Manual of Mental Disorders; American Psychiatric Association, 5<sup>th</sup> Edition. Published 2013 Washington DC.

#### MCG

Frank, R.G., & Glied, S.A. (2008). Shuffling toward Parity-Bringing Mental Health Care under the Umbrella. *NEJM*, 359(2), 113-115.



### UR 14 A- Mental Health Medical Necessity Criteria

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Applies to: KPNW Region	Reviewed: 1/01, 3/02, 1/04, 2/05, 3/06, 10/06,
Review Responsibility: UROC	5/07, 8/08, 8/09, 8/10, 9/11, 10/12, 8/13, 8/14,
SMEs: Jay Roberts, MSW; John Custer, LCSW;	9/16
Julie Peterson, MA	Revised: 9/12, 8/14, 8/15, 9/17

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**UR 14 B: Mental Health Policy for  
Preauthorization and Concurrent Review**

Department: Mental Health

Number: UR 14 B

Applies to: KPNW Region

Issued: 10/97

Review Responsibility: UROC

Reviewed: 2/00, 12/01, 4/02, 1/04, 2/05, 3/06, 6/07, 8/08.

Subject Matter Experts: Jay Roberts, MSW;

8/09, 8/10, 9/11

John Custer, LCSW; Julie Petersen, MA

Revised: 9/12; 8/13, 8/14, 8/15, 9/16, 9/17

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**PURPOSE:**

To define standards, accountabilities, and processes for preauthorization and concurrent review of Mental Health Services request referrals.

**PREAUTHORIZATION AND CONCURRENT REVIEW PROCEDURES:**

1. Criteria:

- a. Requested services must meet medical necessity criteria as defined in policy, UR 14-A Mental Health Medical Necessity Criteria in order to be authorized.

2. Reviewers:

- a. Utilization Management Specialists (UM Specialists) are licensed behavioral healthcare practitioners including appropriately qualified registered nurses, practitioners with a master’s degree in a behavioral health field or practitioners with additional training in accordance with state laws. UM Specialists gather all relevant clinical information in order to determine medical necessity and benefit inclusion.
- b. UM Physician, must be a licensed physician in the state in which the determination request is reviewed.

3. Review Process

- a. Medical necessity criteria will be applied to all benefit requests in the absence of a contracted benefit exclusion for outside referrals.
- b. The intention is for all services to be delivered, when possible, by internal KPNW services.
- c. External referrals may be necessary if the medically necessary care is not available within KPNW such as the following:
  - i. Internal services are not available within a clinically appropriate time frame.
  - ii. Dual relationship concerns.
  - iii. Patients with language or cultural needs that cannot be met internally by available language/interpreter services.
  - iv. Patient requires a mental health subspecialty need that is not available within the department and is determined to be pivotal for therapeutic success.
- d. All requests for authorization must be reviewed and completed within the appropriate amount of time per policies: UR 4 “Utilization Management Medical Necessity Denials” and UR 26 “Appeals and Grievances.”
- e. UM specialists utilize the most recent version of the Pre-Authorization, Concurrent Review and Discharge/Transfer Template to gather clinical information needed for UM determinations.





**UR 14 B: Mental Health Policy for  
Preauthorization and Concurrent Review**

Department: Mental Health

Number: UR 14 B

Applies to: KPNW Region

Issued: 10/97

Review Responsibility: UROC

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Subject Matter Experts: Jay Roberts, MSW;

8/09, 8/10, 9/11

John Custer, LCSW; Julie Petersen, MA

Revised: 9/12; 8/13, 8/14, 8/15, 9/16, 9/17

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- f. UM specialists follow the time frames below to determine the length of the authorization. Authorizations made outside of these guidelines must be reviewed and approved by the UM Physician or UM Supervisor. These time frames are not a treatment limitation but offer the provider and the UM specialist a consistent process. The time frames below offer guidance for the frequency of clinical and care coordination reviews based upon the acuity of the services being provided.
    - i. Inpatient care 1-4 days
    - ii. Residential Care 1-7 day
    - iii. Partial Hospital Program: 1-14 days
    - iv. Intensive Outpatient Program 1-30 days
    - v. ACT services: 1-6 months
    - vi. Acute Outpatient Care: 1-6 months
    - vii. Maintenance Outpatient Care: 1-12 Months
  - g. All Referral documentation and determinations including UM MD review, UM specialist review and authorization and/or denial information will be entered into Tapestry.
4. Denials: Please see associated Regional UM Policy: UR 4: Utilization Management Medical Necessity Denials.
5. Appeals: Please see associated Regional UM Policy: UR 26: Appeals of Adverse Determinations.

**DEFINITIONS**

None

**RESPONSIBILITIES**

- 1. UM Specialist:
  - a. Will gather all relevant clinical information to determine medical necessity.
  - b. Will review member benefits to determine coverage.
  - c. Will track adherence to all required timelines.
  - d. Assist in coordinating care when necessary.
  - e. Complete all required documentation as outlined in all UM policies.
- 2. UM Physician:
  - a. Complete all medical necessity reviews/requests that cannot be authorized by a UM Specialist.
  - b. Consult on cases in which questions around treatment interventions arise.
  - c. Consult on cases where medical issues are present.
  - d. Complete all denial determinations.

**UR 14 B: Mental Health Policy for  
Preauthorization and Concurrent Review**

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Department: Mental Health	Number: UR 14 B
Applies to: KPNW Region	Issued: 10/97
Review Responsibility: UROC	Reviewed: 2/00, 12/01, 4/02, 1/04, 2/05, 3/06, 6/07, 8/08.
Subject Matter Experts: Jay Roberts, MSW; John Custer, LCSW; Julie Petersen, MA	8/09, 8/10, 9/11
	Revised: 9/12; 8/13, 8/14, 8/15, 9/16, 9/17
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**SPECIAL GROUP CONSIDERATIONS**

Commercial: This policy applies

Medicare: This policy applies

Washington Medicaid: When service is a covered benefit, this policy applies

Oregon Medicaid: This policy does not apply. Kaiser Permanente does not provide Mental Health services for Oregon Medicaid

FEDS: this policy applies

PEBB: This policy applies

**REFERENCES****NCQA**

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

**WASHINGTON**

RCW 284-43-410 & RCW 483.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

**OREGON**

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

ORS 743.837: Prior authorization requirements

UR 14 C Mental Health Protocols for Triage  
and Appointment Access

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Department: Mental Health	UR 14 C
Section: Clinical/Triage	Effective: 02/96
Applies to: KPNW Region	Reviewed: 01/02; 9/03; 10/05; 3/06; 6/07, 8/08, 8/09, 8/10, 9/11, 8/13, 9/16
Review Responsibility: UROC	Revised: 10/12, 8/14, 8/15, 9/17
Subject Matter Experts: Jay Roberts, LCSW; John Custer, LCSW; Julie Petersen, MA	Page: 1 of 3

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**POLICY:**

KPNW seeks to assure appropriate care for members with mental health or addiction problems and to document that services are appropriately provided, monitored and professionally managed. It is the Department's policy to ensure that members gain access to appropriate care based on the urgency of their needs. Primary care referral is not required for mental health services. Licensed mental health clinicians are available 24/7 to assist members in urgent or emergent need of access to services. Most member requests are triaged through the Mental Health appointment line during business hours.

**PROCEDURE:**

Members may contact, without referral, Mental Health Triage for mental health services. Care may be co-managed as appropriate with primary care or other providers under department service agreements.

1. Members contacting the appointment line will speak to a Patient Access Specialist who will check benefits and either schedule an appointment for patients currently in service or, for new mental health requests, will transfer the member to a MH Triage clinician.
2. If a member is in immediate crisis, the Patient Access Specialist will warm-transfer the member to speak with an Emergency Psychiatric Services clinician who is available 24/7 to assess and respond to urgent and emergent needs.
3. For all mental health outpatient services, **new** members are screened by a licensed therapist. Protocols address the urgency of the member's clinical circumstances, define the appropriate care settings and treatment resources that are to be used for services, and address all relevant mental health situations.
  - 3a. Mental Health Triage Therapists have immediate access to a licensed, board certified psychiatrist for complex case consultation and complex case review as needed.
  - 3b. Mental Health triage therapists making decisions requiring clinical judgment (for example, assessing a member's potential for self-harm and determining the appropriate level and intensity of care), are fully licensed, trained and experienced mental health practitioners.
  - 3c. Triage therapists assess for possible addictions issues and offer Addiction Medicine Services when indicated.
  - 3d. Supervision of the mental health triage therapists, at a minimum, will be provided by a licensed, masters-level practitioner with five years of post-master's clinical experience. This practitioner is involved on a day-to-day basis and is consistently available to staff, either onsite or by telephone. Examples of duties include ensuring consistent criteria application, participating in staff training and monitoring documentation adequacy. In addition, the program is overseen by a licensed psychiatrist.

UR 14 C Mental Health Protocols for Triage  
and Appointment Access

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Department: Mental Health	UR 14 C
Section: Clinical/Triage	Effective: 02/96
Applies to: KPNW Region	Reviewed: 01/02; 9/03; 10/05; 3/06; 6/07, 8/08, 8/09, 8/10, 9/11, 8/13, 9/16
Review Responsibility: UROC	Revised: 10/12, 8/14, 8/15, 9/17
Subject Matter Experts: Jay Roberts, LCSW; John Custer, LCSW; Julie Petersen, MA	Page: 2 of 3

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Mental Health triage protocols and policies are reviewed, revised as necessary and approved at least every two years.

4. For all members who are already in services with Mental Health providers, The Patient Access Specialist appoints directly into the providers' schedules. Any concerns about timeliness of appointment are sent to the current provider and/or the Service Area Manager for review and assist. Members who are currently in service do not need to go through the triage process.

**PROCEDURE:**

1. Appointing Protocol
  - A. Members call the Mental Health appointment line to request mental health services. .
  - B. The line is answered by a trained Patient Access Specialist who checks benefits and verifies that patient is not already receiving services.
  - C. All new member requests for mental health treatment are transferred to a licensed Triage clinician for assessment and initial treatment planning. Existing members are appointed directly by PAS.
  - D. Triage clinicians will perform a risk and functional assessment, as well a medical necessity determination. Triage therapists will also determine acuity based on the Dept. acuity guidelines (Clinical Acuity and Appointing Criteria Protocol)
  - E. When clinicians are reviewing medication management appointment requests, they will use the Department Service Agreement with the Primary Care Department when setting appointments as well as consulting with their consulting psychiatrist
  - F. For appointment requests that require a benefit or a medical necessity determination, the clinician will send the issue to the Mental Health (MH) Utilization Management Department for review and determination. All requests submitted to the MH Utilization Management department are reviewed by a UM specialist using UM protocols and criteria. The UM specialist, when unable to approve the request, will refer the case to the UM Physician Reviewer for determination. All review and referral communications are documented in the Tapestry system.
  - G. The intention is for all services to be delivered internally when possible except for the below circumstances, in which case, an external appointment authorization may be necessary:
    - a. Internal services are not available within a clinically appropriate timeframe.

UR 14 C Mental Health Protocols for Triage  
and Appointment Access

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Department: Mental Health	UR 14 C
Section: Clinical/Triage	Effective: 02/96
Applies to: KPNW Region	Reviewed: 01/02; 9/03; 10/05; 3/06; 6/07, 8/08, 8/09, 8/10, 9/11, 8/13, 9/16
Review Responsibility: UROC	Revised: 10/12, 8/14, 8/15, 9/17
Subject Matter Experts: Jay Roberts, LCSW; John Custer, LCSW; Julie Petersen, MA	Page: 3 of 3

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- b. Dual relationship concerns exist.
    - c. Patients have language or cultural needs that cannot be adequately addressed by available language/interpreter services.
    - d. Patient requires a mental health subspecialty that is not available within the department and is determined to be pivotal for therapeutic success.
  - H. Members with Medicare must be appointed to providers with the appropriate Medicare certification or by using “incident-to” procedures
- 2. Care Types and Service Delivery Criteria
  - A. Emergent Care:
    - a. Life threatening emergency: patients will have 911 dispatched and directed to the nearest ER.
    - b. Patients with non-life threatening emergencies will be directed to the nearest Kaiser Permanente emergency room, and seen by Emergency Psychiatric Services clinicians (available 24/7) as well as ER physicians, and are seen within six hours.
  - B. Urgent Care: The need of urgent care can be determined by either the appointing clinician or the patient. Urgent appointments are available within 48 hours of request.
  - C. Routine Care: Access to an appointment for a routine office visit within 10 business days.
- 3. Service Location Criteria
  - A. Appointments can be made throughout the region at the various KPNW Medical clinics offering mental health services. Patients select the location based on location convenience and appointment availability.



## UR 16: Addiction Medicine Program Description

Department: Addiction Medicine  
Section:  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Brad Anderson, MD;  
Bruce Zufelt, LCSW, CADC

Number: UR 16a  
Effective: 11/97  
Reviewed and/or revised: 1/04, 2/04, 3/05, 5/06, 9/08, 8/09,  
8/10, 8/12, 8/13, 8/15, 8/16, 9/17  
Revised 8/11, 9/14  
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### Purpose

To define the standards for the Addiction Medicine's program processes and to document that these functions are appropriately implemented, monitored and professionally managed.

### Policy

Kaiser Permanente Addiction Medicine is responsible for the delivery of chemical dependency treatment services for Kaiser Permanente Northwest Region. As such, the Department of Addiction Medicine is part of a group practice Health Maintenance Organization, whose primary responsibility is to subscribers of the prepaid health plan.

Addiction Medicine is committed to providing high quality, effective, and affordable, chemical dependency treatment services. The Utilization Management (UM) program at Addiction Medicine, in accordance with the standards outlined by the National Committee for Quality Assurance (NCQA) for UM, is designed to promote fair and consistent decision making and equitable access to care.

This document describes the UM policy, the program, and the procedures for UM activities at all levels of care under the current benefit contract. Clinical protocols are reviewed and, if necessary, revised at least every two years.

### RESPONSIBILITIES

- Members have direct access to outpatient addiction medicine services. (Added Choice/POS members may directly access any addiction medicine provider under their Tier 2 and Tier 3 benefits, without prior-authorization, for office visits that do not include a procedure). They may also be referred by other Kaiser departments and practitioners as necessary. Patients must meet ASAM (American Society of Addiction Medicine Patient Placement Criteria) criteria for treatment in order to receive a referral for the treatment Program. A diagnosis of substance abuse or dependency, according to current DSM criteria, is required for admission to the addiction medicine program. DSM diagnoses of "substance abuse or dependence in remission", "partial remission", or "remission in a controlled environment" will be considered for admission on a case by case basis, using clinical judgment and/or consultation with the Clinical Services Manager.
- When a patient's benefit does not provide the needed treatment at Kaiser Permanente's Department of Addiction Medicine the counselor must make an appropriate referral for the patient based on the presenting problems. Such a referral could be to mental health, residential treatment, cultural specific treatment programs, other individual treatment within Addiction



## UR 16: Addiction Medicine Program Description

Department: Addiction Medicine  
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Number: UR 16a  
 Effective: 11/97  
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 8/10, 8/12, 8/13, 8/15, 8/16, 9/17  
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Medicine or other community resources. Members will be made aware when the referred services are not covered by the benefit.

- The Addiction Medicine department does not have a centralized triage function, therefore requirements for centralized triage do not apply.
- A clinical assessment is done at the time of the face to face appointment with the KP practitioner; i.e., assessing members’ needs, determining the appropriate levels of service and connecting members to the appropriate levels of care occur directly at the treatment source.

### A. Utilization Management Program Description, Structures, Processes and Responsibilities

#### 1. UM Decision Making

- a. The Chief of Addiction Medicine, Director of Addiction Medicine, Utilization Management Specialist, and all KP clinicians are involved in the UM program and operate under current, unrestricted licenses appropriate to their clinical and/or administrative duties. Addiction Medicine has adopted the American Society of Addiction Medicine's Patient Placement Criteria ("ASAM Criteria" or ASAM). These national criteria are objective, based on medical evidence, and provide a comprehensive guideline for placement, continued stay and discharge of patients with substance-related disorders. The ASAM criteria address all relevant levels of substance abuse situations and define levels of urgency as well as appropriate settings of care for adults and adolescents, including early intervention, outpatient treatment, intensive outpatient/partial hospitalization, residential/inpatient treatment, and medically-managed intensive inpatient treatment. Use of the ASAM criteria is required by regulatory agencies in Oregon and Washington for licensed treatment programs.
- b. Clinicians, certified chemical dependency counselors or licensed professionals with addictions treatment training, make decisions about appropriate levels of care, access to services, admissions and discharges, and treatment resources according to ASAM Criteria policy. All KP encounters with the member are documented in the electronic medical record. Depending on where services are provided, additional regulatory criteria may apply.
  - i. Clinicians diagnose and recommend appropriate treatment interventions.



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Number: UR 16a  
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- ii. The licensed Medical Staff makes clinical decisions about access to medical services (detoxification admission and discharge and Opioid Substitution referrals) according to ASAM criteria.
- iii. Clinical Services Managers, master’s level practitioners with 5 years of post-master’s clinical experience in the chemical dependency field, review all clinicians' treatment decisions in the course of routine supervision (See Supervision of Addiction Medicine Policy & Procedure; Patient Chart Review P&P, available upon request).
- iv. The Utilization Manager oversees the utilization review functions for all benefits authorized to external providers.
- v. For patients who obtain Kaiser Insurance while in the course of previously initiated treatment, the Utilization Management Specialist will review and authorize, as clinically indicated, according to ASAM criteria.
- vi. A medical doctor, or his/her designee, reviews all initial denials of service, including denials of care based on medical necessity, according to ASAM criteria.
  - All requests for services subject to a utilization review process for medical necessity determinations will use established regional policies and procedures. See **UR 4: Utilization Management Medical Necessity Denials** for the regional process and policy.
  - The Director of Addiction Medicine can assist with making sure that denial letters to the member and ordering clinician are handled appropriately.

### B. Medical Necessity Determinations

1. The ASAM criteria and state requirements by Oregon/Washington are used to make medical necessity determinations. The Director of Addiction Medicine and Chief of Addiction Medicine are responsible for reviewing, updating and approving all criteria for medical necessity. State surveys/ASAM review updates are followed by the Director of Addiction Medicine and Chief of Addiction Medicine who supervise the updating, revision and adoption of all UM and medical necessity criteria policies and procedures for the Addiction Medicine program. (See Addiction





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Number: UR 16a  
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Medicine Clinical Policies and Procedures: Placement Criteria, Patient Assessment, and Reassessment, available upon request).

2. Licensed Medical Staff diagnose, recommend and approve patients for medically related services. (See Addiction Medicine Medical Policies and Procedures: Medical Coverage; Medical Referral for Detoxification, also see appropriate job descriptions, available upon request.)

C. Determination of Benefit Coverage

1. The Benefits Coordinator is available to check on benefit status of an individual patient and to relay information regarding the patient's benefit package to the KP clinician. In addition, initial review of coverage status by support staff is done prior to scheduling an appointment. KP clinicians or patients may review benefits as requested by notifying the Benefits Coordinator of their request
2. All determinations for treatment are made by licensed clinical & medical staff. The Benefits Coordinator only relays information about the type of coverage and status of benefits of the patient. (See Addiction Medicine Clinical Policies and Procedures: Admissions Policy, Barriers to Treatment, available upon request).
3. The Utilization Management Specialist can assist with making sure that denial letters to the member and ordering clinician are handled appropriately.

D. Referral Process

1. Patients may self-refer or be referred by any Kaiser Permanente clinician for chemical dependency services. (Added Choice/POS members may directly access any addiction medicine provider under their Tier 2 and Tier 3 benefits, without prior-authorization, for office visits that do not include a procedure). Members seeking services are routinely assessed using the CAGE or AUDIT instrument (survey tool). As part of the assessment, patients are scheduled for an appointment or contacted by the KP clinician of the day (COD) or KP medical doctor of the day (MOD), if disposition is unclear and scheduling assistance is needed.

E. Case Management

1. To ensure that patients receive quality care, it is the policy of Addiction Medicine that each patient will be assigned a counselor as case manager. The case manager is responsible for the



## UR 16: Addiction Medicine Program Description

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Number: UR 16a  
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completeness of records and documentation of progress toward treatment objectives for patients assigned to their caseload. (See Addiction Medicine Clinical Policies and Procedures: Case Management, and Addiction Medicine DNA (Did Not Arrive) Patients, available upon request)

F. Site of Service and Levels of Treatment Evaluation

1. Site of services/levels of care are reviewed by Division of Behavioral Health and Recovery in the State of Washington, and AMH (Office of Mental Health and Addiction Services), in the State of Oregon. External contractors are evaluated during semiannual meetings by the Director of Addiction Medicine, or in joint QM meetings with the Addiction Medicine Administrative team. Opioid Substitution treatment programs are reviewed quarterly by the Opioid Substitution review committee. (See Addiction Medicine Policy and Procedure: Treatment, Case Management, and Utilization Review, available upon request)

G. Appeals:

Please see associated UM Policy(s):

**UR 4: Utilization Management Medical Necessity Determinations**

**UR 26: Appeals of Adverse determination**

H. Integration of Utilization Management and Quality Improvement

1. The KP Utilization Management Specialist routinely completes onsite clinical reviews. Quality issues are brought to the UM Manager, Addiction Medicine leadership and Contracts Manager for review. Meetings with external vendors will be scheduled as necessary for follow-up, program review and program evaluation.

I. Evaluation and Approval of Utilization Management Program

1. The Addiction Medicine UM Program Description is annually approved and revised by the Addiction Medicine Administrative Team: Chief of Addiction Medicine, Director of Addiction Medicine.



## UR 16: Addiction Medicine Program Description

Department: Addiction Medicine

Number: UR 16a

Section:

Effective: 11/97

Applies to: KPNW Region

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Review Responsibility: UROC

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SME: Brad Anderson, MD;

Bruce Zufelt, LCSW, CADC

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### OTHER GENERAL REQUIREMENTS

KP clinicians make internal referrals to the Department of Addiction Medicine creating an Order in the Health Connect Hyperspace Ambulatory Record system or EpicCare. Once at the order page for the patient, KPRR is entered/ accept the first selection: KPRR [IR Addiction Medicine (KPRR)], IR 0034, New Internal Referral.

### Utilization Review: Factors for Consideration

- A. UM is reviewed according to ASAM criteria. These criteria are provided to clinicians for use in UM decision making regarding clinical care (see Addiction Medicine policy: Placement Criteria, available upon request).
- B. Opioid Substitution maintenance- check Contract for benefit coverage when prescribed by a Physician.
- C. Care in a treatment facility not approved or arranged by a Physician is not covered.
- D. Continuation in a course of counseling for patients who are disruptive or physically abusive will not occur.
- E. House calls are generally not conducted, unless a KP Physician determines that necessary care can best be provided in the home.

### Assessment of Clinical Information for UM Decision Making

Clinicians in Addiction Medicine assess clinical information according to ASAM criteria. ASAM criteria are determined by the American Society of Addictions Medicine. All clinicians are certified chemical dependency counselors or licensed professionals with addictions treatment training. All clinicians are considered "qualified" by the state agency for the state in which they practice (AMH - Oregon, and Division of Behavioral Health and Recovery - Washington).

### Timeliness of Response

Clinicians will assess face to face the level of intervention needed and often refer at the same visit for the appropriate level of care indicated. The Opioid Substitution review meeting occurs at least two weeks in advance of implementation of decisions which is every three months for each agency contracted with. Patients and treating providers (clinicians), as appropriate, are notified in writing of denials for services. Patients and treating clinicians may appeal the denial following the appeal rights outlined in their decision letters.

## UR 16: Addiction Medicine Program Description

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Department: Addiction Medicine	Number: UR 16a
Section:	Effective: 11/97
Applies to: KPNW Region	Reviewed and/or revised: 1/04, 2/04, 3/05, 5/06, 9/08, 8/09, 8/10, 8/12, 8/13, 8/15, 8/16, 9/17
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### Medical Necessity Determinations

- A. It is the policy of Addiction Medicine to conduct an assessment interview with all patients seeking services for chemical abuse/dependency. The purpose of the assessment is to confirm a diagnosis and to develop a treatment plan. The KP assessment interview is documented in the patient's electronic chart. The following information is gathered by the clinician: identifying information, presenting problem, family history and social/interpersonal functioning, educational/vocational/employment history, legal history, medical history, alcohol/drug history, psychological history, problems identified, diagnosis, and treatment recommendations.
- B. A discharge plan will be written on all patients as they complete treatment as a condition of graduation. The discharge plan will document referrals to other services and the patient's plan for post treatment services. The clinician will access medical records, consult with the patient's Primary Care Physician, and appropriate Addiction Medicine policies and procedures as needed (see Addiction Medicine: Assessment Policy, Interim Outpatient Services, and Placement Criteria, Discharge Plan, available upon request.)
  1. If the patient disputes the discharge plan, please see the "Concurrent Requests" section of UM-4, Utilization Management Medical Necessity Denials.
  2. The Director of Addiction Medicine can assist with making sure the decision letters to the patient and treating clinician, as appropriate, are handled correctly.
- C. Application of the ASAM criteria provides for those with emotional / behavioral issues and defines the appropriate level of care (internally or by referral) recommended in those cases. If it is medically appropriate as defined by the patient being diagnosed with ASAM disorder and is not so severely mentally impaired that he or she would not be able to participate in his or her treatment, and is willing to sign program guidelines etc. then the patient will receive the care. If a patient refuses to sign the treatment guidelines or authorization for treatment, the reason is documented for refusal and a clinician will meet individually or make the appropriate referral.

### Evaluation of Member and Clinician Satisfaction with Utilization Management Procedures

Clients are surveyed regarding their satisfaction with services following treatment. This information is compiled in the Member Office Visit (MOV) survey by an independent contractor and reviewed annually by the Administrative team. Trends in satisfaction can be tracked and responded to. At admission/



## UR 16: Addiction Medicine Program Description

Department: Addiction Medicine

Number: UR 16a

Section:

Effective: 11/97

Applies to: KPNW Region

Reviewed and/or revised: 1/04, 2/04, 3/05, 5/06, 9/08, 8/09,

Review Responsibility: UROC

8/10, 8/12, 8/13, 8/15, 8/16, 9/17

SME: Brad Anderson, MD;

Revised 8/11, 9/14

Bruce Zufelt, LCSW, CADC

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orientation, staff will explain the grievance procedure and answer questions. The patient will receive a copy of the procedure and the original document (with patient’s signature) is placed in the patient’s chart (see Addiction Medicine Grievance Procedure).

All formal complaints are entered in the Regional Customer Complaint System by the department Administrative Assistant. These complaints are compiled annually by Addiction Medicine to determine trends, correct defaults, improve satisfaction, and retain customers.

### SPECIAL GROUP CONSIDERATIONS

Added Choice/POS- members may directly access non-KP providers under their Tier 2 and Tier 3 benefits, without prior-authorization, for office visits that do not include a procedure. Procedures and levels of care other than office visits require prior-authorization.

### REFERENCES

#### NCQA

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

#### WASHINGTON

RCW 284-43-410 & RCW 483.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

#### OREGON

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

ORS 743.837: Prior authorization requirements



UR 17 Private Duty Nursing Medical Necessity Criteria for WA Medicaid (Molina)

Department: Continuing Care
Section: Home Health
Applies to: KPNW Region
Review Responsibility: UROC, CCS
SME: Preston Peterson, MD, CCS Medical Director; Joclyn Tosch, RN; Sherry Potwora, RN

Number: UR 17
Effective: 11/2016
Reviewed: 11/16, 10/17
Revised:
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MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR PRIVATE DUTY NURSING

PURPOSE

The purpose of these criteria is to define KFHPNW coverage of private duty nursing (PDN) for patients who require complex, long-term care for a condition of such severity and/or complexity that continuous skilled nursing care is required. Persons with medically intensive needs require more individual and continuous care than is available from an intermittent visiting nurse. PDN services are considered supportive to the care provided to the patient by family members or guardians and are decreased as the family/guardian or other caregiver becomes able to meet the patient's needs or when the patient's needs diminish. PDN services must be performed by a Registered Nurse or a Licensed Practical Nurse under the direction of a physician. The patient can still receive other home health services such as therapies. The goal is to avoid institutionalization and to maintain or improve the recipient's function level in a home setting.

PDN consists of at least four, but no more than sixteen hours per day (see exceptions) of continuous skilled nursing services, restricted to the least costly, equally effective amount of care. The cost of PDN does not exceed the cost of institutionalized care.

These criteria were developed by the Washington Administrative Code and the Division of Developmental Disabilities, an organization within the Department of Social and Health Services of Washington.

Note that separate criteria exist for coverage of intermittent home health services.

CRITERIA

To be eligible for private duty nursing (PDN), the patient must meet 1 or 2, in addition to 3-9 below:

- 1) must be 18 years old or older and dependent upon technology every day with at least one of the following skilled care needs (based on WAC 388-106-1010):
a) mechanical ventilation
b) complex respiratory support, requiring at least two of the following treatment needs:
(i) postural drainage and chest percussion;
(ii) application of respiratory vests;
(iii) nebulizer treatments with or without medications;
(iv) intermittent positive pressure breathing;
(v) O2 saturation measurement with treatment decisions dependent on the results; or
(vi) tracheal suctioning.



UR 17 Private Duty Nursing Medical Necessity Criteria for WA Medicaid (Molina)

Department: Continuing Care

Section: Home Health

Applies to: KPNW Region

Review Responsibility: UROC, CCS

SME: Preston Peterson, MD, CCS Medical Director;

Joclyn Tosch, RN; Sherry Potwora, RN

Number: UR 17

Effective: 11/2016

Reviewed: 11/16, 10/17

Revised:

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- c) intravenous/parenteral administration of multiple medications, and care is occurring on a continuing or frequent basis; or
  - d) intravenous administration of nutritional substances, and care is occurring on a continuing or frequent basis.
- 2) must be 17 years old or younger and dependent upon at least one of the following skilled care needs every day (based on WAC 182-551-3000):
- a) skilled assessments (e.g. respiratory assessment, patency of airway, vital signs, feeding assessment, seizure activity, hydration, level of consciousness, constant observation for comfort and pain management);
  - b) administration of treatment related to technological dependence (e.g. ventilator, tracheotomy, BIPAP (bilevel positive airway pressure), IV (intravenous) administration of medications and fluids, feeding pumps, nasal stints, central lines);
  - c) monitoring and maintaining parameters/machinery (e.g. oximetry, blood pressure, lab draws, end tidal CO2s, ventilator settings, humidification systems, fluid balance, etc);
  - d) interventions (e.g. medications, suctioning, IVs, hyperalimentation, enteral feeds, ostomy care, tracheostomy care).
- 3) must otherwise require care in a hospital or meet nursing facility level of care; and
- 4) must have unmet skilled nursing needs that cannot be met in a less costly program or less restrictive environment; and
- 5) must have a complex medical need that requires four or more hours every day of continuous medically necessary skilled nursing care that can be safely provided outside a hospital or nursing facility; and
- 6) must have a caregiver who is authorized and able to supervise the care; and
- 7) must have a family member or other appropriate caregiver who is responsible for assuming a portion of the care; and
- 8) must be medically stable and appropriate for PDN services.
- 9) the cost of PDN does not exceed the cost of institutionalized care.

Exceptions to the 16-hour maximum per day:

The utilization reviewer may authorize additional hours for a maximum of 30 days if any of the following apply:

- The family or guardian is being trained in care and procedures;
- There is an acute episode that would otherwise require hospitalization and the treating physician determines that non-institutional care is still safe for the patient;

These criteria do not imply or guarantee approval. Please check your plan to ensure coverage. Preauthorization requirements are only valid for the month published. They may have changed from previous months, and may change in future months. JULY-18



**UR 17 Private Duty Nursing Medical Necessity  
Criteria for WA Medicaid (Molina)**

Department: Continuing Care

Section: Home Health

Applies to: KPNW Region

Review Responsibility: UROC, CCS

SME: Preston Peterson, MD, CCS Medical Director;

Joclyn Tosch, RN; Sherry Potwora, RN

Number: UR 17

Effective: 11/2016

Reviewed: 11/16, 10/17

Revised:

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- The family or guardian caregiver is ill or temporarily unable to provide care;
- There is a family emergency; or
- The Agency or its designee determines it is medically necessary.

**SPECIAL GROUP CONSIDERATIONS**

Commercial plans, Medicare and FEHB all exclude coverage of private duty nursing and continuous nursing services in the home.

**REFERENCES**

Molina Healthcare Provider Manual:

<http://www.molinahealthcare.com/providers/nm/medicaid/manual/Pages/PrivateDutyNursing.aspx>

Molina Benefits at a Glance:

<http://www.molinahealthcare.com/members/wa/en-US/PDF/Medicaid/benefits-at-a-glance.PDF>

WA Medicaid Managed Care Guidance (WA Apple Health):

<http://www.hca.wa.gov/assets/billers-and-providers/Private-Duty-Nursing-20160401.pdf>

WAC 388-106-1010 (Medicaid funded PDN for 18 years and older)

WAC 182-551-3000 (Medicaid funded PDN for 17 years and younger)



## UR 19: EVALUATION OF NEW MEDICAL TECHNOLOGIES FOR INCLUSION IN BENEFIT PACKAGE POLICY

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Department: KPNW Utilization Review

Number: UR 19

Applies to: KPNW Region

Issued: 11/97

Review Responsibility: UROC

Reviewed: 5/00, 12/01, 2/02, 3/03, 12/04, 11/05, 09/06, 12/06, 2/08, 2/09, 4/10, 4/11, 4/13, 4/15, 4/17

SME: Kathy Fazio, RN

Revised: 4/11, 7/11

Pages: 1 of 4

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### PURPOSE

To provide a formal mechanism to evaluate new developments in technology for inclusion in benefit plans and to provide a written process to assure that the Kaiser Permanente Northwest (KPNW) Region

- keeps pace with advances in technology; and,
- ensures that members have equitable access to safe and effective care.

### POLICY

KPNW evaluates the inclusion and integration of new technologies, and the new application of existing technologies involving medical and behavioral health procedures, pharmaceuticals and devices in clinical practice in order to support evidence-based care.

Decisions on coverage of new and emerging technologies are implemented based first on a clinical evaluation. Evaluation and implementation involve the work of at least one of the following:

- 1) the Inter-regional New Technology Committee (INTC), and/or
- 2) the Regional Formulary and Therapeutics Committee (RFTC)

These groups' reviews include data and information from peer-reviewed, published, scientific, evidence-based medical literature; governmental regulatory bodies (such as CMS and FDA); medical associations; private technology assessment organizations; medical and behavioral healthcare experts; and professionals who have expertise in the technology.

Recommendations related to new technology are reviewed locally by the KPNW Regional Benefits Committee (RBC) regarding the potential inclusion in benefit packages and evaluation of the recommendations in the context of local market forces, and development of processes for local medical management and administration.

### DEFINITIONS

None

### RESPONSIBILITIES

#### Inter-regional New Technology Committee (INTC)

The INTC is the overarching new technology assessment committee for all eight KP regions (membership includes KPNW participants, physician and non-physician). Committee members consider issues that arise in all areas of medical technology (including medical procedures, behavioral healthcare procedures, and devices) and evaluate their medical appropriateness based on demonstrated safety, efficacy, and comparative utility.

The INTC reviews are prioritized in accordance with the professional judgment of the committee members often based on relative impact on all Health Plan membership. Committee membership includes physicians

## UR 19: EVALUATION OF NEW MEDICAL TECHNOLOGIES FOR INCLUSION IN BENEFIT PACKAGE POLICY

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Department: KPNW Utilization Review

Number: UR 19

Applies to: KPNW Region

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Review Responsibility: UROC

Reviewed: 5/00, 12/01, 2/02, 3/03, 12/04, 11/05, 09/06, 12/06, 2/08, 2/09, 4/10, 4/11, 4/13, 4/15, 4/17

SME: Kathy Fazio, RN

Revised: 4/11, 7/11

Pages: 2 of 4

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and non-physicians from different regions and Program Offices within the KP Medical Care Program. Recommendations will take one of the following forms:

1. The technology is medically appropriate for select patients.
2. The technology is generally not medically appropriate for any patient.
3. There is insufficient evidence to determine whether the technology is medically appropriate for any patient.

Committee members of the INTC are tasked with the following responsibilities to discern and recognize new technologies when they become available:

- monitoring the news and web sites for topics of interest (FDA approval, CMS guidelines and other organizations)
- monitoring the Technology Assessment and Guidelines (TAG) inquiry line to see what patients/providers have requested or are requesting information on
- interacting with internal providers and technology groups, such as the Southern California Permanente Medical Group (SCPMG) TAG and The Permanente Medical Group (TPMG), to get topic ideas
- interacting with external technology groups, such as the Blue Cross Blue Shield Association Technology Evaluation Center (TEC), Emergency Care Research Institute (ECRI), and the Hayes Technology Group, to get topic ideas
- interacting with interregional chiefs and other groups, such as the National Product Council, to discern what topics are generating interest
- obtaining regional input from committee members
- pursuing topic selection calls, where other topics may be proposed
- following up on hot topics at KP meetings

### Regional New Technology Group (RNTG)

Members of the RNTG provide NW Permanente practitioners a rapid, evidence based response to new technology questions via “Technology on Tap”, a staff messaging process available through KP HealthConnect. Requests may also be submitted by KP staff, community providers and members. A robust process for evaluating and monitoring new types of medical technology, including devices, equipment, diagnostics, and medical and behavioral healthcare procedures, is followed. The assessments provide guidance related to new and existing medical technology to ensure that physicians of NW Permanente are providing consistent state-of-the-art care that is supported with medical and scientific evidence.

## UR 19: EVALUATION OF NEW MEDICAL TECHNOLOGIES FOR INCLUSION IN BENEFIT PACKAGE POLICY

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Department: KPNW Utilization Review

Number: UR 19

Applies to: KPNW Region

Issued: 11/97

Review Responsibility: UROC

Reviewed: 5/00, 12/01, 2/02, 3/03, 12/04, 11/05, 09/06, 12/06, 2/08, 2/09, 4/10, 4/11, 4/13, 4/15, 4/17

SME: Kathy Fazio, RN

Revised: 4/11, 7/11

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### Regional Formulary and Therapeutics Committee (RFTC)

Evaluation of new pharmaceuticals and new indications for existing pharmaceuticals for coverage under the pharmacy benefit is under the purview of the RFTC (Regional Formulary and Therapeutics Committee). In rare situations, RFTC will evaluate devices used to administer pharmaceuticals for coverage under the pharmacy benefit.

### Regional Benefits Committee (RBC)

Recommendations related to new technology are reviewed locally by the KP Northwest Regional Benefits Committee (RBC) regarding the potential inclusion in benefit packages and evaluation of the recommendations in the context of local market forces, and development of processes for local medical management and administration.

The RBC's overarching goal is to anticipate and respond to customers (both groups and members) by developing benefits that support the organization's business plan, and will be achieved by balancing the following three principles:

1. Support appropriate medical and behavioral healthcare and prevention:
  - a. Balance the needs of all members regardless of medical/behavioral health status (balance the needs of the healthy with the needs of the sick).
  - b. Consider benefit decisions relative to all benefits, plan designs, and long term strategies.
  - c. Focus on and emphasize preventive care.
  - d. Achieve greatest benefit in a cost-effective manner for individuals, groups, and the organization.
2. Competitiveness and market responsiveness:
  - a. Maintain competitive rate and benefit position.
  - b. Minimize adverse selection.
  - c. Design benefits to support appropriate utilization of resources.
  - d. Meet customer need for inter and intra-Regional consistency.
3. Ease and clarity of interpretation and administration:
  - a. Design benefits that are easy to understand and administer for both customers and staff.
  - b. Minimize administration or operational burdens.

## UR 19: EVALUATION OF NEW MEDICAL TECHNOLOGIES FOR INCLUSION IN BENEFIT PACKAGE POLICY

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Department: KPNW Utilization Review

Number: UR 19

Applies to: KPNW Region

Issued: 11/97

Review Responsibility: UROC

Reviewed: 5/00, 12/01, 2/02, 3/03, 12/04, 11/05, 09/06, 12/06, 2/08, 2/09, 4/10, 4/11, 4/13, 4/15, 4/17

SME: Kathy Fazio, RN

Revised: 4/11, 7/11

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The RBC recommendations consider:

- clinical overview (i.e., efficacy)
- legal and regulatory issues
- rate impact
- market environment issues (i.e., other Regions, competition)
- membership impact
- administrative viability in each local market
- relativity to Regional business strategies
- budget forecast issues (i.e., timing)
- stakeholder issues
- product impact (e.g., POS, Medicare, HMO)
- key group impact (e.g., Federal, State)

If KPNW accepts the determinations for new technology from the INTC, RNTG, RFTC and/or RBC and medical necessity criteria are needed, these determinations are reviewed at the Utilization Review Oversight Committee (UROC) for appropriate Regional Utilization Review action.

### SPECIAL GROUP CONSIDERATIONS

None

### REFERENCES

#### NCQA:

UM Standard 1: The organization clearly defines the structures and processes within its utilization management program and assigns responsibility to appropriate individuals.

UM Standard 10: The organization evaluates the inclusion of new technologies and the new application of existing technologies in the benefit plan. This includes medical and behavioral health procedures, pharmaceuticals and devices.

## UR 20.1 Breast Reduction (Mammoplasty) Female Medical Necessity Criteria: Commercial Members

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Department: Surgery	Number: UR 20.1
Section: Plastic Surgery	Effective: 2/00
Applies to: KPNW Region	Reviewed: 2/01, 12/02, 3/03, 6/04, 11/04, 10/05, 10/06, 11/07, 11/08, 10/09, 1/10, 1/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17, 2/18
Review Responsibility: UROC	Last Revised: 2/16
Subject Matter Experts: Jennifer Murphy, MD; Patricia Sandholm, MD	Pages: 1-3

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### MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR FEMALE REDUCTION MAMMOPLASTY FOR COMMERCIAL LINES OF BUSINESS

Medical necessity criteria are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

#### DEFINITIONS

Cosmetic Services (as defined under the Exclusions section of the Evidence of Coverage): Services that are intended primarily to change or maintain appearance and will not result in significant improvement in physical function.

#### CRITERIA

**Please cross reference UR 65 Transgender Surgery criteria for transgender individuals having F2M procedures.**

Relevant history and physical findings must establish medical necessity, including all of the following:

1. The member must have two or more of the following conditions present for at least 6 months, with documented failed therapeutic measures i.e. weight loss strategies, supportive garments, and dermatologic measures:<sup>7</sup>
  - a. Upper back pain, from breast size
  - b. Persistent breast pain (not relieved with hormonal adjustments or analgesics)
  - c. Rash under breast (unresolved with dermatologic therapies)
  - d. Painful bra strap grooves
  - e. Shoulder pain from breast size
  - f. Neck pain from breast size
  - g. Arm pain from breast size
2. Breast size D cup bra size or above<sup>7</sup>
3. Body Mass Index (BMI) less than or equal to 34
4. Predicted removal of the following:
  - a. Minimum of 200 grams of breast tissue from the larger of the two breasts when BMI is less than 25;
  - b. Minimum of 250 grams of breast tissue from the larger of the two breasts when BMI 25-30
  - c. Minimum of 450 grams of breast tissue from the larger of the two breasts when BMI is greater than 30
5. Must have a normal mammogram within the past year in women 40 years or older.

## UR 20.1 Breast Reduction (Mammoplasty) Female Medical Necessity Criteria: Commercial Members

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Department: Surgery	Number: UR 20.1
Section: Plastic Surgery	Effective: 2/00
Applies to: KPNW Region	Reviewed: 2/01, 12/02, 3/03, 6/04, 11/04, 10/05, 10/06, 11/07, 11/08, 10/09, 1/10, 1/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17, 2/18
Review Responsibility: UROC	Last Revised: 2/16
Subject Matter Experts: Jennifer Murphy, MD; Patricia Sandholm, MD	Pages: 1-3

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6. Members who smoke must be actively involved in a smoking cessation program and must be smoke-free for a minimum of 30 days prior to surgery.

### CONTRAINDICATIONS

1. Active smoker with no plans to quit smoking.
2. Obesity is also a risk factor for poor surgical outcome. Members who are obese but otherwise meet the above medical necessity criteria will be assessed on a case by case basis.
3. Surgical contraindications will be surgeon determined.

### SPECIAL GROUP CONSIDERATIONS

Policy applies to all Commercial and Federal groups and WA Medicaid.

Oregon Medicaid: subject to eligibility on OHP Linefinder.

**This policy does not apply to Medicare**, see UR 20.5 Breast Reduction (Female and Male)

If the reduction mammoplasty is to reduce the size of a normal breast, with breast reconstruction after cancer surgery and is governed by the WHCRA (Women's Health and Cancer Rights Act), the reduction is covered and is not considered to be included in these breast reduction criteria.

### REFERENCES

#### NCQA

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

#### CLINICAL

1. Behmand, RA., Tang, DH., Smith DJ. (2000), Outcomes in breast reduction surgery. *Annals of Plastic Surgery*. 45: 575-580.
2. Brown DM, Young VL. (1993), Reduction mammoplasty for macromastia." *Journal of Plastic, Reconstructive & Aesthetic Surgery*. 17: 211-223.
3. Chadbourne, EB., Zhang, S., Gordan, MJ., et al. (2001), Clinical Outcomes in Reduction Mammoplasty: A Systemic Review and Meta-analysis of Published Studies. *Mayo Clinic Proceedings*, 76: 503-510.
4. Chan, LKW., Withey, S., Butler, PEM. (2006). Smoking and wound healing problems in reduction mammoplasty, *Annals of Plastic Surgery*, 56 (2): 111-115
5. Cruz-Korchin, Korchin, Gonzalez-Keelan, Climent & Morales. (2002). Macromastia: how much of it is fat? *Plastic & Reconstructive Surgery*, 109 (1), 64-68
6. Howrigan, P. (1994), Reduction and Augmentation Mammoplasty. *Obstetrics and Gynecology Clinic of North America*. 21: 539-543.
7. Kerrigan, MD, CL., Collins, MD, ED., Kim, ScD HM., Schnur, MD, PL., Wilkins, MD, E., Cunningham, MD, B., Lowery, PhD, J., (2002), Reduction Mammoplasty: Defining Medical Necessity Criteria. *Medical Decision Making*. 208- 217
8. Lin, Johns, Gibson, Long, Drake & Moore. (2001), An Outcome Study of Breast Reconstruction: Pre-surgical Identification of Risk Factors for Complications. *Annals of Surgical Oncology*, 8(7) 586-591
9. Medicare Coverage Database: LCD for Mammoplasty Reduction (L15600)

These criteria do not imply or guarantee approval. Please check your plan to ensure coverage. Preauthorization requirements are only valid for the month published. They may have changed from previous months, and may change in future months. JULY-18

## UR 20.1 Breast Reduction (Mammoplasty) Female Medical Necessity Criteria: Commercial Members

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Department: Surgery	Number: UR 20.1
Section: Plastic Surgery	Effective: 2/00
Applies to: KPNW Region	Reviewed: 2/01, 12/02, 3/03, 6/04, 11/04, 10/05, 10/06, 11/07, 11/08, 10/09, 1/10, 1/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17, 2/18
Review Responsibility: UROC	Last Revised: 2/16
Subject Matter Experts: Jennifer Murphy, MD; Patricia Sandholm, MD	Pages: 1-3

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10. Namba, RS., Paxton, L., Fithian, DC, Stone, ML., (2005). Obesity and Perioperative Morbidity in Total Hip and Total Knee Arthroplasty Patients", *Journal of Arthroplasty*, 20 (7 suppl 3): 46-50
11. Padubidri, Arvind N. MD; Yetman, Randall MD; Browne, Earl MD; Lucas, Armand MD; Papay, Frank MD; Larive, Brett MS; and Zins, James MD, (2001), Complications of Postmastectomy Breast Reconstruction in Smokers, Ex-smokers, and Nonsmokers. *Plastic & Reconstructive Surgery*, 107(2) 342-349
12. Platt, Mohan & Baguley. (2003). The Effect of Body Mass Index and Wound Irrigation on Outcome After Bilateral Breast Reduction. *Annals of Plastic Surgery*, 51(6), 552-555
13. Reduction Mammoplasty. (2002) American Society of Plastic Surgeons Recommended Coverage for Third Party Payors. Available at [http://www.plasticsurgery.org/medical\\_professionals/index.cfm](http://www.plasticsurgery.org/medical_professionals/index.cfm)
14. Seitchik, MW. (1995), Reduction Mammoplasty: Criteria for Insurance Coverage. *Plastic Reconstructive Surgery*. 95: 1029-1032

WHCRA (Women's Health and Cancer Rights Act)

[http://www.cms.hhs.gov/HealthInsReformforConsume/06\\_TheWomen'sHealthandCancerRightsAct.asp](http://www.cms.hhs.gov/HealthInsReformforConsume/06_TheWomen'sHealthandCancerRightsAct.asp)

## UR 20.2 Panniculectomy and Removal of Excess/Redundant Skin Medical Necessity Criteria

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Department: Surgery	Number: UR 20.2
Section: Plastic Surgery	Effective: 4/03
Applies to: KPNW Region	Reviewed: 12/04, 9/05, 10/06, 11/07, 11/08, 10/09, 1/10; 2/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17
Review Responsibility: UROC	Last Revised: 2/16, 2/18
Subject Matter Expert: Jennifer Murphy, MD; Patricia Sandholm, MD	

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### MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR PANNICULECTOMY AND REMOVAL OF EXCESS/REDUNDANT SKIN

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

#### MEDICAL NECESSITY CRITERIA

#### DEFINITIONS

- a. Panniculectomy: The excision of an apron of abdominal subcutaneous fat that lacks adequate supportive tissue in people who are or had been morbidly obese.
- b. Abdominoplasty: Plastic surgery on the abdomen.
- c. Cosmetic Services (as defined under the Exclusions section of the Evidence of Coverage): Services that are intended primarily to change or maintain appearance and will not result in significant improvement in physical function.

#### CRITERIA FOR ABDOMINAL PANNICULECTOMY

Patient must meet all of the following:

1. The pannus hangs below the level of the mons and completely covers the mons on front view.
2. The pannus interferes with activities of daily living.
3. Patient's weight has reached a stable plateau for at least 6 months, AND 1 or more of the following:
  - Adherence to multidisciplinary nonsurgical program of weight maintenance
  - One year or more has elapsed following bariatric surgery.(7)(8)

#### CRITERIA FOR REMOVAL OF EXCESS/REDUNDANT SKIN OR TISSUE (other than abdominal fat/panniculus)

Patient must have one or more of the following, with documented failed therapeutic measures and/or functional compromise as stated below:

1. Documented recurrent or chronic rashes, infections, cellulitis, or non-healing ulcers that do not respond to dermatologic management for a period of 3 months, per dermatology consultation, OR
2. Documented difficulty with ambulation/function and interference with Activities of Daily Living (ADLs), per physiatry consultation.



## UR 20.2 Panniculectomy and Removal of Excess/Redundant Skin Medical Necessity Criteria

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Department: Surgery	Number: UR 20.2
Section: Plastic Surgery	Effective: 4/03
Applies to: KPNW Region	Reviewed: 12/04, 9/05, 10/06, 11/07, 11/08, 10/09, 1/10; 2/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17
Review Responsibility: UROC	Last Revised: 2/16, 2/18
Subject Matter Expert: Jennifer Murphy, MD; Patricia Sandholm, MD	

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### OTHER REQUIREMENTS

Difficult surgical access, where the excess skin will interfere with surgery, requires referring physician to talk with the Plastic Surgeons prior to referral.

Relevant history and physical findings establishing medical necessity must be documented, including consultations and/or visits with dermatology and/or psychiatry.

Panniculectomy or abdominoplasty, with or without diastasis recti repair, for the treatment of back pain is considered not medically necessary.

Cosmetic services (see definition above) are specifically excluded by the members' benefit coverage. This exclusion does not apply to services that are covered under "Reconstructive Surgical Services" or services that are medically necessary.

### CONTRAINDICATIONS

Active smoker (defined as someone who has not refrained from smoking for at least 30 days prior to surgery).

### SPECIAL GROUP CONSIDERATIONS for the criteria, which applies if a group has the benefit coverage:

Policy applies to all Commercial and Federal groups, Medicare, WA Medicaid  
Oregon Medicaid: subject to eligibility on OHP Linefinder

### REFERENCES

#### NCQA

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

### CLINICAL

1. Apfelberg, DB., Results of Multicenter Study of Laser-assisted Liposuction (Clin Plast Surg.), 23(4) (1996), 713-719
2. Elbaz, JS., Flageul, G. and Olivier-Masveyraud, F. Classical Abdominoplasty (Ann Chir Plast Esthet.), 44(4) (1999) 443-461
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4. Lockwood, T., Rectus Muscle Diastasis in Males: Primary Indication for Endoscopically Assisted Abdominoplasty. (Plast Reconstr Surg.), 101(6) (1998), 1685-1691

## UR 20.2 Panniculectomy and Removal of Excess/Redundant Skin Medical Necessity Criteria

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Department: Surgery	Number: UR 20.2
Section: Plastic Surgery	Effective: 4/03
Applies to: KPNW Region	Reviewed: 12/04, 9/05, 10/06, 11/07, 11/08, 10/09, 1/10; 2/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17
Review Responsibility: UROC	Last Revised: 2/16, 2/18
Subject Matter Expert: Jennifer Murphy, MD; Patricia Sandholm, MD	

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5. Manassa, E., Hertl, C., Olbrisch, R., "Wound Healing Problems in Smokers and Nonsmokers after 132 Abdominoplasties" (American Society of Plastic Surgeons), (Plastic and Reconstructive Surgery), (May 2003), 2082-2087
6. Matarasso, A., and Matarasso, SL., "When Does Your Liposuction Patient Require an Abdominoplasty?" (Dermatol Surg.), 23(12) (1997) 1151-1160
7. Ramirez, OM., Abdominoplasty and Abdominal Wall Rehabilitation: A Comprehensive Approach. (Plast Reconstr Surg.), 105(1) (2000) 425-435)
8. Taber's Cyclopedic Medical Dictionary" (Taber's: F.A. Davis Company) 2004  
"Update from the Ultrasonic Liposuction Task Force of the American Society for Dermatologic Surgery (Dermatol Surg.), 23(3) (1997), 211-214

## UR 20.3 Scar Revision Medical Necessity Criteria

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Department: Surgery	Number: UR 20.3
Section: Plastic Surgery	Effective: 8/00
Applies to: KPNW Region	Reviewed: 3/01, 2/02, 4/03, 12/04, 07/05, 09/06, 11/07, 11/08, 10/09, 1/10, 1/11, 2/12; 2/13; 2/14, 2/15, 2/16, 2/17, 2/18
Review Responsibility: UROC	Last Revised: 2/16
Subject Matter Expert: Jennifer Murphy, MD; Patricia Sandholm, MD	

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### MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR SCAR REVISION

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

### DEFINITIONS

Cosmetic Services (as defined under the Exclusions section of the Evidence of Coverage): Services that are intended primarily to change or maintain appearance and will not result in significant improvement in physical function.

### MEDICAL NECESSITY CRITERIA

When a scar revision meets one of the criteria listed below it will be covered as a form of reconstructive surgery. (Determinations which are considered cosmetic services are not covered.)

1. To correct significant disfigurement resulting from an injury or from medically necessary surgery;
2. To treat congenital vascular lesions such as port wine stains on the face for members age 18 or younger;
3. To complete all stages of breast reconstruction following a mastectomy, including surgery to the unaffected breast to produce a symmetrical appearance, and treatment of physical complications including lymphedemas;
4. To correct a congenital defect, disease, or anomaly in order to produce significant improvement in physical function.

### OTHER REQUIREMENTS

Cosmetic services (see definition above) are specifically excluded by the members' benefit coverage. This exclusion does not apply to services that are covered under "Reconstructive Surgical Services" or services that are medically necessary.

### SPECIAL GROUP CONSIDERATIONS for the criteria, which applies if a group has the benefit coverage:

Policy applies to all Commercial and Federal groups, Medicare, WA Medicaid  
Oregon Medicaid: subject to eligibility on OHP Linefinder

## UR 20.3 Scar Revision Medical Necessity Criteria

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Department: Surgery	Number: UR 20.3
Section: Plastic Surgery	Effective: 8/00
Applies to: KPNW Region	Reviewed: 3/01, 2/02, 4/03, 12/04, 07/05, 09/06, 11/07, 11/08, 10/09, 1/10, 1/11, 2/12; 2/13; 2/14, 2/15, 2/16, 2/17, 2/18
Review Responsibility: UROC	Last Revised: 2/16
Subject Matter Expert: Jennifer Murphy, MD; Patricia Sandholm, MD	

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### REFERENCES

#### NCQA

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

#### CLINICAL

1. Bayar A, McGrouther D, Ferguson MWJ. Skin scarring. *BMJ*. 326(7380):88-92, January 11, 2003.
2. McGillis ST, Lucas AR. Scar revision. *Dermatologic Clinics*. 16(1):165-80, 1998 Jan.
3. Clark JM, Wang TD. Local flaps in scar revision. [Review] [15 refs] [Journal Article. Review. Review, Tutorial] *Facial Plastic Surgery*. 17(4):295-308, 2001 Nov.
4. Chang CW, Ries WR. Non-operative techniques for scar management and revision. [Review] [35 refs] [Journal Article. Review. Review, Tutorial] *Facial Plastic Surgery*. 17(4):283-8, 2001 Nov.
5. McGillis ST, Lucas AR. Scar revision. [Review] [36 refs] [Journal Article. Review. Review, Tutorial] *Dermatologic Clinics*. 16(1):165-80, 1998 Jan.
6. Goslen JB. Physiology of wound healing and scar formation. In: Thomas JR, Holt GR, eds. *Facial Scars - Incision, Revision, and Camouflage*. St. Louis: CV Mosby, 1989.
7. Strucker FJ, Shaw GY. An approach to management of keloids. *Arch Otolaryngol Head Neck Surg* 1992;118:63-67.
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## UR 20.4 Gynecomastia (Males) Medical Necessity Criteria; Commercial Members Only

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Department: Surgery	Number: UR 20.4
Section: Plastic Surgery	Effective: 7/09
Applies to: KPNW Region	Reviewed: 1/10; 1/11; 2/12; 2/13; 2/14; 2/15, 2/16, 2/17, 2/18
Review Responsibility: UROC	Revised: NA
Subject Matter Experts: Jennifer Murphy, MD; Patricia Sandholm, MD; Catherine Lum, MD- Peds Endocrinology	

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### MEDICAL NECESSITY CRITERIA FOR GYNECOMASTIA SURGERY

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

### DEFINITIONS

Definition of Cosmetic Services under the Exclusions section of the EOC (member's contract) states: Cosmetic Services are those services intended primarily to change or maintain appearance and will not result in significant improvement in physical function.

### CRITERIA

1. Endocrinology assessment completed by primary care, with consultation by endocrinology or pediatric endocrinology if appropriate.
2. Physical exam completed including breast and testicular exam.
3. Documentation indicating no offending medications, including anabolic steroids and/or illicit substances such as marijuana are contributing to the gynecomastia. <sup>12,17</sup>
4. Documentation indicating no other medical conditions such as renal failure, cirrhosis, endocrine problems, testicular or other HCG (human chorionic gonadotropin) secreting cancer, or malnutrition and refeeding are contributing to the gynecomastia <sup>1,17</sup>
5. Failed conventional medical treatments including stopping offending medications/substances, treating reversible medical conditions, using pain medications or consideration of 6 to 12 week trial of tamoxifen in appropriate candidates. <sup>1, 14</sup>
6. Minimum age 15 or completed or nearly completed puberty <sup>1,12</sup>
7. Firm subareolar or glandular breast tissue > 4 cm in diameter <sup>17</sup>, present x 2 yrs in adolescents and stable x 1 yr in adolescents and adults (>18 yrs)
8. BMI less than or equal to 34 <sup>5,15,18</sup>
9. Nonsmoking at least 30 days.

### CONTRAINDICATIONS

- a. Illicit substance use/anabolic steroid abuse and/or any use of offending medications <sup>12,17</sup>
- b. Active smoker with no plans to quit smoking. To be referred for gynecomastia surgery, the member must be actively involved in a smoking cessation program AND must be smoke free for a minimum of 30 days prior to surgery <sup>3</sup>

## UR 20.4 Gynecomastia (Males) Medical Necessity Criteria; Commercial Members Only

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Department: Surgery	Number: UR 20.4
Section: Plastic Surgery	Effective: 7/09
Applies to: KPNW Region	Reviewed: 1/10; 1/11; 2/12; 2/13; 2/14; 2/15, 2/16, 2/17, 2/18
Review Responsibility: UROC	Revised: NA
Subject Matter Experts: Jennifer Murphy, MD; Patricia Sandholm, MD; Catherine Lum, MD- Peds Endocrinology	

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### **SPECIAL GROUP CONSIDERATIONS for the criteria, which applies if a group has the benefit coverage:**

Policy applies to all Commercial and Federal groups, Medicare, WA Medicaid  
Oregon Medicaid: subject to eligibility on OHP Linefinder

### **REFERENCES**

#### **NCQA**

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

### **CLINICAL INFORMATION**

1. Gynecomastia (enlargement of the male breast) is usually benign. <sup>1</sup>
2. Most cases of gynecomastia result from an imbalance between estrogenic (stimulatory) and androgenic (inhibitory) effects on the breast. <sup>1</sup>
3. Occurrences may appear during puberty, followed by a decline in late teen years and among men ages 50-80. <sup>1</sup>
4. Pseudogynecomastia (fatty breasts) is common in obese men and needs to be differentiated from true gynecomastia. In true gynecomastia there may be a button of firm subareolar tissue, or there may be a more diffuse collection of fibroglandular tissue. <sup>1</sup>
5. Absolute estrogen excess which contributes to gynecomastia: Leydig cell tumors, estrogen-producing adrenal tumors, tumors producing chorionic gonadotropin. <sup>1</sup>
6. Relative estrogen excess which contributes to gynecomastia: primary hypogonadism, Klinefelter syndrome, secondary hypogonadism, puberty, refeeding syndrome, renal failure and dialysis, cirrhosis of the liver, hyperthyroidism <sup>1</sup>
7. Drugs which contribute to gynecomastia include, but are not limited to: histamine H<sub>2</sub>-receptor blockers, phenytoin, digoxin, spironolactone, nifedipine, reserpine and other cardiovascular drugs, diethylstilbestrol, testosterone antagonists, flutamide, leuprolide, finasteride, diazepam, tricyclic antidepressants, phenothiazine, risperidone, haloperidol, alcohol, amphetamines, marijuana, heroin, methadone, anti-tuberculosis drugs, cytotoxic agents. <sup>2,12, 17</sup>
8. Herbal products that can cause gynecomastia include lavender oil or tea tree oil. <sup>2</sup>
9. Lab screening should include: thyroid function, liver enzymes, serum creatinine, serum total testosterone, serum beta-hCG and may also include estradiol, LH, FSH, and prolactin, serum DHEA-S or urine 17-keto-steroids as directed by endocrinology or per practice resource algorithm. <sup>1</sup>
10. Glandular tissue of more than 4 cm in diameter is unlikely to regress spontaneously. <sup>17</sup>

## UR 20.4 Gynecomastia (Males) Medical Necessity Criteria; Commercial Members Only

Department: Surgery	Number: UR 20.4
Section: Plastic Surgery	Effective: 7/09
Applies to: KPNW Region	Reviewed: 1/10; 1/11; 2/12; 2/13; 2/14; 2/15, 2/16, 2/17, 2/18
Review Responsibility: UROC	Revised: NA
Subject Matter Experts: Jennifer Murphy, MD; Patricia Sandholm, MD; Catherine Lum, MD- Peds Endocrinology	

11. Gynecomastia may cause considerable psychological distress, especially in adolescents who are struggling with issues relative to sexual identity and self-image. If neither reassurance *nor* medical treatment is successful, surgery should be considered.<sup>17</sup>
12. Tamoxifen at 10 mg bid for 6 to 12 weeks has been shown to be helpful in several small studies in adolescents and adults. It is usually more effective early in the course of gynecomastia and is less likely to be helpful in long established gynecomastia. Although this is not an FDA approved indication, it is suggested as an option for adolescents and adults in UpToDate and other references if symptoms are significant and persistent. Testosterone is the appropriate treatment in hypogonadal men with gynecomastia. Tamoxifen should not be used in these patients.<sup>2, 6, 12,14, 16, 19</sup>

### Evidence/Source Documentation

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## UR 20.4 Gynecomastia (Males) Medical Necessity Criteria; Commercial Members Only

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Department: Surgery	Number: UR 20.4
Section: Plastic Surgery	Effective: 7/09
Applies to: KPNW Region	Reviewed: 1/10; 1/11; 2/12; 2/13; 2/14; 2/15, 2/16, 2/17, 2/18
Review Responsibility: UROC	Revised: NA
Subject Matter Experts: Jennifer Murphy, MD; Patricia Sandholm, MD; Catherine Lum, MD- Peds Endocrinology	

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## UR 20.5 Breast Reduction (Female and Male) Medical Necessity Criteria; Medicare Only

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Department: Surgery	Number: UR 20.5
Section: Plastic Surgery	Effective: 5/05
Applies to: KPNW Region	Reviewed: 03/06, 11/06, 7/07, 1/08, 1/09, 1/10, 1/11, 2/12, 2/13,
Review Responsibility: Medicare Compliance	2/14, 2/15, 2/16, 2/17, 2/18
Subject Matter Expert: Medicare	Pages: 1-3

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### MEDICAL NECESSITY CRITERIA FOR MEDICARE PLASTIC SURGERY BREAST REDUCTION

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

### DEFINITIONS

Breast hypertrophy- an increase in the volume and weight of breast tissue (one-sided hypertrophy may result in symptoms following mastectomy of the opposite breast).

Gynecomastia- enlargement of breast tissue in males.

Macromastia- abnormally large breasts.

Cosmetic Services, as defined in the Exclusions section of the EOC (member's contract), are those services intended primarily to change or maintain appearance and will not result in significant improvement in physical function. Cosmetic surgery to reshape the breasts to improve appearance is not a Medicare benefit. Cosmetic signs and/or symptoms would include ptosis (drooping), poorly fitting clothing and beneficiary perception of unacceptable appearance.

**MEDICAL NECESSITY CRITERIA:** Medicare's medical necessity criteria for reduction mammoplasty (breast surgery) are limited to circumstances in which:

- A. There are signs and/or symptoms resulting from the enlarged breasts (macromastia) that have not responded adequately to non-surgical interventions.
- B. To improve symmetry following cancer surgery on one breast.
- C. The signs and/or symptoms have been present for **at least** six months.
- D. Medical treatment and/or physical interventions have not adequately eased symptoms.
- E. Please refer to diagnoses section below – diagnoses requirements must be met.

## UR 20.5 Breast Reduction (Female and Male) Medical Necessity Criteria; Medicare Only

Department: Surgery	Number: UR 20.5
Section: Plastic Surgery	Effective: 5/05
Applies to: KPNW Region	Reviewed: 03/06, 11/06, 7/07, 1/08, 1/09, 1/10, 1/11, 2/12, 2/13,
Review Responsibility: Medicare Compliance	2/14, 2/15, 2/16, 2/17, 2/18
Subject Matter Expert: Medicare	Pages: 1-3

**Diagnoses:**

Must include <u>one</u> Primary Diagnosis and <u>one</u> of the Secondary Diagnoses	
Group I - Primary Diagnosis	Group I - Secondary Diagnosis
Hypertrophy of the breast - Gynecomastia, <u>or</u>	Mastodynia (breast pain), <u>or</u>
Hypertrophy of the breast - Not Otherwise Specified, <u>or</u>	Other specified erythematous (redness of the skin) conditions, <u>or</u>
Hypertrophy of the breast - Massive Pubertal	Pain in joint involving shoulder region, <u>or</u>
	Cervicalgia (neck/cervical spine pain), <u>or</u>
	Pain in thoracic spine, <u>or</u>
	Rash and other non-specified skin eruption, <u>or</u>
	Backache, unspecified
Group II - Primary Diagnosis	Group II - Secondary Diagnosis
Malignant neoplasm of the nipple and areola of female breast (which includes) Malignant neoplasm of the breast (female) -unspecified site, <u>or</u>	After care following surgery for neoplasm
Personal history of malignant neoplasm of breast	

**Note:** There are *No BMI (Body Mass Index) requirements.*

**Medicare Documentation Requirements:** Medical documentation prior to referral must include all diagnostic/therapeutic measures attempted, objective member findings, and any response to treatments attempted.

**Additional Comments:** For Medicare purposes, a reasonable and necessary reduction mammoplasty **could be** indicated in the presence of significantly enlarged breasts and the presence of **at least one** of the following signs and/or symptoms:

- A. Back pain from macromastia and unrelieved by ALL:
  - 1. Conservative analgesia
  - 2. Supportive measures (garment, etc.)
  - 3. Physical Therapy
- B. Significant arthritic changes in the cervical or upper thoracic spine, optimally managed, with persistent symptoms and/or significant restriction of activity.
- C. Intertriginous maceration (dermatitis in the folds of the skin) or infection of the inframammary skin (skin underneath the breasts) refractory to dermatologic measures.
- D. Shoulder grooving with skin irritation by supporting garment (bra strap).

## UR 20.5 Breast Reduction (Female and Male) Medical Necessity Criteria; Medicare Only

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Department: Surgery	Number: UR 20.5
Section: Plastic Surgery	Effective: 5/05
Applies to: KPNW Region	Reviewed: 03/06, 11/06, 7/07, 1/08, 1/09, 1/10, 1/11, 2/12, 2/13,
Review Responsibility: Medicare Compliance	2/14, 2/15, 2/16, 2/17, 2/18
Subject Matter Expert: Medicare	Pages: 1-3

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### Diagnostic/Therapeutic measures prior to referral:

Non-surgical interventions preceding reduction mammoplasty should include *as appropriate*, but are not limited to, the following:

1. Determining the macromastia is not due to an active endocrine or metabolic process.
2. Determining the symptoms are refractory to appropriately fitted supporting garments, or following unilateral mastectomy, persistent with an appropriately fitted prosthesis or reconstruction therapy at the site of the absent breast.
3. Determining that dermatologic signs and/or symptoms are refractory to, or recurrent following, a completed course of medical management.

**Removal of breast implants:** For a patient who has had implant(s) placed for reconstructive or cosmetic purposes, Medicare considers treatment of any one or more of the following conditions to be medically necessary:

- A. Broken or failed implant
- B. Infection
- C. Implant extrusion
- D. Siliconoma (tissue response to silicone) or granuloma (tumor or growth in response to a foreign body)
- E. Interference with diagnosis of breast cancer
- F. Painful capsular contracture with disfigurement

### CONTRAINDICATIONS

### REFERENCES:

CMS/Noridan Local Coverage Determination: Plastic Surgery, L35163

<https://med.noridianmedicare.com/documents/10525/5321621/Local+Coverage+Determination+for+Plastic+Surgery+%28L35163%29>

CMS/Noridan Policy” Cosmetic vs Reconstructive

<https://med.noridianmedicare.com/web/jfa/policies/coverage-articles/cosmetic-vs-reconstructive>

UR 20.6 Breast Reconstruction Surgery  
Medical Necessity Criteria

Department: Surgery

Number: UR 20.6

Section: Plastic Surgery

Effective: 9/14

Applies to: KPNW Region

Reviewed: 2/15, 2/16, 2/17, 2/18

Review Responsibility: UROC

Revised: 11/16

Subject Matter Expert: Jennifer Murphy, MD;

Patricia Sandholm, MD

**MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR BREAST RECONSTRUCTION SURGERY**

Medical necessity criteria are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

**DEFINITIONS**

Cosmetic Services: Services that are intended primarily to change or maintain appearance and will not result in significant improvement in physical function (as defined under the Exclusions section of the Evidence of Coverage, however, this exclusion does not apply to 'Reconstructive Surgical Services' or services that are medically necessary).

**CRITERIA**

Patients will be eligible for breast reconstructive surgery under these criteria only 1) after medically necessary mastectomy or lumpectomy related to breast cancer or 2) to correct significant disfigurement resulting from an injury or from medically necessary surgery.

- Reconstructive surgery of the affected side may include any or all of the following:
  - Tissue/muscle reconstruction (e.g., flaps);
  - Use of tissue expanders;
  - Implantation of FDA-approved internal breast prosthesis. Augmentation may be appropriate only when one of the following conditions is met:
    - Patient has undergone lumpectomy but NOT radiation therapy; OR
    - Patient has undergone mastectomy, with or without radiation therapy.
  - Areolar and nipple reconstruction;
  - Areolar and nipple tattooing;
  - Autologous fat grafting.
  - Liposuction
  - Mastopexy or reduction
  - Capsule revision (capsulotomy, capsulectomy, capsulorrhaphy)
- Reconstructive procedures may be performed on the contralateral (unaffected) side to restore the appearance of the breasts to the level of symmetry present prior to mastectomy or lumpectomy ONLY when mastectomy or lumpectomy has produced significant asymmetry.
  - The patient qualifies as having significant asymmetry when the following criteria are met:
    - There is an absence of breast tissue unilaterally where there is no ability to maintain a normal breast shape using non-surgical methods; AND
    - At least 250 g of tissue were removed OR there is a difference of at least 1 cup size.

These criteria do not imply or guarantee approval. Please check your plan to ensure coverage. Preauthorization requirements are only valid for the month published. They may have changed from previous months, and may change in future months. JULY-18

UR 20.6 Breast Reconstruction Surgery  
Medical Necessity Criteria

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Department: Surgery

Number: UR 20.6

Section: Plastic Surgery

Effective: 9/14

Applies to: KPNW Region

Reviewed: 2/15, 2/16, 2/17, 2/18

Review Responsibility: UROC

Revised: 11/16

Subject Matter Expert: Jennifer Murphy, MD;

Patricia Sandholm, MD

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- Reconstructive surgery of the contralateral (unaffected) side may include any of the following when the above criteria are met:
  - Breast reduction by mammoplasty or mastopexy;
  - Augmentation mammoplasty;
  - Areolar and nipple reconstruction;
  - Areolar and nipple tattooing;
  - Capsulotomy;
  - Capsulectomy;
  - Breast implant removal and subsequent re-implantation when original implant was in the unaffected breast prior to disease in the affected breast.
  - Liposuction
  - Autologous fat grafting
- Reconstructive surgical revisions may be performed as deemed necessary by a physician board-certified in plastic surgery.
  - Revisions will not be covered when performed to correct changes in form or symmetry due to natural processes, such as aging or changes in weight.
  - Once the initial sequence of tattoo sessions has been completed, further touch-ups will be considered cosmetic (see Special Group Considerations).

**SPECIAL GROUP CONSIDERATIONS**

**Medicare EOC- Cosmetic Surgery or Procedures** are covered:

- 1) in cases of an accidental injury or for improvement of the functioning of a malformed body member, and
- 2) for all stages of reconstruction for a breast after a mastectomy, as well as for the unaffected breast to produce a symmetrical appearance.

Medicare Manual- 120 states cosmetic surgery or expenses incurred in connection with such surgery is not covered. Cosmetic surgery includes any surgical procedure directed at improving appearance, except when required for the prompt (i.e., as soon as medically feasible) repair of accidental injury or for the improvement of the functioning of a malformed body member. For example, this exclusion does not apply to surgery in connection with treatment of severe burns or repair of the face following a serious automobile accident, or to surgery for therapeutic purposes which coincidentally also serves some cosmetic purpose.

Tattooing is covered when performed in conjunction with breast reconstruction. Generally; the tattooing within six weeks after reconstruction is included in the global code 19350 and not separately reported.

(Reconstruction code has a 90 day global period)

These criteria do not imply or guarantee approval. Please check your plan to ensure coverage. Preauthorization requirements are only valid for the month published. They may have changed from previous months, and may change in future months. JULY-18

**UR 20.6 Breast Reconstruction Surgery  
Medical Necessity Criteria**

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Department: Surgery

Number: UR 20.6

Section: Plastic Surgery

Effective: 9/14

Applies to: KPNW Region

Reviewed: 2/15, 2/16, 2/17, 2/18

Review Responsibility: UROC

Revised: 11/16

Subject Matter Expert: Jennifer Murphy, MD;

Patricia Sandholm, MD

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The touch up tattooing after one year is separately reportable and is covered indefinitely for Medicare members when associated with a covered breast reconstruction (Medicare does not have a NCD (National Coverage Determination) for tattooing to correct color defects of the skin nor does Noridian have a LCD (Local Coverage Determination)).

**REFERENCES**

WHCRA (Women's Health and Cancer Rights Act):

[http://breastreconstruction.org/breast\\_reconstruction\\_insurance\\_coverage.html](http://breastreconstruction.org/breast_reconstruction_insurance_coverage.html)

<https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/publications/whcra.pdf>

ORS 743A.110 Mastectomy-related Services

Oregon House Bill 3616 amending ORS 743A.110- defines "mastectomy" for purposes of statute requiring health benefit plan coverage

## UR 20.7 WA PEBB Breast Augmentation Surgery Criteria for Gender Transition

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Department: Surgery	Number: UR 20.7
Section: Plastic Surgery	Effective: 1/17
Applies to: KPNW Region	Reviewed: 1/17, 2/18
Review Responsibility: UROC, WA PEBB	Revised:

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### MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR BREAST AUGMENTATION SURGERY

Medical necessity criteria are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

NOTE: these criteria pertain to Washington Public Employee Benefit Board (PEBB) members only.

#### CRITERIA

**Breast augmentation will require prior-authorization utilizing the following coverage criteria**

- 1) Diagnosis of gender dysphoria (male to female) **AND**
- 2) Has received at least 1 year of hormone therapy (unless there are contraindications) **AND ONE:**
  - No measurable cup size growth, defined as less than an A cup, in one or both breasts **OR**
  - Asymmetry where one breast did not have a measurable cup size growth, defined as less than an A cup.
- 3) Documentation from surgeon of current cup size and proposed changes as well as photo documentation.

EXAMPLE: Client presents with response to hormone therapy with one breast B cup and one breast A cup=**NON-COVERED**.

EXAMPLE: Client presents with response to hormone therapy with one breast B cup and one breast with no measurable cup size=**COVERED**.

#### SPECIAL GROUP CONSIDERATIONS

This policy pertains to Washington PEBB members only effective 1/1/17.

OHP (Oregon Medicaid) see OHP Prioritized List, Guideline Note 127 for treatment of Gender Dysphoria.

For all other groups, breast augmentation is not covered. See UR 65 Transgender Surgery UM Criteria for covered gender transition procedures.



**Communication Policy**

Department: Utilization Management  
Applies to: KPNW Region  
Review Responsibility: UROC  
Reviewer: Kathy Fazio, RN

Number: UR 24  
Effective: 1/03  
Reviewed: 2/04, 3/05, 5/06, 07/07, 08/07, 8/08; 8/09;  
8/10; 8/12, 8/14  
Revised: 8/11, 8/15, 9/17

**PURPOSE**

To document the access to Utilization Information for members and practitioners seeking information about the Utilization Review (UR) process and/or the authorization of care and to describe the process by which members and practitioners may communicate with Utilization Review staff.

**POLICY**

The Health Plan will ensure access to staff for members and practitioners seeking information about the UR process and the authorization of care. Utilization Review staff will be available at least eight hours daily during normal business hours for inbound calls regarding UR issues. Members or practitioners may leave voice mail messages for UR staff twenty-four hours a day. UR Staff will return member calls and messages during normal business hours and respond to messages received after hours no later than the next business day. Calls received after midnight on a business day will be returned the same day.

All UR staff will identify themselves by name, title & organization name when initiating or returning calls regarding UR issues. Current policies and criteria are posted on the UR Intranet website.

**RESPONSIBILITIES**

I. Questions: Members or practitioners who have questions about the Utilization Review processes or who have questions about utilization review issues can access staff during business hours by contacting:

A. Services or Departments issuing a notice of adverse determination, for example:

- 1. Regional Referral Services 503-813-4560
- 2. DME Department 503-813-4550
- 3. Telephone numbers are provided on all denial letters

B. Membership Services –During business hours (8AM to 6PM)

- 1. 503-813-2000 (Portland Area) or
- 2. 1-800-813-2000

C. After business hours, 503-813-2000 and 1-800-813-2000 will reach the Regional Advice Nurse. The member can leave a message and it will be given to the appropriate staff member for response the following business day.

D. Resource Stewardship and Inpatient Hospital Case Management 503-813-3321

E. Primary Care Physician Office (KPNW Primary Care)

The nurses at the KPNW Medical offices have information about KPNW Utilization Management and can assist members or practitioners in contacting Utilization Review staff.





Communication Policy

Department: Utilization Management  
Applies to: KPNW Region  
Review Responsibility: UROC  
Reviewer: Kathy Fazio, RN

Number: UR 24  
Effective: 1/03  
Reviewed: 2/04, 3/05, 5/06, 07/07, 08/07, 8/08; 8/09;  
8/10; 8/12, 8/14  
Revised: 8/11, 8/15, 9/17

Members are notified annually via a mailer instructing them how to contact Membership Services by toll-free phone number, by TTY number for the speech and/or hearing impaired, or by the Kaiser Permanente website. The mailer also explains how to electronically access or how to obtain a paper copy of a Medical Directory (Member Handbook). The phone numbers, including the TTY number, are also on members' Kaiser Permanente identification card.

Members are also made aware of the availability of non-English language assistance, free of charge, via the annually-distributed mailer. The phone number for language interpretation services is also on each members' Kaiser Permanente identification card.

Practitioners are notified how to contact Membership Services as well as all UR-related departments by phone via the annual Provider Bulletin. The Kaiser Permanente intranet phonebook provides phone and email contact information for all KP employees/practitioners.

II. Notices: Notices of Non-Coverage for acute care for commercial members are generated by Resource Stewardship upon request from the Utilization Resource coordinators, and contain the member's appeal rights with contact numbers. Commercial members who have received an acute care "Notice of Non-Coverage" may contact the appropriate department for an urgent appeal or non-urgent appeal as directed on the notice (including a toll-free phone number).

The Important Message from Medicare (IMM) for Medicare Advantage members who are hospitalized is issued by on-site Utilization Review staff within the acute care setting. The IMM contains the member's appeal rights, including contact information and toll-free phone number for Livanta, Medicare's Quality Improvement Organization, as well as Medicare's toll-free phone number.

**REFERENCES**

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

## UR 25: Ensuring Appropriate Utilization

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Department: Resource Stewardship	Number: UR 25
Applies to: Kaiser Permanente Northwest Region	Issued: 1/04
Review Responsibility: Sam Prochovnic, Resource Stewardship; Tiffany Dorsey, Quality Resource Mgmt	Reviewed: 1/05, 1/06, 1/07, 3/07, 3/08, 3/09, 7/11, 9/17 Revised: 5/13, 5/15
	Page: 1 of 3

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**PURPOSE**

Both Kaiser Foundation Health Plan of the Northwest (KFHPNW) aka Company and Northwest Permanente, P.C. Physicians and Surgeons (NWP) monitor and analyze relevant medical and behavioral health data to identify opportunities for improving continuity and coordination of care and to ensure the appropriate use of services and resources (monitoring for under-, over-, and/or mis-utilization). This process occurs through the Regional Resource Stewardship/Data and Information Management Enhancement Team (RS/DIME Team), the regional governing body for Utilization Management (UM).

**POLICY**

- A. The RS/DIME Team periodically (no less than annually) monitors relevant data for under-, over-, and mis-utilization; analyzes data to identify opportunities for improvement; facilitates quantitative and qualitative analysis; and, takes action to correct any pattern of potential or actual inappropriate utilization.
- B. Relevant data is monitored for each product line as applicable.
- C. For Medicaid members (Oregon Health Plan and Washington Molina/Apple Health) KPNW ensures that services and benefits are provided in an amount, duration and scope that is not less than equivalent for fee-for-service members.
- D. Utilization reports are reviewed by the RS/DIME Team and NWP on a periodic basis, but no less than annually.

**DEFINITIONS: None**

**RESPONSIBILITIES**

- A. At least annually, the RS/DIME Team monitors and analyzes medical utilization data regarding cost, frequency of service(s) and other utilization categories such as levels of service from member populations to assess potential under-, over-, and mis-utilization. Measures may include, but are not limited to:
  1. Inpatient admission rates and length of stay (LOS) for medical/surgical and behavioral health
  2. Inpatient bed days for medical/surgical and behavioral health
  3. Outpatient fee-for-service (FFS) and capitation units
  4. Emergency department utilization
  5. Ambulance utilization
  6. Ancillary utilization (Lab, Radiology, Pharmacy)
  7. HEDIS procedural rates and use of services rates
  8. Readmission rates

## UR 25: Ensuring Appropriate Utilization

Department: Resource Stewardship  
Applies to: Kaiser Permanente Northwest Region  
Review Responsibility:  
Sam Prochovnic, Resource Stewardship;  
Tiffany Dorsey, Quality Resource Mgmt

Number: UR 25  
Issued: 1/04  
Reviewed: 1/05, 1/06, 1/07, 3/07, 3/08, 3/09, 7/11, 9/17  
Revised: 5/13, 5/15  
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9. Rates of selected procedures
  10. Rates of behavioral health utilization
  11. Complaints and appeals related to denials of services (potential for under-utilization)
  12. CAHPS survey questions related to ability to get care and ability to see a specialist (questions # 23 and 27, CAHPS 5.0 Commercial and like questions on Medicare survey)
  13. Rates of referrals to specialists
- B. Annually, the Regional Resource Stewardship Department, in collaboration with Business Consulting, Financial and Analytical Services, and other health services departments, compiles data related to UM utilization.
- C. The RS/DIME Team selects at least four types of utilization data, including at least one related to behavioral health, establishes appropriate thresholds and goals for performance, and recommends to ROQG for final approval.
- D. The results and data are reviewed by the RS/DIME Team, i.e., looking at trends and comparisons to goals or benchmarks that may indicate inappropriate utilization among population groups, individual clinicians, clinician groups, and facilities.
- E. The RS/DIME Team is responsible for comparing data to national and regional information and establishing acceptable ranges of utilization performance. Where analysis indicates potential areas of under-, over-, or mis-utilization, the committee performs a focused review of data and facilitates qualitative analysis, including barrier analysis.
- F. A focused review will be conducted if the data falls outside the established thresholds. This may include as relevant, but not be limited to clinician, provider, or site specific information separated by risk, delegate, specialty type, or other significant categories. Areas of deficiency, identifiable barriers, or specific circumstances are outlined and recommendations for improvement are made and reported to the RS/DIME Team and the specific area impacted as appropriate.
- G. The interventions must be designed to be of sufficient strength and specificity that there is a likelihood that the interventions contribute to a measurable improvement when performance is re-measured.
- H. The RS/DIME Team will evaluate to determine the effectiveness of defined interventions and include assessments in the annual evaluation submitted to ROQG.

**UR 25: Ensuring Appropriate Utilization**

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**SPECIAL GROUP CONSIDERATIONS**

None

**REFERENCES****WASHINGTON**

WAC 284-43-410 and RCW 48.43.520 Requirement to maintain a documented utilization review program description and written utilization review criteria

**OREGON**

ORS 743.804: Requirements to provide criteria and information about utilization management (also, general requirements found in 743.807 and 807)

**MEDICARE**

CMS 42 CFR Chapter IV §422.101 1-2 Requirements Related to Basic Benefits

**MEDICAID**

CMS 42 CFR Chapter IV §438.210 1-2 Coverage and Authorization of Service

## UR 26a: Strict Adherence and Deemed Exhaustion Policy

Department: Member Relations Applies to: KPNW Region Review Responsibility: Kathy Fazio, RN; UROC	Number: UR 26 a Effective: 2/13 Reviewed: 2/13, 10/13, 10/14, 10/16 Revised:
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### POLICY:

1. If the Health Plan fails to strictly adhere to all the requirements of the Interim Final Rules with respect to a claim (initial or appeal), the member is deemed to have exhausted the internal claims and appeals process regardless of whether the Health Plan asserts that it substantially complied with the requirements, unless the violation is considered *de minimus*.
2. The member is then entitled to initiate an external review AND pursue any available remedies under section 502(a) of ERISA or State law, as applicable, on the basis that the Health Plan has failed to provide a reasonable internal claim and appeal process that would yield a decision on the merits of the claim. The claim must still meet the State's eligibility requirements for external review.
3. There is no Deemed Exhaustion when a *de minimus* violation occurs:
  - That does not cause and is not likely to cause harm, prejudice or harm to the claimant.
  - So long as the Health Plan demonstrates:
    - a. Violation was for good cause or due to matters beyond its control, and/or
    - b. Violation occurred during ongoing, good faith exchange of information between the Health Plan and the claimant.
  - However, an exception is not available if the violation is part of a pattern or practice of violations by the Health Plan.
4. The Health Plan is not obligated to proactively report any practice that is in violation of this law.
5. A claimant can allege "deemed exhaustion" for the Health Plan's failure to comply with strict adherence by filing for external review or by sending notice to the Health Plan asking for a written explanation of the violation. The Health Plan, with Regional Legal Counsel input, must respond within 10 days with the specific basis, if any, for asserting the violation should not cause the internal claims and appeals process to be deemed exhausted."
6. The external review entity reviews the claimant's assertion:
  - However, if the external review entity (IRO or court) rejects the member's request for immediate review, *i.e.* no deemed exhaustion, then the member has the right to resubmit and pursue the internal appeal;
  - Within a reasonable time, not to exceed 10 days; the plan shall provide notice to the member regarding the opportunity to resubmit and pursue the internal appeal of the claim;
  - Time period for re-filing the claim shall begin upon the member's receipt of such notice.

## UR 26a: Strict Adherence and Deemed Exhaustion Policy

Department: Member Relations Applies to: KPNW Region Review Responsibility: Kathy Fazio, RN; UROC	Number: UR 26 a Effective: 2/13 Reviewed: 2/13, 10/13, 10/14, 10/16 Revised:
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**PROCESS DESCRIPTION:**

Please see the External Review Policy for Oregon or the External Review Policy for Washington, as applicable, for external review handling procedures.

Upon receipt of an allegation that the Health Plan has not strictly complied with claims/appeal processes:

Member Relations Case Installation	Receives a request from either: <ol style="list-style-type: none"> <li>1) a member requesting an explanation for an alleged violation or requesting deemed exhaustion of the internal claim/appeal process</li> <li>2) an external review organization regarding a member’s allegation of a compliance violation.</li> </ol>
	Sets up case in CIDARS using the correct: <ol style="list-style-type: none"> <li>1) Issue and Issue Detail:                         <ol style="list-style-type: none"> <li>a) Issue- IRO Issue Detail- IRO req. before int. appeal exhaust, or</li> <li>b) Issue-Strict Adherence Issue Detail- Allegation of Non-Strict Adherence.</li> </ol> </li> <li>2) Decision Reason:                         <ol style="list-style-type: none"> <li>a) Deemed Exhaustion, or</li> <li>b) Strict Adherence</li> </ol> </li> </ol>
	Assigns case to a Senior Grievance and Appeal Administrator
Senior Grievance and Appeal Administrator (SGAA)	Solicits input from the Director of Member Relations and Regional Legal Counsel, who will assist in a full investigation and will determine whether the allegation of a compliance violation is substantiated and, if substantiated, will determine whether the violation is considered de minimus. (see Policy section #3 above).  Within 10 days of the receipt of the request, will respond to the member providing the specific basis, if any, for asserting the violation should/should not cause the internal claims and appeal process to be deemed exhausted and will explain the next steps for the member to pursue.

## UR 26a: Strict Adherence and Deemed Exhaustion Policy

Department: Member Relations Applies to: KPNW Region Review Responsibility: Kathy Fazio, RN; UROC	Number: UR 26 a Effective: 2/13 Reviewed: 2/13, 10/13, 10/14, 10/16 Revised:
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	<p>If the appeal coordinator, with input from the Director of Member Relations, determines that sufficient information exists to fully reverse the original decision, the appeal coordinator will notify the independent review organization and the member (via phone and in writing) of a reversal of an original decision and terminate the independent review within 1 business day.</p> <p>If the original decision cannot be reversed and the claimant’s appeal process is deemed exhausted, the appeal coordinator will follow the External Review Policy for OR/WA. In this event, the Health Plan will complete the internal review of the initial request or appeal, will reach a determination and, for quality assessment purposes, will compare the outcome of the IRO’s determination with the internal review outcome.</p>
Analyst	Each Administrator is responsible to track the timeliness of their responses to inquiries/requests on an ongoing basis. A report is run quarterly and provided to the department manager and/or Director to monitor the volume of these requests, the timeliness, the determination of the request (whether to deem exhaustion or not), date of the explanation letter to the member/State and, if deemed not exhausted, the date the member was notified of their right to resubmit and pursue the internal appeal process.

## UR 26b: Appeals of Adverse Determinations Policy

Department: Member Relations Applies to: KPNW Region Review Responsibility: Member Relations/UROC SME: Kathy Fazio, RN	Number: UR 26 Effective: 3/95 Reviewed: 7/97, 1/99, 12/00, 5/00, 1/02, 2/02, 3/03; 12/04, 12/05, 11/06, 1/08, 1/09, 10/09, 10/11, 10/12, 10/14, 10/16 Revised: 10/09, 10/11, 02/13, 10/15, 11/16, 7/17 1 of 11
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### PURPOSE

To define standards, accountabilities, and processes for reviewing appeals from members or their authorized/appointed representatives regarding adverse determinations (denials) whether:

- A. Expedited/urgent concurrent or standard (pre-service or post-service)
- B. Based on medical necessity or contractual issues (benefit determinations)
- C. By KPNW members of Oregon or Washington commercial plans, Medicare Advantage, Oregon Health Plan (Medicaid), and KP Individual plans. This policy does not distinguish between Commercial, Individual, Marketplace/Exchange plans in its application.

NOTE: Self-Funded Plan appeals are reviewed by Harrington Health and are not addressed in this policy.

NOTE: Washington Medicaid (Molina) appeals are not delegated to KFHPNW and are not addressed in this policy.

### POLICY

- A. A member or their authorized/appointed representative may appeal any denial decision. In addition to coverage denials of items/services, this includes denials of membership applications and rescission of coverage, except when cancellation of coverage is due to failure to timely pay premiums or contributions.
  - 1. Oregon commercial members must appeal in writing, except for expedited appeals;
  - 2. Washington commercial members may appeal orally or in writing;
  - 3. Oregon Health Plan members may appeal orally but must confirm the appeal in writing;
  - 4. Except for expedited appeals, Medicare Advantage members must appeal in writing.

Note: Individual coverage will not be rescinded except in the case of an act, practice or omission that constitutes fraud, or an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage.

- B. Decision makers who respond to member appeals for items, services or care based on contractual provisions and/or medical necessity, make decisions in a consistent, equitable, timely manner in accordance with the applicable member agreement or evidence of coverage (EOC) and Utilization Review (UR) or benefit criteria.
- C. Appeal decisions are based on a full investigation of the substance of the appeal, including all aspects of the clinical care involved, the member's perspective and comments, as well as any additional materials submitted by members or practitioners such as medical records (chart



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notes and non-plan records), physician reviews, medical necessity criteria, contractual and policy provisions and other relevant information. If additional information is requested of the member and/or practitioner, the Appeal Administrators will document when members/practitioners fail to submit the information by the specified deadline.

Medicare requires a minimum of three outreach attempts (if the first two are unsuccessful) to request supporting clinical documentation. These outreach attempts will be conducted by the clinical and/or non-clinical staff involved in preparing the case for the reviewing physician or by the reviewing physician him/herself. Outreach to contracted providers who are unresponsive will be done by the reviewing physician. If the initial denial based on lack of information is upheld, the physician making the appeal determination should attempt to communicate with the provider/prescriber about the request before issuing the determination.

Below is a summary of Medicare guidance related to outreach attempts:

<u>Case Type</u>	<u>Date of 1<sup>st</sup> Attempt</u>	<u>Subsequent Attempts</u>	<u>Allowable Contact Methods</u>
<b>Medicare Part C</b>			
Standard Reconsiderations	Within 4 calendar days of receipt of request	Subsequent request should be made in a manner that increases likelihood of making contact (consideration given to whether the Plan used multiple methods of communication)	Phone, fax, email, and/or <u>standard or overnight</u> mail with certified return receipt
Expedited Reconsiderations	Upon receipt of request	Same as above	Phone, fax, email, and/or <u>overnight</u> mail with certified return receipt

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<b>Medicare Part D</b>			
Standard Redeterminations	Within 2 calendar days of receipt of request	Same as above	Phone, fax, email, and/or <u>overnight</u> mail with certified return receipt
Expedited Redeterminations	Upon receipt of request	Same as above	Phone, fax, email, and/or <u>overnight</u> mail with certified return receipt

- D. Appeal decisions are made that do not give deference to the initial denial decision and are made by a person who was neither involved in the previous review nor is a subordinate of a previous reviewer; or by an appeal review panel made up of individuals who were not involved in previous decisions. The reviewer who made the initial decision may review the case and overturn the initial decision.
  
- E. All appeals requiring a quality review, medical necessity review, medical criteria application or experimental service determination, will be reviewed by a physician who practices in the same-or-similar specialty (see definitions) with appropriate training and experience in the field of medicine involved in the UM case appeal.
  
- F. KPNW offers only one level of internal appeal. Members are notified of their internal appeal rights via the state-specific or product-specific Appeal Brochure, which is templated and imbedded in each initial denial notification. When the initial denial is upheld upon appeal, the External Review Brochure, which is templated and imbedded in the appeal denial notification, further explains the external review process and relevant written procedures.
  
- G. Members are notified via the Appeals Brochure, which accompanies each denial notice, that they can obtain, upon request and free of charge, access to and copies of all documents

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relevant to the appeal, including documents and records submitted and relied upon in the course of making the appeal decision by contacting the Member Relations Department.

- H. Members will be provided, without charge, any new or additional evidence considered, relied upon, or generated by (or at the direction of) the Plan in connection with the appeal, as soon as possible and sufficiently before the deadline for the final internal appeal determination to give the member a reasonable opportunity to respond before that deadline.
  
- I. Members will be provided, without charge, any new or additional rationale before issuing a final internal appeal determination, as soon as possible and sufficiently before the deadline for the final internal appeal determination to give the member a reasonable opportunity to respond before that deadline.
  
- J. Members may appoint another person, such as their physician or an attorney, to represent them at all levels of the appeal process. For an expedited appeal, the organization must allow a healthcare practitioner with knowledge of the member's condition (e.g. a treating practitioner) to act as the member's authorized representative. The intent to appoint a representative must be made explicit by the member signing a Release of Information (ROI) document as well as the member and appointed representative signing an Authorization of Representation (AOR) document. Both the ROI and AOR documents are provided by the Member Relations Department and will be mailed or faxed immediately to the member upon request of representation. For Medicare members, a treating provider may appeal for the member without being appointed for both standard and expedited appeals.
  
- K. Members are notified via the annually-distributed Medical Directory of the availability of free language interpretation services. Each denial notice (initial and appeal) sent to an address in a county where a federally-mandated threshold language applies (at least 10% of the population is literate only in the same federally-mandated non-English language) will include an offer of non-English language assistance. These services will be provided, upon request and free of charge, in a linguistically and culturally appropriate manner by a professional interpreter service. (Language thresholds are calculated differently for the Medicare and Medicaid populations and therefore the above calculations do not apply to Medicare and Medicaid members)
  
- L. The substance of all appeals is documented in the Customer Information Documentation and Reporting System (CIDARS) including member's perspective and reason for appealing;

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additional clinical information or other information provided with the appeal request; research; decision; rationale for the decision; actions taken such as previous denial/appeal history and follow-up activities associated with the denial conducted before the current appeal; and notification of the determination.

- M. Records of all claims/requests and notices associated with the internal appeal process will be maintained for six years for Commercial members, ten years for Medicare members, and seven years for Medicaid members and will be made available for examination by the member or state/federal oversight agencies, free of charge, upon request.
- N. If an ongoing course of treatment (over a period of time or number of treatments) has been approved, any reduction or termination of such course of treatment before the end of the authorization period will constitute a denial. The member will be notified of the denial determination sufficiently in advance of the reduction or termination to appeal the denial and, if appealed, coverage will continue throughout the appeal process pending the outcome or until the end of the previously approved treatment period.

If an extension of an ongoing course of treatment has been denied, the member will be notified of the denial determination and, if appealed, coverage will continue throughout the appeal process.

However, if the initial denial determination is upheld upon appeal, the member will be held financially responsible for the charges associated with the denied service(s).

- O. Appeal-related elements within the initial written denial notification include:
  - 1. The state-specific or product-specific Appeal Brochure (which accompanies each initial denial notification) to members and their practitioners contains:
    - i. the available internal appeal process, including the expedited appeal process for urgent pre-service and urgent concurrent services, how to initiate an appeal, the timeframes that appeals will be resolved, and the timelines in which to file an appeal (NOTE: the timeline in which to file an appeal varies by line of business, for example, commercial members are allowed at least 180 days to file an appeal while Medicare Advantage members are allowed 60 days;
    - ii. the right of members to appoint a representative to act on their behalf at all levels of appeal. This must be in a signed, written statement granting specific permission;

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- iii. the right to submit written comments, documents, or other information relevant to the appeal and the right to telephonically present evidence and testimony as part of the internal claims and appeals process;
  - iv. the right to review and/or receive a free copy of the appeal file, upon request;
  - v. the provision of continued coverage pending the outcome of an appeal in urgent and concurrent care situations;
  - vi. the requirement to participate in one internal appeal before a member can take legal action or before a member's appeal can be considered for external review
- Exceptions:
- a. Claimants must first exhaust the internal appeals process unless the health plan failed to comply with appeal rules whereby causing prejudice or harm to the claimant's right to external review.
  - b. Individuals who qualify for an expedited appeal review (urgent care situations and individuals receiving an ongoing course of treatment) will be allowed, upon request, to proceed simultaneously with an expedited external review while pursuing the internal appeal process. In these cases, the internal appeal will be completed according to this policy (NCO).
- vii. contact information and availability of the applicable office of health insurance consumer assistance or ombudsman to assist members with the appeal and external review processes.

2. In addition to receiving a copy of the member's initial denial notification, the ordering practitioner's denial notification contains a description of how to contact the reviewing physician to discuss a medical necessity denial determination.

- P. The appeal denial notification to members or their appointed representative contains:
- i. information sufficient to identify the claim/request including, when applicable, the date of service, the provider, and the claim amount; denial codes and their meaning, when applicable; an offer to provide diagnosis and procedure codes, as well as their meanings, to members upon request;
  - ii. the specific reason and complete explanation of the grounds for the appeal denial communicated in plain, easily understandable language that does not include abbreviations or acronyms that are not defined or healthcare procedure codes that are not explained.
  - iii. either a reference to or the complete criteria, benefit provision, guideline or protocol on which the appeal decision was based or, when complete criteria are not provided,

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- notification that the member can obtain upon request, a copy of the actual benefit provision, guideline, protocol or other similar criterion on which the appeal denial decision was based;
- iv. the title of each reviewer participating in a benefit appeal review; or the title, qualifications and specialty of each reviewer participating in a medical necessity appeal review; and that this/these individual(s) participated in the appeal review (participants' names do not need to be included in the written denial notice and may be provided to members upon request);
  - v. the state-specific or product-specific External Review Brochure explaining the members' right, when applicable, to an external review with an independent review organization (IRO), including the expedited review process, how to initiate an external review, and the timelines in which to file a request for an external review using CMS template notice;
  - vi. the right to review and/or receive a free copy of the appeal file, upon request;
  - vii. the right of members to appoint a representative to act on their behalf at all levels of appeal. This must be in a signed, written statement granting specific permission;
  - viii. the provision of continued coverage pending the outcome of an appeal in urgent and concurrent care situations;
  - ix. contact information and availability of the applicable office of health insurance consumer assistance or ombudsman to assist members with the appeal and external review processes.
- Q. If the denial is completely overturned, the appeal notice will state the decision and the date.
- R. See the following state-specific and product-specific Appeal Brochures (templated and imbedded within the applicable initial denial notification) and External Review Brochures (templated and imbedded within the applicable appeal denial notification):
1. For Oregon commercial
  2. For Washington commercial
  3. For Oregon Health Plan Dispute Resolution
  4. For Washington Medicaid, initial denials include the Molina appeals and external review brochure.
  5. For Federal Employees Health Benefit Plan (FEHBP)

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### DEFINITIONS

Appeal- a request to change a previous decision made by the organization.

Expedited Appeal- a request to change an adverse determination for urgent care. An expedited review will be granted to all requests concerning admissions, continued stay or other health care services for a member who has received emergency services but has not been discharged from a facility and under the following circumstances when application of the non-urgent time period:

- Could seriously jeopardize the life or health of the member, the life or health of a fetus, or the member’s ability to regain maximum function, based on the prudent layperson’s judgment, **or**
- In the opinion of a practitioner with knowledge of the member’s medical condition, would subject the member to severe pain that cannot be adequately managed without the care or treatment that is the subject of the request.

Experimental/Investigational- surgical or medical procedures, supplies or devices, or drugs which, at the time provided or sought to be provided, are not recognized as conforming to accepted medical practice (see member’s specific EOC language).

Medical Necessity Determination (NCQA definition)-the provision of coverage of a service/item is dependent upon the circumstances (for example, a procedure that might be considered cosmetic or medical depending on the circumstances), as opposed to a benefit determination which is or is not covered for all plan members under the same contract, regardless of the circumstances.

Post Service Decisions- decisions regarding any requests for coverage of care or service that a member has already received.

Pre-service or Prospective Decisions- decisions regarding any requests for proposed care that has not been rendered, including requests for continuation of services being reduced or terminated.

Same Specialty- a practitioner with similar credentials and licensure as those who typically treat the condition in question in the appeal.

Similar Specialty- a practitioner who has experience treating the same problem as those in question in the appeal, in addition to experience treating similar complications of those problems.

NWP – Northwest Permanente, P.C., Physicians and Surgeons, is a professional corporation of physicians organized under the laws of Oregon. The NWP Medical Group contracts with the Health Plan to provide professional medical services to the member. Permanente Medical Group

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assumes responsibility for the medical care of their patients. Permanente physicians determine the medical necessity for a member's course of covered treatment.

KFHPNW - Kaiser Foundation Health Plan of the Northwest, an Oregon nonprofit corporation.

### RESPONSIBILITIES

Appeals are classified and documented in CIDARS distinguishing:

- a. the type of appeal (pre-service, post-service, concurrent),
- b. the urgency (whether expedited or not), and
- c. issue (medical necessity, experimental/investigational, benefit).

Routine/Standard Appeals (pre-service and post-service)

- a. Most appeals are acknowledged within seven (7) days of receipt, not to exceed five (5) working days (NOTE: day of receipt of the appeal is day zero). Washington appeals will be acknowledged within 72 hours of receipt.
- b. Determinations are made and notifications are issued within a reasonable time period appropriate to the medical condition involved but will not exceed:
  - For Washington members- 14 days, unless an extension notice is sent to the member stating that additional time is necessary to complete the review. In these circumstances, the review will be completed within 30 days of receipt of the original appeal;
  - For Oregon members- 30 days of receipt of the appeal;
  - For Medicare members- 30 days of receipt of the pre-service appeal unless an extension of up to 14 days is needed to obtain additional information and the extension benefits the member. Post service appeals-60 days of receipt of the appeal (no extension allowed). If a denial is upheld upon appeal, the case is automatically forwarded the same day that the upheld denial determination is sent to MAXIMUS, the Medicare Independent Review Entity (IRE). Members or their representative are notified when upheld denials are sent to MAXIMUS.



## UR 26b: Appeals of Adverse Determinations Policy

Department: Member Relations Applies to: KPNW Region Review Responsibility: Member Relations/UROC SME: Kathy Fazio, RN	Number: UR 26 Effective: 3/95 Reviewed: 7/97, 1/99, 12/00, 5/00, 1/02, 2/02, 3/03; 12/04, 12/05, 11/06, 1/08, 1/09, 10/09, 10/11, 10/12, 10/14, 10/16 Revised: 10/09, 10/11, 02/13, 10/15, 11/16, 7/17 10 of 11
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### Expedited Appeals

- a. Expedited appeals may be submitted orally or in writing and are acknowledged orally or in writing on the day of receipt.
- b. Expedited appeals are reviewed by a physician to determine if the appeal meets the criteria for an urgent request. Appeals not meeting urgent criteria are reviewed through the standard appeal process. Oregon commercial members submitting a non-urgent oral appeal will be asked to also submit the appeal in writing.
- c. An expedited review will be granted for all requests concerning inpatient/ residential admissions and continued stays; and other health care services for a member who has received emergency services but has not been discharged from a facility.
- d. Requests for qualified expedited appeals are responded to as quickly as possible to meet the clinical urgency of the request, not to exceed 72 hours from receipt of the appeal.
- e. Oral decisions are provided within 72 hours of receipt of an urgent appeal, with written confirmation of the appeal decision sent to the member and the ordering clinician (if applicable) within three (3) calendar days of the oral notification or within 72 hours of the decision for Washington members; and (two (2) calendar days for Medicaid members).

Extending the timeframe to obtain additional information is allowable when

- a. The member voluntarily agrees to extend the appeal time frame, or
- b. Kaiser Permanente requests additional information from the member who has Federal Employee Health Benefits (FEHB) and the routine appeal decision is made within 30 days after the date the additional information is received.

If additional medical information is required for an appeal determination, a release of information consent form is either included with the acknowledgment letter or upon determining that additional information is needed. Members are informed that they have a minimum of 48 hours to provide the additional information.

The member will be notified within 14 days of receipt of a standard appeal and within 24 hours of an expedited appeal if the Health Plan does not have sufficient information to complete the internal appeal process. The Health Plan will 1) notify the member that the appeal process cannot

## UR 26b: Appeals of Adverse Determinations Policy

Department: Member Relations Applies to: KPNW Region Review Responsibility: Member Relations/UROC SME: Kathy Fazio, RN	Number: UR 26 Effective: 3/95 Reviewed: 7/97, 1/99, 12/00, 5/00, 1/02, 2/02, 3/03; 12/04, 12/05, 11/06, 1/08, 1/09, 10/09, 10/11, 10/12, 10/14, 10/16 Revised: 10/09, 10/11, 02/13, 10/15, 11/16, 7/17 11 of 11
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effectively proceed unless additional information is provided, and 2) assist the member in gathering the necessary information without further delay.

### REFERENCES

**NCQA:** UM Standard 8: The organization has written policies and procedures for the thorough, appropriate, and timely resolution of member appeals

### WASHINGTON:

*RCW 48.43.530* Requirements for carriers to have comprehensive grievance process—Carrier duties—Procedures—Appeals

*WAC 284-43-510(4)* Review of adverse benefit determinations – Generally.

*WAC 284-43-540(4)* (a) Expedited review.

*WAC 284-43-615* Grievance and Complaint Procedures Generally

*WAC 284-43-620* Procedures for review and appeal of adverse determinations

*WAC 284-43-620* Independent Review of Adverse Determinations

### OREGON:

*OR Senate Bill 89*

*OAR 836-053-1140* Appeal, Utilization Review determinations

### FEDERAL:

*29 CFR 2560.503-1*

*Patient Protection and Affordable Care Act (PPACA), Act 1001(5)* (section 2719 of the Public Health Services Act), 1004, 1251, 10101(g), 10103(d)/Reconciliation 2301(a)/Interim Final Regulations/CFR 43330/Last Revised 072211.

## UR 28: On-Site Utilization Review Process

Department: Utilization Review  
Applies to: KP Northwest Region  
Review Responsibility: Kathy Fazio, RN

Number: UR 28  
Issued: 01/04  
Reviewed/Revised: 1/05, 02/06, 01/07, 3/08, 03/09, 7/10, 10/12,  
10/14  
Revised: 11/16  
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**PURPOSE**

To describe how the Inpatient Utilization Management (UM) On-Site review process is utilized to coordinate care for members in contracted and non-contracted facilities.

**POLICY**

- A. In an effort to provide consistent and coordinated care, designated UM staff will routinely review Kaiser Permanente Northwest (KPNW) member/visiting member medical records, while the member/visiting member remains in an acute care setting, sub-acute skilled nursing care setting, or psychiatric and addictions treatment from an external provider. KPNW utilizes the services of contracted and non-contracted facilities to meet the inpatient needs of the member/visiting member. The following criteria are used in authorizing admissions/continued stays and coordination of care:
  1. Medicare criteria are applied for Skilled Nursing Care, Home Health Care, and Hospice services.
  2. MCG medical necessity criteria are applied for all other contracted/non-contracted facilities (including mental health facilities).
  3. ASAM PPC 2R criteria are applied for all addiction treatment provided by contracted/non-contracted providers.
- B. KPNW-designated UM staff in contracted facilities will follow the guidelines stated in the facility contract regarding access to KPNW members/visiting members and their medical records. The contract guidelines may include, but are not limited to: access to admitted members/visiting members and their medical records, permission for staff to wear KPNW badges, access to coded medical information on members/visiting members, and data collection activities.
- C. For members/visiting members admitted to non-contracted facilities, designated UM staff may initially perform a telephone review, utilizing MCG medical necessity criteria or other approved criteria i.e. Medicare, with the facility utilization review staff. In the event of a complex case, or an extended length of stay, an on-site review may be conducted.
- D. For members/visiting members admitted to contracted/non-contracted mental health and addiction treatment facilities, an on-site or telephonic review will be conducted.

**RESPONSIBILITIES**

- A. KPNW Contracted Hospitals/Facilities: When performing utilization review in contracted facilities, reviewers will follow the guidelines stated in the facility contract, as well as KPNW UM department policies and procedures. Unless otherwise agreed upon, reviewers will schedule onsite reviews in advance.
- B. Non-Contracted Hospitals/Facilities: Designated UM staff will utilize the following process to ensure that facility rules are followed at non-contracted hospitals, sub-acute/skilled nursing facilities, and/or other facilities.



**UR 28: On-Site Utilization Review Process**

Department: Utilization Review  
Applies to: KP Northwest Region  
Review Responsibility: Kathy Fazio, RN

Number: UR 28  
Issued: 01/04  
Reviewed/Revised: 1/05, 02/06, 01/07, 3/08, 03/09, 7/10, 10/12, 10/14  
Revised: 11/16  
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1. The facility UM Department Manager, or designee, will be contacted by telephone prior to an on-site review. The date of the pending review will be established, as well as the purpose of the review.
2. Prior to the review, designated UM staff will present the proposed process and procedures for reviewing the medical record.
3. Facility staff are given the opportunity to ask questions of the KPNW-designated UM staff regarding the on-site review process.
4. Upon arriving at the facility, the reviewer will present a KPNW identification badge and/or letter of introduction, if requested.
5. The reviewer will meet with the facility UM Department Manager, or designee, and assure a current confidentiality statement is on file.
6. If required by the facility, extra training or identification badges are obtained or scheduled.
7. The designated UM staff requests necessary training and copies of appropriate policies, including HIPAA requirements from each facility. Orientation requirements may include, but not be limited to the following: physical tour of the facility; introduction to appropriate staff; review of relevant facility policies and procedures; and issuance of facility identification badge.
8. It is the responsibility of the designated UM staff to follow all facility rules and to adhere to any changes in policies or procedures as they occur.
9. Once the designated UM staff have fulfilled all the required training, signed any required disclosure forms, received any special identification, and been approved by the hospital administration, they are introduced to the appropriate facility staff members and oriented to the facility or inpatient psychiatric unit.

C. Communication: Open communications between KPNW staff and facility staff is encouraged.

**SPECIAL GROUP CONSIDERATIONS:** None

**REFERENCES**

**NCQA**

NCQA Standards and Guidelines are updated annually and are available by contacting Quality Resource Management at 503-813-3850.



**OBSERVATION LEVEL OF CARE**

Department: Utilization Review

Number: UR 29

Applies To: KPNW Region

Effective: 8/2002

Review Responsibility: Inpatient Care Mgmt Director; UROC

Reviewed: 7/04, 7/05, 7/06, 09/07, 9/08, 09/09, 09/10, 9/12, 9/14, 11/16

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**PURPOSE**

To provide a regional standard for appropriate utilization of observation level of care of hospital services that ensures consistent application of the outpatient and acute care benefits for KPNW members regardless of where care is delivered.

**POLICY**

A. Observation level of care for hospital services will be utilized, when in the judgment of the admitting physician, the patient's presenting medical condition requires services which are reasonable and necessary to evaluate a patient's condition or determine the need for a possible inpatient admission. Observation level of care services are defined by Centers for Medicare and Medicaid (CMS). MCG Care Guidelines and the CMS "Two Midnight Rule" may serve as guidance for the attending physician in determining the appropriate use of observation status. Observation is a level of service, not a location therefore, a patient can be in observation status regardless of where the services are performed, i.e. critical care unit, emergency room, recovery room, telemetry, or on a medical floor.

CMS Manual- When a physician orders observation care, the patient's status is that of an outpatient. The purpose of observation is to determine the need for further treatment or for inpatient admission. Thus, a patient receiving observation services may improve and be released, or be admitted as an inpatient.

A physician's order must specify "admit to observation" or "observation status" and be signed electronically.

When a patient has been in observation status for 24 hours, documentation in the clinical record must include the 1) need to continue observation status with plan for discharge within the next 12-24 hours, 2) need to convert to inpatient status, documenting the medical necessity for admission, or 3) medical stability for discharge and plan for follow-up as needed.

Conversion to inpatient status must meet medical necessity criteria for admission and be documented at the time of conversion from observation to inpatient status. A physician's order must specify "admit to inpatient status" and be signed electronically.

To determine the consistency between the physician order (physician intent), the services actually provided (inpatient or outpatient), and the medical necessity of those services, including the medical appropriateness of the inpatient or observation stay, medical records may be evaluated.

C. A patient in observation may improve and be released, or be admitted as an inpatient. In most instances of placement in observation, a disposition will be implemented within 48 hours.



OBSERVATION LEVEL OF CARE

Department: Utilization Review

Number: UR 29

Applies To: KPNW Region

Effective: 8/2002

Review Responsibility: Inpatient Care Mgmt Director; UROC

Reviewed: 7/04, 7/05, 7/06, 09/07, 9/08, 09/09, 09/10, 9/12, 9/14, 11/16

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- D. If a patient is retained on observation status for 48 hours without being admitted as an inpatient, further observation services may be denied as not reasonable and necessary for the diagnosis or treatment of illness or injury.
- E. Conversion from observation status to inpatient status must meet medical necessity criteria (meets MCG Care Guidelines and the attending clinician agrees.)
- F. Medicare does not consider use of observation as a convenience of the patient, the patient’s family or a physician to be appropriate.

**DEFINITIONS**

Medicare CMS definition: Observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge.

Observation services are covered only when provided by the order of a physician or another individual authorized by State licensure law and hospital staff bylaws to admit patients to the hospital or to order outpatient tests. In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours. In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours. *For coverage requirements, see the Medicare Benefit Policy manual, Chapter 6.*

**RESPONSIBILITIES**

**TIMELINESS**

- A. If the attending physician intends to place or retain a patient in observation longer than 48 hours for a non-medical reason, or the patient and/or family are unable or unwilling to make other arrangements for care, a written notice of non-coverage will be issued to advise the patient and/or family of the financial responsibilities for the continuation of non-medically necessary services provided, and the right to appeal that decision. The denial will be generated by Member Relations, in accordance with Medical Necessity Determinations (UM-4).



OBSERVATION LEVEL OF CARE

Department: Utilization Review

Number: UR 29

Applies To: KPNW Region

Effective: 8/2002

Review Responsibility: Inpatient Care Mgmt Director; UROC

Reviewed: 7/04, 7/05, 7/06, 09/07, 9/08, 09/09, 09/10, 9/12, 9/14, 11/16

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PROCESS

Primary Responsibility	Action
<b>Attending/Admitting Physician</b>	<ol style="list-style-type: none"> <li>1. Utilizing clinical judgment and medical necessity criteria, admits the patient to observation status.</li> <li>2. The physician’s order must specify “admit to observation” and be electronically signed.</li> <li>3. The order must clearly document the medical intent of the use of observation, supported by the patient’s presenting medical condition (severity of illness) and plan for observation/treatment (intensity of service).</li> <li>4. When the patient has been in observation status for 24 hours, the physician will document either 1) the need to continue observation status with plan for discharge within the next 12-24 hours, 2) the need to convert to inpatient, documenting the medical necessity for admission, or 3) medical stability for discharge and plan for follow-up as needed.</li> <li>5. Medical necessity for admission must be met and documented at the time of conversion from observation to inpatient status.</li> <li>6. The physician may change admission status prior to discharge.</li> <li>7. The physician may convert a patient from inpatient status to observation status cancelling the inpatient admission prior to discharge if the physician determines that the inpatient admission is unnecessary or the original order was ambiguous and the physician clarifies that order. Any change in admission status must be supported by the contemporaneous medical record (physician notes and orders) and be supported by medical necessity criteria. Notification of the Care Management department is required in this instance.</li> <li>8. The physician may change or clarify the admission status through a direct written order, a verbal order given to a RN and subsequently co-signed by the physician.</li> </ol>
<b>RN Reviewer</b>	<ol style="list-style-type: none"> <li>1. Will conduct a review, utilizing MCG Care Guidelines on all patients admitted to either observation or inpatient status.</li> <li>2. If the patient does not meet the review criteria for the admission status, the RN Reviewer will contact the attending physician and discuss the results of the review with him/her.</li> <li>3. Based upon the review, the attending physician may provide additional documentation to support the admission status, or</li> </ol>



**OBSERVATION LEVEL OF CARE**

Department: Utilization Review

Number: UR 29

Applies To: KPNW Region

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	<p>convert the admission status to the identified appropriate status.</p> <ol style="list-style-type: none"> <li>4. The RN Reviewer may accept a verbal order from the attending physician to either clarify or change the admission status.</li> <li>5. If the RN Reviewer is unable to speak directly with the attending Physician, every effort to clarify will be instituted. It may be through a physician page or other identified means of communication approved by facility guidelines.</li> <li>6. In the event the attending physician does not provide additional documentation to support the admission status or convert the patient to the appropriate status, the RN Reviewer will contact the UM Physician Advisor for further review.</li> </ol>
<p><b>UM Physician Advisor</b></p>	<ol style="list-style-type: none"> <li>1. The UM Physician Advisor may contact the attending physician and review the recommended level of care determination with him.</li> <li>2. The UR physician Advisor will advise the RN Reviewer of the results of the contact.</li> </ol>

**SPECIAL GROUP CONSIDERATIONS**

Commercial: This policy applies to all commercial groups

Medicare: Under certain conditions, Medicare allows up to 2 days for Observation

Washington Medicaid: No special considerations

Oregon Medicaid: No special considerations

**REFERENCES**

**NCQA**

NCQA Standards and Guidelines are updated annually and are available by contacting Quality Resource Management at 503-813-3850.

**WASHINGTON**

WAC 388-531-0200 Physician-related services requiring prior authorization

RCW 284-43-410 & RCW 483.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria

These criteria do not imply or guarantee approval. Please check your plan to ensure coverage. Preauthorization requirements are only valid for the month published. They may have changed from previous months, and may change in future months. JULY-18





OBSERVATION LEVEL OF CARE

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OREGON

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

ORS 743.837: Prior authorization requirements

CMS

<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-07-01-2.html>

<https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/InpatientHospitalReviews.html>

## UR 31: Delegation Policy

Department: KPNW Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Kathy Fazio, RN, UR Administrator

Number: UR 31  
Issued: 8/03  
Reviewed: 10/04, 10/05, 12/06, 2/08, 2/10, 2/11, 3/16  
Revised: 4/12, 5/14, 3/18  
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**PURPOSE**

To establish a minimum set of standards that a delegate and its sub-delegates must meet prior to assuming the authority to perform delegated Utilization Review (UR) functions.

To establish standards for ongoing oversight of UR delegation including documenting approval of the delegate's policies and procedures (P&Ps) with respect to the delegated function.

To establish the minimum set of standards and P&Ps to be used in all care locations to provide for consistent administration of UR delegation.

To define the roles and responsibilities throughout the KPNW region when functions in the area of Utilization Review (UR) are delegated, outlining what the organization remains accountable for and the appropriate structures and mechanisms to oversee delegated UR activities.

To confirm the delegate has met the standards and requirements with the appropriately qualified staff.

**POLICY**

If Health Plan delegates the authority to perform functions in the area of UR, it will not delegate the responsibility for ensuring that the functions are performed appropriately nor any quality improvement functions not specified in the delegation agreement. There will be a formal process in place by which Health Plan contracts with a delegated entity to perform the delegated functions and Health Plan will retain oversight of the contracting activity to ensure the delegated functions are performed in compliance with KPNW and regulatory/accreditation standards.

**DEFINITIONS**

Covered Entity- a health plan, health care clearinghouse or health care provider that transmits any health information by electronic means in connection with an electronic health care transaction (as defined by HIPAA regulations).

**RESPONSIBILITIES****Written delegation agreement**

Whenever Health Plan delegates the authority to perform functions in the area of UR, the relationship will be formalized through a written delegation agreement. This mutually agreed upon document will:

1. Contain a written description of all activities delegated and sub-delegated.
2. Define which party is responsible for conducting the following activities:
  - a. Adoption of criteria
  - b. Monitoring quality and timeliness of decisions
  - c. Pre-certification, by service
  - d. Urgent concurrent review
  - e. Retrospective review, by service
  - f. Approvals & denials

## UR 31: Delegation Policy

Department: KPNW Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Kathy Fazio, RN, UR Administrator

Number: UR 31  
Issued: 8/03  
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- g. Appeals
  - h. Communication with members
  - i. Sub-delegation oversight
3. Outline the responsibilities of the organization and the delegated entity and its sub-delegates.
  4. Be dated and signed documenting that the agreement has been agreed to by both parties.
  5. Contain reporting and communication requirement of both the organization and the delegated entity and its sub-delegates.
  6. Describe the process by which the organization monitors and evaluates the delegate's performance, including the performance of potential sub-delegates.
  7. Entail the remedies, including the circumstances that would cause revocation of the agreement, if the delegated entity and its sub delegate(s) do not fulfill its obligations.
  8. The delegation agreement will include provisions for the delegated entity and its sub-delegates to report any quality concern to the organization, regardless if it is considered resolved.

**Reporting**

1. The delegation agreement will describe the agreed upon reporting relationship for the organization and the delegated entity and its sub-delegates. At a minimum, the entity will report semiannually to the organization, and will include reporting by any sub-delegates. Upon request, KPNW will provide data collected related to the services performed by the delegate, for example, member experience data, clinical performance data (minimum necessary) and appeals data resulting from denials issued by the delegate.
2. Reporting will ensure that the delegate and its sub delegate(s) comply with federal/state regulations and the KPNW medical benefit policies and meet all established standards, including the National Committee for Quality Assurance (NCQA).
3. Review and analysis of delegate and its sub delegate(s) reports will be reported to UROC when aberrant utilization or practices are evident.
4. All reports issued by the delegated entity and its sub-delegates will be evaluated by the organization and must show evidence of having been substantively reviewed and analyzed. Reports from the delegated entity will be reviewed at least semiannually, and will include any reporting by any sub-delegate(s). Reporting must include at least the following items:
  - a. Number of UM cases handled by type (pre-service, urgent concurrent or post-service) and by service (inpatient or outpatient)
  - b. Number of denials made
  - c. Number of cases appealed (when appeals are delegated)
5. Delegates are not prohibited from collecting member experience data directly from the member.

## UR 31: Delegation Policy

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Department: KPNW Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Kathy Fazio, RN, UR Administrator

Number: UR 31  
Issued: 8/03  
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### Annual Evaluation of Delegate

KPNW must periodically verify in the area of UR that monitoring is more or less continuous, in as much as decisions by the delegate and its sub-delegates may be appealed to the organization. However, KPNW must periodically verify that the delegate is, in fact, forwarding requests for appeals, and that its statistical and/or other reporting mechanisms on these processes are accurate.

KPNW shall provide sufficient information to the delegated entity to enable adequate performance of delegated functions. The delegated entity shall provide pertinent information to its sub delegate(s).

1. KPNW will review and approve, at a minimum, the sections of the delegated entities' UR Program that apply to delegated functions, annually. The evaluation may involve a site visit or may be conducted through telephone/email consultation, documentation review or committee meetings.

Evaluation will involve an audit of the delegated entity's denial files and a review of the meeting minutes.

If a delegate is not NCQA-Accredited or NCQA-Certified, the annual evaluation must be based on the contents of the mutually agreed-upon delegation document and the appropriate NCQA standards.

2. KPNW will ensure that monitoring of delegates is carried out by staff qualified to assess the delegate's activities.
3. For delegation arrangements in effect for 12 months or longer, KPNW will evaluate the delegate at least annually against its expectations and NCQA and federal/state regulations and standards. An assessment tool will be used to document compliance with NCQA standards and federal/state regulatory requirements. The evaluation will include, at minimum, a denial file review, a review of the UM Program Description and a review of minutes. The organization will take appropriate action in response to findings which may include a corrective action plan.
4. For delegation agreements that have been in effect for less than 12 months or if the scope of delegation with an existing delegate is going to change substantially, KPNW will evaluate the delegated entity's capacity to handle the delegated duties prior to signing the delegation agreement. This pre-delegation evaluation will be conducted within 12 months of implementing delegation or increasing the delegates' duties. Pre-delegation evaluations may be conducted via site visit, telephone consultation, documentation review, committee meetings and/or virtual review.
5. The UR department will prepare the annual evaluation and, when necessary, the semi-annual reports for UROC. The UR department can recommend actions plans that address areas of concern to the UROC. UROC will determine findings that warrant a corrective action plan in order to improve compliance with standards/regulations and is accountable to ensure that follow-up for corrective action plan(s) is completed.

## UR 31: Delegation Policy

Department: KPNW Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Kathy Fazio, RN, UR Administrator

Number: UR 31  
Issued: 8/03  
Reviewed: 10/04, 10/05, 12/06, 2/08, 2/10, 2/11, 3/16  
Revised: 4/12, 5/14, 3/18  
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**Protection of Protected Health Information (PHI)**

**NOTE: KPNW currently only delegates to “Covered Entities”, the following requirements are therefore not applicable.**

1. When PHI is used by the delegated entity and its sub-delegates, the delegation agreement will include:
  - a. A list of the allowed uses of the PHI
  - b. A description of the reasonable administrative, technical and physical safeguards to ensure the confidentiality, integrity and availability of PHI and to prevent unauthorized or inappropriate access, use or disclosure of PHI
  - c. A stipulation that the delegate will ensure that any sub-delegate will have similar safeguards
  - d. A stipulation that the delegate and its sub-delegates will provide individuals with access to their PHI, including procedures to receive, analyze and resolve members’ requests for access to their PHI
  - e. A stipulation that the delegated entity and its sub-delegates will inform the organization if inappropriate use of the information occurs
  - f. A stipulation that the delegate and its sub-delegates will ensure that PHI is returned, destroyed, or protected should the delegation agreement end.

**SPECIAL GROUP CONSIDERATIONS**

When care for Medicare Members is delegated, the delegated entity must comply with all applicable Medicare laws, regulations, and instructions from the Centers for Medicare & Medicaid Services (CMS).

**REFERENCES****NCQA**

NCQA Standard pertaining to UM Delegation: If the managed care organization delegates any UM activities, there is evidence of oversight of the delegated activity.

**CMS**

Section 40 of Chapter 21 of the Medicare Managed Care Manual and 42 CFR 422.504(i).

**WASHINGTON**

RCW 48.43.550 - Delegation of duties, Carrier accountability [Last update 10/06/06]

**OREGON**

ORS 744.720 (1, 3a) Agreement between insurer and third party administrator [2005 Edition]

ORS 744.740(3) – Responsibility of insurer using third party administrator (Annual Review Requirement) [2005 Edition]



**UR 33: Audit Timeliness Policy**

Department: KPNW Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UR Oversight Committee  
Subject Matter Experts: Kathy Fazio, Theresa DeBois

Number: UR 33  
Issued: 11/04  
Reviewed: 12/05, 12/06, 2/08, 2/09, 4/10; 3/12; 3/14  
Revised: 3/16, 3/18  
Page: 1 of 2

**PURPOSE**

To ensure compliance with regulatory standards and accrediting bodies for pre-service; concurrent, and retrospective medical necessity denial documentation; notification and timeliness of Utilization Review decision-making; and, to ensure the appropriate application of medical necessity criteria.

**POLICY**

- A. Audits are conducted on a quarterly basis on each service/department performing medical necessity denials.
- B. Audits are conducted on a semi-random sample of at least ten denials for each service/department when volume permits a sample size of ten. Denials prepared by each Utilization Review Coordinator are reviewed.
- C. The audit encompasses the complete continuum of the denial process.
- D. The audit ensures that:
  - 1. The organization makes utilization decisions and provides notification of denials in a timely manner to accommodate the clinical urgency of the situation and within the timeliness standard required of the applicable line of business.
  - 2. Relevant clinical information is utilized in making medical necessity decisions and/or consultation with the treating physician.
  - 3. Criteria are applied consistently and appropriately.
  - 4. If based on medical necessity, the denial decision is made by an appropriate MD or DO. (For Washington and Medicare chiropractic requests, a chiropractor may make medical necessity decisions).
  - 5. The organization clearly documents and communicates the reasons for each denial.
  - 6. The member is notified of the decision. The member’s notice includes the denial reason in easily understandable language, a reference to or the provision of the medical necessity criteria, appeal rights, the expedited appeal process and that the member may obtain a copy of the specific benefit provision (e.g. EOC), guideline, protocol or criterion on which the denial decision was based, upon request.
  - 7. The ordering clinician is notified of the decision. In addition to receiving a copy of the member’s notice, the clinician’s notice includes how the treating/referring clinician can contact the reviewing physician to discuss the denial.
- E. The audit review process adheres to appropriate standards as identified by regulatory and accrediting bodies inclusive of Oregon and Washington Statutes & Regulations, the Centers for Medicare and Medicaid Services (CMS) and the National Committee for Quality Assurance (NCQA). Please see UM 4 Medical Necessity Determinations for specific requirements for each line of business.



UR 33: Audit Timeliness Policy

Department: KPNW Utilization Review

Number: UR 33

Applies to: KPNW Region

Issued: 11/04

Review Responsibility: UR Oversight Committee

Reviewed: 12/05, 12/06, 2/08, 2/09, 4/10; 3/12; 3/14

Subject Matter Experts: Kathy Fazio, Theresa DeBois

Revised: 3/16, 3/18

Page: 2 of 2

F. Audit results are reported to the Utilization Review Oversight Committee (UROC) optimally every quarter but at least on a semi-annual basis.

G. Corrective action plans are developed with departments and staff that are not in compliance. The passing threshold is 90%.

DEFINITIONS

No special definitions are needed for this policy.

RESPONSIBILITIES

Process

- A. Utilization Review department staff:
  - 1. Monthly samples to the UR Supervisor- (all denials up to 10 cases per service)
  - 2. Complete quarterly/semi-annual audits, using a modified **NCQA worksheet** (if handwritten, will be in pen or dark pencil).
  - 3. As UR liaison to each department, educate as necessary regarding NCQA standards and application of State or Federal regulations affecting the denial process for creation, management and tracking of denial letters
  - 4. Assist with problem solving/creation of Corrective Action Plans (CAP)
  - 5. Provide summary report, including, total referrals (if available), total denials, any audit deficiencies, and CAP
- B. The Utilization Review Oversight Committee (UROC)
  - 1. Will have first level oversight to evaluate quarterly/semi-annual audit findings
  - 2. As needed, assist with development of the corrective action plan for non-compliant departments.
- C. The Regional Operations Quality Group (ROQG)
  - 1. Provides oversight and direction of the UR Compliance audit program.



**UR 35: Consistency of UM Application  
(Inter-rater Reliability)**

Department: Regional Utilization Review  
Applies to: KPNW Region  
Review Responsibility: Kathy Fazio, RN

Number: UR 35  
Effective: 07/05  
Reviewed and/or revised: 07/06, 09/07, 9/08; 09/09; 9/10;  
9/12, 9/16  
Last revised: 9/14  
Page: 1 of 2

**PURPOSE**

To define standards, accountabilities and the process necessary to ensure consistent application of medical necessity criteria by all UR staff when making determinations regarding covered services or items.

**POLICY**

- A. Kaiser Permanente Northwest evaluates health care professionals and staff involved in UR decision making for consistency in review determinations for all areas utilizing medical necessity criteria in determining authorization of services or items.
- B. The assessment of inter-rater reliability (IRR) applies only to medical necessity determinations made as part of a Utilization Review process.
- C. Evaluation of inter-rater reliability for all individuals making UR determinations will occur on an annual basis, not to exceed 14 months between evaluations.
- D. The evaluation / assessment may be accomplished by any one of the following actions:
  - 1. Use of hypothetical test cases
  - 2. A supervisor may periodically review determinations (which could include side-by-side comparisons of how different UR staff members manage the same cases);
  - 3. Weekly UR “rounds” attended by UR staff members and physicians to evaluate determinations and problem cases;
  - 4. Periodic audits of determinations against medical necessity criteria;
  - 5. Case studies where every reviewer evaluates cases using medical necessity criteria and reaches a determination.
- E. If sample cases are used in the IRR evaluation, one of the following auditing methods will be used:
  - 1. 5% or 50 UM determination files, whichever is fewer, or
  - 2. The NCQA 8/30 methodology, or
  - 3. Another statistically valid method.
- F. The IRR results:
  - 1. results are evaluated;
  - 2. opportunities to improve consistency are identified;
  - 3. corrective action plans are implemented as necessary and a re-evaluation is conducted.
- G. IRR results, evaluations, recommended actions, and corrective action plan updates are reported to the Utilization Review Oversight Committee (UROC) at least annually, in a confidential manner.





**UR 35: Consistency of UM Application  
(Inter-rater Reliability)**

Department: Regional Utilization Review  
Applies to: KPNW Region  
Review Responsibility: Kathy Fazio, RN

Number: UR 35  
Effective: 07/05  
Reviewed and/or revised: 07/06, 09/07, 9/08; 09/09; 9/10;  
9/12, 9/16  
Last revised: 9/14  
Page: 2 of 2

**PROCEDURE**

- A. The UR Administrator will:
  1. notify the applicable departments at least 30 days before their annual IRR is due;
  2. be available for consultation;
  3. document and track departments' completed IRR results;
  4. evaluate IRR results and identify opportunities for improvement;
  5. work with departments to develop corrective action plans when individual scores are <80% or department scores are <85%;
  6. report to UROC, no less than annually.
  
- B. Designee from each department where UR criteria are used will:
  1. Coordinate IRR testing annually;
  2. Identify and follow-through on opportunities for improvement;
  3. Report testing method and results to the UR Administrator.

**SPECIAL GROUP CONSIDERATIONS**

None

**REFERENCES:**

**NCQA**

UM 2: Clinical Criteria for UM Decisions, Element C: Consistency in Applying Criteria

**OTHER**

Sue McQuillan, FSA, Consulting Actuary, Milliman USA, *"Inter-Rater Reliability Testing For Utilization Management Staff"*, Managed Care Magazine, June 2001, pages 49-59

## UR 41: Cochlear Implants Medical Necessity Criteria

Department: KPNW Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Anna Grosz, MD (ENT),  
John Goddard, MD (ENT)

Number: UR 41  
Issued: 4/07  
Reviewed: 4/08, 4/09, 4/10, 4/11, 4/14, 4/15, 4/16,  
Revised: 4/12, 4/13, 4/17, 4/18  
Page: 1 of 3

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage are determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

### MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR COCLEAR IMPLANT

#### DEFINITIONS

- A. Cochlea: a spirally wound, tube-like structure that forms part of the inner ear and is essential for hearing. It is composed of a network of liquid filled tubing and tiny hairs. When sound is sent to the cochlea, it causes ripples in the liquid and the hairs to bend. This movement triggers electrical impulses which are transmitted to the auditory nerve.
- B. Cochlear implant device: an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. The purpose is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired. A cochlear implant consists of two (2) main components:
  - 1. The implant package and electrode array (or receiver-stimulator) – this controls the flow of electrical pulses into the ear and is inserted into the shell-like structure in the inner ear known as the cochlea; and
  - 2. The external speech processor and headset – a coil is held in position against the skin by a magnet and the microphone is worn behind the ear; the body-worn speech processor can be worn in a pocket, in a belt pouch, or in a harness (the other option is an ear-level speech processor).
- C. dB: decibel, unit for expressing loudness of sound
- D. Hz: hertz, unit for expressing frequency of sound
- E. The Lexical Neighborhood Test and the Multi-syllabic Lexical Neighborhood Test, designed for children who may be cochlear implant candidates, assess recognition of words and individual sounds. The results are used as a benchmark for children with hearing impairment.
- F. Middle ear: the hollow portion of the ear behind the eardrum. The middle ear contains one or more ossicles, which amplify vibration of the eardrum into pressure waves in the fluid in the inner ear.

**UR 41: Cochlear Implants Medical Necessity Criteria**

Department: KPNW Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Anna Grosz, MD (ENT),  
John Goddard, MD (ENT)

Number: UR 41  
Issued: 4/07  
Reviewed: 4/08, 4/09, 4/10, 4/11, 4/14, 4/15, 4/16,  
Revised: 4/12, 4/13, 4/17, 4/18  
Page: 2 of 3

**MEDICAL NECESSITY CRITERIA**

- A. Adults (age 18 or older) with:
1. Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing aides.
    - a. Limited benefit from binaural amplification: defined by test scores of  $\leq 50\%$  correct in the best-aided listening condition on tape recorded tests of open set sentence cognition in the ear to be implanted and  $\leq 60\%$  in the opposite ear (See Special Group Considerations below for Medicare criteria).
    - b. Profound sensorineural hearing loss: for individuals older than 24 months, the pure tone average for both ears should equal or exceed 70dB at 500Hz, 1000Hz, and 2000Hz.
  2. Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation.
  3. Medical evaluation to determine there is adequate access to auditory nerve fibers to merit implantation.
- B. Children (age 12 months through 17 years):
1. Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from binaural amplification, defined by test scores of  $\leq 50\%$  correct in the best-aided listening condition on tape recorded tests of open set sentence cognition in the ear to be implanted and  $\leq 60\%$  in the opposite ear.
  2. For children age 12-24 months, profound sensorineural hearing loss: thresholds of 90dB or greater at 1000Hz.
  3. For children age 24 months to 17 years, pure tone average of 70dB or greater at 500Hz, 1000Hz, and 2000Hz.
  4. In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three to six month period.  
In older children, lack of aided benefit is defined as  $\leq 30\%$  correct on the Multi-syllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive ability and linguistic skills.
  5. A three to six month hearing aide trial is required for children without previous experience with hearing aides. Radiographic evidence of labyrinthine fibrosis that would lead to ossification will justify implantation without a trial of amplification.
  6. Medical evaluation to determine there is adequate access to auditory nerve fibers to merit implantation.
  7. Freedom from lesions in the auditory nerve and acoustic areas of the central nervous system.

**UR 41: Cochlear Implants Medical Necessity Criteria**

Department: KPNW Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Anna Grosz, MD (ENT),  
John Goddard, MD (ENT)

Number: UR 41  
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Revised: 4/12, 4/13, 4/17, 4/18  
Page: 3 of 3

**OTHER REQUIREMENTS or CONSIDERATIONS**

Replacement of battery charger is not covered; replacement of batteries is covered for all members. Replacement of a cochlear implant and/or its external components is considered medically necessary when the existing device cannot be repaired or when replacement is required because a change in the member's condition makes the present unit non-functional and improvement is expected with a replacement unit. Must be performed in an ambulatory surgery center (ASC) or an inpatient or outpatient hospital facility.

**CONTRAINDICATIONS**

- A. Agenesis of the 8<sup>th</sup> cranial nerve
- B. Complete CN aplasia
- C. Pathologies of the central auditory pathway
- D. Michel deformity (complete labyrinthine aplasia/non-development) present
- E. Known intolerance to materials used in the implant
- F. Perforated tympanic membrane
- G. Deafness attributed to central damage of the acoustic nerve or central auditory pathway
- H. External or middle ear infection present

**SPECIAL GROUP CONSIDERATIONS**

Medicare: Cochlear implants for Medicare members with open-set sentence recognition tests of scores between 40% and 60% correct are covered if the device is implanted in an acceptable clinical trial or study. Otherwise, open-set sentence recognition tests of scores must be less than 40%.

Oregon Medicaid: See Prioritized List

**REFERENCES**

OREGON: Senate Bill 491 requires that bilateral cochlear implants be provided when medically necessary.

**CLINICAL**

<http://www.cochlear.com/wps/wcm/connect/us/for-professionals/products/cochlear-implants/candidacy>

Department: Mental Health

Section: Clinical

Applies to: KPNW Region

Reviewers: David VandeLindt, MD (psychiatrist)

Number: UR 42

Effective: 9/07

Reviewed and/or Revised: 9/08; 11/08; 09/09; 9/10;

9/11; 9/12; 9/13; 9/14; 9/15; 9/16, 9/17

### **MEDICAL NECESSITY CRITERIA**

The population to be considered for Vagal Nerve Stimulation (VNS) includes the severely depressed, treatment-resistant population. Treatment-Resistant Depression (TRD) is defined as failure to respond to at least four different antidepressant modalities (treatments) of adequate strength and duration.

Treatment must have involved FDA-approved antidepressant drugs, representing at least two or more classes, with or without electroconvulsive therapy (ECT).

The VNS candidate should be offered ECT, if appropriate, or be determined to be a non-ECT candidate. If a patient declines ECT, a second opinion may be obtained before moving forward with VNS treatment. Additional consultation may be obtained when 1) diagnostic clarification is needed or 2) should complex comorbidities (both medical and/or psychiatric) exist which may lead to difficulty tolerating the VNS implant or decrease the chance of response, as determined by the consultant.

The VNS candidate should be considered for Transcranial Magnetic Stimulation (TMS) therapy or be determined to be a non-TMS candidate. If a patient declines TMS, a second opinion may be obtained before moving forward with VNS treatment.

*Please note:* Possible VNS candidates will first require a chart review to determine adequate past trials of medication and psychotherapy as well as an ECT consultation to determine if this is an appropriate initial modality.

### **OTHER REQUIREMENTS**

Once referred for VNS consultation, the patient will be seen by a physician evaluator who has been trained in VNS programming technology.

Eligible treatment trials would not include mood stabilizers, atypical antipsychotics or anxiolytics as monotherapy. Since these agents are not considered antidepressants, their use does not qualify as a treatment trial. Clinically, however, use of these agents should be considered by the treating clinician in pre-VNS augmentation strategies as appropriate.

### **CONTRAINDICATIONS**

VNS therapy should not be used in:

- i. Patients who have had bilateral or left cervical vagotomy<sup>1</sup> or
- ii. Patients receiving shortwave diathermy or therapeutic ultrasound diathermy<sup>2</sup>.

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<sup>1</sup>Cervical vagotomy- cutting of the vagus nerve

<sup>2</sup> Diathermy- the production of heat in body tissues for therapeutic purposes

### UR 43: Physical /Occupational/Speech Therapy Policy

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Department: Utilization Review	Number: UR 43
Applies To: KPNW Region	Effective: 1/1/08
Review Responsibility: UROC	Reviewed: 1/08, 10/08, 11/08, 2/09, 2/10, 3/11, 3/13
SME: Kevi Ames (DA Rehab Services), Kathy Cutter(PT), Jennifer Allen (OT)	Revised: 3/14, 3/16, 11/16, 9/17

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Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

#### PHYSICAL, OCCUPATIONAL, and SPEECH THERAPY POLICY

**Medicare: This policy applies to all Commercial and Medicare with a PT/OT/ST benefit; also, see SPECIAL GROUP CONSIDERATIONS, MEDICARE FOR INFORMATION ADDED AS A RESULT OF THE Jimmo v. Sebelius SETTLEMENT AGREEMENT.**

#### PURPOSE

Describes UR policy for physical, occupational and speech therapy benefit limitations to those of short term therapy for acute conditions, subacute/neurodevelopmental conditions, or acute exacerbations of chronic conditions necessary to restore or improve functional abilities when physical and/or sensori-perceptual impairment exists due to injury, illness, stroke, or surgery. Significant, sustainable, measurable improvement is expected. Describes coverage of sensory integration as part of occupational therapy. Chronic and acute neurodevelopmental conditions are covered for members on a Washington group or individual contract.

#### POLICY

A. Therapy services (physical, occupational, speech) are covered for the treatment of acute conditions, subacute/neurodevelopmental conditions, functional vocal disorders resulting from maladaptive or inefficient use of a mechanism, and acute exacerbation of chronic disorders which, in the judgment of the KP Practitioner, can be expected to show measurable, significant, sustainable improvement as a result of the prescribed therapy. SEE SPECIAL GROUP CONSIDERATIONS FOR MEDICARE. Prescribed outpatient therapy services must have a referral and be evaluated by PT or OT or ST. If a referral is made to a PT/OT/ST outside of KP, or out of the plan service area, it must be authorized by the Regional Referral Center.

1. In all instances, therapy plan of care must include member's diagnosis, with type, amount, frequency, duration, and established goals of treatments.
  - a. Therapy plan of care should be reviewed per state and national compliance guidelines, with documented objective progress and discontinuation of therapy when continued therapy will not restore or improve functional abilities.

B. For Members who have a therapy benefit limit, the benefit is limited to the number of visits per therapy, per calendar year, as defined in the member's benefit coverage.



## Northwest Utilization Review

### UR 43: Physical /Occupational/Speech Therapy Policy

Department: Utilization Review	Number: UR 43
Applies To: KPNW Region	Effective: 1/1/08
Review Responsibility: UROC	Reviewed: 1/08, 10/08, 11/08, 2/09, 2/10, 3/11, 3/13
SME: Kevi Ames (DA Rehab Services), Kathy Cutter(PT), Jennifer Allen (OT)	Revised: 3/14, 3/16, 11/16, 9/17

1. Where there is a visit limitation, this limitation does not apply to hospital inpatient services.
2. Where there is a visit limitation, this limitation does not apply to DSM-V diagnoses (e.g. autism, pervasive developmental disorder, gender dysphoria).
3. Telephone advice visits, missed appointments and cancellations do not count to this benefit limit.

C. Therapy services do not include maintenance rehabilitation therapy for chronic conditions except for neurodevelopmental conditions in children on a Washington group or Washington individual contract.

For these children, Kaiser Permanente Northwest provides maintenance therapy for conditions which, in the judgment of a KP Practitioner, would result in significant deterioration without such treatment (physical, occupational and speech therapy visit limits apply unless therapy is for a DSM-V diagnosis). Neurodevelopmental disorders include a broad spectrum of disabilities, delays in normal development and/or impairments in functional activity. Included is a list which should not be considered all inclusive:

- Acquired brain injury
- Cerebral palsy
- Chromosomal disorders (Down syndrome, Angelman, Williams, etc)
- Congenital anomalies
- Developmental coordination disorder
- Disorders of muscle tone and posture (hypotonia, hypertonia, athetosis, dystonia, ataxia, etc.)
- Epilepsy
- Mucopolysaccharidoses and other metabolic disorders
- Myelomeningocele (spina bifida)
- Neuromuscular and neurodegenerative disorders (muscular dystrophy, spinal muscular atrophy, Guillain-Barre, etc)
- Prematurity
- Secondary acute effects of chronic illness and its treatment (eg, congenital heart disease).
- Visual impairment

D. Multidisciplinary rehabilitation services are covered in the inpatient setting or in the outpatient day treatment program setting.

1. Multidisciplinary rehabilitation services are covered for the treatment of conditions which, in the judgment of a KP Practitioner are subject to significant improvement in function within 60 days and, when received in an inpatient, skilled nursing facility or outpatient day treatment facility, must be prior-authorized as described in the "Prior and Concurrent Authorization" section of the member's benefit coverage.

### UR 43: Physical /Occupational/Speech Therapy Policy

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Department: Utilization Review	Number: UR 43
Applies To: KPNW Region	Effective: 1/1/08
Review Responsibility: UROC	Reviewed: 1/08, 10/08, 11/08, 2/09, 2/10, 3/11, 3/13
SME: Kevi Ames (DA Rehab Services), Kathy Cutter(PT), Jennifer Allen (OT)	Revised: 3/14, 3/16, 11/16, 9/17

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2. Multidisciplinary rehabilitation services provided in a Participating Skilled Nursing Facility will not reduce the covered days of service under this “Multidisciplinary Inpatient Rehabilitation and Multidisciplinary Day Treatment Program services” section in the member’s benefit coverage.
3. This benefit is limited to a maximum of 60 days per condition per calendar year for hospital inpatient and outpatient day treatment program services combined.
4. An MD must review and make the decision before a denial can be generated.

E. Acute catastrophic conditions may be allowed 10 additional visits, when the ordering KP Practitioner believes the additional treatments will result in significant restoration or improvement in functional abilities. These require manager or peer review for medical necessity. In an acute catastrophic situation, if an additional 10 visits is required, the PT, OT, or ST must notify the staff setting the visit count accumulators. Failure to do so will result in a member billing.

F. In some acute catastrophic situations, the patient’s condition may be unique, be longer term, and the provision of more than the 10 catastrophic additional visits is likely to offset future costs or disability. These situations must be reviewed individually via the contract exception process.

1. Social Workers can provide the forms a provider needs to fill out to request this kind of exception.
2. A chief or assistant medical director would need to sign off on these exceptions.

In no case, will the total number of visits for all therapies combined exceed the sum of the total benefit. For example, if each service (physical, speech and occupational therapy) has a 20 visit limit, the total combined limit may not exceed, even in a catastrophic situation, 60 visits. To further clarify, 40 PT visits may be approved but only if the total visits for all therapies received is ≤60 visits.

G. Coverage will not be available for PHYSICAL, OCCUPATIONAL, and/or SPEECH THERAPY if:

1. Medical contraindications exist
2. It is a Cognitive rehabilitation program for chronic conditions
3. It is long-term rehabilitation and/or maintenance therapy
4. It is maintenance rehabilitation therapy, except as mandated by Washington law for children with neurodevelopmental disorders.





## Northwest Utilization Review

### UR 43: Physical /Occupational/Speech Therapy Policy

Department: Utilization Review	Number: UR 43
Applies To: KPNW Region	Effective: 1/1/08
Review Responsibility: UROC	Reviewed: 1/08, 10/08, 11/08, 2/09, 2/10, 3/11, 3/13
SME: Kevi Ames (DA Rehab Services), Kathy Cutter(PT), Jennifer Allen (OT)	Revised: 3/14, 3/16, 11/16, 9/17

#### DEFINITIONS

- A. Acute: Sudden onset, or significant increase in symptoms which have been present for six months or less which require a short course of treatment to improve or restore function. First treatment of symptoms outside the six months window may be considered when significant, sustainable improvement is still expected and/or the overall medical condition precluded the earlier initiation of therapy. Example:
1. Medical acuity precluded start of therapy, such as a burn or post orthopedic event.
  2. Throat cancer patients who receive radiation treatment may be seen 1 time every 1-2 months; however, it may not be until the 12-13 month point that the tissues of the throat have softened and the edema has gone down that full therapy can begin.
  3. Bell's Palsy patient may not have full growth of the facial nerve into the affected muscle tissue until 10 to 12 months have elapsed.
- B. Acute exacerbation: A significant increase (in frequency, duration, intensity, or irritability) of pain, or other signs or symptoms, resulting in a functional impairment related to an underlying condition, for which a short course of therapy would result in measurable and sustainable improvement. Acute exacerbations can often be tied to a precipitating event such as participation in non-routine or extended activity, or a precipitating event such as progression to a new stage of development, for example, a child with dysfluency (stuttering disorder when s/he faces new social or communication challenges as a result of maturation or growth) as can occur in adolescence..
- C. Subacute or neurodevelopmental: conditions present during an early childhood period of rapid developmental progress (typically below age 7 years) where significant sustainable improvement is anticipated with short term targeted interventions. The nature of these disorders is such that most are amenable to intervention; they are not static or chronic.
- D. Catastrophic: Significant functional impairment which limits the patient's motor or sensory functions and activities of daily living. The identified conditions are an acute injury or neurological event such as, but not limited to acute CVA/stroke; a cognitive disorder as a result of an acute head injury; acute swallowing, breathing and feeding disorders; lymphedema, as a result of a catastrophic situation; post orthopedic surgery; crush injury; i.e., significant trauma to neurological or bony tissue, such as a spinal cord injury; extensive burns with contractures; functional receptive and expressive communication, thinking skills including abstract reasoning and problem solving; acute swallowing, breathing and or feeding disorders.
- E. Chronic: long duration, frequent recurrence over a long period of time, slow progression and/or greater than six months duration.

### UR 43: Physical /Occupational/Speech Therapy Policy

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Department: Utilization Review	Number: UR 43
Applies To: KPNW Region	Effective: 1/1/08
Review Responsibility: UROC	Reviewed: 1/08, 10/08, 11/08, 2/09, 2/10, 3/11, 3/13
SME: Kevi Ames (DA Rehab Services), Kathy Cutter(PT), Jennifer Allen (OT)	Revised: 3/14, 3/16, 11/16, 9/17

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F. Maintenance Rehabilitation Therapy Services: any treatment program designed to maintain optimal health in the absence of symptoms or in chronic conditions without exacerbation of symptoms.

G. Pediatric Neurodevelopmental Disorder: A congenital or acquired neurologically based condition in which a child does not reach developmental milestones at normative times, failing to master age-appropriate acquired skills such as self care, gross and fine motor skills, coordination and motor planning skills, and communication skills (including speech, language, sensory/motor skills, pragmatics including social interactive skills, and normal swallowing and feeding abilities).

H. Plateau: Point at which the functional status has remained stable for a given condition, without expectation of additional functional improvement.

I. Sensory integration: A neurological process that reflects an individual's ability to organize internal and environmental sensations to regulate and function efficiently in the environment.

J. Short term will be defined as 6 accumulative months of treatment. That means it may be 2 months in one year and four months in another year. When 6 months of accumulative treatment has occurred, that is the limit for subacute care unless there is an acute exacerbation.

K. Functional Vocal Disorders: Disorders that result in improper, maladaptive or inefficient use of a mechanism, when the physical structure may be normal.

#### RESPONSIBILITIES

##### A. PT/OT/ST designated Initial evaluator

1. Monitor to ensure that all review processes, including Physician review, will be completed and documented within the regulatory timelines, depending upon the clinical urgency of the request.
2. Ensure that all required information is documented.
3. Appoint members, if approved.
4. Notify the accumulator re-set staff if an additional 10 visits are being allowed thru the catastrophic condition process. Failure to do so will result in a member bill.

##### B. Physician Reviewer

1. Review to determine if condition meets PT/OT/ST medical necessity criteria.
2. For continuation of services, a progress report will be reviewed. If additional visits are being requested, medical necessity continuation criteria will be applied to determine eligibility. Additional visits will be authorized if eligibility is met and benefit limit has not been exhausted.
3. Notify PT/OT/ST designated initial evaluator of the determination, within regulatory timelines.



## Northwest Utilization Review

### UR 43: Physical /Occupational/Speech Therapy Policy

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Department: Utilization Review	Number: UR 43
Applies To: KPNW Region	Effective: 1/1/08
Review Responsibility: UROC	Reviewed: 1/08, 10/08, 11/08, 2/09, 2/10, 3/11, 3/13
SME: Kevi Ames (DA Rehab Services), Kathy Cutter(PT), Jennifer Allen (OT)	Revised: 3/14, 3/16, 11/16, 9/17

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#### SPECIAL GROUP CONSIDERATIONS

Commercial; Washington Medicaid; Oregon Medicaid (subject to the OHP Prioritized List); Feds; PEBB; OEBC: Check CM or EPIC for specific benefit coverage. As of 1/1/14, due to the legal, Federal and State guidance on the PPACA and Mental Health parity, therapies for the treatment of Autism Spectrum Disorder and Pervasive Developmental Disorders (PDD), is considered an essential health benefit (EHB) and should no longer have any annual visit limits applied to services.

MEDICARE: January 2014 revisions to the Medicare Benefit Policy Manual related to Skilled Nursing facility, Home Health and Outpatient skilled care clarified that a beneficiary's lack of restoration potential cannot serve as the basis for denying coverage in this context. Rather, such coverage depends upon an individualized assessment of the beneficiary's medical condition and the reasonableness and necessity of the treatment, care, or services in question.

Moreover, when the individualized assessment demonstrates that skilled care is, in fact, needed in order to safely and effectively maintain the beneficiary at his or her maximum practicable level of function, such care is covered (assuming all other applicable requirements are met). Conversely, coverage in this context would not be available in a situation where the beneficiary's maintenance care needs can be addressed safely and effectively through the use of *nonskilled* personnel.

Washington commercial contracts: Neurodevelopmental children may receive chronic, maintenance, and acute care.

## UR 45 Acupuncture Medical Necessity Criteria

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Department: Complementary & Alternative Medicine	Number: UR 45
Section: KPNW Region	Effective: Sept 1999
Applies to: Acupuncture Services	Reviewed: 11/04; 9/05; 10/06; 1/07; 1/08; 1/09; 04/09; 2/10; 2/11; 2/13; 2/14; 2/15, 2/17, 3/18
Review Responsibility: UROC	Revised: 2/11; 10/11; 1/12; 10/12; 8/15, 1/16, 7/16
Subject Matter Expert: Charles Elder, MD	

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### MEDICAL NECESSITY CRITERIA FOR ACUPUNCTURE

#### DEFINITIONS

Acupuncture: A complementary/alternative system of medical theory, oriental diagnosis and treatment used to promote health and treat organic or functional disorders. Acupuncture treats specific acupuncture points or meridians.

Maintenance Treatment/Therapy: Once the functional status has remained stable for a given condition, without expectation of additional functional improvement; any treatment program designed to maintain optimal health in the absence of symptoms or in chronic conditions without exacerbation of symptoms.

#### CRITERIA

A. Acupuncture is covered for nausea associated with pregnancy or chemo, overactive bladder with urge incontinence and for some chronic pain conditions. A condition is considered chronic if it has been present for  $\geq 3$  month (90 days).

B. Telephonic, email or face-to-face evaluation by the referring clinician is required prior to requesting a referral (this must be a KP clinician if the member has an HMO plan). A member request for referral without documented evaluation is generally not sufficient, however, an evaluation will not be required if:

- The condition is an acute exacerbation or recurrence of the same condition which was evaluated recently (within the previous 12 months) or recurrently over many years by a Kaiser Permanente clinician; AND
- The condition previously exhibited significant improvement after the acupuncture treatments; AND
- The previous exam and information otherwise exhibits no contraindications, as outlined below in the Contraindications section.

For all qualifying diagnoses, there must be documentation in the medical record of the intensity of the symptoms for both the initial acupuncture referral and any extensions requested. An example of documenting the intensity of symptoms may be asking the patient to rate their worst pain and their current pain on a scale from 1 to 10. It is important to note that sometimes the intensity of symptoms will be modest but will significantly interfere with a particular activity of importance to the patient. Reviewers need to consider that those making the referral consider it implicit that the condition is of sufficient concern to warrant intervention.

C. Significant, sustainable and measurable improvement must be evident after the initial course of treatments. If objective improvements are documented, additional treatments may be clinically indicated. Services are not provided for on-going chronic conditions or maintenance therapy lacking improvement. In the situation of chronic pain, when the patient's condition is not expected to completely resolve, there must be an expectation of some functional or other improvement for therapy to be continued.

## UR 45 Acupuncture Medical Necessity Criteria

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Department: Complementary & Alternative Medicine	Number: UR 45
Section: KPNW Region	Effective: Sept 1999
Applies to: Acupuncture Services	Reviewed: 11/04; 9/05; 10/06; 1/07; 1/08; 1/09;
Review Responsibility: UROC	04/09; 2/10; 2/11; 2/13; 2/14; 2/15, 2/17, 3/18
Subject Matter Expert: Charles Elder, MD	Revised: 2/11; 10/11; 1/12; 10/12; 8/15, 1/16, 7/16

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### D. Approved Diagnoses:

- i. Nausea of pregnancy
- ii. Nausea associated with chemotherapy
- iii. Overactive bladder with urge incontinence
- iv. Chronic pain syndromes, when due to
  1. musculoskeletal pain, including myofascial neck pain
  2. migraine and tension headache (*defined as a headache for  $\geq 15$  days per month for  $\geq 3$  months*)
  3. osteoarthritis
  4. fibromyalgia
  5. TMJ disorder/pain (NOTE: TMJ services may be a benefit exclusion)
  6. rotator cuff tendonitis
  7. neuropathic pain

### E. Patients actively participating in the KP Pain Clinic program may be considered for other diagnoses if:

1. Patient has intractable chronic pain (lasting greater than 3 months); AND,
2. The pain syndrome has been unresponsive to other reasonable traditional therapies or side effects or side effect/concerns have prevented the patient from using traditional therapies; AND,
3. Patient has tried acupuncture therapy and there is documented evidence of efficacy (i.e., increased function; reduced utilization of services such as prescription drugs; and/or subjective reports of reduced pain).

### CONTRAINDICATIONS

Medical contraindications include:

1. Bleeding dyscrasia
2. Acupuncture at sites of active infection
3. Electro-acupuncture is contraindicated in patients with pacemakers

### OTHER CONSIDERATIONS

Acupuncture is not covered for other conditions, including but not limited to tinnitus, epilepsy, psoriasis, smoking cessation, weight reduction or stroke. CMI (Care Management Institute) does not recommend acupuncture for the treatment of persistent asthma.

### SPECIAL GROUP CONSIDERATIONS

Commercial: Covered for all Washington groups as a mandate; Oregon contracts vary, check CM.

Medicare: Acupuncture is not covered.

Washington Medicaid: Acupuncture is not covered.

Oregon Medicaid: Covered for certain conditions, check Linefinder

## UR 45 Acupuncture Medical Necessity Criteria

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Department: Complementary & Alternative Medicine	Number: UR 45
Section: KPNW Region	Effective: Sept 1999
Applies to: Acupuncture Services	Reviewed: 11/04; 9/05; 10/06; 1/07; 1/08; 1/09; 04/09; 2/10; 2/11; 2/13; 2/14; 2/15, 2/17, 3/18
Review Responsibility: UROC	Revised: 2/11; 10/11; 1/12; 10/12; 8/15, 1/16, 7/16
Subject Matter Expert: Charles Elder, MD	

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#### NCQA

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#### WASHINGTON

RCW 284-43-410 & RCW 483.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

WAC 246-855-010 Definition of Acupuncture.

#### OREGON

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

ORS 743.837: Prior authorization requirements

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## UR 46 C Chiropractic Medical Necessity Criteria Commercial Business Lines, Including Medicaid

Department: Utilization Review	Number: UR 46
Section:	Effective: 8/97
Applies to: Kaiser Permanente Northwest Region	Reviewed: 8/97, 11/98, 2/99, 10/00, 8/03, 2/04, 2/05, 2/06, 4/07, 4/08, 4/09, 2/10, 2/15, 4/16, 2/18
Review Responsibility: UROC	Revised: 2/11; 10/11; 3/12, 8/12, 2/13, 2/14, 7/14, 10/16, 4/17
Subject Matter Expert: Charles Elder, MD	Medicare has separate criteria
	1 of 6

### MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

### DEFINITIONS

Manual Manipulation- treatment by use of hands or with manual devices i.e. those that are hand-held with the thrust of the force of the device being controlled manually.

Maintenance Treatment/Therapy- once the functional status has remained stable for a given condition, without expectation of additional functional improvement; any treatment program designed to maintain optimal health in the absence of symptoms or in chronic conditions without exacerbation of symptoms.

Radiculopathy- disease of the spinal nerve root

Subluxation- a partial or incomplete dislocation.

### CRITERIA FOR INITIAL REFERRAL

For a referral for a course of short-term treatment (2 months or less), all of the following must be met:

- Condition must be acute or subacute ( $\leq 90$  days) and/or related to a new injury and/or acute condition
- Musculoskeletal back or neck pain (cervical, thoracic or lumbar spine; **not** sacrum or sacroiliac joint)

NOTE: chiropractic care is fundamentally for **non-radicular pain**, however, radiculopathy is a relative, not absolute, contraindication to referral. As stated in Other Requirements below, the referring physician or chiropractor should discuss this risk with the patient.

### CRITERIA FOR A TREATMENT EXTENSION

For a treatment extension to be approved, there must be documentation of 1) subluxation of the spine, 2) a treatment plan must be provided which includes measurable goals for continued improvement, and 3) evidence of improvement. The subluxation may be demonstrated by x-ray or by physical examination.

To demonstrate a subluxation based on physical examination, two of the four criteria listed below must be present, one of which must be asymmetry/ misalignment or range of motion abnormality:

- a. Pain/tenderness evaluated in terms of location, quality and intensity;
- b. Asymmetry/misalignment identified on a sectional or segmental level;



## UR 46 C Chiropractic Medical Necessity Criteria Commercial Business Lines, Including Medicaid

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Department: Utilization Review	Number: UR 46
Section:	Effective: 8/97
Applies to: Kaiser Permanente Northwest Region	Reviewed: 8/97, 11/98, 2/99, 10/00, 8/03, 2/04, 2/05, 2/06, 4/07, 4/08, 4/09, 2/10, 2/15, 4/16, 2/18
Review Responsibility: UROC	Revised: 2/11; 10/11; 3/12, 8/12, 2/13, 2/14, 7/14, 10/16, 4/17
Subject Matter Expert: Charles Elder, MD	Medicare has separate criteria 2 of 6

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- c. Range of motion abnormality (changes in active, passive and accessory joint movements resulting in an increase or decrease of sectional or segmental mobility); and
- d. Tissue, tone changes in the characteristics of adjacent or associated soft tissues, including skin, fascia (connective tissue), muscle and ligament.

### OTHER REQUIREMENTS FOR REFERRAL

- The clinical condition must be evaluated by a clinician to determine that the condition is appropriate for manipulation modalities (this must be a KP clinician if the member has an HMO plan).
- A primary care office visit exam will not be required if:
  - The condition is an acute exacerbation or recurrence of the same condition which was evaluated recently (within the previous 12 months) or recurrently over many years by a clinician (this must be a KP clinician if the member has an HMO plan); AND,
  - The condition previously exhibited significant improvement after the chiropractic adjustment(s); AND,
  - The previous exam and information otherwise exhibits no contraindications, as outlined below in Contraindications.
- Therapeutic measures prior to referral must be considered; i.e., standard medical management including medications, physical therapy, exercise programs, etc.
- The result of chiropractic manipulation is expected to be an improvement in, arrest or retardation of the patient’s condition and treatment must have a direct therapeutic relationship to the patient’s diagnosed condition.
- If there is a chronic spinal component, and the patient’s condition is not expected to completely resolve, there must be an expectation of some functional improvement for therapy to be continued. Once the functional status has remained stable for a given condition, without expectation of additional functional improvement, further manipulative treatment is considered maintenance therapy and is not covered.
- **Chiropractic treatment may not be medically indicated** for a condition that adds significant risk of injury to the patient from dynamic thrust, but does not rule out the use of dynamic thrust. The doctor should discuss this risk with the patient and record this in the chart. Such conditions include:



## UR 46 C Chiropractic Medical Necessity Criteria Commercial Business Lines, Including Medicaid

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Department: Utilization Review	Number: UR 46
Section:	Effective: 8/97
Applies to: Kaiser Permanente Northwest Region	Reviewed: 8/97, 11/98, 2/99, 10/00, 8/03, 2/04, 2/05, 2/06, 4/07, 4/08, 4/09, 2/10, 2/15, 4/16, 2/18
Review Responsibility: UROC	Revised: 2/11; 10/11; 3/12, 8/12, 2/13, 2/14, 7/14, 10/16, 4/17
Subject Matter Expert: Charles Elder, MD	Medicare has separate criteria 3 of 6

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- A. Radiculopathy
- B. Presence of osteoporosis
- C. Known herniated disk or prior spinal fusion
- D. Patient has not reached skeletal maturity
- E. Joint hypermobility and circumstances where the stability of the joint is uncertain
- F. Severe demineralization of the bone
- G. Benign bone tumors of the spine
- H. Bleeding disorders and anticoagulant therapy (i.e. medications that thin the blood)

### CONTRAINDICATIONS

1. Acute fractures and dislocations or healed fractures and dislocations with signs of instability
2. Unstable cervical vertebra
3. Infections of bones or joints of the vertebral column
4. Signs and symptoms of spinal cord disease, i.e. cauda equina syndrome
5. Significant major artery aneurysm near the proposed manipulation
6. Neck pain with prior history of dizziness, unsteadiness and/or vertigo, unless vertebral basilar artery disease has been ruled out
7. History of malignancy, without diagnostic studies to rule out metastatic lesions.
8. Malignancies that involve the vertebral column

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## UR 46 C Chiropractic Medical Necessity Criteria Commercial Business Lines, Including Medicaid

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Department: Utilization Review	Number: UR 46
Section:	Effective: 8/97
Applies to: Kaiser Permanente Northwest Region	Reviewed: 8/97, 11/98, 2/99, 10/00, 8/03, 2/04, 2/05, 2/06, 4/07, 4/08, 4/09, 2/10, 2/15, 4/16, 2/18
Review Responsibility: UROC	Revised: 2/11; 10/11; 3/12, 8/12, 2/13, 2/14, 7/14, 10/16, 4/17
Subject Matter Expert: Charles Elder, MD	Medicare has separate criteria 4 of 6

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## UR 46 C Chiropractic Medical Necessity Criteria Commercial Business Lines, Including Medicaid

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Department: Utilization Review	Number: UR 46
Section:	Effective: 8/97
Applies to: Kaiser Permanente Northwest Region	Reviewed: 8/97, 11/98, 2/99, 10/00, 8/03, 2/04, 2/05, 2/06, 4/07, 4/08, 4/09, 2/10, 2/15, 4/16, 2/18
Review Responsibility: UROC	Revised: 2/11; 10/11; 3/12, 8/12, 2/13, 2/14, 7/14, 10/16, 4/17
Subject Matter Expert: Charles Elder, MD	Medicare has separate criteria 5 of 6

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## UR 46 C Chiropractic Medical Necessity Criteria Commercial Business Lines, Including Medicaid

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Department: Utilization Review	Number: UR 46
Section:	Effective: 8/97
Applies to: Kaiser Permanente Northwest Region	Reviewed: 8/97, 11/98, 2/99, 10/00, 8/03, 2/04, 2/05, 2/06, 4/07, 4/08, 4/09, 2/10, 2/15, 4/16, 2/18
Review Responsibility: UROC	Revised: 2/11; 10/11; 3/12, 8/12, 2/13, 2/14, 7/14, 10/16, 4/17
Subject Matter Expert: Charles Elder, MD	Medicare has separate criteria 6 of 6

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## UR 46 Chiropractic Medical Necessity Criteria Medicare Business Line

Department: Utilization Review	Number: UR 46
Section:	Effective: 1/11
Applies to: Kaiser Permanente Northwest Region	Reviewed: 2/12; 2/14; 2/15, 2/16, 2/17, 2/18
Review Responsibility: UROC	Revised: NA
Subject Matter Expert: Medicare criteria	1 of 4

### MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS

#### DEFINITIONS

Manual Manipulation- treatment by use of hands or with manual devices i.e. those that are hand-held with the thrust of the force of the device being controlled manually. (Medicare does not make separate payment for use of any device).

Subluxation- a partial or incomplete dislocation; displacement; or misalignment of a joint. It is defined as a motion segment, in which alignment, movement integrity, and/or physiological function of the spine are altered although contact between joint surfaces remains intact. This may be demonstrated by x-ray or by physical examination.

Common examples of acceptable descriptive terms include:

- off-centered,
- malpositioning,
- spacing- abnormal, altered, decreased, increased,
- rotation,
- listhesis- antero, postero, retro, lateral, spondylo
- motion- limited, lost, restricted, flexion, extension, hyper/hypo mobility, aberrant

Acute Subluxation: a condition is considered acute when the patient is being treated for a new injury identified by an x-ray or physical examination. Result of chiropractic treatment is expected to be an improvement in, or arrest of progression, of the condition.

Chronic subluxation: a condition is considered chronic when it is not expected to significantly improve or be resolved with further treatment (as in the case with an acute condition) but where continued therapy can be expected to result in some functional improvement. When the clinical status has remained stable for a given condition, without expectation of additional objective clinical improvements, further manipulative treatment is considered maintenance therapy and is not covered.

Exacerbation: an exacerbation is a temporary marked deterioration of the patient’s condition due to a flare-up of the condition being treated.

Recurrence: A return of symptoms of a previously treated condition that has been quiescent for 30 days or more. This may require reinstatement of therapy.

Maintenance Treatment/Therapy is a treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or therapy that is performed to maintain or prevent deterioration of a chronic condition. (Medicare covers only for manual manipulation of the spine to correct a subluxation. The subluxation needs to have resulted in a neuromusculoskeletal condition for which manual manipulation is appropriate treatment. Chiropractic maintenance therapy is not



## UR 46 Chiropractic Medical Necessity Criteria Medicare Business Line

Department: Utilization Review	Number: UR 46
Section:	Effective: 1/11
Applies to: Kaiser Permanente Northwest Region	Reviewed: 2/12; 2/14; 2/15, 2/16, 2/17, 2/18
Review Responsibility: UROC	Revised: NA
Subject Matter Expert: Medicare criteria	2 of 4

considered to be medically reasonable or necessary and is therefore not covered by Medicare. When chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy.

### CRITERIA

There must be subluxation of the spine.

- Subluxation of the spine must have resulted in a neuromusculoskeletal condition for which manual manipulation is appropriate treatment. The result of chiropractic manipulation is expected to be an improvement in, arrest or retardation of the patient’s condition and treatment must have a direct therapeutic relationship to the patient’s level of subluxation and diagnosed condition.

#### Demonstrated by X-ray

To demonstrate a subluxation with an x-ray the following applies:

- a. X-ray must have been taken at a time reasonably proximate to the initiation of a course of treatment (i.e., no more than 12 months prior to or 3 months following the initiation of a course of chiropractic treatment).
- b. In certain chronic subluxation cases (e.g., scoliosis) an older x-ray may be accepted if health record indicates condition has lasted longer than 12 months and there is a reasonable basis for concluding condition is permanent.
- c. A previous CT scan and/or MRI is acceptable evidence if a subluxation of the spine is demonstrated.

#### Demonstrated by Physical Examination

To demonstrate a subluxation based on physical examination, **two of the four following criteria must be present, one of which must be a.) asymmetry/ misalignment or c.) range of motion abnormality:**

- a. Asymmetry/misalignment identified on a sectional or segmental level;
- b. Pain/tenderness evaluated in terms of location, quality and intensity;
- c. Range of motion abnormality (changes in active, passive and accessory joint movements resulting in an increase or decrease of sectional or segmental mobility);
- d. Tissue, tone changes in the characteristics of contiguous, or associated soft tissues, including skin, fascia (connective tissue), muscle and ligament.

- If there is chronic subluxation of the spine, and the patient’s condition is not expected to completely resolve, there must be an expectation of some functional improvement for therapy



## UR 46 Chiropractic Medical Necessity Criteria Medicare Business Line

Department: Utilization Review	Number: UR 46
Section:	Effective: 1/11
Applies to: Kaiser Permanente Northwest Region	Reviewed: 2/12; 2/14; 2/15, 2/16, 2/17, 2/18
Review Responsibility: UROC	Revised: NA
Subject Matter Expert: Medicare criteria	3 of 4

to be continued. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is considered maintenance therapy and is not covered.

- Symptoms must bear a direct relationship to the level of subluxation. The subluxation must be causal. A statement that there is “pain” is insufficient. The location of the pain must be described and whether particular vertebra listed is capable or producing pain in the area determined.

### OTHER REQUIREMENTS FOR APPROVING SERVICE CONTINUATION

- The clinical condition must be evaluated by a chiropractic physician who will evaluate for appropriateness when/if asking for the continuation to determine that this condition is appropriate for manipulation modalities. Patient record should include the following and it should be provided with the request for the continuation:
  1. Symptoms causing patient to seek treatment
  2. Family history if relevant
  3. Past health history
  4. Mechanism of trauma
  5. Quality and character of symptoms/problem
  6. Onset, duration, intensity, frequency, location and radiation of symptoms
  7. Aggravating or relieving factors
  8. Prior interventions, treatments, medications, secondary complaints
- A primary care office visit exam will not be required for making a referral if:
  1. The condition is an acute exacerbation or recurrence of the same condition which was evaluated recently (within the previous 12 months) or recurrently over many years by a Kaiser Permanente clinician; OR an xray within the last 12 months which indicates subluxation; AND
  2. The condition previously exhibited significant improvement after the chiropractic adjustment(s); AND,
  3. The previous exam and information otherwise exhibits no contraindications, as outlined below in Contraindications; OR
- Chiropractic treatment may not be medically indicated for a condition that adds significant risk of injury to the patient from dynamic thrust, but does not rule out the use of dynamic thrust. The doctor should discuss the risks of such **relative contraindications** with the patient and record this in the chart. Such conditions include:



## UR 46 Chiropractic Medical Necessity Criteria Medicare Business Line

Department: Utilization Review	Number: UR 46
Section:	Effective: 1/11
Applies to: Kaiser Permanente Northwest Region	Reviewed: 2/12; 2/14; 2/15, 2/16, 2/17, 2/18
Review Responsibility: UROC	Revised: NA
Subject Matter Expert: Medicare criteria	4 of 4

1. Articular hypermobility and circumstances where the stability of the joint is uncertain;
2. Severe demineralization of the bone
3. Benign bone tumors of the spine
4. Bleeding disorders and anticoagulant therapy (i.e. medications that thin the blood)
5. Radiculopathy with progressive neurological signs

### **ABSOLUTE CONTRAINDICATIONS**

Dynamic thrust is absolutely contraindicated near the site of demonstrated subluxation and proposed manipulation in the following:

1. Acute arthropathies characterized by acute inflammation and ligamentous laxity and anatomic subluxation or dislocation; including acute rheumatoid arthritis and ankylosing spondylitis
2. Acute fractures and dislocations or healed fractures and dislocations with signs of instability
3. Unstable os odontoideum
4. Malignancies that involve the vertebral column
5. Infections of bones or joints of the vertebral column
6. Signs and symptoms of myelopathy or cauda equine syndrome
7. For cervical spinal manipulations, vertebrobasilar insufficiency syndrome; and
8. A significant major artery aneurysm near the proposed manipulation.

### **SPECIAL GROUP CONSIDERATIONS: MEDICARE**

Medicare does not pay for x-rays or any other diagnostic test ordered; taken; or interpreted by a chiropractor. 2013 Noridian published guidance for chiropractic that states, "Under the Medicare program chiropractic maintenance therapy is not considered to be medically reasonable or necessary and is not payable." It goes on to say, "When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. The chiropractor should be afforded the opportunity to effect improvement or arrest or retard deterioration in such condition within a reasonable and generally predictable period of time."

### **MEDICARE REFERENCES**

- Medicare Benefit Policy Manual, Chapter 15, 30.5 and 240.1.1 re no coverage for x-rays and any other diagnostic test.
- 42 CFR 410.21 re manual subluxation
- Medicare Benefit Policy Manual, Chapter 15, 240.1.2 re criteria needed for manual manipulation for a subluxation
- Medicare Benefit Policy Manual, Chapter 15, 240.1.3 re maintenance



**UR 47: Utilization Review Massage  
Medical Necessity Criteria**

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Department: Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UROC  
Subject Matter Expert: Charles Elder, MD

Number: UR 47  
Issued: 4/99  
Reviewed: 11/04, 8/05, 9/05, 10/06, 11/07, 1/08, 1/09,  
1/10, 2/10, 2/11, 2/12; 2/13, 2/14, 2/15, 2/16  
Last Revised: 3/11, 3/17

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**MEDICAL NECESSITY CRITERIA FOR MASSAGE THERAPY**

Medical necessity criteria are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

**PURPOSE**

The purpose of this criteria and policy is to describe the policy and process requirements for massage/soft tissue mobilization and the medical necessity criteria for its coverage as a benefit.

**POLICY**

When a member's contract covers massage as a benefit, soft tissue mobilization may be applied as part of an integrated physical therapy plan of care for the treatment of musculoskeletal neck and back conditions. A physician referral to physical therapy is required. The physical therapist will perform an evaluation, and designate treatment interventions based on their objective findings. Soft tissue mobilization will be included only if determined to be clinically indicated. When included in the plan, soft tissue mobilization will be of short duration, and specific to the region being treated.

**DEFINITIONS**

Maintenance Treatment/Therapy: Treatment once the functional status has remained stable for a given condition, without expectation of additional functional improvement; any treatment program designed to maintain optimal health in the absence of symptoms or in chronic conditions without exacerbation of symptoms.

**CRITERIA**

- A. Appropriate standard medical treatment without significant improvements, will have been attempted.
- B. Documentation of previous treatment and functional impairment, including relevant history, physical findings, and evaluation must be documented for determination of appropriateness and/or as part of work-up.
- C. Significant, sustainable and measurable improvement must be evident after the initial trial of Physical Therapy treatments. If objective improvements are evident through documentation, additional Physical Therapy treatments may be clinically indicated. Services are not provided for on-going chronic or maintenance therapy.
- D. Soft tissue mobilization must be specific to the area involved and will not be applied for stress relief, palliative or maintenance treatment.

**CONTRAINDICATIONS**

Acutely inflamed joints, phlebitis (inflammation of vein(s)) or lymphangitis (inflammation of lymph vessel(s)) because of danger of embolism (obstruction of blood vessel), burns, acute dermatitis, local malignancy,



UR 47: Utilization Review Massage  
Medical Necessity Criteria

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osteomyelitis (inflammation of bone), local infection, advanced arteriosclerosis (hardening of arteries), advanced nephritis (inflammation of kidney(s)), and increased pain, swelling or stiffness in a joint persisting for more than two hours following soft tissue mobilization.

**CLINICAL**

1. Anderson LL, et al. Acute effects of massage or active exercise in relieving muscle soreness: randomized controlled trial. *J Strength Cond Res.* 2013 Dec;27(12):33529.
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## UR 48 Naturopathy Medical Necessity Criteria

Department: Utilization Review	Number: UR 48
Section: Alternative Medicine	Effective: 7/03
Applies to: Kaiser Permanente Northwest Region	Reviewed: 7/03, 10/03, 8/04, 7/05, 7/06, 9/07, 9/08, 9/09, 2/10, 2/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17
Review Responsibility: UROC	Revised: 2/11, 10/11, 3/18
Subject Matter Expert: Charles Elder, MD	1 of 5

### MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR NATUROPATHIC SERVICES

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

#### CRITERIA

I. Naturopathic care is limited to the following conditions:

- A. Symptoms of menopause, peri-menopause, or premenstrual syndrome <sup>1-6</sup>
- B. Chronic Irritable Bowel Syndrome <sup>7-11</sup>
- C. Chronic Headache <sup>12-15</sup> (defined as a headache for  $\geq 15$  days per month for  $\geq 3$  months)
- D. Chronic Eczema/Atopic Dermatitis <sup>16-18</sup>
- E. Osteoarthritis <sup>19-22</sup>

- 2. Appropriate diagnostics and specialty consultations must be performed prior to the referral.
- 3. Recommended standard medical therapies (allopathic care) for the condition must be documented as objectively ineffective.

Standard medical therapies (allopathic care) for the above qualifying conditions to be tried are:

#### A. For symptomatic menopause, peri-menopause, or premenstrual syndrome:

- i. For hot flushes/night sweats associated with menopause:  
[ HRT requirement can be waived if there is documentation of a shared decision making between the appropriate clinician and the patient regarding HRT]
  - 1 oral HRT (at least 2 month trial with at least 1 dose adjustment), AND
  - 1 SSRI or NSRI (at least 1 month trial), AND
  - oral Clonidine
- ii. For PMS symptoms:
  - 3 month trial of SSRI, OR
  - 3 month trial of continuous OCP
- iii. For perimenopause bleeding:
  - 6 month trial of progestin containing IUD or OCP
- iv. For perimenopause mood disorder or hot flushes:
  - 2 month trial of low dose OCP, AND
  - 1 SSRI or NSRI (at least 1 month trial)



## UR 48 Naturopathy Medical Necessity Criteria

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Department: Utilization Review	Number: UR 48
Section: Alternative Medicine	Effective: 7/03
Applies to: Kaiser Permanente Northwest Region	Reviewed: 7/03, 10/03, 8/04, 7/05, 7/06, 9/07, 9/08, 9/09, 2/10, 2/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17
Review Responsibility: UROC	Revised: 2/11, 10/11, 3/18
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**B. For Irritable Bowel Syndrome:**

- i. IBS-D:
  - Consider trials of:
    - dairy holiday
    - loperamide (if BM cluster in AM, consider QHS dosing)
    - probiotic
    - cholestyramine
- ii. IBS-Constipation predominant:
  - minimize constipating meds (anti-cholinergics, narcotics), AND
  - Consider trials of:
    - fiber (note that psyllium and metamucil can cause bloating. If prone to bloating try Benefiber, Citrucel)
    - osmotic laxative (Miralax) titrated to effect- start at 17g/day, uptitrate every 3-5 days
    - probiotic
- iii. IBS with generalized abdominal pain and cramping:
  - Consider trials of:
    - dairy holiday
    - dicyclomine 10mg QID (can increase to 20mg QID if tolerated)
    - FODMAP diet
    - nortriptyline QHS

**C. For Chronic headache:**

- Adequate trial of prophylactic treatment:
  - at least 1 antiepileptic medication, AND
  - at least 1 medication from another class (TCA or beta-blocker), AND
  - Botox (for migraine headaches only)

Adequate trial= a maximum tolerated dose of the selected medication for at least 2 months.

**D. For Chronic Eczema/Atopic Dermatitis**

- failed treatment prescribed by a dermatologist

**E. Osteoarthritis:**

- at least 1 month trial of regular (not PRN) use of at least 1 NSAID (prescription or OTC), AND
- at least 2 corticosteroid injections per affected joint in the last 24 months (for knee osteoarthritis)

4. Referrals for naturopathic care must be limited to short term therapy.



## UR 48 Naturopathy Medical Necessity Criteria

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Department: Utilization Review	Number: UR 48
Section: Alternative Medicine	Effective: 7/03
Applies to: Kaiser Permanente Northwest Region	Reviewed: 7/03, 10/03, 8/04, 7/05, 7/06, 9/07, 9/08, 9/09, 2/10, 2/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17
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5. Naturopathic care must be part of an integrated plan of care for a specific medical condition. This condition must be evaluated in the clinic by the referring clinician prior to consideration of referral to a non-plan naturopathic provider.

### ADDITIONAL INFORMATION and REQUIREMENTS

1. The KPNW Complementary and Integrative Medicine (CIM) Clinic can provide patients with advice on diet, behavior modification, herb supplements, and other modalities. The clinic is appropriate for KPNW members with an interest in holistic care who are highly motivated from the standpoint of lifestyle modification. In addition, the Ob/Gyn Department has a Nurse Practitioner who is also a Doctor of Naturopathy.
2. Naturopathic care should be routed through primary care physicians and prescribed under limited circumstances.
3. Internal requests for naturopathic care are submitted as a HealthConnect External Referral Authorization Request (REF Naturopathy). The after-visit summary will instruct the member that a referral has been requested and is subject to authorization.
4. If an external referral is needed, all authorized services for naturopathic care will be provided by a member of NaturoNet through Complementary Healthcare Plans' network. No other community providers will be authorized (for HMO members).
5. Standard authorizations are up to three visits in three months. Additional visits may be authorized when the following circumstances are met:
  - A. The primary care clinician's assessment of the patient's condition demonstrates significant documented objective measurable improvement, AND
  - B. The Treatment Extension Request provided by the Naturopath includes:
    - the patient's initial and current symptoms. The intensity of the symptoms must be documented in measurable terms.
    - a treatment plan with measurable goals for continued improvement in symptoms and functional status and an identified target date for the conclusion of therapy.
    - documentation by the naturopath that improvement in the patient's symptoms and/or functional status is expected to be sustainable with additional short-term treatment.
    - Treatment must have a direct therapeutic relationship to the patient's referral diagnosis.
6. All prescriptions and/or naturopathic services are reviewed for benefit and medical necessity prior to authorization. Herbs and supplements are not covered under the prescription drug benefit. Prescription drugs must be in the Kaiser Permanente formulary to be covered.

## UR 48 Naturopathy Medical Necessity Criteria

Department: Utilization Review Section: Alternative Medicine Applies to: Kaiser Permanente Northwest Region Review Responsibility: UROC Subject Matter Expert: Charles Elder, MD	Number: UR 48 Effective: 7/03 Reviewed: 7/03, 10/03, 8/04, 7/05, 7/06, 9/07, 9/08, 9/09, 2/10, 2/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17 Revised: 2/11, 10/11, 3/18 4 of 5
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7. Procedures, evaluations, and diagnostic testing, including laboratory tests, that are determined by a NWP Physician to be medically necessary and are ordered by a KPNW clinician will be provided within Kaiser Permanente (HMO members).

### **SPECIAL GROUP CONSIDERATIONS, IF BENEFIT IS COVERED**

Commercial: Covered for all Washington groups as a mandate  
 Medicare: No coverage on ID contracts;  
 Washington Medicaid: Check CM or EPIC  
 Oregon Medicaid: Check CM and OR Prioritized List

### **Evidence/Source Documentation**

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### UR 48 Naturopathy Medical Necessity Criteria

Department: Utilization Review	Number: UR 48
Section: Alternative Medicine	Effective: 7/03
Applies to: Kaiser Permanente Northwest Region	Reviewed: 7/03, 10/03, 8/04, 7/05, 7/06, 9/07, 9/08, 9/09, 2/10, 2/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17
Review Responsibility: UROC	Revised: 2/11, 10/11, 3/18
Subject Matter Expert: Charles Elder, MD	5 of 5

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13. Grazzi L, Andrasik F, D'Amico D, Leone M, Usai S, Kass SJ et al. Behavioral and pharmacologic treatment of transformed migraine with analgesic overuse: outcome at 3 years. *Headache* 42(6): 483-90, 2002.
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15. Sinclair S. Migraine headaches: nutritional, botanical and other alternative approaches. [Review][57 refs]. *Alternative Medicine Review* 4(2): 86-95, 1999.
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Department: Utilization Review

Original Date 4/08

Applies to: Kaiser Permanente NW Region

Reviewed: 6/08, 10/08, 10/09, 10/10, 10/11, 10/12, 10/13,  
10/14, 10/15, 10/16, 10/17

Review Responsibility: UROC

Revised:

Subject Matter Experts: Dana Smith, MD;  
Kelly Dezura, DMD

**SURGICAL INTERVENTION MEDICAL NECESSITY CRITERIA**

**DEFINITIONS**

Temporo-mandibular Disorders (TMD) are muscular-skeletal disorders that are medical, not dental, in nature.

Temporomandibular disorders (TMD) are a heterogeneous group of pathologies affecting the temporomandibular joints, the masticatory muscles, or both. The most frequent signs and symptoms are pain or tenderness in the preauricular area or in the masticatory muscles, an alteration of the range of joint motion, and articular sounds, such as click or crepitus, during mandibular movements. For diagnostic purposes, TMD has been classified into 3 groups: muscle disorders, internal derangement (disk displacement), and other joint disorders, such as arthralgia, osteoarthritis, and osteoarthrosis. Anxiety, depression, somatization disorders, and headaches have been associated with TMD symptoms.

**POLICY**

TMD treatment is non-dental, non-orthodontic, non-occlusal and generally non-surgical in its approach. Characteristics of TMD:

- A. TM Joint popping; clicking; grinding; catching; and locking
- B. Facial pain that is not tooth related and is aggravated with use of the jaw
- C. Facial pain which appears related to clenching and bruxing

Diagnostic tests that may help identify TMD:

1. Range of motion (ROM): Restricted; deviates; pain active and/or passive; limited lateral motion; roughness of motion.
2. Compressive loading—biting on tongue blade, first one side, then the contralateral side.
3. Resistive loading—asking the patient to hold, in turn, the variety of mouth positions against resistance provided by the examiner’s hand.
4. Palpation over lateral poles and intrameatally to elicit pain and/or determine irregularities

**MEDICAL NECESSITY CRITERIA**

Surgical intervention is a consideration when pain and dysfunction are persistent and the following are unresponsive to the non-surgical treatments below:

1. recurring and/or persistent lock of TM joint
2. persistent painful popping of TM joint
3. Osteoarthritis of TM joint





Department: Utilization Review

Original Date 4/08

Applies to: Kaiser Permanente NW Region

Reviewed: 6/08, 10/08, 10/09, 10/10, 10/11, 10/12, 10/13,  
10/14, 10/15, 10/16, 10/17

Review Responsibility: UROC

Revised:

Subject Matter Experts: Dana Smith, MD;  
Kelly Dezura, DMD

**OTHER CONSIDERATIONS**

Non-surgical treatment to consider prior to surgical intervention:

1. Physical therapy- rest and reassurance; exercise; stretching; use of heat and cold; avoidance of aggravating factors
2. Analgesics, anti-inflammatory medications
3. Soft diet (nothing firmer than consistency of scrambled eggs)
4. Moist heat if muscle; cold, if joint
5. Bite splints

**SPECIAL GROUP CONSIDERATIONS: Check individual benefits in CM**

GROUP COMMERCIAL: None

OREGON MEDICAID: Check the Prioritized List

WASHINGTON MEDICAID: 2008 Basic Health TMJ treatment is excluded for adults WAC 388-501-070

MEDICARE: TMJ services related to splint fabrication and fitting are only covered if the TM disorder is directly attributable to a medical condition (e.g., direct result of arthritis) or accidental injury (e.g. dislocation of jaw, closed or open).

FEDERAL: None

PEBB: None

**NCQA**

NCQA Standards and Guidelines are updated annually and are available by contacting Quality Resource Management at 503-813-3850.

**WASHINGTON**

RCW 284-43-410 & RCW 483.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

**OREGON**

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

ORS 743.837: Prior authorization requirements

**CLINICAL**

ADA Presidents Council Guidelines

Guidelines of Oregon and Washington State Board of Dentistry

## UR 50: Biofeedback Medical Necessity Criteria

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Department: Non-Behavioral Health	Number: UR 50
Section: KPNW Region	Effective: 12/08
Applies to: KPNW Region	Reviewed: 1/08, 1/09; 10/09; 2/10; 2/11, 5/11; 3/12; 1/13;
Review Responsibility: UROC; Aaron Bayne, MD	1/14
	Revised: 05/11, 1/15, 10/15, 10/16, 10/17

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### BIOFEEDBACK MEDICAL NECESSITY CRITERIA

#### DEFINITIONS

Biofeedback (BFB) is a form of complementary or alternative medicine that measures a person's bodily processes and conveys such information in real time in order to raise the person's awareness and conscious control of the related physiological activities.

#### CRITERIA

Biofeedback may be indicated for **1 or more** of the following:

- 1) Tension or migraine headache and **ALL** of the following:
  - a) Home training is a component of treatment
  - b) Pharmacologic treatment is inadequate or not indicated by reason of **1 or more** of the following:
    - i) insufficient or no response to multiple pharmacological (medication) treatment attempts
    - ii) intolerance of multiple pharmacologic treatment attempts
    - iii) patient has a preference for nonpharmacologic interventions
    - iv) history of long-term, frequent, or excessive use of analgesic (pain medication) or medications that can aggravate headache
    - v) deficient stress-coping skills that remain a significant contributor to headache onset despite counseling of the patient by a qualified professional
    - vi) pregnant patient
    - vii) breast-feeding patient
    - viii) patient attempting to become pregnant
  
- 2) Dyssynergic (muscle incoordination) constipation in adults as indicated by **ALL** of the following:
  - a) evidence of dyssynergic constipation as indicated by **ONE or more** of the following:
    - i) anorectal manometry shows dyssynergic motor pattern
    - ii) non-relaxing puborectalis muscle (responsible for controlling bowel movements) while straining to expel the index finger during a rectal digital examination
    - iii) proctography evidence of non-relaxing puborectalis
    - iv) prolonged delay in transit time (greater than 20% retention of radiopaque markers 5 days after ingestion)
    - v) prolonged expulsion of simulated stool (i.e. balloon expulsion test greater than one minute)
  - b) inadequate response to diet, laxatives, exercise, or hydration therapy for constipation
  - c) negative results of colonoscopy or barium enema
  - d) no evidence of hypothyroidism

## UR 50: Biofeedback Medical Necessity Criteria

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Department: Non-Behavioral Health	Number: UR 50
Section: KPNW Region	Effective: 12/08
Applies to: KPNW Region	Reviewed: 1/08, 1/09; 10/09; 2/10; 2/11, 5/11; 3/12; 1/13;
Review Responsibility: UROC; Aaron Bayne, MD	1/14
	Revised: 05/11, 1/15, 10/15, 10/16, 10/17

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- e) no history of previous major gastrointestinal, pelvic or spinal surgery
  - f) no history of severe cardiac or renal disease
  - g) no use of drugs known to be constipating (i.e. narcotic pain medications)
- 3) Stress and/or urge urinary incontinence (inability to control urination) in females and males as indicated by **ALL** of the following:
- a) the patient is cognitively (mentally) intact
  - b) the patient has failed a trial of pelvic muscle exercise (PME) training. A failed trial is defined as one in which there is no clinically significant improvement in urinary incontinence after completing four weeks of an ordered plan of PMEs to increase periurethral muscle strength (responsible for controlling urination).
- 4) Voiding dysfunction/dyssynergia (muscle incoordination) in children, 5-18 years old, when indicated by **ALL** of the following:
- a) the patient is cognitively intact
  - b) the patient has no spinal cord abnormalities that would interfere with normal voiding
  - c) the patient has been evaluated by a Kaiser Permanente pediatric urologist who is recommending biofeedback based on **ALL** of the following:
    - i) a failed trial of timed voiding
    - ii) if patient is  $\geq 12$  years of age, a failed trial of proper relaxation techniques during voiding.
    - iii) if patient is  $\geq 16$  years of age, a failed trial of pelvic floor exercises.
    - iv) evidence of significant dyssynergia based on pelvic floor EMG during the active phase of voiding (EMG/electromyography tests the electrical activity of muscles).
- Examples of voiding dysfunction/dyssynergia include: dysfunctional elimination syndrome (DES), detrusor/sphincter dyssynergia, vesicoureteric reflux, pelvic floor dysfunction.
- 5) Fecal incontinence when ALL of the following exist:
- a) documentation of a treatment plan including goals and frequency of treatment
  - b) the patient is motivated to actively participate in the treatment plan and is responsive to care plan requirements
  - c) the patient is cognitively intact and deemed capable of participating in the treatment plan by the consulting physician
  - d) the patient has some degree of rectal sensation and can voluntarily contract the external anal sphincter as determined by either manometry OR physical exam findings
  - e) the patient does not have existing pathology that would prevent treatment completion.

## UR 50: Biofeedback Medical Necessity Criteria

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Department: Non-Behavioral Health	Number: UR 50
Section: KPNW Region	Effective: 12/08
Applies to: KPNW Region	Reviewed: 1/08, 1/09; 10/09; 2/10; 2/11, 5/11; 3/12; 1/13;
Review Responsibility: UROC; Aaron Bayne, MD	1/14
	Revised: 05/11, 1/15, 10/15, 10/16, 10/17

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6) The following pain related conditions when at least two appropriate treatment modalities have been tried and failed:

- a) temporo-mandibular joint syndrome (NOTE: TMJ services may be a benefit exclusion)
- b) cancer pain
- c) cervical (neck) strain

### **SPECIAL GROUP CONSIDERATIONS**

Medicare: The Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations Manual. Chapter 1, part 1.30.1- requires Biofeedback Therapy (done as outpatient PT) coverage for the Treatment of Urinary Incontinence if the provider deems biofeedback the desired treatment option. It is the decision of Kaiser Permanente to cover conditions in addition to urinary incontinence, in accord with the provisions of the Biofeedback medical necessity criteria. Home Biofeedback is not covered.

Also see KPNW **BEAM Policy**

### **CLINICAL**

Milliman Care Guidelines, Ambulatory Care; 21st Edition, published 2017

Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations Manual. Chapter 1, part 1.30.1- Biofeedback Therapy for the Treatment of Urinary Incontinence

Bogaards MC, ter Kuile MM. Treatment of recurrent tension headache: A meta-analytic review. Clin J Pain. 1994;10(3):174-190.

Vasconcelos M, Lima E, Caiafa L et al. Voiding dysfunction in children; pelvic-floor exercises or biofeedback therapy; a randomized study. Pediatr Nephrol. 2006 Dec;21(12):1858-64.

Kibar Y, Ors O, Demir E et al. Results of biofeedback treatment on reflux resolution rates in children with dysfunctional voiding and vesicoureteral reflux. Urology. 2007 Sep;70(3):563-7.

Barroso U Jr, Lordelo P, Lopes AA et al. Nonpharmacological treatment of lower urinary tract dysfunction using biofeedback and transcutaneous electrical stimulation: a pilot study. BJU Int. 2006 Jul;98(1):166-71.

Yagci S, Kibar Y, Akay O et al. The effect of biofeedback treatment on voiding and urodynamic parameters in children with voiding dysfunction. J Uro. 2005 Nov;174(5):1994-8.

## UR 51: Satisfaction Assessment Policy

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Department: KPNW Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Tiffany Dorsey, QRM

Number: UR 51  
Issued: 2/09  
Reviewed: 03/09, 7/11, 5/13, 5/15  
Revised: 4/17  
Page: 1 of 2

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**PURPOSE**

To ensure that practitioner (internal and contracted) and member satisfaction with Utilization Management (UM) processes is assessed at least annually and action is taken to improve satisfaction when areas needing improvement are identified.

**POLICY**

At least annually, the Quality Resource Management Department collects and analyzes data related to practitioner and member satisfaction for the identification of improvement opportunities regarding UM processes.

- A. The source of the practitioner data will include NW Permanente practitioners as well as community practitioners with whom Kaiser Permanente contracts. The method of data collection for practitioner satisfaction will include at least one of the following and will be approved by the Utilization Review Oversight Committee (UROC) prior to collection of data:
1. Conduct a practitioner satisfaction survey with specific questions about the UM process,
  2. Track practitioner complaints and appeals by type that relate specifically to UM,
  3. Solicit feedback from practitioners who have been involved in UM appeals.
- B. The method of data collection for member satisfaction will include at least one of the following:
1. HEDIS/CAHPS 5.0H survey results: Q14 and Q25 (commercially insured version) which specifically address member experience with the UM process. When applicable, comparable questions in the Medicaid and Medicare versions of CAHPS 5.0H will be used.
  2. Member complaints and appeals, tracked by type/category, that specifically relate to UM may be compared against established performance thresholds.
  3. Conduct member satisfaction surveys with specific questions about the UM process, such as determining the level of satisfaction with the process of getting a service approved or obtaining a referral.
  4. Solicit feedback from members who have had UM appeals.

Action is taken designed to improve practitioner and member satisfaction based on the assessment of data and/or complaints and appeals. The action taken is likely to have a positive impact on satisfaction.

- C. A written overview of the process will include the methodology of data collection, a summary of the results of the data analysis, and the action taken in response to the analysis designed to improve satisfaction.

**DEFINITIONS**

HEDIS- Healthcare Effectiveness Data and Information Set

CAHPS- Consumer Assessment of Healthcare Providers and Systems



**UR 51: Satisfaction Assessment Policy**

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Department: KPNW Utilization Review  
Applies to: KPNW Region  
Review Responsibility: UROC  
SME: Tiffany Dorsey, QRM

Number: UR 51  
Issued: 2/09  
Reviewed: 03/09, 7/11, 5/13, 5/15  
Revised: 4/17  
Page: 2 of 2

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**RESPONSIBILITIES**

Satisfaction data is analyzed by Quality Resource Management. Recommendations related to improving satisfaction with UM processes are made to the Utilization Review Oversight Committee (UROC) who is responsible for implementing actions to improve practitioner and member satisfaction with UM processes, such as revising UM policies and processes, and providing education/training and additional communication.

**SPECIAL GROUP CONSIDERATIONS**

None

**REFERENCES**

**NCQA**

QI 4 Element G: Assessing experience with the UM process

## UR 53: Repatriation/Transfer Guidelines

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Department: Regional Telephonic Medicine Ctr	Number: UR 53
Section: KPNW Region	Effective: 08/09
Applies to: KPNW Region	Reviewed: 8/09, 9/10, 10/10, 10/11, 9/12, 7/13, 7/14, 8/15, 8/16
Review Responsibility: Tony Carnevale, MD	Last Revised: 8/15, 9/17, 2/18
Initial Author: KP Southern CA	

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**REPATRIATION/TRANSFER GUIDELINES****PURPOSE**

These guidelines are utilized when determining whether a patient is stable for repatriation/transfer from a non-KP facility (inpatient or ED) to a KP-contracted or Kaiser Foundation Hospital (inpatient or ED).

In addition to these guidelines, the capability of both the sending facility and the receiving facility will be considered in addition to the appropriate provider availability.

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PLEASE NOTE: "Higher Level of Care" transfers are those which are done to obtain a higher level of care or service for the patient than is available at the Sending Facility. The Screening Exclusion Criteria are not used by the Regional Telephonic Medicine Center (RTMC) for transfers being considered for a higher level of care. In these cases, the sending and accepting physicians will consider both the advantages to obtaining the higher level of care and the risks of transport in order to make a decision about transfer.

SUBJECT TO CHANGE: Confirm prior to a transfer to Kaiser Sunnyside OR Kaiser Westside Medical Center that a patient weighing  $\geq 550$  lbs can be accommodated.

Air transport	p 3
Burns	p 3
Cardiac	p 4-5
Critical Illness	p 6-8
Gastrointestinal Bleeding	p 9
General Surgery	p 10
Neurology, including stroke	p 11
Neurosurgery, adult	p 12
Neurosurgery, pediatric	p 12
Orthopedics	p 13
Plastic Surgery	p 14
Pediatrics	p 14
Psychiatry	p 15
Renal	p 16
Respiratory	p 17
Trauma	p 18-19
• Blunt	p 18
• Head and spine	p 19



## AIR TRANSPORT

### GENERAL

The level of transport is identified by the sending physician.

#### GUIDELINES FOR USE OF AIR TRANSPORT

- a) Distance - ground transport time greater than 2.5 hours;
- b) Terrain - ground transport is not advisable or impossible;
- c) Other considerations - patient status, weather;
- d) Helicopter generally used for short distance high acuity emergency air transports.

## BURNS

### MILD BURNS OR BURNS OF QUESTIONABLE SEVERITY

#### Stable for transfer:

- a) Patients with vital signs reflecting hemodynamic stability; and
- b) Patients that received adequate initial treatment; and
- c) They will advise as to the need for transfer to a burn center rather than to a Kaiser Permanente facility.

#### Unstable for transfer (Unless higher level of care requested):

- a) Patients exhibiting hemodynamic instability; or
- b) Patients requiring tertiary services due to other injuries or illnesses who are at a facility capable of providing appropriate care. (E.g. Smoke inhalation at a facility offering hyperbaric treatment.)

### MODERATE / SEVERE BURNS (calls from KP ED's and NKP ED's)

These are primarily higher level of care transfers to the burn unit at Legacy Emanuel Hospital. Generally >20% total body surface area burn will be considered for transfer.

#### Candidates for Burn center: (meet any of the following):

- 2nd & 3rd degree burns of more than 10% BSA in patients under 10 and over 50 y/o;
- 2nd & 3rd degree burns of more than 15% BSA in other age groups;
- 2nd & 3rd degree burns with serious threat of functional or cosmetic impairment that involve - face, hands, feet, genitalia, perineum and major joints;
- 3rd degree burns greater than 2% BSA any age group;
- Significant electric burn injuries including lightning injury;
- Chemical injuries with serious threat of functional or cosmetic impairment;
- Inhalation injury with burn injury;
- Circumferential burns of an extremity or chest;
- Burn injury in patients with preexisting medical disorders which could complicate management, prolong recovery, or affect mortality;
- Major trauma with burns

**GENERAL**

Diagnoses to be considered in this category include but are not limited to unstable angina, acute coronary syndrome, or “rule out” MI.

**Stable for transfer:**

Patients may be appropriate for transfer consideration (Advanced Life Support (ALS) or Critical Care Transport (CCT)) as long as the following conditions are met:

1. No persistent acute EKG changes (acute injury current ST elevation or ST depression);
2. A patient who has received fibrinolytics or has unstable angina with dynamic EKG changes but otherwise stable (as defined here) is appropriate for transfer;
3. Patient has stable vital signs, and appears hemodynamically stable;
4. Patient is free of active ischemic chest pain (Pharmaceutical intervention up to and including IV nitroglycerin is acceptable), titrate dose/amount acceptable.

**Unstable for transfer: (UNLESS HIGHER LEVEL OF CARE REQUIRED/REQUESTED)**

1. Persistent acute EKG changes (acute injury current ST elevation or ST depression);
2. Active ectopy (greater than 6 PVC's/min. or short runs of V-Tach), acute MI.

**CARDIAC CATH / PTCA/PCI**

Patients requiring cardiac catheterization/PTCA/PCI (per the community MD)

Transfer for primary PTCA can be considered if:

- a) There is evidence of an acute MI;
- b) There is an absolute contraindication to thrombolysis; and the facility in which the patient is being treated does not have the capability to perform the procedure.

**AORTIC DISEASE**

Criteria for management of Aortic Dissections and Aortic Aneurysms

- a) Ascending Dissection - surgical emergency - requires immediate transfer to Kaiser Sunnyside MC or OHSU depending on stability and location; contact on-call cardiologist to determine best disposition.
- b) Type B Dissection – Call Cardiology first for advice. Cardiac Surgery needs to evaluate the case, but often medically managed in ICU;
- c) Patients > 80 years of age - Cardiac Surgery needs to evaluate the case, but often medically managed;
- d) Abdominal Aneurysm – Consult Vascular Surgeon on-call. This can generally be handled at any plan facility, unless higher level of care is required.

Patients who may be considered **stable for transfer**:

- a) Have responded to appropriate therapies;
- b) Are not significantly hypoxic or dyspneic;
- c) Remain alert without evidence of hypercapnea;
- d) Maintain stable vital signs;
- e) Have no persistent acute EKG changes (acute injury current ST elevation or ST depression);
- f) Meet general cardiac criteria.

### **Exclusion Criteria: Cardiac-EXCEPT FOR HIGHER LEVEL OF CARE REQUESTS**

#### Cardiovascular/Hemodynamic

- Hypotension or hypertension not controlled
  - SBP < 90 or >180. Check for baseline BP.
- On moderate-to-high-dose vasopressors
  - Norepinephrine > 10 mcg/min
  - Dopamine > 10 mcg/kg/min
- On any dose of vasopressor/inotrope without central venous access or without multiple secure peripheral catheters (central access preferred)
- Brisk ongoing hemorrhage or high risk of recurrent hemorrhage

#### **Other exclusion criteria:**

1. ST Elevation Myocardial Infarction (STEMI) who are within 12 hours of onset of symptoms or are having ongoing symptoms and ST elevation consistent with active ischemia.
2. Non-STEMIs whose pain/symptoms cannot be stabilized acutely with medicinal therapy and are having symptoms consistent with ongoing cardiac ischemia.
3. Ischemic syndromes with evidence of cardiogenic shock.
4. Patients with recurring sustained ventricular tachycardia or life threatening bradycardias.
5. Ischemic syndromes requiring an intra-aortic balloon pump to maintain adequate blood pressure.
6. Sustained bradycardia or tachycardia with cardiogenic shock or hemodynamic instability.
7. Valvular heart disease with cardiogenic shock and/or active ischemic symptoms.
8. Pericardial effusion with hemodynamic compromise from tamponade.
9. Patients with resuscitated sudden cardiac death on mechanical ventilation in the 24 hours post event or who are receiving therapeutic hypothermia and have not yet been re-warmed

## GENERAL

Patients with critical illness are those requiring ICU-level care.

The criteria for transfer of critically ill patients are the same regardless of whether the accepting service is Critical Care Medicine or another specialty. In all cases, there should be multisystem review of the case to determine stability for transfer.

**“Lateral” transfers** are those done between facilities which can provide the same level of care. This includes patients who are in an ICU at a non-plan hospital and those who are in an ED at a non-plan hospital that has an ICU bed available and that hospital can provide the services needed by the patient. For lateral transfers, the RTMC should use the Screening Exclusion Criteria below to determine which patients should be immediately excluded for transport. If there are no exclusion criteria present, then a potential accepting physician can be identified. The potential accepting physician will then review the case and integrate all the available information to determine if the patient is sufficiently stable for transport.

**“Higher Level of Care” transfers** are those which are done to obtain a level of care or service for the patient than is available at the Sending Facility. The Screening Exclusion Criteria are not used by RTMC for transfers being considered for a higher level of care. In these cases, the sending and accepting physicians will consider both the advantages to obtaining the higher level of care and the risks of transport in order to make a decision about transfer.

## SCREENING EXCLUSION CRITERIA FOR LATERAL TRANSFERS

The below Screening Exclusion Criteria are in place for lateral transfers, and do not apply to 1) patients with the need for a level of care available at Sunnyside or Westside, and that are not available at the originating facility (e.g. coronary intervention); and 2) patients being transported due to the need for a higher level of care (SEE ABOVE).

If exclusion criteria are present, then do not pursue transfer. Even if no exclusion criteria are present, the patient still needs to be considered stable for transport by Sending and Accepting Physicians.

### Exclusion Criteria

- Patients under 18 years of age for transfer to a Kaiser ICU

#### Cardiovascular/Hemodynamic

- Symptomatic hypertension
- SBP < 90 or MAP < 60
  - Exception: Baseline blood pressure is similarly low, and hypotension not related to primary diagnosis.
- On moderate-to-high-dose vasopressors
  - Norepinephrine >10 mcg/min >0.1 mcg/kg/min
  - Epinephrine >10 mcg/min >0.1 mcg/kg/min
  - Phenylephrine >100 mcg/min >1 mcg/kg/min
  - Dopamine >10 mcg/kg/min

- Dobutamine >10mcg/kg/min
- On any dose of vasopressor/inotrope without central venous access or without multiple secure peripheral catheters (central access is preferred)
- Brisk ongoing hemorrhage or high risk of recurrent hemorrhage
- Other exclusion criteria as described in the Cardiac section\*

#### Respiratory

- On ventilator with high levels of support required
  - FiO<sub>2</sub> > 0.7
  - PEEP >14
  - Minute ventilation > 13
  - Peak pressures > 45
- < 1 hour since intubation unless intubated for airway protection
- < 6 hours since extubation
- No ABG on current ventilator settings
- Not intubated, and requiring high-flow oxygen (> 15 L/min)
- Not intubated, questionable ability to protect airway, and vomiting
- Sat < 92% or PaO<sub>2</sub> < 70 on settings achievable during transport, intubated or not intubated
  - BiPAP or CPAP-dependent (reference BiPAP Guidelines under Respiratory section)
  - Unable to be off BiPAP or CPAP for at least 2 hours (must demonstrate)
  - Exceptions:
    - Patient is DNI
    - Patient is on chronic home or SNF non-invasive ventilation and the primary acute problem is not cardio-respiratory

#### Neurological

- Elevated intracranial pressure (suspected or proven)
- Expanding intracranial hemorrhage or midline shift present (See NS section)
- Actively deteriorating level of consciousness or otherwise evolving neurological exam
- Received alteplase for stroke within past 24 hours and are in a Certified Stroke Center (if patient is not in a Stroke Center, transfer patient)
- Seizures: if has had 2 seizures within less than 30 min of each other, patient is excluded from transfer until 4 hours have passed without seizures and patient has returned to baseline mental status or EEG demonstrates that status epilepticus is not present
- Severe agitated delirium not safely controlled

#### Metabolic abnormalities

- Temp < 36 (induced or spontaneous)
- Hyperkalemia with EKG changes or K > 7 even without EKG changes
- Symptomatic hyper/hyponatremia:
  - Acute seizures in setting of hyponatremia
  - Acute (or presumed acute) severe hyponatremia, Na<115
  - Acute severe hypernatremia, Na>165
- pH < 7.25 unless part of controlled hypoventilation strategy

\*Cardiac Exclusion Criteria **(unless higher level of care request)**

1. ST Elevation Myocardial Infarction (STEMI) who are within 12 hours of onset of symptoms or are having ongoing symptoms and ST elevation consistent with active ischemia.
2. Non-STEMIs whose pain/symptoms cannot be stabilized acutely with medicinal therapy and are having symptoms consistent with ongoing cardiac ischemia.
3. Ischemic syndromes with evidence of cardiogenic shock.
4. Patients with recurring sustained ventricular tachycardia or life threatening bradycardias.
5. Ischemic syndromes requiring an intra-aortic balloon pump to maintain adequate blood pressure.
6. Sustained bradycardia or tachycardia with cardiogenic shock or hemodynamic instability.
7. Valvular heart disease with cardiogenic shock and/or active ischemic symptoms.
8. Pericardial effusion with hemodynamic compromise from tamponade.
9. Patients with resuscitated sudden cardiac death on mechanical ventilation in the 24 hours post event or who are receiving therapeutic hypothermia and have not yet been re-warmed.

## **USE OF CRITICAL CARE TRANSPORT (CCT)**

Critical Care Transport service is provided by Life Flight in conjunction with MetroWest Ambulance.

## GENERAL

Due to the nature of GI bleeds and the lack of specific markers, the RTMC MD should always overlay their medical knowledge and judgment when determining the stability for transfer of these cases.

### **Stable for transfer:**

- a) Patient has stable vital signs including orthostatics where indicated;
- b) GI hemorrhage inactive without evidence of current brisk bleed;
- c) Stable CBC or H/H as compared to baseline;
  - 1) Patients may require transfusion at the community ED prior to transfer;
  - 2) Transfusion may also be continued during transfer if indicated. (Note: RN transport may be needed when patient is receiving blood transfusion).

### **Unstable for transfer (unless higher level of care required):**

- a) Patient has unstable vital signs (hemodynamically unstable- see Critical Care Exclusion Criteria, pg 6-8) after resuscitation is completed;
- b) Patient has an active brisk bleed from rectum or NG tube (if used), i.e. maroon-colored stool with decreasing H&H (decrease in Hgb >1 g/dl);
- c) Evidence of esophageal obstruction with airway compromise or inability to manage secretions;
- d) Patient requires urgent transfusion not available in the ED.

## **GENERAL SURGERY**

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Includes patients with diagnoses such as appendicitis, cholecystitis, diverticulitis, and SBO.

### **Stable for transfer:**

- a) Patient has stable vital signs; and
- b) Normal neurologic exam without airway compromise; and
- c) Stable HCT without significant active bleeding; and
- d) GS guidelines
- e) If transporting to KP facility, patient is  $\geq 16$  years of age

### **Unstable for transfer (unless higher level of care required):**

- a) Patient has unstable vital signs (see Critical Care Exclusion Criteria, pg 6-8); or
- b) Patient has active or significant potential for airway compromise or deterioration;  
or
- c) Patients with evidence of ongoing significant bleeding.

### **General Surgery Transfer Guidelines (Non-Trauma)**

**Stable for Transfer**, assuming facility and provider availability at Plan facility:

- a. Patient has stable vital signs, good general appearance
- b. No signs of a surgical abdomen
- c. Antibiotics if applicable have been started
- d. Acute abdominal series +/- or abdominal/pelvic CT scan if performed does not demonstrate;
  - 1) Free air
  - 2) Acute Dissecting AAA (discussion with vascular surgeon will occur as needed)
  - 3) Ischemic Small Bowel
  - 4) Air in the Biliary Tree (not post procedural)
  - 5) Ruptured AppendixNOTE: 1), 3), 4) and 5) will be discussed with surgeon prior to transfer
- e. Early Appendicitis
  - 1) Onset of symptoms and physical exam consistent with early presentation
  - 2) Reading of abdominal CT by radiologist indicates "Early Appendicitis"
- f. Sending facility has no plans or opportunity to operate for >6 hours
- g. If transporting to KP facility, patient is  $\geq 16$  years of age



## CVA - Ischemic Stroke

### Stable for transfer:

- Patient has:
- 1) stable vital signs;
  - 2) stable neurologic exam; determined optimally by a neurologist at non-plan facility, if available;
  - 3) symptoms/deficit stable;
  - 4) head CT scan (CTA, if facility has the capability) should be done prior to making decision to transfer patient to a non-neurosurgical facility (always request that a copy of CT/CTA accompany the patient in transfer).

### Unstable for transfer (unless higher level of care request for transfer):

- Patient has:
- 1) unstable vital signs (see Critical Care);
  - 2) unstable neurologic exam;
  - 3)  $\geq 1/4$  hemisphere infarct
  - 4) cerebellar or cortical hematomas with midline shift;
  - 5) brainstem involvement
  - 6) intracerebral hemorrhage/cerebral hematoma;
  - 7) acute surgical intervention indicated and available at treating facility;
  - 8) symptoms consistent with evolving stroke;
  - 9) patient not surgical candidate but with impending demise, unless patient's family requests transfer to Kaiser.

### Other Considerations:

- 1) Receiving facility must be within 2 hours transit time.
- 2) The decision to administer thrombolytics for acute CVA rests with the treating physician.
- 3) For an anterior circulation infarct that is outside the window for appropriate thrombolytics (<3 hours) but <6 hours of onset, patient must be considered for intravascular intervention at appropriate facility for transfer.
- 4) For a posterior circulation infarct that is within 24 hours of onset, discuss case with KP neurologist to determine if patient is appropriate for intravascular intervention and the most appropriate facility to receive the patient.

### Exclusion Criteria: (unless higher level of care, not in a stroke center)

#### Neurological

- Elevated intracranial pressure
- Expanding intracranial hemorrhage or midline shift present
- Actively deteriorating level of consciousness or otherwise evolving neurological exam
- Seizures: if has had 2 seizures within less than 30 min of each other, patient is excluded from transfer until 4 hours have passed without seizures and patient has returned to baseline mental status or EEG demonstrates that status epilepticus is not present
- Severe agitated delirium not safely controlled

## NEUROSURGERY, ADULT

### Patients in Non-KP EDs

#### Normal CT

Patients presenting with traumatic closed head injuries with a normal CT and Glasgow Coma Scale  $\geq 13$  will be transferred to a KP facility (or other facility, as deemed appropriate) when observation is indicated.

Patients presenting with traumatic closed head injuries with a normal CT and Glasgow Coma Scale  $< 13$  will be transferred to KSMC and evaluated by the Neurosurgeon to determine why GCS is so low, complete any indicated toxicology screen, and conduct other tests as indicated. If admission to another service is deemed more appropriate, the RTMC will arrange the admission and the Neurosurgeon will communicate with the accepting Physician and/or family if requested.

#### Abnormal CTs

All acute intracranial bleeds and cervical spinal cord injuries in non-KP neurosurgical EDs should have an onsite neurosurgical consult to ensure their safe transfer if available and indicated. If it is determined that the patient is not a candidate for neurosurgical intervention, the neurosurgeon will notify the hospitalist or intensivist and the patient will be admitted to that service with neurosurgery as consult. Neurosurgeon will communicate with the family if requested.

#### Spine:

Patients with spinal injury and subjective or objective neurologic deficit should be transferred to KSMC. Consult spine on call. Patients less than 18 years of age should be referred to DCH.

- Reference Trauma section
- Reference Critical Care Exclusion Criteria
- Reference Higher Level of Care

## NEUROSURGERY, PEDIATRIC

General issues: Need to communicate with the Pediatric Neurosurgeon on call regarding each case. All cases should be referred to OHSU/Doernbecher.

- a) The patient should receive care in a setting capable of providing all services required by a child, including care for potential complications;
- b) Neonatal neurosurgical cases must be in a facility with Neonatal ICU level 3-4 capability (depending on severity);
- c) Patients who will likely require Pediatric ICU (PICU) services may only be transferred to Doernbecher PICU (unless also suffering severe burns- which would require Legacy Emanuel PICU);
- d) Patients with coma or depressed Glasgow Coma Score require pediatric intensive care services.
  - All pediatric patients  $< 18$  should be cared for at Doernbecher/ OHSU by the trauma service;
  - Glasgow coma score (GCS)  $< 10$ ;

**GENERAL****Stable for transfer:**

- a) Patients with stable vital signs;
- b) Patients with closed fracture without neurovascular compromise  
Note: Displaced **acetabular** fractures are not usually repatriated.  
Note: closed tibial fractures sustained with high energy mechanisms of injury will require some objective evidence indicating normal (or near normal) compartment pressures even in the setting of normal neurovascular status.
- c) Patients with open fractures without neurovascular compromise.
  - i. Grade 1, <1 cm laceration- can potentially go to OR more than 6 hours from the time of injury, check with on call KP orthopedist.
  - ii. Grade 2, >1 cm laceration- ideal to get to OR within 6 hours from the time of injury, but decision of time to surgery is left to the discretion of the KP orthopedist.
    - Do not transfer if it has been >4 hours since the time of injury, unless the sending facility is unable to deliver care or get the patient to the OR in a timely fashion.
  - iii. Grade 3 would be handled at a trauma center.
  - iv. Distal phalanx can be managed with ER/urgent care washout and antibiotics only, does not need urgent OR.
- d) Pediatric closed fractures can be handled at KSMC. Check with on-call KP orthopedist.

NOTE: For each case the RTMC MD is expected to provide complete information to the orthopedist including:

- Patient's age and gender;
- Time of the injury;
- Mechanism of the injury;
- Extent of injury including all systems;
- Current location of the patient;
- Name and phone number of the current treating physician, if requested;
- Estimated transportation time.

**Unstable for transfer (Unless higher level of care is requested):**

- a) Patients with unstable vital signs (see Critical Care Exclusion Criteria);
- b) Patients with evidence of vascular compromise;
- c) Patients with evidence of compartment syndrome;
- d) Patients with multiple trauma/multiple system injuries that cannot be managed within the Kaiser Permanente system;
- e) Patients with amputation injury requiring reimplantation.
- f) Gustillo Fracture Classification, Grades II-III (see description of Grade I above)

**GENERAL**

Mandibular fractures, facial fractures, laceration repairs, epistaxis, etc.

**Stable for transfer:**

- a) Patient has stable vital signs;
- b) Normal neurologic exam without airway compromise;
- c) Stable HCT without significant active bleeding;
- d) Significant oral edema should be evaluated by non-Plan ENT when available prior to transfer.

**Unstable for transfer (unless higher level of care required):**

- a) Patient has unstable vital signs (see Critical Care Exclusion Criteria);
- b) Patient has active or significant potential for airway compromise;
- c) Patients with evidence of ongoing significant bleeding or epistaxis.

**PEDIATRICS**

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**GENERAL**

Pediatric cases are managed by the Kaiser Pediatrician on call at Doernbecher, who can be reached by calling the OHSU transfer center at 503-494-7000 or by paging the pediatrician directly (contact number on intranet clinician availability). If the child is felt to be critically ill or injured, then the Pediatric ICU attending physician at Doernbecher would manage the case/transfer. Also of note, the Doernbecher PANDA (Pediatric and Neonatal Doernbecher Ambulance) transport team may use air transport, typically at the discretion of the pediatric ICU attending physician at DCH. Closed fractures requiring closed reduction can typically be handled at KSMC, therefore transfer to Doernbecher may not be indicated.

Common pediatric diagnoses encountered include, but are not limited to, asthma, croup, dehydration, head injuries, infections and poisonings.

**Stable for transfer:**

- 1) Patients with vital signs reflecting hemodynamic stability;
- 2) Patients who received adequate initial treatment;
- 3) Patients accepted by Kaiser Permanente pediatric Doernbecher hospitalist MD or PICU attending on call. Appropriate mode of transfer is arranged (ACLS or PANDA).

**Unstable for transfer (Unless higher level of care requested):**

- 1) Patients exhibiting hemodynamic instability;  
NOTE: We may opt to transfer (in particular PANDA) if the sending facility is not able to stabilize as the transport team often is better skilled in getting the patient stabilized than some of our local ER's.
- 2) KP pediatric MD unwilling to accept due to clinical concerns.

Decisions will be made by Doernbecher KP hospitalist and PICU attending.

**GENERAL**

**Medical Clearance** – The patient is determined to be medically cleared when all medical conditions have been evaluated and treated so that the patient could return home if there was no underlying psychiatric condition. The extent of the evaluation to determine medical clearance is at the discretion of the treating physician in consultation with the Brookside on call MD. Specific drug or alcohol levels are not required unless clinically pertinent to the medical clearance. However, most cases require toxicology screen.

**Stable for transfer:**

- a) Patients with vital signs reflecting hemodynamic stability;
- b) Patients that received adequate initial evaluation and treatment;
- c) Patients meeting medical clearance criteria for transfers directly to psych facilities.

**Unstable for transfer (Unless higher level of care requested):**

- a) Patients exhibiting hemodynamic instability;
  - b) Patients with significant overdoses and evidence of pending cardiovascular complications (i.e.: TCA's).
-

Hemodialysis patients exhibiting volume overload or electrolyte imbalance and are often in need of urgent or emergent dialysis.

**Stable for transfer:**

- a) Patients with vital signs reflecting hemodynamic stability;
  - b) Renal failure patients presenting with serum potassium below 7.0 without EKG changes (second potassium may need to be obtained after medical therapy at the community ED);
  - c) Patients with appropriate mental status;
  - d) Patients with adequate oxygenation with low or moderate O<sub>2</sub> supplementation.
- Before repatriating dialysis patients, make sure the nephrologist on call is notified and that dialysis capacity has not been exceeded
  - Notify the hospitalist so they can admit the patient

**Unstable for transfer (Unless higher level of care requested):**

- a) Patients exhibiting hemodynamic instability;
- b) Renal failure patients with serum potassium above 7.0.
- c) Patients with pulmonary edema not responsive to initial medical therapy and in need of emergent dialysis to avoid respiratory failure.

**RENALTRANSPLANT PATIENTS:**

The patient can receive related care at the transplant facility for a maximum of 3 months post transplant. After 3 months the patient is usually transferred for care to their home Kaiser Permanente facility. The appropriate nephrologist on call should be consulted after hours to aid in the disposition of these cases.

**Other Organ transplants:** Refer to NTN Database for information on: Centers of Excellence (COE), transplant Coordinator's name, Transplant MD's name and case rate ending date.

# RESPIRATORY

## GENERAL

Note that the Pulmonary Service is not an admitting service at KSMC. The following sections address certain respiratory therapies that may be encountered when considering transport of patients to any accepting service.

### Oxygen Therapy

Patients cannot be transported on high flow nasal cannula oxygen. Adequate oxygenation on flows up to 15 L/min by mask must be demonstrated prior to transport. Reference Critical Care Exclusion Criteria.

### NIV, BiPAP, CPAP

Ventilatory support with noninvasive ventilation (NIV), BiPAP, or CPAP is not considered to be as reliable as invasive ventilation and has only been proven to be effective for a limited number of indications.

#### **Lateral Level of Care Transfers or Transfers to a Lower Level of Care**

Lateral transfers should not be initiated for patients who are dependent on NIV, Bipap, or CPAP.

“Dependency” is defined as being unable to be off the device at least 2 hours. However, after demonstrating NIV/BiPAP/CPAP independency at the Sending Facility, NIV/BiPAP/CPAP can and should be utilized during transport if it has been a part of the treatment regimen up until that point.

#### Exceptions—lateral transfers may be considered in these situations:

1. NIV/BiPAP/CPAP is being used for palliative purposes
2. DNI and DNR status
3. Patient is on chronic home NIV/BiPAP/CPAP and the acute medical problem is not cardio-pulmonary.
4. NIV/BiPAP/CPAP is being used for COPD or CHF, and a physician privileged in advanced airway management is part of the transport team.

In all cases of lateral transfer, an RT or nurse with competency in administering non-invasive ventilation must be part of the transport team. This implies that Critical Care transport will typically be required.

#### **Transfers to Achieve a Higher Level of Care**

Alternatives to transporting a patient on NIV, BiPAP or CPAP should be thoroughly explored before deciding on transport for a higher level of care. Consideration should be given to intubation prior to transport. Keeping the patient at the sending facility long enough to demonstrate improvement in the clinical respiratory status and in blood gas results on noninvasive therapy is strongly encouraged prior to transport.

If transport must take place using NIV, the transport team should be assembled with the best available skills in NIV and advanced airway management available in a time frame consistent with patient safety. Efforts should be made to enlist both an RT or RN with NIV competency and a physician with advanced airway management skills for the transport team.

#### **Higher Level of Care Transports**

Critical Care Transport should be used whenever possible. However, if the use of CCT would result in a delay which would put the patient at risk, then transport without the CCT can be considered as part of the decision-making process which weighs the overall risks and benefits of transfer.

## **TRAUMA**

### **GENERAL**

Major, multi-system trauma would never be appropriate for repatriation to a KP hospital. If the non-Plan MD requests, assistance may be provided in the transfer of these patients to the appropriate higher level of care setting.

### **PENETRATING: (GUN SHOT WOUND / STAB WOUND) –DO NOT TRANSFER**

#### **Blunt Trauma-**

For patient in a non-KP facility

a) Chest: Stable for transfer if:

- 1) Hemodynamically stable during 2 hour observation; and
- 2) Chest x-ray, EKG without change; and
- 3) ABG pH > 7.3, pO<sub>2</sub> > 65, pCO<sub>2</sub> < 50; and
- 4) No signs of aortic disruption - CT scan or aortogram.

b) Abdomen: Stable for transfer if:

- 1) Hemodynamically stable during 2 hour observation; and
- 2) CT scan performed prior to transfer shows no signs of acute injury to spleen, liver, or pancreas; no free fluid, free air, or pelvic fracture.

#### **Trauma Criteria**

For KP patients presenting at a non-KP facility. Transfer to Trauma Center if:

a) Critical Trauma Victim (CTV): a victim of blunt or penetrating trauma, which results in any of the following alterations in vital signs.

Respirations	< 12 or > 30
Pulse	< 50 or > 130
Systolic BP	< 80

b) Moderate Trauma Victim (MTV) : a victim of blunt or penetrating trauma with parameters to consider for trauma center designation including:

- 1) Mechanism of injury - pedestrians struck by auto, ejection from vehicle;
- 2) Unable to follow commands;
- 3) Abnormal capillary refill;
- 4) Age <5 or > 65 years old and with precarious previous medical histories;
- 5) Prolonged extrication;
- 6) Fatalities involved in the event;
- 7) Adults with systolic BP < 90 or children with systolic BP <60;
- 8) No spontaneous eye opening;
- 9) Penetrating cranial injury;
- 10) Penetrating thoracic injury between the midclavicular lines;
- 11) Gunshot wound (GSW) to trunk
- 12) Blunt injury to chest with unstable chest wall (flail chest );
- 13) Penetrating injury to neck;
- 14) Diffuse abdominal tenderness following blunt trauma;
- 15) Fall from height >15 feet;
- 16) Intrusion of motor vehicle into passenger space



Patients with an acute isolated **head trauma** and persistent Glasgow Coma scale of 14 or less should be referred to KSMC.

Patients with an isolated **spinal injury** and subjective or objective neurologic deficit should be transferred to KSMC. Consult Spine on call.

**Stable for transfer:**

- a) Patient has stable vital signs;
- b) Stable neurologic exam without evolving deficit;
- c) Determination of stability by neurosurgeon at non-Plan facility, if available;
- d) Spinal fracture immobilized appropriately prior to transfer if determined to be stable by treating physician.

**Unstable for transfer (unless higher level of care):**

- a) Patient has unstable vital signs;
- b) Patient has unstable neurologic exam;
- c) Patients with acute epidural, subdural, or subarachnoid hemorrhage, especially with midline shift (at facilities where neurosurgical service are available);
- d) Patients with unstable spine fractures or spine fractures with deficit at facilities with appropriate surgical services available.

**SPECIAL GROUP CONSIDERATIONS**

Added Choice/POS: members may access non-KP facilities for routine and post-emergency care under their Tier 2 and Tier 3 benefits, however prior-authorization is required.



## UR 56 Dental Anesthesia Policy and Medical Necessity Criteria: Commercial and Oregon Medicaid Contracts

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Department: Northwest Permanente	Number: UR 56
Applies to: KPNW Region/NW UM Physician	Effective: 04/10
Review Responsibility: PDA Dental Services Hospital Operating Room Committee; UROC	Reviewed: 04/10, 4/18
Subject Matter Expert: Juanita Boettcher, DMD	Revised: 4/11, 4/12, 4/13, 4/14, 5/15, 4/16, 4/17
	Number of pages: 6

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**Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.**

### PURPOSE

Describes the policy, medical necessity criteria, and responsibilities for the provision of dental care under general anesthesia (GA) in an operating room (OR) of a hospital or ambulatory surgical treatment setting when a member has both Kaiser Foundation Health Plan (KFHP) medical and dental coverage and when s/he has KFHP medical coverage and non-KFHP dental coverage.

### POLICY

Dental services that cannot be safely performed within a KPNW dental office are considered noncovered benefits under the KFHP *dental* Evidence of Coverage (EOC). If a dental service under general anesthesia outside a KPNW dental office is needed, this service may be covered under the member’s Kaiser Foundation Health Plan of the Northwest (KFHPNW) **medical** contract.

The medical and utilization management (UM) process is the same for all patients; however, age may be a deciding factor when considering accepted community standards of care.

### DEFINITIONS

- General Anesthesia (GA): A reversible state of controlled unconsciousness produced by intravenous and/or inhaled anesthetic agents which results in the total loss or partial loss of reflexes and absence of pain over the entire body.
- Operating Room (OR): An operating theatre, operating room, or a surgery suite within a hospital or ambulatory treatment center within which surgical operations are carried out.
- General dentistry: The general practice of dentistry
- Pediatric dentistry: The practice of dentistry specializing in patients generally 12 years of age and younger
- Special Needs: Conditions include, but are not limited to: Autism, Cerebral Palsy, Downs Syndrome, severe intellectual disability, paralysis, severe uncontrolled seizure disorders, or severe sensory disorders. **Dental phobia is NOT considered a special need.**

### MEDICAL NECESSITY CRITERIA

It is an accepted standard to provide dentally necessary dental services under general anesthesia if a physically or mentally handicapped patient (of any age) and other medically complicated patient (of any age) has a documented medical diagnosis (such as Alzheimer's or uncontrolled Parkinson's) or special needs, (such as Downs syndrome, cerebral palsy or autism) and/or other



## UR 56 Dental Anesthesia Policy and Medical Necessity Criteria: Commercial and Oregon Medicaid Contracts

Department: Northwest Permanente  
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Subject Matter Expert: Juanita Boettcher, DMD

Number: UR 56  
Effective: 04/10  
Reviewed: 04/10, 4/18  
Revised: 4/11, 4/12, 4/13, 4/14, 5/15, 4/16, 4/17  
Number of pages: 6

medical or *developmental* needs of such a severity that the member would be at undue risk if the dental procedure were performed in the dental office.

All potentially eligible mental or physical conditions/diagnoses require oversight by a Permanente medical doctor up to and including an anesthesia review.

### OTHER CONSIDERATIONS

Unless otherwise mandated by federal or State law, members are **ineligible** for GA if any of the following exist:

- the dental services are either cosmetic or any other not covered by the member's Dental Plan; or
- the patient can't be safely transported to a Kaiser Permanente facility to receive dental care; (e.g.: ventilator dependent, combative) or
- the member did not receive a "surgical clearance" from a licensed Permanente medical physician, or
- after a consultation with a licensed anesthesiologist, GA risk outweighs the benefits of dental treatment in the OR.

### PROCESS

#### WHEN THE PATIENT HAS PDA OR COMMUNITY DENTAL AND MEDICAL COVERAGE THROUGH KFHPNW, THE EXPECTED PROCESS INCLUDES:

- 1) Dental consultation by a dentist with experience in hospital dentistry for all patients both with and without a PDA dentist
- 2) An anesthesia review via the chart when indicated based on the patient's medical condition or risk status
- 3) Use of Plan facilities (***coverage of non-plan facilities must be approved by the Regional Referral Center or URMD***)

#### PROCESS STEPS:

- A treating dentist believes the work cannot be safely performed in the dental office and, in his/her opinion, general anesthesia must be used to perform necessary dental services;
- A treating dentist (community dentists or Permanente Dental Associate Dentists), will submit a request to the KPNW dentist consultant for a consultation request for general



## UR 56 Dental Anesthesia Policy and Medical Necessity Criteria: Commercial and Oregon Medicaid Contracts

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anesthesia in the OR setting because it is believed the dental care cannot be safely performed in the dental office.

- The dentist consultant evaluates the dental treatment plan, secures a medical clearance through a Permanente medical provider from a safety and clinical appropriateness perspective, and secures an anesthesia consult as necessary based on the patient’s medical condition.
- The NWP physician will make a medical determination regarding medical necessity of anesthesia and OR services.
- A medical contract benefit coverage determination will be done. Concurrently, the URMD will make the final coverage determination related to the provision of anesthesia, OR services and site of service. Services are expected to be provided in Plan OR rooms. If the OR is a non-plan OR outside of a Kaiser Permanente Dental Office or KP hospital, the referral must go to the Regional Referral Center for authorization.

### SPECIAL GROUP CONSIDERATIONS

Policy applies to all commercial groups.

Medicare: Policy applies to Medicare: Social Security Act section 1862 (a)(12) says: Payment may be made under part A in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services.

Washington Medicaid: Policy does not apply, see WA contract language

### Oregon Medicaid: Unique criteria FOR OHP Members ONLY

The purpose of hospital dentistry is to provide safe, efficient dental care when providing routine (non-emergency) dental services for OHP clients who present special challenges that require the use of general anesthesia or IV conscious sedation services in an Ambulatory Surgical Center (ASC), inpatient or outpatient setting. Hospital dentistry is intended for:

1. Children (18 or younger) who:
  - a. Through age 3 and have extensive dental needs;
  - b. 4 years of age or older and have unsuccessfully attempted treatment in the office setting with some type of sedation or nitrous oxide;



## UR 56 Dental Anesthesia Policy and Medical Necessity Criteria: Commercial and Oregon Medicaid Contracts

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Department: Northwest Permanente	Number: UR 56
Applies to: KPNW Region/NW UM Physician	Effective: 04/10
Review Responsibility: PDA Dental Services Hospital Operating Room Committee; UROC	Reviewed: 04/10, 4/18
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	Number of pages: 6

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- c. Have acute situational anxiety, fearfulness, extremely uncooperative behavior, uncommunicative such as a client with developmental or mental disability, a client that is pre-verbal or extreme age where dental needs are deemed sufficiently important that dental care cannot be deferred;
  - d. Need the use of general anesthesia (or IV sedation) to protect the developing psyche;
  - e. Have sustained extensive orofacial or dental trauma;
  - f. Have physical, mental or medically compromising conditions; or
  - g. Have a developmental disability or other severe cognitive impairment and one or more of the following characteristics that prevent routine dental care in an office setting:
    - i. Acute situational anxiety and extreme uncooperative behavior; and/or
    - ii. A physically compromising condition.
2. Adults (19 or older) who:
- a. Have a developmental disability or other severe cognitive impairment and one or more of the following characteristics that prevent routine dental care in an office setting:
    - i. Acute situational anxiety and extreme uncooperative behavior; and/or
    - ii. A physically compromising condition
  - b. Have sustained extensive orofacial or dental trauma; or
  - c. Are medically fragile, have complex medical needs, contractures or other significant medical conditions potentially making the dental office setting unsafe for the client

### REFERENCES

#### NCQA

NCQA Standards and Guidelines, Utilization Management, are updated annually and are available by contacting Quality Resource Management at 503-813-3850.

#### WASHINGTON

##### **RCW 48.43.185 General anesthesia services for dental procedures.**

Each group health benefit plan or group dental plan that provides coverage for dental services must cover medically necessary general anesthesia services in conjunction with any covered dental procedure performed in a dental office if the general anesthesia services are



## UR 56 Dental Anesthesia Policy and Medical Necessity Criteria: Commercial and Oregon Medicaid Contracts

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Department: Northwest Permanente	Number: UR 56
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medically necessary because the covered person is under the age of seven or physically or developmentally disabled.

**RCW 284-43-410 & RCW 483.43.520:** Requirement to maintain a documented utilization review program description and written utilization review criteria.

### CLINICAL

American Academy of Pediatrics Oral Health Policy 2005, Hospitalization and Hospital Operating Room Access for Dental Care of Infants, Children and Adolescents, and Persons with Special needs

PDA Dental Services Hospital Operating Room Committee: members include a general dentist; a pediatric dentist with hospital operating room privileges; a general dentist with hospital operating room privileges.

See NW Dental Care Program Policy 22: Policy and Procedure for Handling Requests for General Anesthesia in Operating Room for members with 1) KP dental coverage only; or, 2) KP dental and KP medical coverage.

## UR 57: Facial Dermal Fillers Policy and Medical Necessity Criteria

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Departments: Immunology	Number: UR 57
Section: KPNW Region	Effective: 08/10
Applies to: KPNW Region	Reviewed: 08/10, 1/11, 2/12, 2/13, 2/14, 2/15, 3/16, 2/17, 2/18
SME: Molly Stenzel, MD- Immunology;	Revised: 8/11
	Pages: 2

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**FACIAL DERMAL FILLER criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.**

The purpose of these criteria is to provide coverage of limited facial enhancement to patients with HIV-associated lipodystrophy in order to alleviate the stigma associated with this condition. Due to their appearance, patients with facial lipodystrophy syndrome (LDS) may become depressed, socially isolated, and in some cases, may stop their HIV treatments in an attempt to halt or reverse this complication.

Many systemic illnesses cause bodily shape changes. Any weight loss from illness, chemotherapy, or voluntary weight loss will lead to some facial skin sagging. Kaiser Permanente does not cover the correction of these conditions. The specialist administering the injections will use his/her best judgment in determining the difference between HIV lipodystrophy and natural, age-appropriate atrophy and aging. Kaiser Permanente coverage extends to improving the gaunt look of lipodystrophy, and coverage is not meant to be a yearly touch up.

### DEFINITIONS

Facial Lipodystrophy/lipoatrophy: a progressive, symmetrical loss of subcutaneous fat that results in a facial abnormality such as severely sunken cheeks. This fat loss can be a result of aging or weight loss or can arise as a complication of HIV and/or highly-active antiretroviral therapy (HAART).

Dermal filler: an injectible substance that stimulates the production of new collagen, increasing facial volume.

### CRITERIA

- 1) Dermal filler injections are indicated for the following conditions:
  - a) diagnosis of human immunodeficiency virus (HIV) **and**
  - b) diagnosis of facial lipodystrophy/lipoatrophy, grades 3-4, related to HIV or highly-active antiretroviral therapy (HAART) **and**
  - c) diagnosis of depression secondary to the physical stigma of facial lipodystrophy

## UR 57: Facial Dermal Fillers Policy and Medical Necessity Criteria

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Departments: Immunology	Number: UR 57
Section: KPNW Region	Effective: 08/10
Applies to: KPNW Region	Reviewed: 08/10, 1/11, 2/12, 2/13, 2/14, 2/15, 3/16, 2/17, 2/18
SME: Molly Stenzel, MD- Immunology;	Revised: 8/11
	Pages: 2

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2) The dermal filler is approved by the Food and Drug Administration for Facial Lipodystrophy Syndrome (LDS), e.g. Sculptra® and Radiesse®.

### CONTRAINDICATIONS

Coagulopathy, active infection (whether or not related to HIV disease), inadequate immune function as determined by HIV provider.

### OTHER CONSIDERATIONS

Multiple sessions may be necessary to complete the therapy depending upon the severity of the lipodystrophy. Grade 3 may take up to 4 sessions; and Grade 4 may take up to 8 sessions. The following link provides photographic examples of the Carruthers grading system (scale of 1- 4): [www.facialwasting.org](http://www.facialwasting.org). If additional treatments are desired, repeat photos of the face will be evaluated by the IDC providers to determine if further treatments are warranted. Re-treatment is usually necessary one to two years after the initial therapy.

Radiesse® will be provided as the standard treatment unless the following criteria are met for Sculptra®:

- 1) Radiesse tried and not effective
- 2) Allergic reaction to Radiesse

### SPECIAL GROUP CONSIDERATIONS

This policy/criteria apply to Medicare and Commercial group/individual members. It does not apply to Medicaid members.

### REFERENCES

**NCQA:** NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

### CLINICAL

Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations Manual, Chapter 1, part 250.5- Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS)- Rev. 122, Issued: 06-04-10, Effective: 03-23-10, Implementation: 07-06-10)



## UR 58 CR: Physician Review Form and Post Claim Review Process

Department: Clinical Review

Section: KPNW Region

Review Responsibility: Pat Hodney-Gould, RN; UROC

Number: UR 58

Effective: 10/11

Reviewed: 3/12, 3/14

Revised: 3/16, 3/18

**PURPOSE**

To define the process in which the Payment Integrity Clinical Review staff would complete and route a request for review (See Attachment) to a Utilization Review Medical Director (URMD).

**DEFINITIONS AND ABBREVIATIONS**

Clinical Review is CR

Health Record Number is HRN

Post Claim refers to after the bill for services has been received

**POLICY**

It is the policy of Kaiser Permanente to assure that services are covered benefits, medically necessary, not cosmetic in nature and not found to be experimental/ investigational.

**RESPONSIBILITIES**

When a claim for a Kaiser member is received within the claim processing area and Payment Integrity Clinical Review (CR) believes that the service(s) listed on the claim or a portion of the claim may not be medically necessary, or may be cosmetic; or may be experimental/ investigational, the **Physician Review Form** will be prepared in order to assure the appropriate physician clinical review has been performed.

1. The CR RN will complete the Physician Review Form with the Patient Name, Gender, HRN, DOB, Member's Age, Claim numbers involved, as well as summarize the documents that are being attached for review. The RN will then "Check" the reason for the referral.
2. In the **Overview** area, the CR RN will give a synopsis of her findings and state the question for the Utilization Review Medical Director (URMD) to answer. The RN will then sign his/her name and date the form.
3. The case will then be forwarded to the URMD for review and response. The URMD's decisions are made based on a full investigation of the substance of the documentation, including all aspects of the clinical care involved. Any additional materials submitted, medical records including chart notes and non-plan records, contractual and policy provisions and all relevant criteria are considered. The URMD will document his/her decision in the area marked **Physician Decision** with his/her rationale. The physician will sign and date the form in the area provided and return the form to the CR RN.
4. Once a decision on a medical necessity review has been made, the Clinical Review team will notify the area that initially sent the claim as to the decision in order to finalize the claim. Rationale will be documented in order to respond to any appeals at a later date.

These criteria do not imply or guarantee approval. Please check your plan to ensure coverage. Preauthorization requirements are only valid for the month published. They may have changed from previous months, and may change in future months. JULY-18

**UR 58 CR: Physician Review Form and Post Claim Review Process**

Department: Clinical Review

Section: KPNW Region

Review Responsibility: Pat Hodney-Gould, RN; UROC

Number: UR 58

Effective: 10/11

Reviewed: 3/12, 3/14

Revised: 3/16, 3/18

**SPECIAL GROUP CONSIDERATIONS**

This process applies to all business lines

**REFERENCES****NCQA**

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

**WASHINGTON**

RCW 284-43-410 &amp; RCW 483.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

**OREGON**

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

ORS 743.837: Prior authorization requirements

UR 58 CR: Physician Review Form and Post Claim Review Process

Department: Clinical Review  
Section: KPNW Region  
Review Responsibility: Pat Hodney-Gould, RN; UROC

Number: UR 58  
Effective: 10/11  
Reviewed: 3/12, 3/14  
Revised: 3/16, 3/18

**ATTACHMENT: PHYSICIAN REVIEW FORM**

Physician Review Form

Patient Name: \_\_\_\_\_  Male  Female

HRN \_\_\_\_\_ DOB: \_\_\_\_\_ Age: \_\_\_\_\_

Claim # (s) \_\_\_\_\_

Documents Attached:  HH  H&P,  Lab reports,  Member contract,  Provider Reconsideration request,  Radiology Reports,  
 Other (List) \_\_\_\_\_

Reason for Referral:  Medical Necessity;  Cosmetic;  DRG Review;  Experimental/ Investigational

Overview:

RN Preparing: \_\_\_\_\_ Date: \_\_\_\_\_  
Physician Decision: \_\_\_\_\_

Physician Signature \_\_\_\_\_ Date: \_\_\_\_\_

Proprietary and Confidential; Internal Use Only Related to KP Business Purposes; Do Not Distribute Externally

**UR 59: CR: Post Claim Reconsideration of DRG Determination Policy**

Department: Clinical Review

Number: UR 59 (MNR 10)

Section: KPNW Region

Effective: 09/11

Review Responsibility: Pat Hodney-Gould, RN; UROC

Reviewed: 3/14, 3/16, 3/18

Revised:

**PURPOSE**

To define standards, accountabilities, and processes for reviewing reconsideration requests from providers regarding initial determinations on DRG reimbursement.

**DEFINITIONS AND ABBREVIATIONS**

DRG- Diagnostic Related Group

Clinical Review - CR

Post Claim- Claim for services has been received

Health Record Number: HRN

**POLICY**

It is the policy of Kaiser Permanente that a provider may request reconsideration on any initial determination of a DRG reimbursement decision made by Clinical Review.

**RESPONSIBILITIES**

1. A provider may request reconsideration on any initial determination of a DRG reimbursement decision made by Clinical Review.
  - a. The provider must request a reconsideration in writing with specific rationale as to why additional reimbursement should be allowed;
  - b. Supporting documentation should accompany the request for reconsideration.
2. The request for reconsideration is received in the Clinical Review Section from Claims Processing, Provider Service or Provider Relations via existing, established work flow systems.
3. The Clinical Review staff will prepare the request for reconsideration and forward to a Medical Director for further review. Decision makers, who respond to DRG reconsiderations, make decisions in a consistent, equitable, timely manner in accordance with the applicable provider agreement or evidence of coverage (EOC); Utilization Review (UR) or benefit criteria; and DRG/coding guidelines.
4. Decisions are based on a full investigation of the substance of the request for reconsideration, including all aspects of the clinical care involved. The additional materials submitted, medical records including chart notes and non-plan records, physician reviews, contractual and policy provisions and other relevant documents are considered during the reconsideration process.
5. DRG reconsideration determinations that cannot be reversed based upon the additional documentation must be made by a licensed medical doctor (MD).

6. ~~Once a decision on a DRG reconsideration has been made, the Clinical Review team will notify the area~~

These criteria do not imply or guarantee approval. Please check your plan to ensure coverage. Preauthorization requirements are only valid for the month published. They may have changed from previous months, and may change in future months. JULY-18

**UR 59: CR: Post Claim Reconsideration of  
DRG Determination Policy**

Department: Clinical Review

Number: UR 59 (MNR 10)

Section: KPNW Region

Effective: 09/11

Review Responsibility: Pat Hodney-Gould, RN; UROC

Reviewed: 3/14, 3/16, 3/18

Revised:

that initially sent the request as to the decision in order to respond to the Provider. Rationale will be provided in order to respond to the request for reconsideration.

7. Reconsideration decisions will be made within 30 days of the request.

**SPECIAL GROUP CONSIDERATIONS**

This process applies to all business lines using DRG reimbursement:

Commercial; Medicare; Washington Medicaid; Oregon Medicaid; FEDS; WASHINGTON and OREGON PEBB

**REFERENCES****NCQA**

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

**CMS**

None

**WASHINGTON**

WAC 284-43-410 & RCW 48.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

**OREGON**

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

## UR 60: CR Post Claim Length of Stay Review

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Department: Clinical Review

Section: KPNW Region

Review Responsibility: Pat Hodney-Gould, RN; UROC

Number: UR 60 (MNR 1)

Effective: 09/11

Reviewed: 3/14, 3/16

Revised: 3/18

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### PURPOSE

To define standards, accountabilities, and processes for reviewing facility claims when the Length of Stay for the Added Choice Point of Service (POS) Commercial group product PPO (Tier 2) and Out Of Network (Tier 3) providers does not match the length of stay authorization(s) on file for POS members.

### DEFINITIONS AND ABBREVIATIONS

CR – Clinical Review

POS- Point of Service

### POLICY

Also see Policy UR 4- Utilization Management Medical Necessity Determinations

### RESPONSIBILITIES

1. When a Tier 2 or 3 facility inpatient claim for a POS member is received within the claim processing area and the length of stay does not match the authorized days on file for the approved stay:
  - a. The claim will be forwarded to Clinical Review (CR) to perform the appropriate clinical review for any days not authorized;
  - b. Medical records for the complete stay will be requested if they are not attached to the claim for review.
2. Once the complete medical documentation is received in the Clinical Review Section from Claims Processing, Provider Service or other Operational area via existing, established work flow systems, a medical necessity review will be performed. If the additional day(s) meet criteria, the RN can approve and return the claim for further processing.
3. If the medical documentation does not meet criteria, the Clinical Review staff will prepare the Physician Review Form (see UR Policy 58) and forward to a Medical Director for further review. Decision makers who respond to length of stay review requests make decisions in a consistent, equitable, timely manner in accordance with the applicable regulations; provider agreement if appropriate or evidence of coverage (EOC) and Utilization Review (UR) and benefit criteria.
4. Decisions are made based on a full investigation of the documentation, including all aspects of the clinical care involved. Any additional materials submitted, medical records including chart notes and non-plan records, physician reviews, contractual and policy provisions and other relevant documents

## UR 60: CR Post Claim Length of Stay Review

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Department: Clinical Review

Section: KPNW Region

Review Responsibility: Pat Hodney-Gould, RN; UROC

Number: UR 60 (MNR 1)

Effective: 09/11

Reviewed: 3/14, 3/16

Revised: 3/18

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are considered during the consideration process.

5. Once a decision on a medical necessity review has been made, the Clinical Review team will notify the area that initially sent the claim as to the decision in order to finalize the claim. Rationale will be documented in order to respond to any appeals at a later date.

6. Reconsideration decisions will be made within 30 days of the request.

### **SPECIAL GROUP CONSIDERATIONS**

This process applies to all business lines

### **REFERENCES**

#### **NCQA**

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

#### **CMS**

None

#### **WASHINGTON**

WAC 284-43-410 & RCW 48.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

#### **OREGON**

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

**UR 61: Applied Behavior Analysis (ABA) Medical Necessity Criteria**

Department: Behavioral Health

Section: KPNW Region

Applies to: KPNW Region

Review Responsibility: UROC

Subject Matter Expert: Sara Cuthill, MD; Han Liang, MD;  
Scott Brown, MD; Krystle Alligood, BCBA

Number: UR 61

Effective: 10/24/12-NEW

Reviewed: 10/13, 10/16

Revised: 10/14, 11/15, 03/17, 3/18

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**DEFINITIONS**

Qualified Provider- as it pertains to Applied Behavior Analysis (ABA), providers considered qualified to evaluate and diagnose an Autism Spectrum Disorder are Developmental Pediatricians, Psychologists and Psychiatrists.

ABAS III-Adaptive Behavior Assessment System, 3<sup>rd</sup> Edition provides a complete assessment of adaptive skills by assessing composite norms for three general areas of adaptive behavior: conceptual, social and practical.

**POLICY**

Kaiser Foundation Health Plan of the NW (KFHPNW) has reviewed the best available literature related to Applied Behavior Analysis (ABA) and consulted with internal Licensed Behavior Analysts. The literature points to potential (particularly in pre-school-aged children) evidence supporting ABA as an effective EARLY INTERVENTION treatment modality for behaviors associated with autism. ABA is the most empirically validated and clinically endorsed intervention for autism spectrum disorders. ABA will be covered when patients, providers and programs meet the following conditions:

**CRITERIA:****Member**

1. The member has had a documented diagnostic assessment and final diagnosis of an Autism Spectrum Disorder (ASD) by:
  - a) a qualified Kaiser Permanente provider or multi-disciplinary team appropriately licensed and trained in the diagnosis and treatment of autism; or
  - b) a qualified non-Kaiser Permanente provider whose evaluation and diagnosis has been reviewed and confirmed by a qualified Kaiser Permanente provider or multi-disciplinary team appropriately licensed and trained in the diagnosis and treatment of autism; AND
2. There is documentation of a severe challenging behavior and/or communication and social interaction issues, clearly related to characteristics of ASD that:
  - a) presents a health or safety risk to self or others (such as self-injury, aggression toward others, destruction of property, elopement, severe disruptive behavior); **OR**
  - b) presents a significant functional interference within the home and/or community (as demonstrated by scores  $\geq 2$  SD below the mean on ABAS-III); AND



**UR 61: Applied Behavior Analysis  
(ABA) Medical Necessity Criteria**

Department: Behavioral Health

Section: KPNW Region

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Scott Brown, MD; Krystle Alligood, BCBA

Number: UR 61

Effective: 10/24/12-NEW

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3. There is a reasonable expectation on the part of a qualified treating practitioner or multi-disciplinary team that the individual's behavior will improve significantly with ABA therapy.

**ABA Provider**

1. The lead behavioral therapist providing treatment and/or clinical supervision must meet criterion a or b, in addition to c below:
  - a) is a mental health professional licensed to practice independently in the state in which the ABA is provided; or
  - b) is currently certified by the BACB (Behavior Analyst Certification Board) as a BCBA (Board Certified Behavior Analyst); and
  - c) is approved by the Health Plan; and
2. Clinical Oversight of supervised staff must be included if utilizing staff with the following credentials:
  - a) RBT (Registered Behavior Technician)  
The RBT must be supervised for at least 5% of service hours provided and one of those supervised visits must be face-to-face with the supervising practitioner per month;
  - b) BCaBA (Board Certified assistant Behavior Analyst)  
The BCaBA must be supervised by a BCBA for at least 2% of service hours provided per month.
3. Family members may not be paid providers.

**ABA Program**

1. After a Permanente evaluation and diagnosis, Permanente will submit an internal referral for ABA services if deemed appropriate after the evaluation. Upon conclusion of the evaluation, the parent will be provided with a letter outlining the next steps to take to determine which ABA provider they would like to receive services through. After the parent chooses a provider, the ABA provider will then contact PDEV UM to initiate an external referral to that provider when the provider and patient are ready to begin services. The ABA provider will then review historical data and collect additional information to initiate the assessment and determine treatment goals. After the initial assessment is completed, the provider will submit the assessment results and treatment goals to PDEV UM and the treatment plan will be reviewed for medical necessity to ensure the patient is receiving the appropriate ABA therapy. Treatment plans will be reviewed at least every six months to ensure the patient is progressing throughout the treatment.

**UR 61: Applied Behavior Analysis (ABA) Medical Necessity Criteria**

Department: Behavioral Health

Section: KPNW Region

Applies to: KPNW Region

Review Responsibility: UROC

Subject Matter Expert: Sara Cuthill, MD; Han Liang, MD;  
Scott Brown, MD; Krystle Alligood, BCBA

Number: UR 61

Effective: 10/24/12-NEW

Reviewed: 10/13, 10/16

Revised: 10/14, 11/15, 03/17, 3/18

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- Treatment plans should not be submitted prior to 10 days before the authorization expires to ensure the data provided reflects the current treatment with the patient; AND
2. The services offered are not duplicative of services offered by or required of the school/educational system; AND
  3. The program, unless explicitly authorized as part of the treatment plan, will not include other services/therapies; AND
  4. The presence and active participation of an adult caregiver or parent/foster parent/legal guardian is addressed in the child's treatment plan, including, as appropriate, family education, support and training.

**Continuation Criteria****ALL of the following must be reviewed and approved (or denied) by the appropriate utilization management reviewer:**

1. The criteria for treatment must continue to be met. The patient will need to be reassessed by a Qualified Provider upon the appearance of new maladaptive behaviors that meet the medical necessity criteria.
2. The provider will submit an updated treatment plan no more than 10 days before the authorization expires. The treatment plan should include the progress toward goals since the previous authorization period and the plan for the authorization period being requested.
3. The individual treatment plan must include:
  - a. Patient demographics including:
    - Full name, date of birth, age, identified gender, contact information, medical record number (MRN), and primary diagnosis
  - b. Reason for referral
  - c. Psychosocial/background information
  - d. Clinical and historical information
  - e. Assessment procedures and results
  - f. Observable and measurable baseline data
  - g. Observable and measurable treatment goals

**UR 61: Applied Behavior Analysis (ABA) Medical Necessity Criteria**

Department: Behavioral Health

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Applies to: KPNW Region

Review Responsibility: UROC

Subject Matter Expert: Sara Cuthill, MD; Han Liang, MD;  
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Number: UR 61

Effective: 10/24/12-NEW

Reviewed: 10/13, 10/16

Revised: 10/14, 11/15, 03/17, 3/18

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- h. Behavior support plan (if needed)
  - i. Risk/benefit analysis
  - j. Parent goals/involvement requirements
  - k. Recommendation on the number of units/hours that are being requested for treatment. This should include the CPT codes of the services being requested and a clinical summary that justifies the number of units/hours that are being recommended.
  - l. Coordination of care with other providers supporting the patient.
  - m. Criteria for discharge from treatment
  - n. Crisis management plan
    - i. This should address any medical, behavioral, or environmental concerns.
  - o. Supervision Protocol (only applies if utilizing BCaBA and/or RBT providers)
    - i. Frequency and duration of supervision per month
    - ii. Team members involved.
4. There is documentation that progress toward goals have been made and that there is a reasonable expectation the patient will improve significantly with the continuation of ABA services.

**Transition to Discharge**

1. Transition Plan to discharge must be submitted to PDEV UM within 3 months of the discharge date and the Plan must include how services will be transitioned to the next level of care recommended.
2. Upon discharge, the provider will submit a case closure summary signed by the parent/guardian to PDEV within 30 days of discharge. The case closure summary will include:
  - a. Date of discharge
  - b. How treatment will be maintained
  - c. Any recommended support services

**Criteria for Discharge**, ONE of the following must be met:

1. No significant, measurable improvement has been documented in the patient's targeted behavior(s) reasonably attributable to the services provided or, after a period of 6 months of appropriate treatment, there is no reasonable expectation that termination of the current

**UR 61: Applied Behavior Analysis (ABA) Medical Necessity Criteria**

Department: Behavioral Health

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Subject Matter Expert: Sara Cuthill, MD; Han Liang, MD;  
Scott Brown, MD; Krystle Alligood, BCBA

Number: UR 61

Effective: 10/24/12-NEW

Reviewed: 10/13, 10/16

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treatment would put the patient at risk for decompensation or the recurrence of signs and symptoms that necessitated treatment.

- For changes to be “significant”, they must result in improved function, be durable over time beyond the end of the actual treatment session, and be generalizable outside the treatment setting.
2. Treatment is making the symptoms persistently worse.
  3. The patient has achieved adequate stabilization of the challenging behavior and less-intensive modes of therapy are appropriate.
  4. The patient demonstrates an inability to maintain long-term gains from the proposed plan of treatment.

**SPECIAL GROUP CONSIDERATIONS**

Applies to all commercial groups (including Feds, PEBB, OEGB) and Medicare  
Washington Medicaid: Does not apply to WA Medicaid members.  
Oregon Medicaid: Check LineFinder

**CLINICAL**

1. The Permanente Medical Group (TPMG) Practice Guidelines for Behavioral Health Treatment Services Available to Members with Autism Spectrum Disorder
2. Behavior Analyst Certification Board (BACB)- Applied Behavior Analysis Treatment of Autism Spectrum Disorder- Practice Guidelines for Healthcare Funders and Manager
3. Behavior Analyst Certification Board (BACB)- Professional and Ethical Compliance Code for Behavior Analysts

## UR 62: Robotic Assisted Surgery Review Policy

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Department: Clinical Review

Section: KPNW Region

Review Responsibility: Pat Hodney-Gould, RN; UROC

Number: UR 62

Effective: 05/12

Reviewed: 7/12, 7/13, 7/14, 3/16, 3/18

Revised:

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### PURPOSE

To define the process in which the Payment Integrity Clinical Review staff would complete a review for a request for reimbursement of Robotic assisted surgery.

### DEFINITIONS AND ABBREVIATIONS

Clinical Review is CR

Registered Nurse is RN

Health Record Number is HRN

### POLICY

It is the policy of Kaiser Permanente to assure that services are medically necessary, not cosmetic in nature and not found to be experimental/ investigational.

### GENERAL BACKGROUND

Robotic-assisted surgery refers to a technology used to assist the surgeon in controlling the surgical technique. The surgeon generally views the operative field via a terminal and manipulates robotic surgical instruments via a control panel. Views of the surgical site are transmitted from tiny cameras inserted into the body. The use of computers and robotics is intended to enhance dexterity to facilitate microscale operations.

Robotic-assisted surgical devices have been proposed for various types of surgery, including but not limited to:

- Cardiac
- Gastrointestinal
- Gynecology
- Maxillofacial
- Neurosurgery
- Ophthalmology
- Orthopedic
- Urology

The following code should be used in addition to the primary procedure to report the use of robotic assistance during a procedure:

HCPCS Code S2900 – Surgical techniques requiring use of robotic surgical system (list separately in addition to code for primary procedure). This add-on code was released as a new code in July 2005.

Kaiser Permanente does not provide additional reimbursement based upon the type of instruments, technique or approach used in a procedure. Such matters are left to the discretion of the surgeon. Additional professional or technical reimbursement will not be made when a surgical procedure is performed using robotic assistance.

## UR 62: Robotic Assisted Surgery Review Policy

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Department: Clinical Review

Section: KPNW Region

Review Responsibility: Pat Hodney-Gould, RN; UROC

Number: UR 62

Effective: 05/12

Reviewed: 7/12, 7/13, 7/14, 3/16, 3/18

Revised:

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### RESPONSIBILITIES

When a claim for a Kaiser member is received within the claim processing area and Payment Integrity Clinical Review (CR) identifies that the service(s) listed on the claim or a portion of the claim is related to robotic surgical assisted services:

1. The CR RN will complete the review of the claim and determine if the HCPCS Code has been correctly utilized on the claim. If HCPCS code S2900 has been identified, return to claims processing as no additional benefit allowed. If no HCPCS code found, and request for reimbursement of CPT for procedure is aberrantly high, request medical records.
2. Once medical records are received, review the procedure to determine cause of aberrant billing, if possible. If records indicate robotic assistance was used, return claim and request corrected bill be submitted. If no robotic assistance was found, review record for any further concerns with care/coding/medical necessity and follow normal process.
3. Once a decision on a medical necessity review has been made, the Clinical Review team will notify the area that initially sent the claim as to the decision in order to finalize the claim. Rationale will be documented in order to respond to any appeals at a later date.

### SPECIAL GROUP CONSIDERATIONS

This process applies to all products in all market segments.

### REFERENCES

#### NCQA

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

#### CMS

None

#### WASHINGTON

WAC 284-43-410 & RCW 48.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

#### OREGON

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

Department: Non-Behavioral Health Section: KPNW Region Applies to: KPNW Region Subject Matter Expert: Dana Smith, MD (ENT); Kelly Dezura, DMD; James Rapson, DDS	Number: UR 64 Effective: 01/2013 Reviewed: 1/14, 1/15, 2/16, 1/17, 1/18 Revised: 02/13
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Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

## **MAXILLOFACIAL ANOMALIES POLICY and MEDICAL NECESSITY CRITERIA**

The purpose of these criteria is to define KFHPNW coverage of limited maxillofacial prosthetic services included as part of a medical treatment plan for members with a maxillofacial anomaly when medically necessary to restore function.

ORS 743A.148 and 743.706 require health benefit plans to provide coverage for maxillofacial prosthetic services when necessary for restoration and management of head and facial structures that cannot be replaced with living tissue and are defective because of disease, trauma, or birth and developmental deformities when performed for the purpose of controlling or eliminating infection; controlling or eliminating pain; or restoring facial configuration or function.

Note that separate policies/criteria exist for coverage of:

1. dental and orthodontic services for treatment of craniofacial anomalies (UR 67),
2. general anesthesia for dental procedures performed in an inpatient/ambulatory operating room (UR 56),
3. surgical interventions for temporo-mandibular disorders (UR 49).

## **DEFINITIONS**

Adjunctive treatment (as defined by ORS 743.706): secondary or ancillary prosthetic services provided in conjunction with the primary treatment of a medical condition.

Maxillofacial: related to or involving the bony structures of the upper jaw and the face.

## **CRITERIA: Prosthetic Services for treatment of a MAXILLOFACIAL ANOMALY**

NOTE: although dental implants are excluded from medical coverage, prosthetic services (including dental implants) must be covered when **ALL** of the following criteria are met.

- 1) An anomaly affecting the head and facial structures exists that are defective:
  - Because of disease, trauma, birth or developmental deformity; **AND**
  - Not due to the result of bacterial disease or poor hygiene, i.e. common dental and/or periodontal disease.

The requested prosthetic services are a necessary adjunctive treatment for the purpose of:

- Controlling or eliminating infection
- Controlling or eliminating pain
- Restoring facial configuration or functions such as speech, swallowing, or chewing, but not including cosmetic procedures rendered to improve the normal range of conditions.
  - a Participating speech pathologist or other appropriate Participating specialist has determined that the **inability to speak or swallow** (or ineffectiveness) is the result of missing teeth; OR

Department: Non-Behavioral Health Section: KPNW Region Applies to: KPNW Region Subject Matter Expert: Dana Smith, MD (ENT); Kelly Dezura, DMD; James Rapson, DDS	Number: UR 64 Effective: 01/2013 Reviewed: 1/14, 1/15, 2/16, 1/17, 1/18 Revised: 02/13
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--an appropriate Participating specialist has determined that the **inability to chew** (or ineffectiveness) is the result of missing teeth.

- 2) An appropriate Participating specialist agrees that the success and sustainability of the prosthesis is likely and that the prosthesis is expected to improve function (e.g. the bone and/or oral structures can support the prosthesis).
- 3) The service(s) is not requested in order to alter the alignment of teeth unless necessary for retention of a maxillofacial prosthesis.
- 4) The requested prosthesis is necessary for restoration and management of head and facial structures that cannot be replaced with living tissue.
- 5) The requested prosthetic services are the least costly, clinically appropriate treatment as determined by a Participating Provider.

**CONTRAINDICATIONS:** Bone or tissue cannot sustain a prosthesis

### **SPECIAL GROUP CONSIDERATIONS**

OR/WA Commercial: Applies to all commercial groups

Oregon Medicaid: Mandate Not applicable to OR Medicaid; benefit coverage TBD

FEDS: Applies

PEBB: Applies

Medicare: Applicable when related to Local Coverage Determination L11571 which requires coverage of facial prostheses when there is a loss or absence of **facial tissue** due to disease, trauma, surgery or a congenital defect.

Washington Medicaid: Mandate Not applicable to WA Medicaid: If services are provided by a dentist or oral surgeon for dental diagnoses they are covered through DSHS FFS. The exception to this would be in the ED (the health plan is responsible for services provided in ED). Please see the following excerpt from the Benefit Index:

Excluded are services provided by dentists and oral surgeons for dental diagnoses, and anesthesia for dental care. (HO-BH Contract Exhibit A 3.6.3.6)

Covered through WA Medicaid Fee-For-Service for:

- 1) Children under age 21 through DSHS Fee-For-Service. (HCA Dental Related Services Medicaid Provider Guide)
- 2) Effective 7/1/11 verifiably pregnant women; aged and disabled adults age 21 and over residing in one of the following:



Department: Non-Behavioral Health Section: KPNW Region Applies to: KPNW Region Subject Matter Expert: Dana Smith, MD (ENT); Kelly Dezura, DMD; James Rapson, DDS	Number: UR 64 Effective: 01/2013 Reviewed: 1/14, 1/15, 2/16, 1/17, 1/18 Revised: 02/13
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- Nursing home.
  - Nursing facility wing of a state veteran’s home.
  - Privately operated intermediate care facility for the intellectually disabled (ICF/ID).
  - State-operated Residential Habilitation Center (RHC).
- 3) Effective 7/1/11 aged and disabled adults age 21 and over under an Aging and Disability Services Administration (ADSA) 1915 (c) waiver program.
  - 4) Effective 10/1/11 disabled adults age 21 and over under Division of Developmental Disabilities. (HCA Dental Related Services Medicaid Provider Guide page B.1)

**REFERENCES:**

Commercial Medical EOC EXCLUSIONS: Dental Services. Dental care including dental x-rays; dental services following accidental injury to teeth; dental appliances; dental implants; orthodontia; and dental services necessary for or resulting from medical treatment such as surgery on the jawbone and radiation treatment is limited to: (a) emergency dental services; or (b) extraction of teeth to prepare the jaw for radiation treatment.

The EOC also excludes “dental appliances and dentures” under DME section.

**NCQA**

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

**WASHINGTON**

NA

**OREGON**

ORS 743A.148 and 743.706

# Kaiser Permanente

## Transgender Surgery Utilization Management Clinical Guidelines

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### Internal & Outside Referral Guidelines:

Kaiser Foundation Health Plan (KFHP) provides Sexual Reassignment Surgery (SRS) for the treatment of patients with gender dysphoria who meet the medical criteria below.

Members whose employer groups do not cover Transgender Surgery but who wish to access these services out of pocket, will be evaluated according to the same medical criteria.

### Covered Sexual Reassignment Surgeries and Procedures:

**Male-to-Female (MtF):** Clitoroplasty, Intersex Surgery, Labiaplasty, Orchiectomy, Penectomy, Vaginoplasty. Tracheal Shave is covered when referred by a Gender Pathways provider. Coverage of facial hair removal, by electrolysis or laser, will be determined in accordance with the member's benefits when referred by a Gender Pathways provider.

**Female-to-Male (FtM):** Glansoplasty, Hysterectomy, Intersex Surgery, Mastectomy with Chest Reconstruction, Metoidioplasty, Mons Resection, Penile Implant, Phalloplasty, Salpingo-Oophorectomy, Scrotoplasty, Testicular Prosthesis, Urethroplasty, Vaginectomy.

### Genital Surgery Clinical Review Criteria:

Members are eligible for genital surgery coverage if they meet all of the following criteria:

1. Member is at least 18 years old; and
2. Member has been diagnosed with persistent, well-documented gender dysphoria, i.e.
  - a. Member experiences discomfort or distress that is caused by a discrepancy between person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics); and
  - b. Member's gender dysphoria is not due to a chromosomal disorder<sup>1</sup>; and
  - c. Member's gender dysphoria is not due to a psychiatric disorder (such as schizophrenia); and
3. Member has the capacity to make fully informed decisions and to consent to treatment; and
4. If significant medical or mental health concerns are present, they are well controlled; and
5. Member has completed a program of gender identity treatment, as evidenced by all of the following:
  - a. Member has undergone or is in the process of completing 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless the patient has a medical contraindication or is otherwise unable or unwilling to take hormones); and
  - b. Member has two referrals for SRS from qualified mental health professionals who have independently assessed the patient. If the first referral is from the patient's psychotherapist, the second referral should be from a person who has only had an evaluative role with the patient. Two separate letters, or one letter signed by both (e.g. if practicing within the same clinic) may be sent. For providers working within a multidisciplinary specialty team, a letter may not be necessary, rather, the assessment and the recommendation can be documented in the patient's chart. Each referral letter is expected to cover the following recommended content:
    - i. The client's general identifying characteristics
    - ii. Results of the client's psychosocial assessment, including any diagnoses;
    - iii. The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date;

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<sup>1</sup> Coverage for the treatment of gender dysphoria resulting from a chromosomal disorder is included in the member's

## **Kaiser Permanente**

### **Transgender Surgery Utilization Management Clinical Guidelines**

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- iv. An explanation that the criteria for surgery have been met, and a brief description of the clinical rationale for supporting the patient's request for surgery;
  - v. A statement about the fact that informed consent has been obtained from the patient;
  - vi. A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this; and
- c. FtM members requesting metoidioplasty or phalloplasty and MtF members requesting vaginoplasty must have undergone or be in the process of completing 12 continuous months of living in a gender role that is congruent with their gender identity.

#### **Mastectomies with Chest Reconstruction Clinical Review Criteria:**

FtM members are eligible for Mastectomies with Chest Reconstruction (areola tattooing, including touch-ups, are covered when the areola can't be salvaged and the tattooing is referred by a Gender Pathways provider) if they meet all of the following criteria:

1. Member is at least 18 years old\*; and
2. Member has been diagnosed with persistent, well-documented gender dysphoria, i.e.
  - a. Member experiences discomfort or distress that is caused by a discrepancy between person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics); and
  - b. Member's gender dysphoria is not due to a chromosomal disorder<sup>2</sup>; and
  - c. Member's gender dysphoria is not due to a psychiatric disorder (such as schizophrenia); and
3. Member has the capacity to make fully informed decisions and to consent to treatment; and
4. If significant medical or mental health concerns are present, they are reasonably well controlled; and
5. Member has one referral for breast/chest surgery from a qualified mental health professional who has independently assessed the patient. For providers working within a multidisciplinary specialty team, a letter may not be necessary; rather, the assessment and the recommendation can be documented in the patient's chart. The referral is expected to cover the following recommended content:
  - i. The client's general identifying characteristics
  - ii. Results of the client's psychosocial assessment, including any diagnoses;
  - iii. The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date;
  - iv. An explanation that the criteria for surgery have been met, and a brief description of the clinical rationale for supporting the patient's request for surgery;
  - v. A statement about the fact that informed consent has been obtained from the patient;
  - vi. A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this; and

\*For FtM members under the age of 18, chest surgery can be carried out on adolescents 16 years or older after ample time of living in the desired gender role and after one year of testosterone treatment. Adolescent FtM patients seeking chest surgery must also meet criteria 2-6 above and must have parental consent or be legally emancipated.

# Kaiser Permanente

## Transgender Surgery Utilization Management Clinical Guidelines

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### Surgical Revisions

Surgical revisions following gender-confirming surgery may be considered medically necessary if at least one of the following is true as determined by a physician board-certified in plastic surgery (or other specialty physician, as appropriate):

- Revision would result in improved function; OR
- Revision is likely to result in relief of pain associated with the gender confirming surgery; OR
- Revision is intended to change a physical appearance that is NOT within normal anatomic variation consistent with the member's gender identity.

Surgical revision of prior gender-confirming surgery will not be covered 1) when intended only to correct changes in form or symmetry that are due to natural processes, such as aging or changes in weight or 2) when determined by the reviewing physician to be necessary due only to deficiencies associated with the original surgery, in which case any revisions would be provider liability.

### Contributors/Clinical Experts

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Developed and approved by:	
Chair of Chiefs of Plastic Surgery 5/3/12	Chair of Chiefs of Urology 5/9/12
Chair of Chiefs of Psychiatry 5/3/12	APICs for Outside Services 6/15/12
Chair of Chiefs of Endocrinology 5/4/12	Quality Oversight Committee (QOC) 7/11/12
Chair of Chiefs of Internal Medicine 4/24/12	Resource Management Compliance Committee (RMCC) 6/26/12
Chair of Chiefs of Obstetrics & Gynecology 4/30/12	

### Definitions:

Male-to-Female SRS Procedures:	Female-to-Male SRS Procedures:
-Clitoroplasty: creation of clitoris -Labiaplasty: creation of labia -Orchiectomy: removal of testicles -Penectomy: removal of penis -Vaginoplasty: creation of vagina	-Glansoplasty: procedure to give the head of the neophallus the appearance of a genetic male glans -Hysterectomy: removal of uterus -Mastectomy: removal of the breasts -Metoidioplasty: creation of micro-penis using the clitoris -Mons resection: removal of excess skin to improve access and visibility of the penis -Penile implant: implantation of artificial penis -Phalloplasty: creation of penis, with or w/o urethra -Salpingo-Oopherectomy: removal of fallopian tubes and ovaries -Scrotoplasty: creation of scrotum -Testicular Prosthesis: implantation of artificial testes -Urethroplasty: creation of urethra w/in the penis -Vaginectomy: removal of vagina
Intersex surgery: genital reconstructive surgery including surgery performed for the purpose of transforming normal adult genitalia of one sex to that of the other (also referred to as sexual reassignment surgery)	

### References:

- *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7<sup>th</sup> Version*. The World Professional Association for Transgender Health (WPATH)

These criteria do not imply or guarantee approval. Please check your plan to ensure coverage. Preauthorization requirements are only valid for the month published. They may have changed from previous months, and may change in future months. JULY-18

## UR 66: Continued Access to Practitioners When Contract Ends

Department: QRM (custodian of policy)  
Section: Medical Operations  
Applies to: Network Practitioners  
Review Responsibility: Aimee Guardado, QRM

Number:  
Effective: 01/2008  
Reviewed: 1/10, 1/13, 5/16, 4/18  
Revised: 4/14  
Page: 1 of 4

### PURPOSE

- A.** To coordinate transitions in medical care across the delivery system when a primary or specialty care practitioner leaves the Kaiser Foundation Health Plan (KFHP) network or when a practitioner or provider contract is terminated.
- B.** This policy applies to primary care and specialty care physicians or medical groups in the network contracted by KFHP or Northwest Permanente Physicians and Surgeons, P.C. (NWP) to provide services to KFHP of the NW members.

### DEFINITIONS

**Active course of treatment:** A medically necessary situation in which discontinuity could cause a recurrence or worsening of the condition under treatment and interfere with expected outcomes. Examples include but are not limited to post-surgical care, acute illness recovery, or active treatment for an acute exacerbation of a chronic condition. The member is entitled to continuity of care with the terminating practitioner through the completion of the active course of treatment, but no longer than 120 days from the date of referral for continued access.

**Pregnancy:** The member is entitled to continuity of care after commencement of the second trimester of the pregnancy and may receive care until the later of the following dates: (a) the 45th day after the birth; or as long as she is under an active course of treatment, but not later than the 120th day after the date of referral for continued access.

**Contracted Provider:** Any licensed physician who is an employee of the Medical Group, or any licensed physician who, under a contract directly or indirectly with Company, has agreed to provide covered Services to Members with an expectation of receiving payment, other than Copayment or Coinsurance, from Company rather than from the Member.

### POLICY

When an individual practitioner contract or an entire group practice contract is terminated, KFHP ensures continuity of care for members. KFHP allows members continued access for a limited period of time under certain member and practitioner conditions as described in this policy.

KFHP allows continued access for members undergoing an active course of treatment for an acute episode of chronic illness or an acute medical condition through the current period of active treatment up to 120 days, and for those in the second or third trimester of pregnancy through postpartum care (45th day after birth), or as long as member is under active treatment, up to 120 days.

In all cases, continued access expires 120 calendar days from date of the request/referral for continued access.

These criteria do not imply or guarantee approval. Please check your plan to ensure coverage. Preauthorization requirements are only valid for the month published. They may have changed from previous months, and may change in future months. JULY-18

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## UR 66: Continued Access to Practitioners When Contract Ends

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Department: QRM (custodian of policy)  
Section: Medical Operations  
Applies to: Network Practitioners  
Review Responsibility: Aimee Guardado, QRM

Number:  
Effective: 01/2008  
Reviewed: 1/10, 1/13, 5/16, 4/18  
Revised: 4/14  
Page: 2 of 4

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- A.** This policy applies to the following providers:
- i.** NWP Primary Care Providers
  - ii.** NWP Specialty Care Providers
  - iii.** NWP Behavioral Health & Addiction Medicine Providers
  - iv.** Contracted Providers
- B.** This policy applies to the following members:
- i.** Members paneled to physicians for primary care
  - ii.** Members with > 2 visits in the past 12 months to applicable specialty care providers
  - iii.** Members in the 2nd or 3rd trimester of pregnancy
- C.** KFHP allows continued access when the provider meets all of the following criteria:
- i.** Continues practicing and remains in the Service Area
  - ii.** Holds an active unrestricted license
  - iii.** Agrees to continue to see KFHP members
  - iv.** Agrees to accept the prior contracted payment rate
  - v.** Has no attributed significant quality concerns or professional review actions
    - Determination of significant quality concerns shall be made by the Directors of Operations for Primary Care, Directors of Operations for Specialty Care or Regional Assistant Medical Director of Quality Management and Systems. Professional review actions are determined by the Regional Credentials Committee and Chiefs are notified.
- D.** The clinician who is willing to provide continued care must agree to the following conditions:
- i.** Continue member treatment based on transition plan goals.
  - ii.** Share information regarding the treatment plan with KPNW.
  - iii.** Continue to follow KPNW utilization management policies and procedures (all lab, imaging, and other support services must be provided at a KP facility; OB patients must deliver at a KP Plan hospital; inpatient admissions must be at Plan hospitals)
  - iv.** Not charge the patient an amount over member's current KPNW benefit co-pay.
- E.** The terminating practitioner is accountable to review the member panel or caseload to determine which members require specific transition care plans, assist members in making the transition to a new provider.
- F.** The departing practitioner is accountable to ensure a safe and effective handoff through communication and coordination of care.

### UR 66: Continued Access to Practitioners When Contract Ends

Department: QRM (custodian of policy)  
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 Effective: 01/2008  
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- G.** Assessment for continuity of care must be initiated at the member’s request, or by the treating provider on the member’s behalf.
- H.** The Regional Referral Center (RRC) allows continuation of any active referrals for the duration of the original referral and processes any new referrals required for continued access.
- I.** Kaiser Permanente customarily includes a contractual requirement to provide a minimum of 90 days’ notice for network physicians; NWP takes accountability for transitioning care for members during that 90 day period.

#### PROCEDURE

- A.** For NWP Primary Care Providers, see “Member Notification of Panel Changes P&P” and “Panel Management of Departing Provider P&P” for procedures used in ensuring safe and effective handoff of patients.
- B.** For NWP Specialty Care Providers, see Exit Checklist and Specialty Care Workflow.
- C.** For NWP Behavioral Health & Addiction Medicine Providers, see “Departing Prescriber –Caseload Management P&P”.
- D.** For contracted providers, the following steps are taken when a termination or resignation letter is received:

Responsible Party	Action
Provider Contracting /Relations	<ol style="list-style-type: none"> <li>1) Receives notification of termination from contracted individual practitioners or contracted group practices not employed by Northwest Permanente Physicians and Surgeons, P.C.</li> <li>2) Notifies NCSS (for claims) and Regional Referral Center (for auths)</li> <li>3) Requests from departing practitioner a plan to transition care for current referrals when necessary if he/she does not meet condition for continued access.</li> <li>4) Conducts departing provider’s continued access eligibility and advises <i>Regional Referral Center</i> to generate the appropriate notification letter.</li> </ol>
Regional Referral Center	<ol style="list-style-type: none"> <li>5) Generates list of affected members for mailing notification letter.</li> <li>6) Generates and mails to affected members appropriate letter depending on:</li> </ol>

### UR 66: Continued Access to Practitioners When Contract Ends

Department: QRM (custodian of policy)  
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Number:  
 Effective: 01/2008  
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	<p>a. Departing practitioner meets condition for providing continued care, generate “Continued Care Letter”</p> <p>b. Departing practitioner is <u>not</u> a candidate for continued access, generate “Member Notification Letter”</p>
Member Services/Call Center	<p>7) Anticipates calls from affected members and/or written request for continued access</p> <p>8) Refers to Continued Access Algorithm/Script</p> <p>9) Refers members to Member Relations for UM review</p>
Utilization Management	<p>10) For members whose departing provider meets condition for providing continued care, observes departmental process for eligibility review (see UR 4: Utilization Management Medical Necessity Determinations)</p> <p>11) For denied cases, sends denial notice to Member Relations</p>
Member Relations	<p>12) For denied cases, enters denial into CIDARS</p> <p>13) Generates and sends denial notification to the member</p>

#### References

**NCQA:** *National Committee for Quality Assurance, 2018 Health Plan Standards and Guidelines NET 5 Continued Access to Care, Element B- Continued Access to Practitioners.*

**OREGON:**

ORS 743.854 Continuity of Care, pages 342-343  
 RCW 48.43.515 – Access to Appropriate Healthcare Providers

**WASHINGTON:**

WAC 284-43-251 Covered person’s access to providers

**KPNW Related Work flows, Policies and Procedures:**

- Member Notification of Panel Changes Policies & Procedures
- Panel Management of Departing Provider Policies and Procedures
- UR4: Utilization Management Medical Necessity Determinations
- Specialty Care Work Flow and Transitional Care P&P
- Mental Health Departing Prescriber and Therapist – Caseload Management P&P
- Member Services Continued Access Algorithm/Script



Department: Non-Behavioral Health Section: KPNW Region Applies to: KPNW Region Subject Matter Expert: Dana Smith, MD (ENT); James Rapson, DDS; Kelly Dezura, DMD	Number: UR 67 Effective: 01/2013 Reviewed: 2/13; 1/14, 1/15, 1/16, 1/17, 1/18 Revised: 2/13, 3/18
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Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

## CRANIOFACIAL ANOMALIES POLICY and MEDICAL NECESSITY CRITERIA

The purpose of these criteria is to define KFHPNW coverage of limited dental and orthodontic services associated with congenital craniofacial anomalies when medically necessary to improve or restore function.

Oregon House Bill 4128 requires health benefit plans to provide coverage for dental and orthodontic services for the treatment of craniofacial anomalies if the services are medically necessary to improve or restore function.

Note that separate policies/criteria exist for coverage of:

1. Maxillofacial prosthetic services for treatment of maxillofacial anomalies (UR 64),
2. general anesthesia for dental procedures performed in an inpatient or ambulatory operating room (UR 56),
3. surgical interventions for temporo-mandibular disorders (UR 49).

### DEFINITIONS

Congenital: present at birth

Craniofacial Anomaly (as defined by Oregon House Bill 4128): a physical disorder identifiable at birth that affects the bony structures of the face or head, including but not limited to: cleft palate, cleft lip, craniosynostosis, craniofacial microsomia and Treacher Collins syndrome. It does not include:

- Temporomandibular joint disorder (TMJ)
- Developmental maxillofacial conditions that result in overbite, crossbite, malocclusion or similar developmental irregularities of the teeth.

**CRITERIA:** Dental and Orthodontic Services as part of a treatment plan for CRANIOFACIAL ANOMALIES are covered when ALL of the following criteria are met.

NOTE: When the patient has one of the diagnoses listed in criterion 1 (including attachment), a referral to the Craniofacial Clinic (for HMO members) will be authorized for the member's condition to be assessed. The KP multi-disciplinary Craniofacial Clinic team will make the clinical decision as to medical necessity and treatment plan that may include dental and orthodontic services necessary to improve or restore a physical function.

- 1) A congenital anomaly exists affecting the bony structures of the face or head which disrupts function and includes at least one of the following (see Attachment for more possible diagnoses):
  - Cleft palate and/or cleft lip
  - Craniosynostosis
  - Craniofacial microsomia
  - Mandibulofacial Dysostosis (Treacher Collins Syndrome)

Department: Non-Behavioral Health Section: KPNW Region Applies to: KPNW Region Subject Matter Expert: Dana Smith, MD (ENT); James Rapson, DDS; Kelly Dezura, DMD	Number: UR 67 Effective: 01/2013 Reviewed: 2/13; 1/14, 1/15, 1/16, 1/17, 1/18 Revised: 2/13, 3/18
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- 2) The indication for dental and/or orthodontic services is directly related to the craniofacial anomaly. The requested services are not related to treatment of a temporo-mandibular joint disorder or developmental maxillofacial condition resulting in an overbite, crossbite, malocclusion or similar developmental irregularity of the teeth.
  
- 3) Dental and/or orthodontic services for the treatment of craniofacial anomalies are medically necessary to improve or restore function.

### **SPECIAL GROUP CONSIDERATIONS**

OR/WA Commercial: Applies to all commercial groups

Oregon Medicaid: Mandate Not applicable to OR Medicaid; benefit coverage TBD

Added Choice/POS: members may directly access non-KP providers under their Tier 2 and Tier 3 benefits, without prior-authorization, for office visits that do not include a procedure. Procedures and levels of care other than office visits require prior-authorization.

Medicare: Applicable when related to Local Coverage Determination L11571 which requires coverage of facial prostheses when there is a loss or absence of **facial tissue** due to disease, trauma, surgery or a congenital defect.

Washington Medicaid: Mandate Not applicable to WA Medicaid: If services are provided by a dentist or oral surgeon for dental diagnoses they are covered through DSHS FFS. The exception to this would be in the ED (the health plan is responsible for services provided in ED). Please see the following excerpt from the Benefit Index:

Excluded are services provided by dentists and oral surgeons for dental diagnoses, and anesthesia for dental care. (HO-BH Contract Exhibit A 3.6.3.6)

Covered through WA Medicaid Fee-For-Service for:

- 1) Children under age 21 through DSHS Fee-For-Service. (HCA Dental Related Services Medicaid Provider Guide)
- 2) Effective 7/1/11 verifiably pregnant women; aged and disabled adults age 21 and over residing in one of the following:
  - Nursing home.
  - Nursing facility wing of a state veteran's home.
  - Privately operated intermediate care facility for the intellectually disabled (ICF/ID).
  - State-operated Residential Habilitation Center (RHC).
- 3) Effective 7/1/11 aged and disabled adults age 21 and over under an Aging and Disability Services Administration (ADSA) 1915 (c) waiver program.
- 4) Effective 10/1/11 disabled adults age 21 and over under Division of Developmental Disabilities. (HCA Dental Related Services, Medicaid Provider Guide page B.1)

Department: Non-Behavioral Health Section: KPNW Region Applies to: KPNW Region Subject Matter Expert: Dana Smith, MD (ENT); James Rapson, DDS; Kelly Dezura, DMD	Number: UR 67 Effective: 01/2013 Reviewed: 2/13; 1/14, 1/15, 1/16, 1/17, 1/18 Revised: 2/13, 3/18
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### REFERENCES:

COMMERCIAL Medical EOC EXCLUSIONS: Dental Services. Dental care including dental x-rays; dental services following accidental injury to teeth; dental appliances; dental implants; orthodontia; and dental services necessary for or resulting from medical treatment such as surgery on the jawbone and radiation treatment is limited to: (a) emergency dental services; or (b) extraction of teeth to prepare the jaw for radiation treatment. The EOC also excludes “dental appliances and dentures” under DME section.

#### Relevant part of **Limited Dental Services Exclusions**

The following dental Services are not covered, except where specifically noted to the contrary in the EOC:

- Extraction of teeth, except as described in the “Covered Dental Services” section.
- Orthodontics, except as described in the “Covered Dental Services” section.

#### Relevant part of **Covered Dental Services**

We cover dental Services only as described below:

- Dental and orthodontic Services for the treatment of craniofacial anomalies if the Services are Medically Necessary to improve or restore function.

### NCQA

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

### WASHINGTON

RCW 284-43-410 & RCW 483.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

WAC 246-855-010 Definition of Acupuncture.

### OREGON

ORS 743.804: Requirements to provide criteria and information about utilization management

ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party

ORS 743.807: Utilization review requirements for insurers offering health benefit plans

ORS 743.837: Prior authorization requirements

### CLINICAL:

**ATTACHMENT 1:** ICD 10 diagnosis codes for skull, facial and jaw anomalies.:

Department: Non-Behavioral Health Section: KPNW Region Applies to: KPNW Region Subject Matter Expert: Dana Smith, MD (ENT); James Rapson, DDS; Kelly Dezura, DMD	Number: UR 67 Effective: 01/2013 Reviewed: 2/13; 1/14, 1/15, 1/16, 1/17, 1/18 Revised: 2/13, 3/18
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### **ATTACHMENT 1**

#### **Cleft palate, not otherwise specified: Q35.9**

- Formerly ICD 9: 749.00 – 749.25

#### **Congenital anomalies/malformations of skull and face bones, not otherwise specified: Q75.0**

- Formerly ICD 9: 756.0
- This code applies to:
  - Absence of skull bones
  - Acrocephaly
  - Congenital deformity of skull or facial bones
  - Craniosynostosis
  - Crouzon's disease
  - Delayed closure of anterior fontanel
  - Goldenhar syndrome
  - Hypertelorism
  - Imperfect fusion of skull
  - Mandibulofacial dysostosis
  - Oculomandibular dysostosis
  - Oxycephaly
  - Platybasia
  - Premature closure of cranial sutures
  - Robin syndrome
  - Tower skull
  - Treacher Collins syndrome
  - Trigonocephaly

#### **Congenital deformities and asymmetry of skull, face, and jaw: Q67.0**

- Formerly ICD 9: 754.0

**These may or may not be congenital anomalies but will be evaluated further by the Craniofacial Clinic team.)**

- Unless otherwise specified below, this code applies to:
  - Compression facies **Q67.1**
  - Depressions in skull
  - Deviation of nasal septum, congenital
  - Dolichocephaly **Q67.2**
  - Plagiocephaly **Q67.3**
  - Potter's facies
  - Squashed or bent nose, congenital



## UR 68: Assisted Reproductive Technology (ART) Medical Necessity Criteria

Department: Non-Behavioral Health	Number: UR 68
Section: KPNW Region	Effective: 05/16
Applies to: KPNW Region	Reviewed: 05/16, 6/17, 5/18
Review Responsibility: Eric Warshaw, MD, OB/GYN	Revised:

### ASSISTED REPRODUCTIVE TECHNOLOGY MEDICAL NECESSITY CRITERIA

#### DEFINITIONS

ART- Assisted Reproductive Technology refers to procedures in which pregnancy is attempted through the manipulation of sperm and egg outside the body, such as in vitro fertilization (IVF) or gamete intra-fallopian transfer (GIFT).

IVF- In-vitro fertilization involves retrieving an egg from the woman, combining with sperm in a lab, observing and raising the embryos in the lab for 3 to 5 days, then transferring the resulting embryo back into her uterus.

GIFT- gamete intra-fallopian transfer is a modified version of in vitro fertilization (IVF). GIFT involves retrieving an egg from the woman, combining with sperm in a lab then immediately transferring the unfertilized egg and sperm into her fallopian tube with fertilization taking place in the fallopian tube instead of in a laboratory dish.

ZIFT- zygote intra-fallopian transfer is a modified version of in vitro fertilization (IVF). ZIFT involves retrieving an egg from the woman, combining with sperm in a lab then transferring the fertilized egg (called a zygote) into her fallopian tube before cell division takes place. The zygote is transferred the next day after fertilization occurs.

IUI- Intra-uterine insemination is the placement of washed and concentrated sperm via a catheter into a woman's uterus when she is ovulating. It is often combined with superovulation medicine to increase the number of available eggs, which can result in multiple gestation.

#### CRITERIA

**Assisted reproductive technology may be indicated when A-C below are present:**

A. Female 45 years or younger with use of autologous oocytes

1. Infertility, as defined by **1 or more** of the following:

- a) Failure to conceive after regular unprotected sexual intercourse for 1 year or more for female 35 years or younger
- b) Failure to conceive after regular unprotected sexual intercourse for 6 months or more for female older than 35 years
- c) Female with cancer chemotherapy-induced ovulatory failure (eg, from cyclophosphamide)
- d) Female with history of bilateral oophorectomy

- e) Female with impending infertility due to planned cancer treatment for cure (eg, chemotherapy or oophorectomy)
  - f) Male partner is HIV positive and **ALL** of the following:
    - i. Adherent with highly active antiretroviral therapy
    - ii. Washed sperm needed for insemination to prevent HIV transmission to female partner
  - g) Male partner with infertility due to cancer therapy (eg, orchiectomy or chemotherapy)
  - h) Male partner with nonobstructive azoospermia or severe oligospermia
  - i) Male partner with paraplegia, and sperm retrieval needed to achieve pregnancy (eg, electro-ejaculation or surgical sperm retrieval)
  - j) Prior failed cycle of in vitro fertilization or intracytoplasmic sperm injection
2. Infertility evaluation and treatment performed, as indicated by **1 or more** of the following:
- a) Female with impending infertility due to planned cancer treatment for cure (eg, chemotherapy or oophorectomy)
  - b) Female with infertility due to oophorectomy or cancer treatment and **ALL** of the following:
    - i. No evidence of tumor recurrence, as indicated by **1 or more** of the following:
      - Two years or more after completion of cancer treatment for gynecologic tumors
      - Two years or more after completion of hematopoietic stem cell transplant
      - Three years or more after initial diagnosis in female with breast cancer without axillary lymph node involvement
      - Five years or more after initial diagnosis in female with breast cancer with axillary lymph node involvement
      - After completion of adjuvant tamoxifen, if appropriate, for breast cancer
    - ii. Patient had embryo or oocyte cryopreservation prior to oophorectomy or cancer treatment.
  - c) Hysterosalpingogram shows absent or nonpatent fallopian tube (eg, from prior ectopic pregnancy or pelvic inflammatory disease)
  - d) In vitro fertilization or intracytoplasmic sperm injection needed, as indicated by **1 or more** of the following:
    - i. Cryopreserved sperm needed from male partner (eg, after chemotherapy)
    - ii. Prior in vitro fertilization or intracytoplasmic sperm injection cycle resulted in failed fertilization or pregnancy
    - iii. Surgical sperm retrieval needed for azoospermia or severe oligospermia in male partner
  - e) Treatment for infertility, including specific disorders, as indicated by **1 or more** of the following:
    - i. Anovulatory female without polycystic ovary syndrome or other endocrinopathy and **1 or more** of the following:
      - For female 34 years or younger: trial of at least 4 cycles of clomiphene citrate or letrozole and intrauterine insemination
      - For female 35 to 37 years of age: trial of at least 3 cycles of clomiphene citrate or letrozole and intrauterine insemination
      - For female 38 years or older: proceed with in vitro fertilization or 2-3 cycles of intrauterine insemination without gonadotropin.

- ii. Endocrinopathy in female (eg, hypothyroidism, adrenal disorders, pituitary tumor)
  - iii. Endometriosis
  - iv. Failure of 12 cycles of intrauterine insemination
  - v. Hypogonadotrophic hypogonadism in male partner
  - vi. Intrauterine pathology (eg, adhesions, polyps)
  - vii. Pelvic adhesions
  - viii. Polycystic ovary syndrome, treated with **ALL** of the following:
    - Other causes of infertility ruled out or treated (eg, thyroid disease, hyperprolactinemia, male factor infertility)
    - Treated with at least 6 cycles of clomiphene citrate or letrozole
  - ix. Repair of varicocele in male partner
  - x. Retrograde ejaculation in male partner treated with pharmacotherapy
  - xi. Submucosal leiomyomas
  - xii. Tubal anastomosis (ie, reversal of tubal ligation)
- f) Unexplained infertility and **ALL** of the following:
- i. Conventional treatment of unexplained infertility has failed, as indicated by **1 or more** of the following:
    - For female 34 years or younger: trial of at least 4 cycles of controlled ovarian stimulation (eg, clomiphene citrate or letrozole ) and intrauterine insemination
    - For female 35 to 37 years of age: trial of at least 3 cycles of controlled ovarian stimulation (eg, clomiphene citrate or letrozole) and intrauterine insemination
    - For female 38 years or older: proceed with in vitro fertilization or 2-3 cycles of intrauterine insemination without gonadotropin.
  - ii. Normal female serum levels of **ALL** of the following:
    - Anti-Mullerian hormone
    - Estradiol
    - FSH
    - Progesterone (in midluteal phase)
    - Prolactin
    - TSH
  - iii. Normal hysterosalpingogram or sonohysterography
  - iv. Normal sperm count, motility, and morphology in male partner

3. **1 or more** of the following:

- a) Embryo cryopreservation needed for impending infertility due to planned cancer treatment
- b) Maximum number of embryos to be transferred is consistent with current evidence to limit risk of multiple-birth pregnancies, as indicated by **1 or more** of the following:
  - i. One fresh or frozen single-embryo transfer for female 36 years or younger during first 3 in vitro fertilization cycles
  - ii. Up to 2 fresh or frozen embryos transferred for female 36 years or younger after first 3 failed single-embryo transfer in vitro fertilization cycles
  - iii. One fresh or frozen single-embryo transfer for female 37 years of age during first in vitro fertilization cycle

- iv. Up to 2 fresh or frozen embryos transferred for female 37 years of age after first failed in vitro fertilization cycle
- v. Up to 2 fresh or frozen embryos transferred for female 38 years of age if prognosis is favorable and/or additional embryos are available for cryopreservation
- vi. Up to 3 fresh or frozen embryos transferred for female 38 years of age if prognosis is unfavorable and no additional embryos are available for cryopreservation
- vii. Up to 3 fresh or frozen embryos transferred for female 39 to 40 years of age if prognosis is favorable and/or additional embryos are available for cryopreservation
- viii. Up to 4 fresh or frozen embryos transferred for female 39 to 40 years of age if prognosis is unfavorable and no additional embryos are available for cryopreservation
- ix. Up to 5 fresh or frozen embryos transferred for female 41 to 45 years of age

B. No hydrosalpinx or after treatment with tubal occlusion or salpingectomy

C. No prior in vitro fertilization cycle, or maximum number of prior in vitro fertilization cycles has not exceeded a total of 6 cycles without a live birth

#### **SPECIAL GROUP CONSIDERATIONS**

ART is typically excluded from coverage. Check CM for exceptions.



## UR 69: Orthognathic Surgery Medical Necessity Criteria

Department: Non-Behavioral Health Section: KPNW Region Applies to: KPNW Region Review Responsibility: Kelly Dezura, DMD; Alexis Kleinman, DMD	Number: UR 69 Effective: 01/2017 Reviewed: 03/17, 3/18 Revised:
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### ORTHOGNATHIC SURGERY MEDICAL NECESSITY CRITERIA

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

#### PURPOSE

The purpose of these criteria is to define KFHPNW coverage for orthognathic surgery to treat a limited number of medical conditions, as mandated by WAC 284-43-5640.

#### DEFINITIONS

Orthognathic Surgery- the surgical correction of abnormalities of the mandible and/or maxilla. The underlying abnormality may be present at birth or may become evident as the patient grows and develops or may be the result of traumatic injuries.

Malocclusion- imperfect positioning of the teeth when the jaws are closed. The condition may also be referred to as an irregular bite, crossbite, or overbite.

Congenital- a condition present at birth such as a cleft lip or cleft palate.

#### CRITERIA

Orthognathic surgery and supplies are covered for any of the following:

- 1) conditions resulting from TMJ (temporomandibular joint) disorder or injury including post traumatic skeletal malocclusion which is not amenable to orthodontic therapy alone such as a skeletal malocclusion which resulted from TMJ arthritis, ankylosis, trauma or tumor.
- 2) sleep apnea with a referral from the Sleep Medicine department. Patient must have documented severe OSA (obstructive sleep apnea) or the patient has documented mild-moderate OSA with severe symptoms (based on Epworth Sleepiness Scale) with an identifiable dentofacial deformity such as maxillary or mandibular hypoplasia. Patient is also either intolerant or unable to use CPAP.
- 3) a congenital anomaly with a referral from the Cranio-facial Clinic.

Orthognathic surgery to treat other developmental skeletal malocclusions is not covered.

## **SPECIAL GROUP CONSIDERATIONS**

Although this is a WA State mandate, the coverage criteria will be universally applied to all lines of business beginning 1/1/17 except as follows:

Washington and Oregon Medicaid- these criteria do not apply to Medicaid.

Added Choice/POS: members may directly access non-KP providers under their Tier 2 and Tier 3 benefits, without prior-authorization, for office visits that do not include a procedure. Procedures and levels of care other than office visits require prior-authorization.

## **REFERENCES**

WAC 284-43-5640; Essential health benefit categories, section (3)b,iii,B

## UR 70: Extenuating Circumstances related to Pre-Authorization

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Department: Non-Behavioral Health	Number: UR 70
Section: KPNW Region	Effective: 01/18
Applies to: KPNW Region	Reviewed: 10/17
Review Responsibility: UROC	Revised:
Initial Author: Kathy Fazio, RN	

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These extenuating circumstances around pre-authorization and admission notification are based on the Best Practice Recommendations (BPR) put forth by the Washington Healthcare Forum operated by OneHealthPort but are applicable to all lines of business in Oregon and Washington.

### Summary:

It is recognized that there are a number of extenuating circumstances where providers are not able to request a pre-authorization prior to treating the patient and/or to notify the health plan within a pre-defined time period of the patient's admission. If/when these circumstances occur, the recommended best practices will be followed so that claims and related appeals will be processed AS IF a pre-authorization had been requested or admission notification had been submitted within the required time period. *Benefit coverage and medical necessity will still be evaluated for the service(s) requested.*

### Extenuating Circumstances:

The circumstances below outline a number of extenuating situations when providers are not able to contact a patient's health plan prior to treating a patient and/or within a pre-defined period of the patient's admission. In these situations, claims will not be automatically denied for lack of timely admission notification (e.g. 24 hours) or for lack of prior-authorization as long as the services are covered benefits for the patient and meet Kaiser Permanente's criteria for medical necessity.

- I. Unable to Know Coverage
- II. Unable to Anticipate Service
- III. Inherent Components
- IV. Misinformation
- V. Delayed Notification

## NOTES:

- Any service for which a pre-authorization was previously denied for that patient does not qualify as an extenuating circumstance.
- Medical necessity criteria and benefit coverage *must be* met even in cases of extenuating circumstances. Only the prior authorization requirement does not need to be met in these circumstances.

### I. Unable to Know Coverage

These are circumstances where the provider organization made every reasonable attempt but were unable to ascertain the responsible health plan so that any pre-authorization requirements, including admission notification, could be known or met.

In these circumstances, the provider organization does not have current insurance information on file for the patient and are unable to get correct insurance information from the patient. As such, it is impossible for providers to request a pre-authorization or to notify the health plan of admission.

The possible scenarios are:

- A. The patient is unable to tell the provider about their insurance coverage before treatment. Acceptable reasons may include:
  1. Psychiatric, trauma or unresponsive patients
  2. Child needing immediate medical attention, not attended by parent
  3. Non-English speaking patients and a translator cannot be obtained in a timely manner.
- B. The patient initially indicated that they were self-pay and that no medical coverage was in place at time of treatment. It was later determined that medical coverage was actually in place or that the patient was retroactively enrolled.
- C. The provider asked the patient about current coverage prior to the service, the patient provided current insurance coverage information and the **provider verified that the coverage was in force at time of treatment**. After the patient was treated, it was discovered that another health plan is primary and is responsible for coverage.
- D. The patient falsely posed as another individual using that individual's health information as coverage for services. Coverage was verified. After the patient is treated, the provider discovers that the patient either had other or no insurance

'Unable to Know Coverage' situations **DO NOT INCLUDE**:

When the provider was able to communicate with the patient prior to giving treatment, but insurance coverage information was not obtained and/or was not verified prior to the service(s). (The provider may have had insurance information on file for the patient

and assumed it was still in force, or may have copied the patient's insurance card but not verified it). The provider later discovered that the coverage was not in force.

Providers are expected to verify each time that the patient's current insurance information is obtained from the patient by asking the following questions:

- a. What is the current insurance coverage for this patient?
- b. Are there any other insurance coverages for this patient, e.g multiple employers, multiple responsible parties, etc.?
- c. What are the birthdates of both parents?

## II. Unable to Anticipate Procedure

Defined as circumstances where the provider, prior to seeing the patient, could not anticipate the need for a procedure requiring a pre-authorization and any delay in the delivering the procedure in order to obtain an authorization would adversely impact the health of the patient.

Procedure is defined as a treatment, e.g. injection, medication, limb support or a diagnostic test such as imaging or biopsy

### A. In the course of an office visit:

The patient made an appointment with a provider and the need for any service except the consultation was not known at that time. In the course of the visit, the provider determines the need for an in-office procedure to be urgent or non-urgent-time-sensitive (see definitions below). That procedure is then provided in the course of the office visit and/or the patient is referred to another provider for the urgent/time-sensitive procedure. The secondary provider may also determine the need for an alternative/additional urgent/time-sensitive procedure.

#### 1. A procedure is ‘**urgent**’ if not providing the care would:

- Seriously jeopardize the life or health of the patient,
- Seriously jeopardize the patient's ability to regain maximum function,
- Subject the patient to severe pain that cannot be adequately managed without the care or treatment that is the subject of the request.

#### 2. A procedure is ‘**non-urgent-time-sensitive**’ when:

- Not providing the care would adversely impact the quality of health of the patient, e.g. pain/restricted function, etc,
- Extending the timeframe for diagnostic confirmation/care coordination of a suspected acute condition would compromise health outcomes,
- The patient would incur excessive travel and/or expense to return to obtain the service.

These services might include but are not limited to curative, rehabilitative or palliative actions whose clinical effectiveness largely depends on time-sensitive intervention.

Clarifying Note: The following are possible examples of applicable procedures:

- Joint injection for pain, biopsy, imaging and/or limb support.
- A change in treatment or medication where delay could diminish clinical outcome.

- B. In the course of a performing a procedure (which may or may not require pre-authorization), a different procedure or the need for an add-on procedure is clinically indicated. That newly indicated procedure requires pre-authorization.

This scenario is only considered an Extenuating Circumstance if the newly indicated procedure is performed at the time of the original procedure or on the same day.

Both Unable to Anticipate circumstances (A & B) DO NOT INCLUDE:

- When the provider performs a procedure or provides a service that is considered experimental or investigational.
- When the service is scheduled for provider convenience rather than for clinical need.
- When the service does not meet benefit coverage or medical necessity criteria.

### **III. Inherent Component Services**

These are circumstances where the provider obtained a pre-authorization for at least one service in an inherently related set of services but not for other inherently related services in the set.

Some services have multiple inherent components (see DEFINITION below). In some cases, pre-authorization is required for each component. In these cases:

When pre-service review is requested by a provider and, at the time of review (based on regulatory timelines consistent with the submitted requests), the health plan determines that one or more inherent components of a service for which separate pre-authorization or medical necessity review is absent, the health plan will contact the provider to determine if all component services were submitted. The preferred method is phone or electronic notification.

There may be situations when, at the time of a pre-service review, the provider did not include all inherent component services AND the health plan did not notice the absent components. Later, at the time of post-service medical necessity review, the health plan may notice that a pre-authorization was obtained for only a subset of the inherent components that were submitted on a claim. In these cases, the health plan will not deny the added inherent component service(s) for lack of pre-authorization.

An **inherent component** extenuating circumstance is when the health plan denies, for lack of pre-authorization, one or more services within an inherent component set when at least one of the services in the set had been pre-authorized.

**DEFINITION:** Inherent component services – where one service is an essential attribute of another, i.e. one can't be provided without the other. Examples might include:

- an infused/injectable medication and the service to administer that medication,
- a device and the procedure related to implanting the device,
- a sleep study and the interpretation of the study,
- the placement of a drainage tube and the radiological guidance,
- Hyperbaric oxygen under pressure and the physician supervision.

**IV. Mis-information**

These are circumstances where the provider organization can demonstrate that a health plan representative and/or the health plan's web site gave inaccurate information about the need for a pre-authorization or admission notification.

**V. Delayed Notification**

These are circumstances when the health plan's decision/notification took longer than the timeframes required by overseers and the provider can demonstrate that they met all of their supporting documentation and timeframe requirements in submitting requested information, i.e. the service was provided after the pre-authorization was requested and the notification timeframes had passed, but before a pre-auth notification decision was given to the provider.

Providers will provide the following documentation to support the Extenuating Circumstance.

<b>Extenuating Circumstance</b>	<b>Documentation from provider organization</b>
I. Unable to Know Coverage	Identify extenuating circumstance condition that applies from section I. above along with appropriate documentation to support attempts made to determine coverage, and response from other health plan(s) that were queried, e.g. below as appropriate to the circumstance: <ul style="list-style-type: none"> <li>• Dated documentation, e.g. admission face sheet, obtained at the time of service indicating:               <ul style="list-style-type: none"> <li>○ The insurance information provided by the patient/representative</li> <li>○ The patient's/representative's inability to provide insurance information</li> <li>○ The patient's/representative's reporting self pay,</li> </ul> </li> <li>• Verification of no Medicaid coverage (ProviderOne result) at the time of inquiry (though eligibility at date of service was later confirmed),</li> </ul>

Extenuating Circumstance	Documentation from provider organization
	<ul style="list-style-type: none"> <li>• Dated documentation obtained at time of service showing eligibility confirmation from another payer, e.g. web eligibility screen shot or copy of electronic eligibility confirmation, AND/OR that payer's EOB denying the service as not eligible for coverage (e.g. denied due to alternate primary coverage).</li> </ul>
<p>II. Unable to Anticipate Service</p> <p>In the course of an office visit (or referred-to visit)</p>	<p>Identify clinical rationale that applies.</p> <p>Applicable office visit chart note for either the date of service or the referral along with other clinical documentation (as needed), e.g. diagnosis, H &amp; P, failed alternative treatment(s), or interim/alternative treatment(s) as appropriate, indicating the medical necessity for the procedure and the rationale for providing the procedure at that time without prior authorization, i.e. procedure is time sensitive. The treatment decision and the supporting document may be submitted by the provider and/or the referred-to provider, as appropriate, as outlined in section II. A. above.</p>
<p>V. Delayed Notification</p>	<p>Identify that supporting documentation and timeframe requirements associated with a pre-authorizations request were met.</p> <p><u>Timely submission of pre-authorization request and support documentation</u></p> <ul style="list-style-type: none"> <li>• Documentation indicating the date that the pre-authorization request was made and any faxes where supporting information was provided, AND/OR</li> <li>• Documentation of a call to the health plan to provide information, including if available, a reference number, time of call and name of who was spoken with and what was discussed, AND/OR</li> <li>• Evidence of mailed-in documentation in form of tracking number or postage stamp date.</li> </ul> <p><u>Non-timely documentation request or decision notification from health plan</u></p> <p>Documentation (e.g. dated office phone log or dated electronic submission.) indicating that a request for supporting documentation and/or a decision notification was not received (timely) from the health plan.</p> <p><u>Timely verification of status of the pre-auth request</u></p> <p>Documentation that the status of the request was checked within the decision timeframe to determine if information submitted by the provider, and the web site shows no indication of outstanding actions or documentation required of the provider.</p>

Note: Submission of the above referenced documentation does not guarantee payment. Even if the Extenuating Circumstance applies, the service is subject to benefit coverage and medical necessity.



The health plan's post-service decision-making/notification process will be completed within the regulatorily required timeframe of notification of the extenuating circumstance by the provider. In addition to assessing the extenuating circumstance, the health plan will conduct a benefit coverage review and a medical necessity review and will inform the provider of the result, via phone, fax and/or letter.

If the provider submits a claim for the service prior to the health plan completing this process, the claim may be denied for lack of pre-authorization.

If the provider's claim is denied for lack of pre-authorization, the provider may request an appeal of the denial. Once an Appeal has been initiated, the health plan's decision-making/notification process will be completed within the states' required timeframes for post-service review.

If providers follow the above process related to extenuating circumstances, the health plan will process the service AS IF a pre-authorization had been requested prior to service delivery or notification of admission was given within the specified time period of admission, e.g. 24 hours. Services will be subject to benefit coverage and medical necessity.

#### **SPECIAL GROUP CONSIDERATIONS**

No special group considerations

#### **REFERENCES**

WAC 284-43-2060 Extenuating circumstances in prior authorization.

## EPIDURAL STEROID INJECTIONS

**Policy Number: 0001**

**Effective Date: Jan 20 2015**

**Reviewed Date: June 19 2017**

**Next Review: June 19 2018**

### BACKGROUND

#### **CLINICAL BACKGROUND** (*excerpted directly from Hayes 2013*)

“Approximately 25% of the adults in the United States reported low back pain in the past 3 months (Deyo et al., 2006), and low back pain is a global health issue that is likely to increase over future decades (Hoy et al., 2012). In addition, sciatica, or leg pain originating from injury to or pressure on the sciatic nerve, is also a common cause of pain and disability, with reports of this condition ranging from 1.2% to 43% of patients with low back pain (Konstantinou and Dunn, 2008; Lewis et al., 2011). According to some estimates, the total annual economic cost for patients with low back pain in the United States approaches \$100 billion (Crow and Willis, 2009).

Despite the increased sensitivity of diagnostic tools in detecting abnormalities in the structures of the lumbar spine, the cause of back pain may remain unknown in many patients. However, if back pain is not due to malignancy or underlying infection, 90% of patients will experience symptom resolution in  $\leq 2$  months. Causes that are identified include herniation of a lumbar intervertebral disc and spinal stenosis, or narrowing of the spinal canal (Valat et al. 2010; Jacobs et al., 2011). Conservative treatments for low back pain and sciatica include rest, analgesics, and anti-inflammatory medications; physical therapy; and advice regarding posture and exercise (Manchikanti et al., 2012a).

If symptoms persist, injections of local anesthetics and/or steroids along the nerve root or into the epidural space can provide a nonsurgical treatment option for some patients. Since low back pain and sciatica may also be due to other potentially serious spinal conditions, such as spinal tumor, infection, fracture, or cauda equina syndrome, these conditions must be ruled out based on medical history, physical examination, and laboratory and imaging studies before epidural steroid injections (ESIs) are considered (WebMD Medical Reference, 2012).

The rationale for the use of ESIs to treat low back pain and sciatica rests on the idea that steroids reduce inflammation and decrease pain by inhibition of inflammatory mediators such as phospholipase A2, stabilization of hyperexcitable nerve membranes, and reduction of capillary permeability.

Delivery of steroids directly into the epidural space exposes the spinal nerve roots to higher concentrations of medications for a longer period of time than systemic administration. Although positive reports of pain reduction by ESIs have led to widespread acceptance and prescription of this treatment, some studies have suggested that steroids do not provide additional pain relief beyond the anesthetic that is typically included in ESIs, and safety concerns have been raised (Price et al., 2005; Abdi et al., 2007).”

### POLICY AND CRITERIA

#### **For patients initiating epidural steroid treatment**

The patient may receive up to 2 epidural steroid injections at least 2 weeks apart to determine adequacy of response if the following criteria are met:

- A) The patient has neck or back pain with a radicular component, AND

- B) Pain has been present for at least 1 month duration without improvement despite medical treatment OR has severe radicular pain from an acute disc herniation, AND
- C) The patient has none of the following contraindications for epidural steroid injection:
  - a. Use of Coumadin or platelet inhibitors, or other signs of compromised blood clotting status
  - b. Local site infection
  - c. Ongoing infection (acute viral or bacterial illness)
  - d. Patient refusal
  - e. Allergy to steroid or anesthetics

Additional injections for patients not experiencing at least 50% reduction in pain during the 6 weeks following the first injection are not medically necessary.

**For patients with documented prior positive response**

- D) The patient has experienced a documented reduction in pain of at least 50% during the 6 weeks following the previous injection; AND
- E) The patient has NOT received an epidural steroid injection within the previous 6 weeks for the same pain; AND
- F) The patient has NOT received 3 epidural steroid injections within the last year for the same pain.

Repeat injections extending beyond 12 months will be reviewed for continued medical necessity.

**RATIONALE**

**EVIDENCE BASIS**

“For radiculopathy due to herniated lumbar disc, evidence on benefits of epidural steroid injection is mixed, with some trials finding moderate short-term benefits and others finding no differences. There is no convincing evidence that epidural steroids are associated with long-term benefits and most trials found no reduction in rates of subsequent surgery. For nonradicular low back pain, there is likewise no convincing evidence that injections and other interventional therapies are effective, while there is consistent evidence that facet joint steroid injection, prolotherapy and intradiscal steroid injections are no more effective than sham therapies.” (HERC 2012)

“For radiculopathy due to herniated lumbar disc, evidence on benefits of epidural steroid injection is mixed. Although some higher-quality trials found epidural steroid injection associated with moderate short-term (through up to 6 weeks) benefits in pain or function, others found no differences versus placebo injection. Reasons for the discrepancies between trials is uncertain, but could be related to the type of comparator treatment, as trials that compared an epidural steroid injection to an epidural saline or local anesthetic injection tended to report poorer results than trials that compared epidural steroid injection to a soft-tissue (usually interspinous ligament) placebo injection. Regardless of the comparator intervention, there is no convincing evidence that epidural steroids are associated with long-term benefits and most trials found no reduction in rates of subsequent surgery. Although serious complications following epidural steroid injection are rare in clinical trials, there are case reports of paralysis and infections. There is insufficient evidence on clinical outcomes to recommend a specific approach for performing epidural steroid injection, or on use of fluoroscopic guidance. In addition, insufficient evidence exists to recommend how many epidural injections to perform, though one higher-quality trial found that if

an initial epidural steroid injection did not result in benefits, additional injections over a 6-week period did not improve outcomes.” (HERC 2012)

“There is insufficient evidence to guide specific recommendations for timing of epidural steroid injection, though most trials enrolled patients with at least subacute (greater than 4 weeks) symptoms. Evidence on efficacy of epidural steroid injection for spinal stenosis is sparse and shows no clear benefit, though more trials are needed to clarify effects. Although chymopapain chemonucleolysis is effective for radiculopathy due to herniated lumbar disc, it is less effective than discectomy and is no longer widely available in the United States, in part due to risk of severe allergic reactions. Three trials suggest that intradiscal steroid injection has similar efficacy to chemonucleolysis, although none were placebo controlled.” (HERC 2012)

“For local injections, there is insufficient evidence to accurately judge benefits because available trials are small, lower-quality, and evaluate heterogeneous populations and interventions. Trials of IDET and radiofrequency denervation reported inconsistent results. There were a small number of higher quality trials, and in the case of radiofrequency denervation, the trials had technical or methodologic shortcomings, making it difficult to reach conclusions about benefits. For other interventional therapies, data are limited to one to two small placebo-controlled randomized trials (botulinum toxin injection, epidural steroid injection for nonradicular low back pain, PIRFT and sacroiliac joint steroid injection), or there are no placebo-controlled randomized trials (therapeutic medial branch block, coblation nucleoplasty....or other medications). (HERC 2012)

### **RELEVANT GUIDELINES**

In guidelines issued by the American Society of Interventional Pain Physicians (ASIPP), patients may receive diagnostic injections (no more than two) at least one week apart (preferably two). If patients experience at least a 50% reduction in pain, they are eligible for therapeutic injections, to be provided every two to three months if there is evidence of at least 8 weeks of at least 50% pain relief. (ASIPP 2009).

### **CODES**

<b>CPT Code</b>	<b>Description</b>
62310	Injection, single (not via indwelling catheter), not including neurolytic substances, with or without contrast (for either localization or epidurography), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), epidural or arachnoid; cervical or thoracic
62311	Injection, single (not via indwelling catheter), not including neurolytic substances, with or without contrast (for either localization or epidurography), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), epidural or arachnoid; lumbar, sacral (caudal)
64479	Injection, anesthetic agent and/or steroid, transforaminal epidural, cervical or thoracic, single level
64480	Injection, anesthetic agent and/or steroid, transforaminal epidural; cervical or thoracic, each additional level
64483	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level
64484	Injection(s), anesthetic agent and/or steroid, transoframinal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional level (List separately in addition to code for primary procedure)
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural, subarachnoid, or sacroiliac joint), including neurolytic agent destruction
77012	Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation
J1020	Injection, methylprednisone acetate, 20mg

J1030	Injection, methylprednisone acetate, 40mg
J1040	Injection, methylprednisone acetate, 80mg

ICD-10 Code	Description
M47.20 – M47.28	Other spondylosis with radiculopathy
M50.10 – M50.13	Cervical disc disorder with radiculopathy
M51.14 – M51.17	Intervertebral disc disorders with radiculopathy
M53.0 – M53.1	Cervicocranial – cervicobrachial syndrome
M53.81 – M53.83	Other specified dorsopathies [cervical region]
M54.10 – M54.18	Radiculopathy
M54.2	Cervicalgia
M54.30 – M54.5	Sciatica and lumbago
M54.6	Pain in thoracic spine
M54.9	Dorsalgia, unspecified

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## VISCOSUPPLEMENTATION (INTRA-ARTICULAR HYALURONIC ACID INJECTIONS) FOR OSTEOARTHRITIS OF THE KNEE

**Policy Number: 0002**

**Effective Date: Feb 17 2015**

**Reviewed Date: June 19 2017**

**Next Review: June 19 2018**

### BACKGROUND

#### **CLINICAL BACKGROUND** *(excerpted directly from HERC 2014)*

Osteoarthritis (OA) is the most common form of chronic articular disease, affecting approximately 27 million adults in the United States. The most commonly affected joint is the knee, with prevalence estimates ranging from 12% to 16%. To date, there is no known cure for OA nor is there a disease-modifying agent. Optimal management generally requires a combination of both nonpharmacological and pharmacological therapies, and joint replacement surgery or a joint salvage procedure may be considered for selected patients with severe symptomatic OA who have not obtained adequate pain relief and functional improvement from medical therapy. Pharmacological therapy generally begins with acetaminophen, followed by nonsteroidal anti-inflammatory drugs (NSAIDs) if sufficient pain relief is not obtained. There is a small risk of systemic adverse effects with NSAIDs. Aspiration of fluid followed by intraarticular injection of a corticosteroid ameliorates pain in some patients, but duration of relief is usually limited to one to three weeks. Additionally, repeated intraarticular injections of corticosteroids have the potential to cause postinjection flare, infection, and progressive, long-term cartilage damage.

Recently, viscosupplementation with hyaluronan has been introduced as an alternative intraarticular injection therapy for OA. Hyaluronans are also known as sodium hyaluronate or hyaluronic acid (HA). Hyaluronic acid is a normal component of synovial fluid and cartilage. The viscous nature of the compound allows it to act as a joint lubricant, whereas its elasticity allows it to act as a shock absorber. Hyaluronic products are characterized by their molecular weight, which varies according to the source of the compound and method of preparation. Five HA products are currently marketed in the United States: Euflexxa® (Ferring), Hyalgan® (SanofiAventis), Orthovisc® (Anika Therapeutics), Supartz® (Seikagaku Corporation), and Synvisc® (Genzyme). Synvisc is a derivative of HA that consists of cross-linked polymers; the compound is referred to as Hylan G-F 20. Hyaluronate preparations have been approved by the Food and Drug Administration (FDA) for treatment of pain associated with OA of the knee in patients who have not had an adequate response to nonpharmacological, conservative treatment and simple analgesics.”

### POLICY AND CRITERIA

Intra-articular hyaluronic acid injections for osteoarthritis of the knee have not been found to be more effective than conventional treatment, and are therefore considered not medically appropriate.

### RATIONALE

#### **EVIDENCE BASIS**

The Kaiser Permanente Interregional New Technologies Committee reviewed the evidence on viscosupplementation in 2012. Their findings and conclusions were as follows:

“The current body of evidence on single treatment course of viscosupplementation for osteoarthritis of the knee consisted of over 60 RCTs including over 9000 patients derived from 9 systematic reviews and/or meta-analyses. Findings from available assessments and systematic reviews found positive

results in favor of viscosupplementation compared to placebo. One recent review including 54 RCTs with a total of 7545 patients found IA-HA to be effective at 4 weeks, reaches peak effectiveness at 8 weeks and exert a residual effect at 24 weeks post-treatment compared to placebo.<sup>1</sup> Another review of 7 RCTs including a total of 606 patients found that corticosteroids were more effective than HAs in the short-term (up to 4 weeks), whereas HAs may be more effective in the long-term (4 – 26 weeks).<sup>2</sup> Two RCTs published subsequent to the reviews reported mixed results with one study finding significant pain reduction and patient's global assessment improvement in favor of HA over placebo, while the other found no significant differences in pain, function, patient's global assessment, and responder rates between HA and placebo.<sup>3,4</sup> One of the RCTs also noted a substantial placebo effect (84%) detected.<sup>4</sup>

Assessments, one meta-analysis and recent RCTs found no significant difference in risk of adverse events for HA compared to placebo; however, adverse event data were often poorly reported. One review noted an increase in frequency of minor local acute reactions. A recent meta-analysis, which also included some data from unpublished trials, indicated that viscosupplementation had an increased risk for serious adverse events.<sup>5</sup>

A CTAF review from 2012 reviewed the body of evidence on repeated courses of viscosupplementation for osteoarthritis of the knee. The review included a total of 9 studies (3 RCTs, 1 nonrandomized controlled trial and 6 cohorts) including 2305 patients. Four studies found that repeated courses of HA showed improvement in pain outcomes (VAS, WOMAC scores) and responder criteria compared to single treatment. One RCT reported 4 courses of HA over 2.5 years improved clinical symptoms compared to placebo. Two lower-quality uncontrolled studies (n=411) suggested more clinical improvement after >2 courses of HA than after single course treatment; however, the lack of appropriate controls preclude definitive conclusion on the true magnitude of effect. A subsequent open-label trial including 433 patients who completed a prior randomized placebo-controlled trial also suggested that patients who completed extension trial had further improvements in pain (VAS), stiffness (WOMAC), and patient's global assessment scores.<sup>6</sup>

Results are unclear for safety of repeated HA treatments. The CTAF review concluded that repeated IA-HA injections for OA-K met CTAF criteria for safety for osteoarthritis treatment when compared with usual care, based on one RCT that showed similar AEs between repeated HAs and controls. A subsequent open-label trial found that 4.8% had events considered related to IA-HA. Conversely, a Hayes Assessment referenced an open-label extension of another RCT examining 3 different HAs that found non-significant trend toward greater AEs in Synvisc vs. Orthovisc or Ostenil groups in 1st course (2.2% difference; 95% CI, -2.4 - 6.7) and trend was more pronounced following 2nd course (6.4% difference; 95% CI, 0.6 - 12.2). Additional, well-designed RCTs are need to elucidate the safety of repeated HA treatments.

At least 5 RCTs including a total of 1746 patients have examined different formulations of HA agents, either head-to-head or versus placebo. Two RCTs compared Orthovisc vs. Synvisc vs. placebo/Ostenil, while 1 RCT assessed Synvisc with Artzal/Supartz and placebo, 1 RCT evaluated OrthoVisc with Supartz and placebo, and 1 RCT investigated Hylan G-F 20 to sodium HA. Most trials reported no significant differences in HA treatment arms. It is difficult to determine if any one HA agent is superior to another based on the available sparse and limited data from these trials.

Overall the evidence on viscosupplementation had considerable uncertainty due to the presence of large placebo effect, variable trial quality and a high risk of publication bias. A majority of publications were industry-sponsored and there is a high risk of treatment contamination due to concomitant use of other pharmacologic therapies." (INTC 2012)

"There is sufficient evidence that a single course of intra-articular hyaluronic acid injection is not more effective than conventional therapy, including NSAIDs, nonprescription analgesics, exercise, physical therapy and injectable corticosteroids, in improving pain and function.

There is insufficient evidence to determine whether or not repeated treatment using intra-articular hyaluronic acid injections is a medically appropriate treatment option.



There is insufficient evidence to determine the relative safety and effectiveness of any one HA product versus another.” (INTC 2012)

A bridge search was conducted from the date of the INTC report through April 2016. No evidence was identified that alter the conclusions made by the INTC.

### **RELEVANT GUIDELINES**

The American Academy of Orthopedic Surgeons (AAOS) updated their clinical practice guideline on treatment of osteoarthritis of the knee in 2013. Based on their review of 14 studies (including three high-strength studies and 11 moderate-strength studies), they make the following strong recommendation: “We cannot recommend using hyaluronic acid for patients with symptomatic osteoarthritis of the knee.” The guideline noted that the strength of the recommendation was based on lack of efficacy, not on potential for harm.

In guidelines issued by the National Institutes for Clinical Excellence (NICE), hyaluronic acid injections for knee osteoarthritis are recommended against (NICE 2014).

Milliman Care Guidelines on hyaluronic acid injections (ACG: A-0306) indicate that intra-articular hyaluronic acid may be indicated when all of the following are present:

- Age 18 years or older
- Failure to respond to or inability to tolerate non-operative treatments, including ALL of the following
  - Intra-articular corticosteroid injections
  - Lifestyle modifications (eg, exercise, weight reduction)
  - Non-narcotic analgesics
  - NSAIDs
- Knee osteoarthritis, with pain affecting daily activity and quality of life
- No infection or skin disease at injection site

### **CODES**

CPT or HCPCS Code	Description
20610	Arthrocentesis, aspiration, and/or injection; major joint or bursa (e.g. shoulder, hip, knee joint)
27440	Arthroplasty, knee tibial plateau
27441	Arthroplasty, knee tibial plateau; with debridement and partial synovectomy
27442	Arthroplasty, femoral condyles, or tibial plateau(s) knee
27443	Arthroplasty, femoral condyles, or tibial plateau(s) knee; with debridement and partial synovectomy
27445	Arthroplasty, knee, hinge prosthesis (e.g., Walldius type)
27446	Arthroplasty, knee condyle and plateau, medial or lateral compartment
27437	Arthroplasty, patella; without prosthesis
27438	Arthroplasty, patella; with prosthesis
27447	Arthroplasty, knee condyle and plateau; medial and lateral
J7321	Hyaluronan or derivative, Hyalgan or Supartz, for intra-articular injection, per dose
J7323	Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose
J7324	Hyaluronan or derivative, Orthovisc, for intra-articular injection
J7325	Hyaluronan or derivative, Synvisc or Synvisc-One, for intra-articular injection, 1mg

ICD-10 Code	Description
M15	Polyarthrosis

M15.0	Primary generalized (osteo)arthrosis
M15.3	Secondary multiple arthrosis
M15.4	Erosive (osteo)arthrosis
M15.8	Other polyarthrosis
M15.9	Polyarthrosis, unspecified
M17	Gonarthrosis (arthrosis of knee)
M17.0	Primary gonarthrosis, bilateral
M17.1	Other primary gonarthrosis
M17.2	Post-traumatic gonarthrosis, bilateral
M17.3	Other post-traumatic gonarthrosis
M17.4	Other secondary gonarthrosis, bilateral
M17.5	Other secondary gonarthrosis
M17.9	Gonarthrosis, unspecified
M19	Other arthrosis

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## TRIGGER POINT INJECTIONS FOR MYOFASCIAL PAIN

**Policy Number: 0003**

**Effective Date: XXX XX 2016**

**Reviewed Date: June 19 2017**

**Next Review: June 19 2018**

### BACKGROUND

#### **CLINICAL BACKGROUND** *(extracted verbatim from Hayes 2013)*

“Myofascial pain syndrome is a chronic condition affecting the connective tissue (i.e., fascia) surrounding the muscles that is characterized by pain and inflammation. A key characteristic of this condition is the presence of one or more myofascial trigger points (TPs) that are located in the muscle or muscle fascia. TPs are hyperirritable and exquisitely tender spots found in a taut, palpable band of skeletal muscle. Stimulation of TPs by either firm compression (palpation) or needle penetration can elicit local pain and tenderness, as well as motor dysfunction and autonomic dysfunction. However, palpation or other stimulation of TPs may also cause a pattern of referred pain that spreads or radiates distally to a target area that is characteristic of each muscle. Snapping (or rapid) palpation at or fast needle insertion into a TP may elicit a local twitch response (LTR), or a brisk contraction of the muscle fibers in and around the TP. Patients may have active TPs, or active and latent TPs. Active TPs cause pain at rest whereas latent TPs do not produce spontaneous pain, but instead may limit movement and cause muscular weakness.

TPIs involve the injection of a solution via a needle directly into the myofascial TP. The injectate may contain a local anesthetic, steroid, botulinum toxin, nonsteroidal anti-inflammatory drug (NSAID), 5-HT antagonist, or a combination of these substances. The goal of TPI therapy is to alleviate pain and restore function by inactivating the TP.”

### POLICY AND CRITERIA

Trigger point injections of anesthetic and/or corticosteroid for myofascial pain may be considered medically necessary when the following criteria are met

- Local pain lasting longer than 3 months with all of the following:
  - Tenderness and/or weakness; AND
  - Motion restriction; AND
  - A palpable band that produces referred pain when compressed
- Documented failure or contraindication to standard conservative management (e.g., physical therapy, pharmacotherapy, or cardiovascular exercise); AND
- Injections are provided as part of a comprehensive, multidisciplinary pain program; AND
- No more than 4 injections are provided per session.

Those who exhibit at least 50% improvement in pain level and at least three months of improved function may be eligible for up to 4 sessions per year, at least 3 months apart. Additional injections are considered NOT medically necessary if these criteria are not met.

### RATIONALE

#### **EVIDENCE BASIS**

Northwest Permanente Evidence-based Medicine Services reviewed the evidence on trigger point injections for myofascial pain in 2015. A recent, good quality technology assessment from Hayes provided most findings from the evidence base (Hayes 2013). A bridge search from the date of the Hayes

report through April 2016. Six additional relevant studies were identified, including four randomized trials, one non-randomized trial, and one systematic review. Findings in subsequently published studies did not significantly differ from those reported in the Hayes review, and conclusions regarding the safety and efficacy of trigger point injections for myofascial pain remain the same.

Findings and conclusions of the Hayes review were as follows:

“The literature search identified 1 prospective study with 193 patients that investigated factors associated with the outcome of TPI for myofascial pain syndrome (Hopwood 1994). Thirty-one factors were identified for analysis based on published literature of mixed groups of pain patients, physicians’ views of clinical importance, and ease of assessment in a typical clinical setting. Factors were analyzed via univariate and logistic regression analyses both for independent association with short-term treatment outcome and for magnitude of risk of failure associated with each factor following adjustment for other factors. The univariate analysis determined that an elevated risk of treatment failure was associated with unemployment arising from pain, inability of analgesic medication to provide pain relief, constant pain, high levels of pain-at-its worst and pain at-its least, extended duration of pain, alterations in social pursuits, and lower ability to cope with pain. Alcohol use was associated with lower risk for treatment failure according to the univariate analysis. The logistic regression analysis found that only unemployment, prolonged pain duration, and change in social activities were independently associated with treatment outcome.

In a randomized, double-blind trial, Hong (1994) compared lidocaine TPI and dry needling for relief of myofascial trigger points in patients that did or did not exhibit a local twitch response (LTR). Patients that showed an LTR during treatment exhibited statistically significant improvements from baseline in pain intensity, pressure pain threshold (PPT), and range of motion (ROM) immediately after treatment. However, for those patients that did not display an LTR, there was no change from baseline in pain intensity, PPT, or ROM. Thus, the beneficial effects of TPI and dry needling appear to depend upon the elicitation of an LTR during treatment.

**Comparative Efficacy of TPI Versus Dry Needling:** Three of the reviewed studies compared TPI therapy to dry needling for treatment of myofascial pain syndrome (Hong 1994; Ay 2010; Eroglu 2013). Findings from all 3 studies suggest that TPI is not superior to dry needling for reducing pain intensity and improving range of motion.

**Duration of Treatment Benefit:** Limited evidence pertaining to the duration of treatment benefit of TPI was available. Follow-up duration only extended up to 3 months following cessation of treatment. Only 4 studies reported data from more than 2 follow-up assessments after the end of treatment (Ferrante et al., 2005; Göbel 2006; Ozkan 2011; Seo 2013); 3 of these studies evaluated BTX-A TPIs and 1 study (Ozkan 2011) evaluated TPIs with lidocaine. The final follow-up assessment in 3 studies was 12 weeks after end of treatment, with 3 to 6 in-person total assessments (excluding baseline) depending on the outcome measure and the study (Ferrante 2005; Göbel 2006; Ozkan 2011). The fourth study included a total of 8 assessments up to 16 weeks posttreatment (Seo 2013). This evidence was insufficient to draw any conclusions about how long treatment efficacy persists after TPI therapy.

**Trigger Point Injections as an Adjunct to Other Pain Management Strategies:** In a systematic review of TPI for chronic nonmalignant pain, the authors note that most of the studies included in the review evaluated TPI as a stand-alone treatment. However, they indicate that the procedure is routinely used as an adjunctive to other therapies in clinical practice and the effectiveness of TPI may be underestimated in research studies where TPI is a stand-alone therapy (Scott 2009).”

## **RELEVANT GUIDELINES**

The American Society of Anesthesiologists (ASA) and American Society of Regional Anesthesia and Pain Medicine (ASRA) Task Force on Chronic Pain Management evaluated the efficacy of TPIs for patients with chronic pain. The guideline concluded that there was insufficient literature to determine efficacy, but

concluded that TPIs may be considered for treatment of myofascial pain when included as part of a multimodal pain management program due to evidence from observational studies.

The Colorado Division of Workers' Compensation issued a guideline entitled "Chronic pain disorder medical treatment guidelines" that addressed trigger point injections for myofascial pain. The guideline notes that "trigger point injections may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other active treatment modalities." The guideline also states that "patients should be reassessed after each injection session for an 80% improvement in pain (as measured by accepted pain scales) and evidence of functional improvement for 3 months. A positive result would include a return to baseline function, return to increased work duties, and measureable improvement in physical activity goals including return to baseline after an exacerbation." The guideline specifies that optimum treatment consists of 4 sessions per year, with no more than 4 injections per session.

#### CODES

CPT or HCPCS Code	Description
20552	Injection(s); single or multiple trigger point(s), one or two muscle(s)
20553	Injection(s); single or multiple trigger point(s), three or more muscles

ICD-10 Code	Description
M79.1	Myalgia (excl. myositis)

#### REFERENCES

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## ELECTIVE SURGERY

**Policy Number: 0004**

**Effective Date: March 17 2015**

**Reviewed Date: June 19 2017**

**Next Review: June 19 2018**

### BACKGROUND

#### CLINICAL BACKGROUND

Elective surgery is surgery that is subject to choice, either by the patient or doctor. The procedure may be beneficial to the patient but does not need to be done at a particular time. Elective surgery is surgery that is non-emergent. The majority of surgeries performed are elective, with more than 85% being elective as estimated by a study of the Nationwide Inpatient Sample (Ingraham 2011). Although there may be less risk associated with elective procedures, there remains potential for morbidity and mortality with many of these procedures. This policy is intended to ensure that patients scheduled to undergo surgery with increased risk of mortality or morbidity are receiving appropriate care.

### POLICY AND CRITERIA

Elective surgical procedures may be considered medically necessary when ALL of the following criteria (A-C) are met:

- A. The patient is expected to benefit in terms of prolonging of life, symptom improvement, or quality of life improvement;
- B. The patient is deemed to be an acceptable candidate for surgery as determined by the surgeon performing the procedure AND has documented one of the following
  - a. The patient's 30-day risk of death or serious complication resulting from surgery is estimated to be less than 2% as calculated by a validated risk assessment tool; OR
  - b. The patient's 30-day risk of death or serious complication is estimated to be less than 10% as calculated by a validated risk assessment tool AND there is at least a 20% probability (i.e., 1 in 5 chance) of clinically significant benefit to the patient as judged by two physicians with expertise in the field; OR
  - c. The patient's 30-day risk of death or serious complication is estimated to be more than 10% as calculated by a validated risk assessment tool AND there is at least a 20% probability (i.e., 1 in 5 chance) of clinically significant benefit to the patient as judged by three physicians with expertise in the field.
- C. The patient does not have any significant comorbidities that are believed to limit life expectancy or functional status such that the patient would be unable to realize the expected benefits of surgery.

Validated risk assessment tools include:

- ACS NSQIP Surgical Risk Calculator
- P-POSSUM
- RCRI

### RATIONALE

#### EVIDENCE BASIS

Ingraham evaluated the incidence of surgery-related morbidity, serious morbidity, and mortality among patients undergoing elective surgery between 2005 and 2008 across the United States (Ingraham 2011).

Overall mortality was reported to be 0.8%, while serious morbidity was 4.7%, and overall morbidity was 8.8%. The most common elective procedures were cholecystectomy, hernia repair, colectomy, and mastectomy.

Similarly, in another 2011 retrospective analysis, the 30-day mortality following elective surgery was 0.43% (Sessler 2011). The most common procedures were knee arthroplasty, nephrectomy, prostatectomy, spinal fusion, hysterectomy, and colorectal resection.

In another study that evaluated surgical risk by day-of-the-week for elective surgeries, authors reported that overall mortality risk ranged from 0.55% to 0.82% (Aylin 2013). The authors also specified rates per procedure for high-risk procedures, including excision of the esophagus and/or stomach (2.58% to 4.92%), excision of the colon and/or rectum (2.01% to 5.73%), coronary artery bypass graft (1.76% to 2.26%), repair of aortic aneurysm (3.22% to 6.93%), and excision of the lung (1.71% to 3.92%). Combined mortality rates for lower risk procedures ranged from 0.17% to 0.24%. Estimates from the Aylin study may not be completely representative of practice in the United States because data came from English hospitals. According to a 2005 study of all surgical procedures, the overall 30-day risk of mortality for all procedures ranges between 0.7% and 1.7% (Boyd 2005).

### **EXPLANATION AND RATIONALE**

The identified evidence indicates that the average 30-day mortality for all elective procedures is between about 0.5% and 2.0%. Based on this threshold, this policy sets a threshold of 2% risk of mortality before an additional clinical expert opinion is needed to determine medical appropriateness. If the patient's predicted risk of 30-day mortality is greater than 2% (i.e., higher than average), an additional opinion should be obtained from another specialist clinician in the field to determine whether the patient's likelihood of benefit is great enough to justify the high-risk procedure. If the 30-day mortality risk exceeds 10%, two additional clinician opinions must evaluate and deem the procedure medically appropriate.

### **REFERENCES**

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## BOTULINUM TOXIN INJECTION FOR CHRONIC MIGRAINE PROPHYLAXIS

**Policy Number: 0005**

**Effective Date: May 1 2015**

**Reviewed Date: June 19 2017**

**Next Review: June19 2018**

### BACKGROUND

#### CLINICAL BACKGROUND

Chronic migraine (CM) is a type of chronic daily headache that can be severely disabling. Individuals diagnosed with CM must have experienced headaches more than 15 days per month for three months, with headaches on at least eight days that possessed migrainous features (IHS 2003). Approximately three million adults in the United States (1.3% of the population) are estimated to be affected by CM (Natoli 2010). One in five of these individuals are occupationally disabled. Research has also shown that CM is associated with reduced quality of life (Bigal 2008, Dodick 2006).

Treatment for chronic migraine typically includes pharmacotherapy, but may include complementary treatments such as changes in diet, sleep, and exercise. Acute pharmacotherapy includes options such as simple analgesics, non-steroidal anti-inflammatory drugs, triptans and ergotamines. Preventive pharmacotherapy options include antidepressants, anticonvulsants, beta-blockers, calcium channel blockers and botulinum type A (e.g., BTA or Botox) injections (Chawla 2011). Currently, Botox is the only drug specifically FDA-approved for chronic migraine prophylaxis. The use of BTA for chronic migraine involves injections into the muscles of the head and neck approximately every 12 weeks.

### POLICY AND CRITERIA

Injection of onobotulinumtoxinA (Botox) may be considered medically necessary for chronic migraine prophylaxis when all of the following criteria are met:

- Diagnosis of chronic migraine as described by the International Headache Society Classification with attacks occurring at least 15 days per month for more than 3 months
- Member has documented failure of (or intolerance to) prophylactic migraine medications from at least 3 different drug classes. Each trial must have lasted at least 2 months. Classes include:
  - Anti-depressants
  - Anti-convulsive medications
  - Beta blockers
  - Angiotensin-converting enzyme inhibitors/angiotensin II receptor blockers
  - Calcium channel blockers

Members meeting the above criteria may receive no more than 4 treatments in a 12 month period.

If a previous trial of botulinum toxin injection for chronic migraine prophylaxis has NOT produced at least a 7 day reduction in monthly frequency of migraines or reduced total headaches duration by at least 100 hours per month, additional injections are considered NOT medically necessary.

### RATIONALE

#### EVIDENCE BASIS

Northwest Permanente Evidence-based Medicine Services reviewed the evidence on botulinum toxin for migraine prophylaxis in 2015. Findings and conclusions were as follows:

Aurora 2010 (n = 679) reported results from the Phase III Research Evaluating Migraine Prophylaxis Therapy I (PREEMPT I) study, assessing the efficacy, safety and tolerability of BTA as chronic migraine prophylaxis. PREEMPT I consisted of a 24-week, double-blind, parallel-group, placebo-controlled phase followed by a 32-week, open-label phase. Investigators assessed the frequency of headache episodes (the primary outcome of interest), as well as numerous secondary outcomes, including the frequency of headache days, the frequency of migraine days, and the frequency of migraine episodes. The study reports no improvement in reduction of headache episodes over placebo (p = 0.344). However, the study does report that BTA produced a 7% reduction in headache days over placebo, meaning that patients receiving BTA injections had, on average, 1.4 fewer headache days per month than those receiving placebo (p = 0.006, 95% CI: -2.40, -0.40).

Diener 2010 (good-quality RCT): Diener et al. (n = 705) reported results from the Phase III Research Evaluating Migraine Prophylaxis Therapy II (PREEMPT II) study, assessing the efficacy, safety and tolerability of BTA as chronic migraine prophylaxis. Like PREEMPT I, PREEMPT II consisted of a 24-week, double-blind, parallel-group, placebo-controlled phase followed by a 32-week, open-label phase. Whereas the primary outcome of interest in PREEMPT I was the frequency of headache episodes, PREEMPT II focused instead on the frequency of headache days. Investigators also measured numerous secondary outcomes, including the frequency of headache episodes, the frequency of migraine days, and the frequency of migraine episodes. The study reports that BTA produced an 11.5% reduction in headache days over placebo, i.e., 2.3 fewer headache days per month (p < 0.001, 95% CI: -3.25, -1.31). Dodick 2010 (pooled data from two good-quality RCTs detailed above): Dodick et al. (n = 1384) pooled data from the PREEMPT I and PREEMPT II studies to address again the efficacy, safety and tolerability of BTA as chronic migraine prophylaxis. Again, investigators focused on the mean change from baseline in frequency of headache days, and reported that BTA produced a 9% decrease in mean headache days over placebo, i.e., 1.8 fewer headache days per month (-8.4 BTA vs -6.6 placebo, p < 0.001, 95% CI: -2.52, -1.13; Number Needed to Treat [NNT] = 9 for one person to experience at least a 50% reduction in the frequency of headache days).

Within both PREEMPT I and PREEMPT II, there is a potential for “unblinding” of the study participants to their treatment group allocation. Because BTA produces a numbing sensation and physical differences in facial appearance following injection, it is possible that participants were able to determine whether they were receiving BTA or placebo. This has the potential to result in ascertainment bias that may bias these studies’ results. However, investigators did expend rigorous effort to conduct a double-blind study, and we do not see room for methodological improvement to overcome this potential issue with subject masking to the receipt of active drug versus placebo.

In both trials, more than 60% of participants reported acute headache pain medication overuse. The International Classification of Headache Disorders 2nd edition (ICHD-2) does not classify patients with acute head pain medication overuse as having chronic migraine: “\*migraine headache occurring on 15 or more days per month for more than three months in the absence of medication overuse.” If practitioners are using the ICHD-2 criteria for chronic migraine, their patient population would differ from the PREEMPT I study population. It is important to take this difference into consideration when attempting to generalize these findings.

There were significant differences between the treatment and placebo groups at baseline in both PREEMPT I (Aurora 2010) and in the pooled analysis of PREEMPT I and PREEMPT II (Dodick 2010). The placebo group had significantly more baseline headache episodes (Aurora 2010: placebo = 13.4, BTA = 12.3, p = 0.023; Dodick 2010: placebo = 13.0, BTA = 12.2, p = 0.004) and migraine episodes (Aurora 2010: placebo = 12.7, BTA = 11.5, p = 0.006; Dodick 2010: placebo = 12.2, BTA = 11.4, p = 0.004) than the treatment group. The treatment group reported significantly more cumulative headache hours (Aurora 2010: placebo = 274.9, BTA = 295.7, p = 0.022; Dodick 2010: placebo = 281.22, BTA = 295.93, p = 0.021) at baseline. If there is a differential in the magnitude of the placebo response among individuals with more or less frequent headaches or among individuals reporting more or less headache hours these imbalances in baseline characteristics might act as confounders. Because the placebo

response is particularly relevant when measuring patient-reported outcomes (Hróbjartsson 2010) as was done in these trials, these possible confounders should be considered when interpreting study findings.

All studies report that treatment with 155 Units (U) to 195 U of BTA every 12 weeks over 24 weeks was well-tolerated. Pooled results from PREEMPT I and PREEMPT II showed that 62.4% of individuals receiving BTA reported adverse events, compared to 51.7% receiving placebo. Serious adverse events were reported by 4.8% of individuals receiving BTA compared to 2.3% receiving placebo. Additionally, 3.8% of those receiving BTA discontinued because of adverse events, compared to 1.2% of those receiving placebo. Adverse events most frequently cited for discontinuation of the study were neck pain (0.6%), muscular weakness (0.4%), headache (0.4%) and migraine (0.4%). No deaths were reported within either group. Both PREEMPT I and PREEMPT II had 32-week open label phases following the 24-week randomized, double-blind phases to study adverse events further.

A search to update the literature in May 2016 identified only reports of new analyses of previously reported data, including 4 subgroup analyses, 1 pooled analysis, 1 systematic review, 1 meta-analysis, and 1 cost-effectiveness analysis. None of the reported analyses alter the conclusions of the previous review.

### **RELEVANT GUIDELINES**

The American Academy of Neurology (AAN) reviewed evidence related to BTA for various indications, including migraine prophylaxis, in their 2008 guideline (Naumann 2008). At that time, the group concluded that “[botulinum toxin] injection is probably ineffective in the treatment of episodic migraine.” As of February 2015, the AAN is in process of updating their evaluation and recommendations.

In guidelines issued by the National Institutes for Clinical Excellence (NICE), botulinum toxin type A is recommended as a treatment option for chronic migraine. NICE states the following:

1.1 Botulinum toxin type A is recommended as an option for the prophylaxis of headaches in adults with chronic migraine (defined as headaches on at least 15 days per month of which at least 8 days are with migraine):

- That has not responded to at least three prior pharmacological prophylaxis therapies and
- Whose condition is appropriately managed for medication overuse

1.2 Treatment with botulinum toxin type A that is recommended according to 1.1 should be stopped in people whose condition:

- Is not adequately responding to treatment (defined as less than a 30% reduction in headache days per month after two treatment cycles) or
- Has changed to episodic migraine (defined as fewer than 15 headache days per month) for three consecutive months

1.3 People currently receiving botulinum toxin type A that is not recommended according to 1.1 and 1.2 should have the option to continue treatment until they and their clinician consider it appropriate to stop.

### **CODES**

<b>CPT or HCPCS Code</b>	<b>Description</b>
64615	Chemodeneration of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)
J0585	Botulinum toxin type A, per unit [Botox]

ICD-10 Code	Description
G43.001 – G43.919	Migraine headache

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## Monitored Anesthesia Care for Gastrointestinal Endoscopic Procedures

**Policy Number: 0008**

**Effective Date: August 1, 2015**

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**Next Review: February 2019**

### BACKGROUND

#### **CLINICAL BACKGROUND** *(extracted from KP MTAT 2010)*

##### **Usual Care for Sedation During Colonoscopy and Routine Upper Endoscopy Procedures**

Traditional sedation for routine colonoscopy and upper endoscopy procedures, including esophagoduodenoscopy (EGD), has involved a benzodiazepine with or without an opioid. These agents have known antidotes and are usually administered by a registered nurse (RN) under the supervision of an endoscopist.

##### **Administration of Propofol** (Source: verbatim from Singh et al., 2008; Vargo et al., 2009)

In recent years propofol (2, 6-di-isopropylphenol) has increasingly been utilized as an alternative method of sedation in endoscopy suites. Propofol was initially introduced in 1989 and has since then been widely used in critical care units and emergency departments for providing sedation. Although propofol is associated with a more rapid onset of action, its use for sedation during endoscopy by non-anesthesiologists in many parts of the world (particularly North America) has been limited by concerns of potential side-effects. This agent has also been administered by anesthesiologists and certified registered nurse anesthetists (CRNAs) within KP SCAL for endoscopy procedures. Emergency medicine physicians also appear to be privileged for at least select medical centers for GI procedures. Unlike other standard sedation agents, propofol does not have an antidote/reversal agent.

There are several key terms and definitions related to methods for the administration of propofol. Several terms and definitions were summarized recently in a position statement from the American Gastroenterological Association (AGA) (Vargo et al., 2009):

**Monitored Anesthesia Care (MAC):** Monitored anesthesia care (MAC) is the service provided by an anesthesia specialist to the patient undergoing a diagnostic or therapeutic procedure. In many instances, although not all, MAC results in deep sedation, and the normal airway protective reflexes may be lost. MAC can include general anesthesia with endotracheal intubation.

**Standard Sedation:** Standard sedation refers to the administration of intravenous drugs, usually a benzodiazepine and an opioid, under the supervision of an endoscopist. A level of moderate sedation is usually targeted.

**Nonanesthesiologist-administered propofol (NAAP)** Administration of propofol under the direction of a physician who has not been trained as an anesthesiologist. Propofol may be used either alone or in combination with 1 or more additional agents. A level of moderate-to-deep sedation is targeted with NAAP.

**Nurse-administered propofol sedation (NAPS)** Describes the administration of propofol as a single agent under the direction of a physician who has not been trained as an anesthesiologist. A level of deep sedation is targeted with NAPS.

**Balanced propofol sedation (BPS)** (Source: Vargo et al., 2009) Administration of the combination of a benzodiazepine, and opioid, and propofol under the direction of a physician who is not an anesthesiologist. The opioid and benzodiazepine are each given as a single dose, which is followed by small incremental doses of propofol administered to achieve a target level of moderate sedation.

Another potential method for administering propofol involves computer assistance.

**Computer Assisted Propofol Administration (CAPS)** The SEDASYS (Ethicon Endo-Surgery, Inc., Cincinnati, Ohio) system is a computer-assisted personalized sedation that integrates a suite of patient monitors (pulse oximetry, capnometry, EKG, noninvasive blood pressure (NIBP), and patient responsiveness) with oxygen and computer-controlled propofol delivery. Details on the published evidence on computer-assisted personalized sedation (CAPS) can be found in a SCPMG Technology Assessment and Guidelines Unit (TAG) assessment from February 2009.

## POLICY AND CRITERIA

Monitored anesthesia care (MAC) is considered medically necessary during gastrointestinal endoscopic procedures when there is documentation by the operating physician and the anesthesiologist that demonstrates any of the following higher risk situations exist:

- A. Prolonged or therapeutic endoscopic procedure requiring deep sedation; OR
- B. A history of anticipated intolerance to standard sedatives; OR
- C. Increased risk for complication due to severe comorbidity. American Society of Anesthesiologists ASA class III physical status or greater; OR
- D. Pediatric age group (16 years or younger); OR
- E. Pregnancy; OR
- F. History of active drug or alcohol abuse; OR
- G. Morbid obesity (BMI > 50); OR
- H. Uncooperative or acutely agitated patients (e.g., delirium, organic brain disease, senile dementia); OR
- I. Spasticity or movement disorder complicating procedure; OR
- J. Increased risk for airway obstruction due to anatomic variant including any of the following:
  - a. Documented history of previous problems with anesthesia or sedation; OR
  - b. History of stridor or severe sleep apnea requiring oxygen and BIPAP; OR
  - c. Dysmorphic facial features, such as Pierre-Robin syndrome or trisomy 21; OR
  - d. Presence of oral abnormalities including but not limited to a small oral opening (less than 3 cm in an adult), high arched palate, macroglossia, tonsillar hypertrophy, or a non-visible uvula (not visible when tongue is protruded with patient in sitting position, e.g., Mallampati class greater than II), as documented by anesthesia; OR
  - e. Neck abnormalities including but not limited to short neck, obesity involving the neck and facial structures, limited neck extension, decreased hyoid-mental distance (less than 3 cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation, or advanced rheumatoid arthritis as documented by anesthesia; OR
  - f. Jaw abnormalities including but not limited to micrognathia, retrognathia, trismus, or significant malocclusion as documented by anesthesia.

## RATIONALE

### **EVIDENCE BASIS**

A 2010 Kaiser Permanente review of monitored anesthesia care for gastrointestinal disorders reported findings from systematic reviews, meta-analyses, randomized controlled trials, and published internal data (KP MTAT 2010). Their findings included the following:

“There is good evidence of improved patient satisfaction and reductions in discharge and recovery times with propofol used alone or in combination with other agents compared to standard sedation for colonoscopy exams. There is fair evidence from a KP SCAL-based comparative study of improved cecal intubation rates with propofol used as a single agent for sedation during colonoscopy. The evidence is of insufficient quantity or quality to draw definitive conclusions on differences in polyp detection. There is less comparative data on EGD procedures, but some evidence of improved recovery and patient satisfaction with propofol sedation. The evidence is of insufficient quantity and/or quality to draw definitive conclusions on comparative risk of serious adverse events, including death, neurologic injury,

endotracheal intubations, bleeding, and colonic perforations during these procedures. There does not appear to be a significant difference in the risk of cardiopulmonary and respiratory events with propofol compared to standard sedation and no evidence of greater risk for serious adverse events for either colonoscopy or EGD procedures in lower risk patients (ASA I or II).

Following the review of one systematic review and two comparative observational studies, the evidence is of insufficient quantity and quality to draw definitive conclusions on the safety of anesthesiologist- versus non anesthesiologist-directed or administered propofol sedation in GI endoscopy. Controlled prospective studies with standardized protocols, patient selection, and reporting are needed.

**Serious Adverse Events:** The best available comparative evidence from the United States is a large observational registry study that suggests comparable rates of serious adverse events for anesthesiologist-directed propofol under monitored anesthesia care and gastroenterologist-administered propofol during colonoscopy procedures (0.16% and 0.14%) but a significantly increase risk of serious adverse events with gastroenterologist-administered propofol for upper endoscopy procedures, including EGDs (0.16% vs 0.5%). However, it is likely that these events differentially occurred in higher risk patients (ASAI III) who were also included in the study. Overall Cardiopulmonary Adverse Events. There is evidence from the same study of a significant increased risk of overall cardiopulmonary events with endoscopic-administered propofol in ASA I or II patients undergoing colonoscopy and upper endoscopy. The majority of the cardiopulmonary events are most likely to be of minor clinical consequence, but the challenge remains to identify which cardiopulmonary events are more likely to result in serious adverse events and what risk factors are specific to upper versus lower endoscopy procedures.

The evidence is of insufficient quantity and quality to draw conclusions on the safety of RN-administered propofol as compared to standard sedation for colonoscopy and EGD in ASA I and II patients. Based on a review of several systematic reviews and randomized controlled trials, there is no evidence of a significant increase in risk of adverse events with propofol compared to standard sedation and the risks appear to be comparable. However, these studies were not adequately sampled to detect or compare rates of serious adverse events. Comparative data from large and well-designed observational studies is needed. The existing series of RN-administered propofol are large and report low rates of adverse events.”

## CODES

CPT or HCPCS Code	Description
00740	Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum
00810	Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum

ICD-10 Code	Description
	All diagnoses

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## Pre-implantation Genetic Diagnosis

**Policy Number: 0009**  
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### BACKGROUND

#### **CLINICAL BACKGROUND** (*excerpted verbatim from NHS 2013*)

“Preimplantation genetic testing is a technique used in reproductive medicine to identify inherited genetic defects in embryos created through in vitro fertilization (IVF). Preimplantation genetic diagnosis (PGD) can be offered when one or both parents have, or are carriers of, a known genetic abnormality; testing is performed on embryos created through IVF to determine whether they are at risk of genetic disease.

The use of PGD enables couples at risk of passing on an inherited disorder to decrease the risk of having an affected child significantly... PGD represents the only way for parents to have an unaffected child to whom they are both biological parents, without risking the need for termination of pregnancy. PGD is one of several reproductive options available for couples at risk of passing on a genetic condition, but the fact that the technology requires a highly skilled technical team and laboratory set up means it is significantly more expensive than the more common prenatal diagnosis option (PND)... The two commonly used post-conception diagnosis procedures [for PND] are amniocentesis and chorionic villus sampling (CVS) at 16 and 11 weeks, respectively. If the fetus is found to have the genetic condition of concern, the parents have to make difficult decisions about whether or not to opt for termination of the pregnancy. Termination of pregnancy is not an acceptable option for some couples.”

#### **DESCRIPTION OF THE TECHNOLOGY** (*excerpted verbatim from Dahdouh 2015*)

“PGD requires IVF with or without intra-cytoplasmic sperm injection (ICSI), embryo biopsy for DNA sampling, genetic testing, and selected embryo transfer. DNA can be extracted from the oocytes (polar bodies) or from embryonic cells as one blastomere from a cleavage-stage embryo or 5 to 10 trophectoderm cells from a blastocyst-stage embryo. The genetic material is then tested for either single-gene mutations, using molecular biology techniques (PCR, PCR-multiplex), or for chromosomal translocation and de novo aneuploidy, using cytogenetic techniques such as FISH or CCS. The latter is the emergency new cytogenetic technique that consists of identifying the whole chromosomal complement (24 chromosomes). CCS can be accomplished through microarray technology such as aCGH and SNP or through qPCR. As the cells are being tested, the embryos remain in IVF media culture. If the biopsied cell or cells are shown to be unaffected for the genetic disorder in PGD or to carry a euploid embryo in PGS, then that particular embryo is considered an apt candidate for transfer into the uterus.”

### POLICY AND CRITERIA

Pre-implantation genetic diagnosis is considered medically necessary when BOTH of the following criteria are met:

1. There must be documentation confirming that PGD is medically necessary to detect a single gene disorder or chromosomal abnormality whose expression in the fetus or child would be expected to have a significant adverse medical impact and that detection in the pre-implantation period would directly affect reproductive decisions; AND
2. One of the following clinical circumstances must be documented:
  - a. One genetic parent has a balanced, reciprocal translocation or Robertsonian translocation; OR

- b. One genetic parent has a single gene autosomal dominant disorder; OR
- c. Both genetic parents are known carriers of the same autosomal recessive disorder; OR
- d. The female genetic parent is a known carrier of an X-linked disorder.

The biopsy procedure to obtain a cell sample from an embryo and perform the necessary genetic testing for PGD is covered when the above criteria are met. However, the procedures and services (such as IVF) required to create the embryos to be tested and the transfer of embryos to the uterus after testing, are covered ONLY for members with advanced reproductive technology (ART) benefits and who meet medical necessity criteria for IVF (in vitro fertilization).

PGD is considered NOT medically necessary when the above-outlined criteria are not met.

## RATIONALE

### **EVIDENCE BASIS**

There is moderate strength of evidence that pre-implantation genetic diagnosis may accurately identify the presence of single gene defects in high-risk embryos of couples with a known genetic disorder. Estimates of sensitivity range from 96% to 99%, and estimates of specificity range from 80% to 85%.

There is low strength of evidence that pre-implantation genetic diagnosis does not affect neonatal outcomes such as birth weight.

There is insufficient evidence to estimate the cost-effectiveness of PGD compared to traditional prenatal testing in couples with a known genetic disorder because no studies have formally evaluated this question.

In May 2015, the Society of Obstetricians and Gynaecologists of Canada performed a comprehensive review of the literature regarding preimplantation genetic diagnosis and screening (Dahdouh 2015). The review was conducted to inform SOGC recommendations regarding preimplantation genetic testing, which are outlined under the Guidelines section of this document. The Dahdouh review did not directly report findings regarding the diagnostic accuracy of preimplantation genetic diagnosis. However, the references discussed in the Dahdouh review provided the additional detail needed. The estimated sensitivity of PGD for single gene mutations was between 96.6% and 99.2%, with estimated false negative rates between 0.8% and 3.4%. False positives were more common, with rates between 9.1% and 14.3% (Dreesen 2008 and Dreesen 2013 in Dahdouh 2015).

“Generally, the most reliable PCR-PGD protocols employ multiplex PCR. In addition to amplification of a DNA fragment encompassing the mutation site, extra fragments containing linked polymorphisms are amplified to avoid misdiagnosis due to ADO, and at least one highly polymorphic marker is amplified to detect possible contamination. Another strategy used to decrease ADO is blastocyst biopsy, with frozen embryo transfer for PGD of monogenic diseases. It has been associated with higher genotyping and implantation rates and lower amplification failure and ADO than traditional blastomere biopsy.”

Eldar-Geva (2014) performed a prospective analysis of 242 children born after PGD, along with 242 born after intracytoplasmic sperm injection (ICSI) and 733 born after spontaneous conception. Authors compared neonatal outcomes and reported that birth weight among babies born after PGD was not significantly different from those born after spontaneous conception. The overall low birth weight rate was 4.4% for PGD (compared to 12.0% for ICSI and 5.7% for spontaneous conception), and intrauterine growth restriction rate was 5.1% for PGD (compared to 9.5% for ICSI and 5.5% for spontaneous conception). Authors made the following conclusion: “Embryo biopsy itself did not cause intrauterine growth restriction or low birth weight compared with SC, despite lower gestational ages with PGD. The worsened outcomes in ICSI compared with PGD pregnancies may be due to the infertility itself.”

Dreesen (2014) reported the sensitivity and specificity of PGD for identification of monogenic diseases as part of the ESHRE PGD consortium study. Authors performed a retrospective analysis of 940

untransferred embryos, and estimated sensitivity of 99.2% and specificity of 80.9%. Overall, 93.7% of embryos were correctly classified. Authors noted that diagnostic accuracy was statistically significantly better when PGD was performed on two cells than one cell ( $p=0.001$ ).

## **RELEVANT GUIDELINES**

### **American College of Obstetricians and Gynecologists**

ACOG issued a committee opinion in March 2009 (reaffirmed 2014) that addressed preimplantation genetic screening, which differs from preimplantation genetic diagnosis. Although the ACOG guideline on PGS does not make recommendations regarding PGD, it notes the following:

“Preimplantation genetic screening differs from preimplantation genetic diagnosis (PGD) for single gene disorders. In order to perform genetic testing for single gene disorders, PGD was introduced in 1990 as a component of in vitro fertilization programs. Such testing allows the identification and transfer of embryos unaffected by the disorder in question and may avoid the need for pregnancy termination (1). Assessment of polar bodies as well as single blastomeres from cleavage stage embryos has been reported, although the latter is the approach most widely practiced. Preimplantation genetic diagnosis has become a standard method of testing for single gene disorders, and there have been no reports to suggest adverse postnatal effects of the technology. Preimplantation genetic diagnosis has been used for diagnosis of translocations and single-gene disorders, such as cystic fibrosis, X-linked recessive conditions, and inherited mutations, which increase one's risk of developing cancer.”

In October 2015, a committee opinion on “Identification and Referral of Genetic Conditions in Pregnancy” addressed the use of PGD. The committee made the following recommendation for those with a known causative mutation:

“Patients with established causative mutations for a genetic condition, and who desire prenatal genetic testing, should be offered preimplantation genetic testing with in vitro fertilization by a reproductive endocrinologist or prenatal diagnostic testing once pregnancy is established.”

In March 2017, ACOG issued a committee opinion entitled “Carrier Screening for Genetic Conditions” (ACXOG 2017). Specifically with regard to hemoglobinopathies, the authors state the following regarding preimplantation genetic diagnosis:

“Couples at risk of having a child with a hemoglobinopathy may benefit from genetic counseling to review their risk, the natural history of these disorders, prospects for treatment and cure, availability of prenatal genetic testing, and reproductive options. Prenatal diagnostic testing for the mutation responsible for sickle cell disease is widely available. Testing for  $\alpha$ -thalassemia and  $\beta$ -thalassemia is possible if the mutations and deletions have been previously identified in both parents. These DNA-based tests can be performed using chorionic villi obtained by chorionic villus sampling or using cultured amniotic fluid cells obtained by amniocentesis. For some couples, preimplantation genetic diagnosis in combination with in vitro fertilization may be a desirable alternative to avoid termination of an affected pregnancy. Preimplantation genetic diagnosis has been successfully performed for sickle cell disease and most types of  $\beta$ -thalassemia.”

### **American Society of Reproductive Medicine**

The ASRM issued a practice committee opinion on preimplantation genetic diagnosis. The committee opinion outlines the following as indications for PGD:

“PGD is indicated for couples at risk for transmitting a specific genetic disease or abnormality to their offspring. For carriers of autosomal dominant disorders, the risk that any given embryo may be affected is 50%, and for carriers of autosomal recessive disorders, the risk is 25%. For female carriers of X-linked disorders, the risk of having an affected embryo is 25% (half of male embryos). PGD also can be performed and may be elected by patients who carry mutations such as BRCA1 that do not cause a specific disease but are thought to confer significantly increased risk for a disease. In some cases, there may be more than one indication for PGD, such as when

human leukocyte antigen (HLA) matching is performed in conjunction with testing for a specific mutation.

For individuals who carry a balanced chromosomal translocation, inversion, or other structural chromosomal rearrangement, there is increased risk that their gametes will have an unbalanced genetic composition due to excess missing genetic material. An embryo derived from the union of such an unbalanced gamete with a partner's normal gamete also will have an unbalanced genetic composition and may be identified using telomeric probes specific for the loci of interest that must be selected for individual patients, according to their unique abnormality."

Overall, the ASRM practice committee opinion made the following recommendations regarding PGD (ASRM 2007):

- "Before PGD is performed, genetic counseling must be provided to ensure that patients fully understand the risk for having an affected child, the impact of the disease on an affected child, and the limitations of available options that may help avoid the birth of an affected child.
- PGD can reduce the risk for conceiving a child with a genetic abnormality carried by one or both parents if that abnormality can be identified with tests performed on a single cell.
- Prenatal diagnostic testing to confirm the results of PGD is encouraged strongly because the methods used for PGD have technical limitations that include the possibility for a false negative result."

ASRM also issued an ethics committee opinion specifically addressing the use of PGD for serious adult-onset conditions. The committee made the following conclusions:

"After careful review and consideration, the Committee concludes, based on the arguments outlined above, that PGD for adult-onset conditions is ethically justified when the condition is serious and no safe, effective interventions are available. The Committee further concludes that reproductive liberty arguments ethically allow for PGD for adults-onset conditions of lesser severity or penetrance. In the latter cases, the application of the technology hinges on evidence that PGD is a relatively low-risk procedure; this evidence may change. The complexity of the scientific, psychological, and social issues involved in this arena compels the Committee to strongly recommend that an experienced genetic counselor play a major role in counseling patients considering such procedures."

### **Society of Obstetricians and Gynaecologists of Canada (SOGC)**

The SOGC guideline recommendations are based off the systematic review by Dahdouh and colleagues (2015). Authors made the following recommendations, with the overall quality of the evidence assessment and classification of the recommendation noted in parentheses (see Appendix I for the rating key used by SOGC):

1. Before preimplantation genetic diagnosis is performed, genetic counselling must be provided by a certified genetic counsellor to ensure that patients fully understand the risk of having an affected child, the impact of the disease on an affected child, and the benefits and limitations of all available options for preimplantation and prenatal diagnosis. (III-A)
2. Couples should be informed that preimplantation genetic diagnosis can reduce the risk of conceiving a child with a genetic abnormality carried by one or both parents if that abnormality can be identified with tests performed on a single cell or on multiple trophoctoderm cells. (II-2B)
3. Invasive prenatal or postnatal testing to confirm the results of preimplantation genetic diagnosis is encouraged because the methods used for preimplantation genetic diagnosis have technical limitations that include the possibility of a false result. (II-2B)
4. Trophoctoderm biopsy has no measurable impact on embryo development, as opposed to blastomere biopsy. Therefore, whenever possible, trophoctoderm biopsy should be the method of choice in embryo biopsy and should be performed by experienced hands. (I-B)

5. Preimplantation genetic diagnosis of single-gene disorders should ideally be performed with multiplex polymerase chain reaction coupled with trophectoderm biopsy whenever available. (II-2B)
6. The use of comprehensive chromosome screening technology coupled with trophectoderm biopsy in preimplantation genetic diagnosis in couples carrying chromosomal translocations is recommended because it is associated with favourable clinical outcomes. (II-2B)
7. Before preimplantation genetic screening is performed, thorough education and counselling must be provided by a certified genetic counsellor to ensure that patients fully understand the limitations of the technique, the risk of error, and the ongoing debate on whether preimplantation genetic screening is necessary to improve live birth rates with in vitro fertilization. (III-A)
8. Preimplantation genetic screening using fluorescence in situ hybridization technology on day-3 embryo biopsy is associated with decreased live birth rates and therefore should not be performed with in vitro fertilization. (I-E)
9. Preimplantation genetic screening using comprehensive chromosome screening technology on blastocyst biopsy, increases implantation rates and improves embryo selection in IVF cycles in patients with a good prognosis. (I-B)

### **European Society for Human Reproduction and Embryology (ESHRE)**

In 2011, the ESHRE made recommendations regarding multiple aspects of PGD testing (Harton 2011). Relevant to this review are recommendations made regarding inclusion/exclusion criteria specific to amplification-based PGD:

#### **Inclusion**

2.6. Testing can be carried out for confirmed pathogenic germline mutation(s) that have been identified in one parent for dominantly inherited diseases or in each parent for recessively inherited disorders giving a disease recurrence risk of 50 or 25%, respectively.

2.7. The germline mutation(s) is known to be causative of serious health effects that may manifest at birth, in childhood or as an adult.

2.8. For recessive and some X-linked (e.g. Duchenne muscular dystrophy) disorders, where a single germline mutation has been diagnosed in the proband and only one parent, it is acceptable to offer diagnosis if the pathogenic genotype can be attributed to a single gene and there is sufficient family history to identify a haplotype linked to the germline mutation.

2.9. Exclusion testing can be carried out for late-onset disorders, such as Huntington's disease to avoid presymptomatic testing of the partner with a family history of the disease (Sermon 2002; Moutou 2004; Jasper 2006; Pecina 2009 in ESHRE 2011).

#### **Exclusion**

2.10. Where the genetic diagnosis is uncertain, for example, owing to genetic/molecular heterogeneity or uncertain mode of inheritance and recurrence risk is low (e.g. 10%).

### **CODES**

<b>CPT or HCPCS Code</b>	<b>Description</b>
88271 – 88299	Molecular cytogenetics
89290 – 89291	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); less than, equal or greater than 5 embryos [not covered to enhance delivery rates in advanced reproductive technologies]
S3820 – S3840	Genetic sequence analysis
S3841 – S3855	Genetic testing

<b>ICD-10 Code</b>	<b>Description</b>
D56.0 – D56.9	Thalassemia
D57.0 – D57.819	Sickle-cell disorders

D61.01 – D61.09	Constitutional aplastic anemia
E75.02	Tay-Sachs disease
E75.19	Other gangliosidosis
E75.4	Neuronal ceroid lipofuscinosis
E72.00 – E72.9	Other disorders of amino-acid metabolism
E84.0 – E84.9	Cystic fibrosis
G71.0	Muscular dystrophy
G71.2	Congenital myopathies
Q05.0 – Q05.9	Spina bifida
Q06.0 – Q06.9	Other congenital malformations of spinal cord
Q87.40 – Q87.89	Marfan's syndrome
Q90.0 – Q99	Chromosomal abnormalities, not elsewhere classified
Z14.1	Cystic fibrosis carrier
Z14.8	Genetic carrier of other disease
Z81.0	Family history of intellectual disabilities
Z82.0	Family history of epilepsy and other diseases of the nervous system
Z83.2	Family history of diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
Z83.31 – Z83.49	Family history of other endocrine, nutritional, and metabolic diseases
Z82.79	Family history of other congenital malformations, deformations and chromosomal abnormalities
Z84.89	Family history of other specified conditions

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**POLICY HISTORY**

Date	Action
August 1, 2015	New policy
March 21, 2017	Updated literature search; ACOG 2015 and ACOG 2017 committee opinions added; language revised to specify that “biopsy” procedure is the procedure covered to obtain cells for testing; ICD-9 codes replaced with ICD-10 codes.
April 27, 2018	Updated literature search identified relevant European guidelines regarding best practices for preimplantation genetic diagnosis of cystic fibrosis; no change in policy.

# 2018 KPNW Resource Stewardship & Utilization Management Program Description

## Introduction

Kaiser Foundation Health Plan of the Northwest (KFHP-NW), Kaiser Foundation Hospitals, and the Northwest Permanente Medical Group (NWP), jointly referred to as Kaiser Permanente Northwest (KPNW), have developed a Resource Stewardship (RS)/Utilization Management (UM) Program designed to monitor, evaluate, and guide decision making about the cost and quality of healthcare services delivered to all KPNW members.

Resource Stewardship represents a shift from the historical cost containment focus of UM to a more proactive approach that includes continuous quality improvement and evidence-based practice. The Resource Stewardship program augments UM with care coordination activities which help prevent unnecessary use of resources by identifying and managing at-risk patients. Resource Stewardship also encompasses opportunities to improve timely access and the use of resources through analysis of efficiency and the reduction of waste.

Resource Stewardship programs and activities align with Kaiser Permanente's national strategy for quality. Kaiser Permanente uses the concept of "Big Q", encompassing clinical effectiveness, risk management, patient safety, service, and resource stewardship to describe the multiple methods we employ to reach our goal of being the safest, most effective, affordable and personal health care delivery system in the country.

Unless otherwise specified, the Program Description and Utilization Management Policies apply to all product lines: Commercial, Medicare, Medicaid and Marketplace.

## Program Scope

The RS/UM Program addresses appropriateness, timeliness, efficiency and coordination in the following settings of care and services:

- Emergency and urgent care
- Inpatient hospitalization
- Outpatient surgeries
- Rehabilitative services
- Home health services
- Pharmaceutical services
- Physician office services
- Out-of-network services
- Durable Medical Equipment, Prosthetics and Orthotics
- Skilled nursing
- Hospice Care
- Behavioral Health and Chemical Dependency Services
- End Stage Renal Disease
- Laboratory and Pathology Services
- Radiology/Diagnostic Imaging Services
- Complementary Health services

The RS/UM Program has been designed to ensure the following:

1. Services are medically necessary, consistent with the patient's diagnosis, and delivered at appropriate levels of care.
2. Authorized care matches the member's benefit.
3. Services are provided by NWP or its contracted providers unless otherwise authorized.
4. Guidelines, standards, and criteria set by regulatory and accrediting agencies are adhered to as is appropriate to health plan product and specific population (e.g. Commercial, Medicare, Medicaid, Marketplace):

- KPNW uses written, current versions of criteria based on sound clinical evidence to make RS/UM decisions (e.g., MCG, Medicare, and those developed by NWP) taking into account the local delivery system and members' individual circumstances.
5. The UM team of physicians, licensed staff, and unlicensed staff are trained and qualified to assess clinical information used to make UM decisions. Appropriately licensed health professionals supervise all review decisions.
  6. A written RS/UM Work Plan and Program evaluation are approved annually by the KPNW Regional Operations Quality Group (ROQG).

## Program Goals

The Resource Stewardship Program goal is to assure care is delivered to KP members with consistent quality, safety and efficiency, regardless of the place or provider of service. The Program seeks to monitor, evaluate, and improve continuity and coordination of care; identify potential quality of care, service and patient safety issues.

The objectives of the RS/UM Program are to:

1. Elevate the importance of “affordability” in the mindset of all clinicians and employees.
2. Establish the annual and long-range regional resource stewardship priorities.
3. Determine the metrics and targets to be used to measure success on each of the priorities.
4. Identify the system/process changes required to achieve success on the resource stewardship priorities.
5. Collaborate with appropriate regional and operational leadership to implement improvement initiatives.
6. Charter and sponsor or lead task forces and/or standing committees to support the work. Provide clear objectives and due dates. Obtain regular updates to monitor progress.
7. Take a regional resource stewardship view and ensure that resource stewardship activities in one area of the organization do not adversely impact other areas of the organization.
8. Develop clear, efficient, and effective decision-making processes between committees and line management.
9. Address barriers to achieving the resource stewardship priorities.
10. Monitor and communicate performance on all key indicators. Alert ROQG when performance is not meeting targets or shows declining trend(s).
11. Ensure that KP HealthConnect, Data Warehouse applications, and other tools support the resource stewardship priorities. Prioritize and sponsor proposals for new or expanded functionality.
12. Stay abreast of changes, innovations and best practices in resource stewardship across the Program and outside KP. Make recommendations for which practices should be imported to KPNW.
13. Recommend appropriate use of such tools as Lean Thinking, Accelerated Improvement Methodology, Reliability Science, and other proven methodologies to assist in achieving resource stewardship priorities.
14. Understand and act on the interfaces between Resource Stewardship and Quality to improve affordability.
15. Ensure all utilization review (UR) compliance requirements are met in the most streamlined, efficient way possible. Follow-up on all audit findings to successful completion.
16. Provide oversight to delegated UM functions.

## Structure and Accountability

### National Program Accountability

The Kaiser Foundation Health Plan, Inc. (Health Plan) is a California not-for-profit public benefit corporation, which is governed by Boards of Directors. The Kaiser Foundation Health Plan (KFHP) Board of Directors has the ultimate accountability and responsibility for overseeing the quality of care and service provided to Kaiser Health Plan members. The KFHP and Kaiser Foundation Hospital (KFH) Boards of Directors (BOD) established the Quality and Health Improvement Committee (QHIC) to oversee quality of care and service across all KP programs on its behalf. The Quality and Health Improvement Committee (QHIC) provides:

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1. Strategic direction for quality assurance and improvement systems
  2. Oversight of systems designed to ensure that quality care and services are provided at a comparable level to all members and patients throughout the Program and across the continuum of care
  3. Oversight of the Program's quality assurance, health improvement systems and organizational accreditation and credentialing

The Kaiser Permanente National Quality Committee (KPNQC) is a KFHP quality committee whose membership includes KFHP and KFHP senior quality leaders and Permanente Medical Groups' medical directors for quality. Its mission is to provide leadership, direction, and oversight of processes to improve continuously the quality of clinical care and services provided by the organizations that constitute the Kaiser Permanente Medical Care Program. The KPNQC is accountable to and acts at the direction of QHIC.

### **Regional Accountability**

#### Regional Operations Quality Group (ROQG)

The KPNW Regional Operations Quality Group (ROQG) serves as the highest level quality committee for KPNW. ROQG is responsible for implementing and assessing medical and dental services, both internal and contracted. ROQG uses the Big Q model to focus resources on five key areas that impact quality performance: resource stewardship, clinical quality, service, patient safety and risk management. Committees and departments accountable for each focus area provide recommendations to ROQG including priorities, strategies, and short and long-term targets. ROQG is co-chaired by the health plan's Vice President of Quality, Patient Safety, Care Experience and Population Health and NWP's Vice President of Quality, Care Experience and Patient Safety who are accountable to ensure appropriate oversight of all areas of the Big Q. ROQG charges the UM and Resource Stewardship leaders to monitor and communicate performance, identify challenges, implement improvement activities, and promote consistency across the region. ROQG sponsors are the KPNW Regional President and the Executive Medical Director.

#### Resource Stewardship

The Resource Stewardship Program and UM Department are responsible for systematically stewarding KPNW's resources in order to provide superior quality and value for its members and purchasers; and for ensuring KPNW's compliance with all utilization management accreditation and regulatory requirements (NCQA, Federal, State, etc.). The UM Department is led by the NWP Regional Medical Director for UM and the NWP Senior Administrator of UM.

#### Utilization Review Oversight Committee

The Utilization Review Oversight Committee (UROC) is a multi-disciplinary committee co-chaired by the Regional Medical Director for UM and the Administrator of Utilization Review. The committee is comprised of staff who represent the areas of Quality Management, Compliance, Clinical Operations, and Insurance Administration, as well as physicians and staff representing physical and behavioral health as needed. UROC oversees the annual review and approval of medical necessity criteria used in the region; reviews and approves policies and procedures addressing UM and UR activities; analyzes denial and appeal data including reporting by product line (Medicare, Medicaid, Commercial); conducts inter-rater reliability activities; performs audits of UR decisions and processes to ensure compliance with regulatory, accreditation and program requirements; provides oversight of contracted entities to whom UM/UR activities have been delegated; and other functions related to UR. UROC reports to ROQG at least annually. (*See UROC charter*)

#### Regional Formulary and Therapeutics Committee

The Regional Formulary and Therapeutics Committee (RFTC) has accountability for the clinically appropriate use of pharmaceuticals and includes representatives from KFHP and NWP. (*See RFTC charter.*) The RFTC considers additions and exceptions to the formulary based on medical necessity. Appropriate prescribing practitioners are involved to consider exception requests. Pharmaceutical management policies and procedures define criteria used to adopt pharmaceutical management practices, including use of clinical evidence from appropriate external resources. Pharmaceutical management procedures and formulary changes are communicated to practitioners annually and when changes are made. As patient safety is critical, processes are in place for identifying and communicating potential drug interactions and for FDA-required or voluntary recalls.

### New Technology Committee

The evaluation process for the inclusion of new technology within KPNW involves both national and local structures. The KP Interregional New Technologies Committee (INTC) monitors and evaluates new technologies and new applications of existing medical and behavioral technologies. INTC makes a recommendation to each region for adoption. The Regional Benefits Committee (RBC) reviews new technology and makes decisions regarding if/when to integrate in KPNW. RBC hands off to the Utilization Review Oversight Committee if medical necessity criteria or a UR process (authorization processes or development of local criteria for medical necessity) are applicable. The KPNW Regional Benefits Committee also determines if the new technology will be included in plan benefits.

### Mental Health and Addiction Services (Behavioral Health)

As Chair of the Utilization Review Oversight Committee (UROC), the Regional Medical Director for **UM** has direct responsibility for the RS/UM Program's integration of behavioral health. In addition, a designated behavioral health practitioner, a board-certified, senior mental health physician, is involved in the UM Program implementation through:

- the oversight of the authorization and denial processes related to behavioral healthcare services.
- the annual review/revision/approval process of the mental health and addiction medicine utilization review criteria and policies.
- participation on the Mental Health and Addiction Medicine Utilization Management Committee (UMC), responsible for identifying and analyzing behavioral health trends in utilization, discussing systems and care gaps, evaluating Kaiser and non-Kaiser service sites and their levels of care, and assessing inter-rater reliability among review staff. The UMC is comprised of UM and Benefit Coordinators, Care Coordinators, the Behavioral Health Senior Administrator, as well as the clinical representatives who provide departmental oversight and coordination of utilization management activities.
- participation on the Behavioral Health Clinical Consultation and Review Committee (CCRC), responsible for discussing complex behavioral health cases and reviewing medical necessity criteria. In addition to the designated behavioral health physician, the CCRC is comprised of Care Coordinators, UM Reviewers and the Behavioral Health Senior Administrator.

The Behavioral Health Senior Administrator and/or a designee participate on both the UMC and CCRC, described above, and is also a member of UROC, acting as the representative and liaison for behavioral health UM issues applicable to these committees, such as departmental inter-rater reliability and revisions to UM criteria, policies and processes.

### Physician Leadership

The Regional Medical Director (RMD) for UM has direct responsibility for the UM Program implementation and provides oversight for day-to-day activities, including supervision, oversight and evaluation of the UM Program functions. The RMD has accountability to the Vice President, Value and Resource Stewardship of the Northwest Permanente Medical Group.

### Operational Leadership

The Senior Administrator of UM shares day-to-day responsibility for the UM Program. The Senior Administrator of UM reports to the NWP Vice President, Administration and Business Affairs, who reports to the NWP Executive Medical Director.

The RS/UM Program provides specifically trained and designated nursing professionals who are responsible for Care Coordination for inpatient services, patient transfers, out-of-plan care, and selected pre-service, concurrent, and retrospective review activities, including screening of cases through the use of published and organizationally developed criteria. A staff position is responsible to monitor compliance with guidelines.

## Resource Stewardship Functions

Resource Stewardship is an organization-wide interdisciplinary approach to balancing cost, quality and risk concerns in the provision of health care. It includes utilization review, coordination of care (episodic, case management, complex case management and disease management) and monitoring systems.

The RS/UM Program provides for comprehensive monitoring of RS/UM data for KPNW and for individual product lines to detect potential under-, over-, and mis-utilization. The program has annual performance targets linked and integrated with KPNW financial, service and quality improvement goals. Physical and behavioral health performance targets include inpatient discharges and lengths of stay, use of emergency services, and other important measures as defined annually in the RS/UM Workplans. The RS Program collaborates closely with Medical Operations, particularly the Regional Telephonic Medicine Center and the Clinical Quality and Services Support Department (CQSS) to foster appropriate care and services for all members and special populations.

## Utilization Review Decision-Making

Utilization Review decision-making is based only on appropriateness or medical necessity of services and the existence of coverage. Kaiser Permanente does not specifically reward practitioners or other individuals for issuing denials of coverage or service/care. Financial incentives for utilization management decision makers do not encourage decisions that result in under-utilization.

All Utilization Review (UR) medical necessity criteria (MNC), purchased or developed, are based on medical evidence, on a consensus of relevant health professionals, and/or, are imposed by a funding source, e.g. Medicaid or Medicare. UR MNC are adopted with input/oversight by NWP physicians with clinical expertise in the area of service for which the MNC apply.

While written criteria direct UR decisions, physicians involved in making medical necessity determinations utilize clinical expertise, knowledge of availability of resources/services in the local delivery system, and supporting clinical information that may include consultation with a board-certified specialist in making coverage decisions. As outlined in the Regional UR Medical Necessity Policy (UR 4), staff and physicians involved in review processes review appropriate clinical information sent with the request for service, access the patient's electronic or paper medical record, and/or consult with the ordering clinician as needed.

## Utilization Review Criteria

### Medical Necessity Criteria

KPNW applies objective and evidence-based criteria when making UR decisions. In many cases, nationally recognized criteria are used including MCG and Medicare criteria. In some cases, the region has adopted evidence-based criteria developed by appropriate NWP practitioners. All criteria are reviewed and modified when necessary, but at least annually, by appropriate practitioners. They are then reviewed and approved by the Utilization Review Oversight Committee (UROC). If updates are necessary between review cycles, they are evaluated and applied as needed after approval by the UROC.

The region recognizes that other factors must be considered when making UR decisions, therefore, factors such as age, comorbidities, complications, member's progress with the treatment plan, psychosocial situation and the home environment are assessed before a decision is made. Benefit application and the availability of resources are also factored into decision making. These resources may include skilled nursing facilities, subacute care facilities, acute rehabilitation facilities and home care organizations to care for members after hospital discharge. If the member requires additional inpatient care, the local hospital's ability to provide all recommended services within the estimated length of stay is considered.

### Behavioral Health Services Criteria

Criteria for mental health services are based on clinical evidence and currently accepted industry practice as defined in the current editions of the Diagnostic and Statistical Manual of Mental Disorders and MCG. The criteria address all covered mental health settings of care and levels of urgency. The process of applying the review criteria for Mental Health (MH) is overseen by the designated behavioral health UM physician.

Mental Health uses written triage assessment criteria to ensure that members gain access to appropriate mental health care based on the urgency of their needs. Mental Health triage therapists are fully licensed Mental Health practitioners

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with appropriate training and appropriate years of experience. Supervision of the Mental Health Triage Therapists, at a minimum, will be provided by a licensed masters-level practitioner with at least five years of post-master's clinical experience. The Chief of the Mental Health Department, who is a board-certified psychiatrist with a current unrestricted license, oversees the Mental Health triage protocols, reviewed/ revised every two years, as well as the quality of the clinical services delivered by the triage therapists.

Addiction Medicine has adopted the American Society of Addiction Medicine's Patient Placement Criteria, 2<sup>nd</sup> Edition (ASAM-PPC-2R). These national criteria are objective and based on medical evidence. Use of the ASAM-PPC-2R criteria is required by regulatory agencies in Oregon and Washington for licensed treatment programs. The Chief of Addiction Medicine, Clinical Director, Addiction Medicine Manager, and all clinicians are involved in the UM program and operate under current, unrestricted licenses appropriate to their clinical and/or administrative duties. (For a more complete description of the Program's mental health and addiction medicine aspects, see UR Policy #14a- Mental Health Medical Necessity Criteria; UR Policy #14c- Mental Health Protocols for Triage and Referral Assessment; and UR Policy #16a- Addiction Medicine Program Description).

Members self-refer to the addiction medicine department. At the initial face-to-face appointment, the addiction medicine counselor utilizes the ASAM-PPC-2R criteria to help determine whether a patient is appropriate for chemical dependency program services. When a patient's treatment needs can not be provided at Kaiser Permanente's Department of Addiction Medicine, the counselor must make an appropriate referral for the patient, based on the presenting symptoms and diagnoses. Such a referral could be to mental health, residential treatment, cultural-specific treatment programs, individual treatment within Addiction Medicine, or to community services for non-covered treatment.

## Utilization Review Process

### Prior Authorization - Pre-service Review

Most decisions about the appropriateness or medical necessity of specific services are made by the treating practitioner, however, when prior authorization is required, medical criteria and/or the specific judgment of the designated physician reviewer are applied. Examples of services that require prior authorization include: services provided by non-KPNW clinicians (not employed by KFH or KFHP and not members of the NWP medical group), durable medical equipment (DME), bariatric surgery, certain inpatient services, breast reduction, some acupuncture and chiropractic care, skilled nursing care, routine foot care, organ transplants, etc. Post-stabilization services after treatment of an emergency condition also require prior authorization.

Appropriate clinical staff (such as Regional Referral Center staff and nurses, DME staff, pharmacists, medical assistants and nurses in various medical operations departments) review requests for services and items that require prior authorization, verify benefit availability of the requested service/item and apply medical necessity criteria. Services/items that are not a covered benefit, as specified on the Common Membership (CM) System or in a member's contract, are denied as "not a covered benefit". Services/items that are a covered benefit on a member's plan and meet criteria are authorized. Services/items that are a covered benefit but do not meet criteria or that need further review are reviewed by the designated physician reviewer who makes the final decision. Designated physician reviewers also review requests from prescribers for medications that have medical necessity criteria in place.

Although a referral for mental health services is not required, a triage therapist assesses new and returning members and directs them to the appropriate resources within the department.

Written RS/UM medical necessity criteria based on current, reasonable, and sound clinical evidence (e.g. MCG, Medicare, and NWP recommendations) are used to conduct benefit and medical necessity determinations. Specific procedures demonstrate fair and consistent RS/UM decision-making. NWP involves appropriate, actively practicing practitioners in the development or adoption of criteria and in the development and review of procedures pertaining to criteria application.

### Concurrent Review

Concurrent review occurs when a member is in the process of receiving care and an evaluation for the continuation of care is conducted. Concurrent reviews generally occur when a member is receiving inpatient care or ongoing ambulatory

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care that requires prior authorization initially or post stabilization care after an emergency. Often an extension of services is being requested. Clinical staff within the respective departments (i.e. nurse reviewers/UM coordinators in Mental Health for inpatient services, DME staff for DME requests, referral center staff and nurses for referral extensions to non-KPNW practitioners) review and involve designated physician reviewers as required. Any services that are denied based on medical necessity must be reviewed by the designated physician reviewer prior to issuing the denial.

**Retrospective or Post Service Review**

Retrospective reviews occur after the member has received care, usually at non-KPNW locations, without a referral, and after they have submitted a claim for payment or filed an appeal. Staff in the Claims Department review and make benefit decisions on claims. Retrospective issues related to medical necessity or prior authorization disputes are reviewed by staff in Member Relations, the Regional Referral Center or the Medical Necessity Review Department. All issues related to medical necessity decisions are reviewed by physician reviewers prior to issuing a denial.

**Escalation of Medicare Advantage Issues**

While case-by-case decisions regarding medical necessity are managed locally by Northwest physician and operational leadership, issues of particular concern regarding Medicare beneficiaries may be identified by the UROC. As issues are identified in the UROC, they may be elevated to the KPNW Medicare Compliance Department, who may engage the Medical Director for Medicare Advantage, Cost and Part D plans through written or telephonic communication as expeditiously as required to resolve the issue or mitigate risk to KP Medicare beneficiaries or to KP.

Issues for concern that may be suitable for escalation to the Medicare Compliance Department include:

- a. awareness of a situation or event that has potential for KFHP, Inc. operation-wide concern, i.e. an issue that may impact all Medicare Advantage Plans, Cost Plans, and Prescription Drug Plans;
- b. a UM or quality-related occurrence or event that has the potential to put the organization or member at risk;
- c. an opportunity to request consultative advice or opinion from the Medical Director, such as a review of a challenging case;
- d. notifying the medical director of a decision on appeal from an Administrative Law Judge (ALJ) or Medicare Appeals Council (MAC).

**Utilization Review Policies**

**Utilization Review**

KPNW has approved policies and procedures addressing the review, authorization, and notification process with associated time frames for medical necessity decisions, benefit determinations and appeals. These policies and procedures support decision-making that is consistent, equitable, and done in a timely manner in accordance with applicable medical and hospital service agreement or members’ evidence of coverage (EOC) and UR criteria.

Utilization Management denial determinations must be made by a licensed MD or DO; however, chiropractic denial determinations for Washington commercial members and Medicare members may be performed by a chiropractor.

Decision-makers who respond to member appeals related to services based on contractual provisions and/or medical necessity, will not have been involved in previous reviews related to the appeal and will not be a subordinate of a previous reviewer. Appeals requiring quality review, medical necessity, medical criteria application or experimental service determinations, will be reviewed by a physician who practices in the same or similar specialty that treats the medical condition involved and, in some instances, by an appeal review panel made up of medical and regulatory personnel.

Decisions are made based on a full investigation of the substance of the request or appeal, including any aspect of clinical care involved. The member’s perspective and any additional materials submitted, medical records including chart notes and non-plan records, physician reviews, medical necessity criteria, contractual and policy provisions and other relevant documents are considered.

The member’s initial notification of denial contains the reason for the decision, informs the member of the number of days allowed to file an appeal and provides a description of their appeal rights, including the right to submit written

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comments, documents, or other information relevant to the appeal. The written appeal notification contains the reason for the decision, additional appeal rights if applicable, and the right to a review by an independent review organization (IRO). The notice specifies the title and credentials of the reviewer; the complete criteria used in reaching the decision or how to access the complete criteria (when applicable); insurance-specific appeal rights; and insurance division and group-specific required language. Appeal notices include the right to review/receive a free copy of the appeal file. Notices for urgent pre-service or urgent concurrent requests include a description of the expedited appeal process. Unless the requested service is urgent, members are required to participate in the internal appeal process before they can take legal action and/or before their appeal can be considered for external review.

The denial notification to the ordering clinician (when applicable) informs clinicians how to contact the reviewer making the determination and how to appeal.

### **Oversight of Decision Process**

Appropriately licensed health care professionals will supervise all UR decisions. A licensed physician will review any denial that is based on medical necessity (except for chiropractic care for Medicare members and some Washington members when a chiropractor performs the review). As appropriate, board-certified physician consultants from applicable specialty areas will assist in making medical necessity determinations.

Staff involved in UR decisions do not receive financial incentives which encourage decisions resulting in underutilization.

Denials are audited monthly in some areas and quarterly for region-wide compliance and quality monitoring. Audits are used to confirm that documentation for case review and denial of service reflects efforts to obtain all pertinent clinical information to support the decision-making process. Audits confirm that reviews include attention to whether there may be a disruption in care or service, appropriate patient transition to alternative resources, and adequate accommodation for the clinical urgency of a member's situation. The content and timeliness of notices are also audited.

### **Inter-rater Reliability (IRR) and Consistency of Decision Making**

KPNW uses an Inter-rater Reliability process directed by UROC to evaluate consistency in the application of UR criteria. IRR tools are developed with input from subject matter experts. Physicians and non-physician staff involved with UR decision-making participate in the IRR process annually. Corrective action is taken to address sub-threshold scores.

### **Member and Physician Satisfaction**

There are documented mechanisms to evaluate the satisfaction of members and practitioners with the RS/UM program on an annual basis. The Consumer Assessment of Healthcare Providers and Systems (CAHPS) is used to measure member satisfaction. Additionally, member complaints are used to provide department specific and region-wide information regarding member satisfaction with access, coverage and benefit determinations, as well as timeliness and process issues. Provider satisfaction is measured using a KPNW RS/UM fielded survey. Review of these data sources assist the program in targeting areas which require training, additional communication, or improvement.

### **Coordination of Care at End of Coverage**

The RS/UM staff assist members with a transition to other types of care, if necessary, when their coverage of benefits end. Members are educated about and helped with obtaining alternatives in care.

### **Episodic and Complex Case Management**

KPNW addresses the needs of members with episodic and complex care needs through an integrated program involving a team of multidisciplinary clinical staff. Coordination of members' transitions of care from inpatient to home or skilled nursing is provided. A Panel Support Tool and other data systems are used to track and anticipate needed services, including medication use, screenings and appointments with primary care and specialty providers. Plans of care are developed with the goal of preventing deterioration and the need for higher levels of care.

## Delegation

### Delegated Resource and Utilization Management Activities

The Utilization Review Department and UROC have responsibility for oversight and evaluation of any UR activities delegated to contracted entities. KPNW conducts a pre-contractual evaluation to determine the contractor's capability to perform the required UR functions. The contractor's UR Program is evaluated annually by the Utilization Review Department and is submitted to UROC for review. A mutually agreed upon contract for delegated UR functions include the following:

- Specific delegated UR activities for which the contractor and KPNW are responsible
- Reporting responsibilities and frequency requirements of the contractor.
- KPNW's evaluation process of the contractor's performance.
- KPNW's annual approval of the delegated contractor's UR Program.
- Remedies for non-fulfillment of contractor obligations.

## Monitoring and Reporting of RS/UM

### Ongoing Monitoring

KPNW conducts ongoing monitoring of resource management and utilization management processes and uses several reports that are distributed widely to medical and operations staff to support clinical and quality initiatives and improve practitioner awareness of utilization of key services.

Resource Stewardship metrics are defined for strategic priorities, and include at minimum, data on inpatient, emergency department, and ambulance utilization.

HEDIS (Health Plan Employer Data Information Set) is a set of standardized measures developed by the National Committee for Quality Assurance (NCQA) designed to allow reliable comparison of the performance of managed health care plans. The Use of Service data includes utilization measures for selected procedures and inpatient hospitalization which are reviewed for external comparability.

The National Big Q Performance Dashboard includes national and inter-regional data for risk adjusted, per member per month costs. These reports identify variances across KP regions in overall costs, and costs for inpatient, outpatient, pharmacy, laboratory, and specialty care services. Industry benchmarks, provided by MCG, compare KP's overall and regional health plan results against national benchmarks for well managed plans.

### Resource Stewardship Work Plan

To facilitate execution of the RS/UM program's goals, an annual Work Plan is developed. The Work Plan includes targets related to clinical and quality goals, timelines and accountabilities.

### Evaluation of the Resource Stewardship Program

The evaluation of the RS/UM Program is included in the overall Quality Program evaluation, which is reviewed and approved annually through the KPNW regional quality structure and the Quality and Health Improvement Committee of Kaiser Foundation Health Plan Board of Directors. To determine if the RS/UM Program remains current, appropriate and effective, an annual (and as necessary) evaluation occurs of the program structure; program scope; program processes; information sources used to determine benefit coverage and medical necessity; and the level of involvement of the senior-level physician(s). The analysis of the outcomes of the work plan in relationship to goals and objectives, including identification of any improvement opportunities, are then used to develop the next year's work plan. The Utilization Review Administrator prepares a draft of revisions to the RS/UM Program Description, work plan and annual evaluation document and presents them to the UROC for review and approval annually and as needed.