Uniform Medical Plan coverage limits

Updates effective 10/1/2020

The benefit coverage limits listed below apply to these UMP plans:

- Uniform Medical Plan (UMP) Classic (PEBB)
- UMP Consumer-Directed Health Plan (UMP CDHP) (PEBB)
- UMP Plus–Puget Sound High Value Network (UMP Plus–PSHVN) (PEBB)
- UMP Plus–UW Medicine Accountable Care Network (UMP Plus–UW Medicine ACN) (PEBB)

- UMP Achieve 1 (SEBB)
- UMP Achieve 2 (SEBB)
- UMP High Deductible Plan (SEBB)
- UMP Plus–Puget Sound High Value Network (UMP Plus–PSHVN) (SEBB)
- UMP Plus–UW Medicine Accountable Care Network (UMP Plus–UW Medicine ACN) (SEBB)

Some services listed under these benefits have coverage limits. These limits are either determined by a Health Technology Clinical Committee (HTCC) decision or a Regence BlueShield medical policy. **The table below does not include every limit or exclusion under this benefit. For more details, refer to your plan's Certificate of Coverage.**

Uniform Medical Plan Pre-authorization List

The Uniform Medical Plan (UMP) Pre-authorization List includes services and supplies that require pre-authorization or notification for UMP members.

Inpatient Admissions

See the substance use disorder and mental health sections for substance use disorder and mental health admissions.

These services or supplies have coverage limits	The rules or policies that define the coverage limits	
Hospital admissions	Pre-authorization is required for inpatient admissions. Read our Frequently Asked Questions. Notification of a hospital admission or discharge is necessary within 24 hours of admission or discharge (or one business day, if the admission or discharge occurs on a weekend or a federal holiday). Elective early delivery, prior to 39 weeks gestation, is not a covered benefit (not applicable to emergency delivery or spontaneous labor). Notification is required via electronic medical record, when available. If electronic medical records are not available, notifications are required via fax or by calling 1 (800) 423-6884. Providers should not call Customer Service to notify of patient admissions or discharge. Learn more about this requirement in the Facility Guidelines section of our Administrative Manual.	
Inpatient Hospice	Notification of admission or discharge is necessary within 24 hours of admission or discharge (or one business day, if the admission or discharge occurs on a weekend or a federal holiday). Notification is required via electronic medical record, when available. If electronic medical records are not available, notifications are required via fax. Learn more about this requirement.	
Long Term Acute Care Facility (LTAC)	Pre-authorization is required prior to patient admission.	
Rehabilitation	Pre-authorization is required prior to patient admission.	
Skilled Nursing Facility (SNF)	Pre-authorization is required prior to patient admission.	
Extracorporeal Circulation Membrane Oxygenation (ECMO) for the Treatment of	Regence Medical Policy MED152	• 33946, 33947, 33948, 33949, 33952, 33954, 33956, 33958, 33962, 33964, 33966, 33984, 33986, 33987, 33988, 33989

Respiratory Failure in Adults		• ECMO for UMP is subject to HTCC Decision for initiation. Regence Medical Policy is used for continued use criteria not addressed in the HTCC. • Subject to review.

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Pre-authorization for Elective Inpatient Admissions and Services
Frequently Asked Questions

OVERVIEW

Pre-authorization/pre-certification will be required for all services that occur during an elective inpatient admission. An authorization must be on file to ensure proper claims payment. This includes all applicable professional and facility claims:

- Effective April 1, 2019, for professional services
- Effective May 1, 2019, for facility services

These requirements apply to all Regence plans (group, Individual, Uniform Medical Plan [UMP], Medicare Advantage) and the Blue Cross and Blue Shield Federal Employee Program® (BCBS FEP®) Blue Focus plan in Oregon and Utah. They **do not apply** to BlueCard® members outside of our four-state service area or to BCBS FEP Blue Focus, Basic Option and Standard Option members in Idaho and Washington.

Effective July 1, 2019, these requirements will apply to BCBS FEP Basic Option and Standard Option members in Oregon and Utah.

Claims will be subject to pre-authorization requirements. If pre-authorization is not obtained, we may administratively deny the primary surgeon claim and the facility claim. We do not deny associated claims related to administrative denials.

Facilities should continue to notify us of admission.

Professional providers can begin pre-authorizing these services and admissions now through Availity®'s electronic authorization tool.

Do associated services and ancillary providers, such as anesthesia, radiology or laboratory services, have to be pre-authorized?
No. This pre-authorization requirement applies only to the primary surgeon claim and the facility claim.

Will professional claims be reviewed?
Yes. Professional claims may be reviewed post-payment; if pre-authorization was not obtained, we may request a refund.

What are the most common procedures that will be affected by this change?
We already required pre-authorization for most elective admissions prior to May 1, 2019. This new requirement applies to all elective admissions except child birth. This pre-authorization expansion includes such services as knee surgeries, hysterectomies, tubal ligations, vasectomies and gallbladder removal. We expect fewer than 1% of members who seek services to be affected by this new requirement.

Do these requirements apply to elective behavioral health services and admissions?
Yes.

Do these requirements apply to pregnancy deliveries?
No. Vaginal and C-section elective delivery admissions, as well as newborns, are exempt from these pre-authorization requirements.

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Pre-authorization for Elective Inpatient Admissions and Services
Frequently Asked Questions

Do these requirements apply to hospice?
No. Hospice admissions for non-BCBS FEP plans are exempt from these pre-authorization requirements. BCBS FEP plans will continue to require pre-authorization.

Which admissions are considered elective?
Elective admissions are admissions that are not urgent or emergent. They typically occur in association with an elective procedure; for example, a surgery that is beneficial to the patient but does not need to be performed at a particular time.

What is the purpose of these pre-authorization changes?
Reviewing inpatient stays, an industry standard, is part of our effort to ensure the member receives the right care in the right setting. An increasing number of procedures that have traditionally been done inpatient can now safely be performed in the outpatient setting for substantially less cost.
Pre-authorizing these admissions and professional services helps members and providers:

- For members, it alerts them pre-service to potential liability, which could occur if:
  - The pre-authorization is declined
  - The procedure isn't covered by their benefits
  - They have a procedure at an out-of-network facility
- For providers, it confirms whether the procedure is a covered benefit and is considered medically necessary.

How should professional providers request pre-authorization for these services and admissions?
Providers should submit the pre-authorization request through the electronic authorization tool on the Availity Portal, which will ensure all required information is submitted. This tool allows providers to check the status of their request without having to contact us.

Where can I find the instructions about submitting a pre-authorization request through Availity?
If you need help getting started, training is available in the Availity Learning Center. In the Availity Portal, click Help>Training>Get Trained and search the Availity Learning Center Catalog using keyword *authorizations*.

Do pre-authorization requests need to include the facility where the service and admission will occur?
Yes. Without this information, the facility may not be notified of the pre-authorization.

If pre-authorization is approved for a service but the inpatient admission request is denied for place of service, how will the provider and facility be notified?
Pre-authorization requests list the service/procedure code and the admission. Denials for admission are noted in the admission line. Providers and facilities will receive notification of the denial.

If we deny a request for either a service or the place of service, how do we notify the provider and the facility?
We will notify the provider by phone, fax or letter.

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Pre-authorization for Elective Inpatient Admissions and Services
Frequently Asked Questions

Are pre-authorization letters sent to the provider's physical or billing address?
Letters are sent to the address listed on the pre-authorization request.

Does the facility need to request a separate pre-authorization in addition to the provider's pre-authorization for the procedure?
No. The provider is responsible for requesting the pre-authorization, but the facility should confirm that a pre-authorization is in place.

Can the facility confirm the pre-authorization is complete in the Availity Portal?
No. They will need to request the pre-authorization information, including the authorization number, from the provider.

Can the facility request the pre-authorization?
It is the professional provider's responsibility to request the pre-authorization. These requirements concern elective inpatient stays at an acute care hospital. In these circumstances, the facility usually does not have the full clinical picture to request this pre-authorization and must rely on the provider to furnish this information.

These changes do not affect the current process for residential care facilities (RTC), partial hospitalizations (PHP), skilled-nursing facilities (SNF), long-term acute care (LTAC) and inpatient rehabilitation facilities (IPR).

If a facility has requested pre-authorization for admissions in the past, will their process change?
No, it will not. Facilities can continue to request pre-authorization as they have in the past.

When is a denied claim considered provider liability?
If the contracted provider does not obtain pre-authorization for the elective service, the denied claim is considered provider liability; providers cannot balance bill the members for provider liability.

When is a denied claim considered member liability?
A denied claim is only considered member liability if the pre-authorization request was denied, the member was notified of this denial, and the member received the denied services.

How have you notified providers?
The pre-authorization requirement for inpatient services was announced in our December 2018 issue of the provider newsletter, *The Connection*SM. We notified providers and facilities of the admissions change in our February 1, 2019, provider newsletter. The pre-authorization pages of our website have been updated to reflect the admissions pre-authorization requirement.

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Facility Guidelines

We follow specific guidelines for billing and payment for facilities that are outlined in this section.

To the extent the terms of this administrative manual are inconsistent with the terms of the participating agreement, the terms of the agreement prevail.

Effective October 1, 2020: For purposes of clarification, payment for inpatient services (whether priced as a diagnosis-related group, per diem or other methodology) shall be based on the reimbursement schedule in effect as of the relevant member's date of admission irrespective of contract amendments that take effect during the term of that member's inpatient admission. Any amendments to compensation amount shall be applied to services rendered to members admitted after such amendment's effective date.

Pre-authorization, eligibility and benefits
Please verify the patient's eligibility and benefits. Services in this section may require pre-authorization for medical necessity. Pre-authorization requirements can be found in the Pre-authorization section of our website.

Audits
We may audit any claim for appropriate coding, payment per contract and payment per Medical and Reimbursement policy. We will request any combination of invoice, medical records or itemized bill to support audit. All documentation requested must be provided within the time frame specified in the audit letter.

Inpatient hospital guidelines
An **inpatient hospital** is a facility, which primarily provides diagnostic, therapeutic (both surgical and non-surgical) and rehabilitation services by or under the supervision of physicians, to patients admitted for a variety of medical conditions.

Inpatient hospital claims are submitted electronically on an ANSI 837I (Institutional) format and exclude all professional components and air ambulance. Inpatient hospital claims must include the appropriate room and board revenue codes. Professional components, including pathology, radiology, anesthesia, emergency, etc., should be submitted electronically on an ANSI 837P (Professional) format.

An **outpatient facility** is that portion of a hospital which provides the following to sick or injured persons who do not require hospitalization.

- Rehabilitation services
- Diagnostic, therapeutic (both surgical and no-surgical) services
- May perform laboratory tests that are billed by the hospital
- May provide services in an emergency room or outpatient clinic
- May offer ambulatory surgical procedures and/or medical supplies

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Billing inpatient versus outpatient stays

We use MCG at **mcg.com** to determine appropriate level of care. Inpatient hospital claims must include the appropriate room and board revenue codes. The total units billed on the room and board revenue codes should match the length of stay as calculated as discharge date less admit date plus one.

Observation

Hospital observation is intended to allow a physician an opportunity to monitor and observe a patient and make a decision about on-going care. We reimburse for up to 48 hours of observation, if clinically appropriate, per the outpatient reimbursement terms. Observation stays beyond 48 hours may be rebilled by the provider as an inpatient stay and will process per inpatient guidelines. Applicable pre-authorization and notification requirements will apply.

If inpatient level of care is not met, reimbursement will be made for up to 48 hours per outpatient reimbursement terms. Covered charges, generally billed under revenue code 0760 or 0762 will be for the number of hours a patient is in observation, up to 48 hours. Charges for any twenty-four (24) hour period of observation cannot exceed the Hospital/Providers usual semi-private room rate.

Revenue code 0760 is not accepted for use to identify observation room charges.

We use MCG to determine appropriate level of care. In addition, we follow Centers for Medicare & Medicaid Services (CMS) guidelines regarding proper documentation of observation stays, including the *Medicare Outpatient Observation Notice* (MOON), form *CMS-10611* for Medicare members receiving outpatient observation care for more than 24 hours. All hospitals, including critical access hospitals, are required to provide this notice. You can find the notice and accompanying instructions at **cms.gov/Medicare/Medicare-General-Information/BNI/**.

Hospital-based physician services

To the extent your hospital and/or provider agreement does not address hospital-based physician services, the following guidelines will apply:

- Professional fees for covered services rendered to members by hospital-based physicians during a covered inpatient hospital stay, are not included in the hospital Maximum Allowable.
- Professional services should be submitted in an electronic ANSI 837P (Professional) format.

Pre-admission services

Pre-admission services are considered:

- Outpatient hospital services rendered two calendar days prior to an inpatient admission
- Diagnostic services (including clinical diagnostic laboratory tests) provided to a patient by the hospital and/or provider, or by an entity wholly owned or wholly operated by the hospital and/or provider (or by another entity under arrangements with the hospital and/or provider), within two days prior to and including the date of the patient's

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admission are deemed to be inpatient hospital services and included in the inpatient payment.

Hospital readmission review (group and Individual plans)
All hospital readmissions for the same, similar or related condition which occur within 48 hours of the original discharge from hospital/facility or as defined in the Hospital Provider Contract is considered a continuation of initial treatment.

The two Diagnosis Related Group (DRG) hospital claims (identified using the assigned provider identifier) will be consolidated into one, combining all necessary codes, billed charges and the length of stay. The maximum allowable for Covered Services will be recalculated per the reimbursement terms of the hospital/facility contract so that reimbursement is for a single, per case reimbursement.

This policy applies to the following but not limited to:

- Emergent readmissions
- Psychiatric readmissions
- Clinically related readmissions

This policy does not apply to the following:

- Readmission for unrelated condition
- Transfer from one acute care hospital to another
- Patient discharged from the hospital against medical advice
- Readmission for the medical treatment of rehabilitation care
- Readmission for cancer chemotherapy or transfusion for chronic anemia

For additional information view the *Inpatient Hospital Readmissions* (Administrative #111) reimbursement policy on our provider website: Policies & Guidelines>Reimbursement Policy.

Hospital readmission review (Medicare Advantage Plans)
Our policy aligns with CMS and includes readmission to the same hospital (using the assigned provider identifier) within 30 days of the initial admission. Hospital stays are subject to clinical review to determine if the readmission is related to or similar to the initial admission. Readmissions occurring:

- On the same day (or within 24 hours) will be processed as a single claim
- Within 2-30 days will be subject to clinical reviews. If the clinical review indicates that the readmission is for the same or similar condition, it may be considered a continuation of the initial admission for the purposes of reimbursement.

When we receive Diagnosis Related Group (DRG) claims for both an initial and subsequent hospital stay, we combine the subsequent hospital stay with the initial claim within our system. When this occurs, we will send you a notification reflecting these changes and additional payment, if applicable.

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This applies to, but is not limited to:

- Emergent readmissions
- Psychiatric readmissions
- Clinically related readmission
- Planned readmission or leave of absence

This policy does not apply to the following:

- Readmission for unrelated condition
- Transfer from one acute care hospital to another
- Readmission for the medical treatment of rehabilitation care
- Patient discharged from the hospital against medical advice
- Readmission for cancer chemotherapy, transfusion for chronic anemia or similar repetitive treatments

For additional information view the *Inpatient Hospital Readmissions* (Medicare Administrative #111) reimbursement policy on our provider website: Policies & Guidelines>Reimbursement Policy.

Submission of maternity/newborn claims
Separate claims must be submitted for the mother and newborn services. Claims that reflect both maternity and newborn charges on the same claim form will be returned to the hospital and/or provider for correct billing.

Interim billing
Interim bills will not be accepted. To properly adjudicate an inpatient claim, the patient must be discharged.

Late charges
Late submissions in general are not accepted. Late charges are defined as Type of Bill (TOB) code 115 and are not reimbursable. The hospital and/or provider must submit a corrected billing of the entire claim with TOB code 117 to receive reimbursement for charges not included when the original bill was submitted.

Hospital corrected billings and/or adjustments
Corrected claims must be submitted using TOB code 117. All claims must contain all pertinent information including all applicable International Classification of Diseases (ICD) diagnosis and procedure codes, present on admission (POA) flags and discharge status. Charges included on previously submitted claims, whether billed as interim or complete claims, must be included on the corrected claim. Itemizations or records may be requested to re-adjudicate the corrected claim.

Grouper use
To determine the Diagnosis Related Group (DRG) for an inpatient stay, we use the grouper version in effect on the date of admission. The Grouper used for reimbursement purposes is the

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DRG Grouper version as defined in the Inpatient Reimbursement Schedule found in your hospital and/or provider agreement and shall also be based on the date of admission.

Ungroupable DRGs

Ungroupable DRGs are defined as the following:

- MS DRG 998 and 999
- AP DRG 469 and 470
- MS DRG version 24 or lower: 469 and 470

Member deductible and coinsurance calculation

Member deductible, copayment and coinsurance amounts will be calculated based on the billed charges or maximum allowable, whichever is less.

DRG methodology

The following charges and fees are included in the DRG reimbursement:

- Late discharge
- Observational/outpatient
- Diagnostic laboratory services
- Emergency or after-hours admission
- Admission or utilization review paperwork
- Discharge (take home) prescription drugs
- Emergency room, if the patient is admitted
- Medical transportation (excluding air ambulance)
- Room and board, including services and supplies
- Pre-admission services two days prior to admission and one day post discharge

In general, for hospitals reimbursed using DRG methodology, most inpatient claims will be processed using DRG methodology. Some types of services and situations are excluded from this methodology, such as:

- Transfer patients
- Other circumstances specified in the provider contracts
- Hospitalization during the time insurance becomes effective with us

Note: Any exceptions will be specified in a hospitals current payment attachment(s).

Medicare post-acute transfer policy

It is important to follow the CMS requirements to report the correct discharge status when transitioning to another hospital, nursing facility, home health, hospice, inpatient rehabilitation facility, long-term care hospital or psychiatric hospital. We will audit and, if applicable, adjust claims based on the appropriate discharge status indicator.

The CMS policy is outlined in the MLN Matters article Fiscal Year (FY) 2006 Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) PPS Changes

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(MM4046) at **cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM4046.pdf**.

Facility pre-authorization requirements
Please note facility pre-authorization is required for:

- Rehabilitation
- Detoxification
- Skilled nursing facility (SNF)
- Long-term acute care facility (LTAC)
- Intensive outpatient for mental health and chemical dependency
- Partial hospitalization for mental health and chemical dependency
- Residential treatment for mental health and chemical dependency
- All elective inpatient admissions, including behavioral health (effective May 1, 2019)

Admission and discharge notification requirements
Notification of admission should occur within 24 hours of admission to assist with coordination of care and reduce 30-day readmission. These require notification be received within 24 hours after the actual weekday admission (or by 5:00 p.m. local time on the next business day, if 24-hour notification would require notification on a weekend. Facilities that submit patient data, including admission and discharge data, via electronic record submission/EDIE are no longer required to submit notification of inpatient admissions in another format.

Admission notification includes:

- All inpatient hospice admissions
- Chemical dependency detoxification
- All unplanned acute care admissions
- All planned and elective acute care admissions
- All admissions that follow an outpatient surgery
- All admissions that follow outpatient observation
- Intensive outpatient admissions for chemical dependency
- All newborns who are admitted to the neonatal intensive care unit
- All newborns who remain hospitalized after the mother is discharged

Admission and discharge notification, must be made via fax to 1 (800) 453-4341 or by providing us with access to the information via an electronic medical record application**. For Medicare lines of business, if the admission notification is not completed, we will review post-payment.**

- Admission notification by the facility for non-Medicare lines of business is required even if a pre-authorization was completed by the physician or other health care professional and a pre-authorization approval is on file with us.
- Receipt of an admission notification does not guarantee or authorize payment. Payment of covered services is contingent upon coverage within our individual member's benefit

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plan, the facility being eligible for payment, any claim processing requirements, and the facility's participation agreement with us.

- Admission notifications must contain the following details regarding the admission:
  - Member/patient's full name, date of birth and member number
  - Facility name and TIN or NPI
  - Actual admission date and anticipated discharge date
  - Admitting/attending physician full name and TIN or NPI
  - Description for admitting diagnosis or valid ICD diagnosis code
- Discharge Notifications must also contain the following on related to patient discharge:
  - Member/patient's full name, date of birth and member number
  - Primary diagnosis
  - Discharge disposition
  - Date of actual discharge
  - Facility name and TIN or NPI

Notification timeframe reimbursement

There may be exceptions to obtaining pre-authorization. The six situations listed below may apply as part of our Extenuating Circumstances Policy Criteria:

1. Member presented with an incorrect member card or member number.
2. Natural disaster prevented the provider or facility from securing a pre-authorization or providing hospital admission notification.
3. Member is unable to communicate (e.g., unconscious) their medical insurance coverage. Neither family nor other support present can provide coverage information.
4. Compelling evidence the provider or facility attempted to obtain pre-authorization or provide hospital admission notification. The evidence shall support the provider or facility followed our policy and that the required information was entered correctly by the provider office or facility into the appropriate system. *Note*: A copy of the faxed preauthorization request showing the information was entered correctly or a copy of the provider's or facility's fax cover sheet for hospital admission notifications indicating the member health plan information and a fax confirmation from the fax machine showing the fax was successfully sent to the appropriate health plan fax number will be considered compelling evidence
5. A surgery which requires pre-authorization occurs in an urgent/emergent situation. Services are subject to review post-service for medical necessity.
6. A participating provider or facility is unable to anticipate the need for a pre-authorization before or while performing a service or surgery.

Inpatient concurrent review

Effective May 1, 2020, we will require concurrent clinical review for the following types of acute inpatient medical and behavioral health admissions:

- Elective admissions that exceed the authorized goal length of stay for in-network facilities (commercial and self-insured plans only)
- Urgent medical admissions for in-network percentage-of-billed-charge or per diem facilities beginning two midnights or three days after admission

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- Critical access hospitals for Medicare beginning two midnights or three days after admission
- Urgent behavioral health admissions for in-network percentage-of-billed-charge or per diem facilities, including critical access hospitals and freestanding psychiatric hospitals, beginning four midnights or five days after admission
- Urgent admissions for in-network diagnosis-related group (DRG) facilities beginning on day 21 of the admission
- Urgent admissions for out-of-network facilities beginning on the day of admission (commercial and self-insured plans only)
- Urgent or on-going elective admissions for DRG facilities beginning on day 21 of the admission (Medicare Advantage only)

We will initiate concurrent reviews once we receive records by fax.

Urgent and emergent admissions: Facilities are required to submit inpatient notifications within 24 hours of admission and send us medical records upon request. Concurrent review on and extracorporeal membrane oxygenation (ECMO) for the treatment of cardiac and respiratory failure in adults will continue.

We require facilities to provide documentation when requested for extended length of stays and assist us with discharge and care coordination to reduce readmissions.

Please note for all facilities:

- Clinical records are no longer required, unless requested.
- All reviews are based on MCG Goal Length of Stay national/industry standards.
- Continued notification of inpatient admissions within 24 hours or one business day of the admission is still required.

It is our intent to conduct post-service reviews for medical necessity when such reviews are not conducted concurrently. Documentation for review via records requests may continue, as needed, for care coordination or upon receipt of the claim(s). If a claim does not meet MCG guidelines for the inpatient stay, it will be denied. Facilities should rebill Medicare Advantage claims using Type of Bill 0127, following CMS guidelines. Commercial claims can be rebilled with Type of Bill 0127 or 0137, whichever is appropriate. For more information, view the:

- Medicare Benefit Policy Manual (Chapter 6): **cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c06.pdf**
- MLN Matters® Number (MM8820): **cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8820.pdf**

<u>Payment implications for failure to pre-authorize services</u>

Failure to secure approval for services subject to pre-authorization requirements will result in an administrative denial, claim non-payment and facility liability. Our members must be held harmless and cannot be balance billed.

Please note the following:

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- Facility claims for services that require pre-authorization will be reimbursed based upon the member's contract only when the pre-authorization has been completed and approved. Facilities should verify the services have been approved.
- Admissions for services that require pre-authorization will be administratively denied if there is no approved pre-authorization. Administrative denials are a provider/facility write-off and cannot be charged to the member.
- When scheduling a service that requires pre-authorization, facilities should develop a method with the professional provider to ensure the pre-authorization request has been performed. The pre-authorization request submitted should designate the facility where the treatment will occur to ensure proper reconciliation with related inpatient claims.
- We will not accept retrospective requests for pre-authorization. If a member receives services that require pre-authorization and services are either started or completed before pre-authorization is obtained, the requestor will be advised that the service required pre-authorization and it was not obtained. Facility claims will be administratively denied and cannot be charged to the member.
- If a service that requires pre-authorization needs to occur during an inpatient admission and that need could not be foreseen prior to admission, the facility/provider can request pre-authorization for the service while the member is inpatient (before the service occurs). If pre-authorization does not occur during the stay, services are subject to review post-service for medical necessity.

Other facility guidelines

Level of Care

When a member's procedure or service is performed in a place other than the site of service approved by the health plan during the pre-authorization process, the member will not be liable for the charges and they will become a facility write-off.

Preventable Adverse Events

We follow our *Preventable Adverse Events* (Administrative #106) reimbursement policy. We also encourage the use of a Surgical Safety Checklist at **http://www.who.int/patientsafety/safesurgery/checklist/en**.

Reimbursement of Room and Board

We follow our *Reimbursement of Facility Room and Board* (Facility #103) reimbursement policy.

Medical management

Services and supplies that are eligible for reimbursement must be medically necessary, as defined in the medical policies.

Examples of medical management responsibilities may include, but are not limited to, the following:

- Preadmission review to determine whether a scheduled inpatient admission is medically necessary

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- Admission review to determine whether an unscheduled inpatient admission or an admission not subject to preadmission review is medically necessary
- Concurrent review to determine whether a continued inpatient admission is medically necessary, including the management of patient care by suggesting alternative sites and methods of care
- Length-of-stay review to assign the number of inpatient days appropriate for an inpatient stay
- Retrospective review to determine whether services and supplies were medically necessary including the assignment of appropriate diagnostic and procedure codes
- Case management to coordinate the care for patients whose medical needs are extensive and usually longer term, when applicable
- Review of the hospital's health care practices and utilization patterns
- Utilization guidelines to determine appropriate rendering of health-care services
- Collaboration with us on clinical guidelines/pathways and disease management programs
- Post-payment review for appropriate level of care when concurrent management has not occurred.
- Our on-site reviewers will have access from the provider, and appropriate personnel, to chart documents to assure the above. Concurrent reviewers will have access to charts and patients as needed on the nursing floors. Retrospective and quality reviewers will have access to chart documents in the provider's medical records department. Our reviewers will make best efforts to work with the provider and to audit policies
- Quality improvement activities that support credentialing, re-credentialing, clinical and service studies and other medical management functions

Outpatient hospital guidelines

Claims for all outpatient services, as defined below, must be submitted electronically in an ANSI 837I claim format using current CPT coding. Professional services that are billed in an ANSI 837P format are not affected. All claims must be submitted electronically.

- One procedure typically equals one unit of services (except: laboratory, radiology, mental health and physical therapy services).
- Claims that include a service that has a CPT code, but one is not listed, will be returned to the hospital for resubmission using the required code.
- Services will be subject to identical requirements for all outpatient providers (e.g., National Correct Coding Initiative (NCCI) at **cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html?redirect=/NationalCorrectCodInitEd/** and correct coding editor (CCE)
- Reimbursement is based upon a maximum allowable fee schedule (if submitted charges are less than the fee schedule, we will reimburse at the charged amounts).
- Claims for the same date of service for the same patient must be submitted as one claim, similar to inpatient claims. We will not accept interim bills for outpatient services, except monthly billing for rehabilitative services

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High-technology services
We will work with hospitals to identify high-technology services and supplies performed in an outpatient setting to establish appropriate billing protocols and standards for reimbursement.

Emergency room services
Most contracts include an emergency room copayment that may be collected at the time services are rendered. This copayment is waived in certain circumstances, such as when the patient is admitted to inpatient care directly from the emergency room. All services provided in the emergency room in conjunction with an inpatient hospital stay should be included on the inpatient hospital claim.

Rehabilitation services
Services for rehabilitative care, when it is medically necessary to restore and improve function previously normal but lost due to illness or injury are covered. If a child was covered from birth on one of our health plans, rehabilitation services for congenital anomalies may be covered.

Inpatient and outpatient rehabilitation services (physical, speech or occupational therapy) are eligible for reimbursement up to a specific dollar amount per condition. Some member contracts may require pre-authorization. The hospital must be approved for these services to receive reimbursement.

The following services or items are not covered:

- Gym or swim therapy
- Non-medical self-help
- Custodial care, maintenance
- Recreational, education or vocational therapy
- Chemical dependency rehabilitative treatment
- Learning disabilities (e.g., attention deficit disorders or development delay)
- Hippotherapy (Aqua and/or hippotherapy may be covered under some contracts if specific criteria are met.)

Note: Include the referring physician's name on all claims.

Pre-admission outpatient services
Claims processing system edits are in place to capture claims for outpatient services that are provided two days before a related inpatient admission and within one day after hospital discharge. Auditing is performed on a post payment basis.

Claims for outpatient diagnostic and non-diagnostic services billed within the two-day pre-admission and one-day post-discharge time frame will be re-processed by our auditors and denied because the charges are included in reimbursement for the inpatient stay. The patient is not responsible for the charge. The provider will be notified that this is a write off and not billed to the patient on the payment voucher.

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Outpatient reimbursement guidelines
Outpatient surgery is reimbursed based on rate classifications. Procedures that have not been classified may be paid using a discount of billed charges (if the procedure qualifies for reimbursement).

Refer to your agreement for specific details regarding outpatient reimbursement that may differ from the above-mentioned process.

Note: Outpatient prescription drugs are covered under a separate prescription drug benefit.

Multiple surgical procedures
The procedure with the highest fee will be paid to the maximum allowable rate for surgeries that involve more than one procedure. The second procedure will be paid at 50% of the maximum allowable rate. There will be no additional reimbursement for the third and subsequent procedures. Outpatient services will be subject to identical requirements for all outpatient providers (e.g., National Correct Coding Initiative (NCCI) at **cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html?redirect=/NationalCorrectCodInitEd/** and correct coding editor (CCE).

Non-reimbursable revenue codes
Unless otherwise specified in the contract:

- Clinic charges 0510-0529 are non-reimbursable.
- Revenue code 0761 must be appropriately billed. As directed in the UB-04 Editor, bill revenue code 0761 for actual use of a treatment room in which a specific procedure has been performed or a treatment rendered. Do not bill evaluation & management (E&M) CPT codes with revenue code 0761.
- E&M codes billed with revenue codes that include, but are not limited to: 0280, 0480, 0760, 0762-0769 and 0960-0989 are not reimbursable.

Freestanding ambulatory surgery centers
Freestanding ambulatory surgery centers (ASC) provide an alternative setting for surgical procedures that would otherwise be performed in a hospital on an outpatient basis.

ASCs:

- In most cases, are freestanding facilities
- Some may be co-located with a hospital, physician office or clinic
- Must meet the state's criteria for licensure when sharing a location
- Must have a registered nurse on duty at all times when patients are in the facility

Facility accreditation
Before reimbursement can be approved, or contracted for facility fees, a freestanding ASC must be credentialed. The freestanding ASC must have:

- A current passing state quality review survey
- A current onsite quality assessment completed by us, or
- A current passing quality review from the Centers for Medicare & Medicaid Services (CMS)

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CMS or state surveys cannot be more than three years old and may be submitted upon recredentialing.

Reimbursement

A fee schedule is used for these claims. Fees for multiple procedures are calculated as follows:

- The code with the highest fees is reimbursed at 100%.
- The subsequent codes are reimbursed at 50% of the fee.
- Any code not subject to cuts is removed from consideration before reductions are applied.
- For any single procedure code, reimbursement is never more than the charged amount.

Unlisted codes (defined by CPT as a code used for services or procedures that do not have a specific code) that are covered CPT Category III Codes, may be reimbursed at percentage of charges or as outlined in the provider agreement.

ASCs are not reimbursed for:

- Procedures usually performed in an inpatient or outpatient hospital setting
- Minor surgeries customarily performed in a physician's office and for which use of a facility is generally considered part of the physician's office overhead. (e.g., where the Relative Value Unit (RVU) assigned includes a consideration for overhead)

Billing guidelines

- Include Modifier SG on all surgical codes.
- Facility charges should be submitted on an ANSI 837P.
- Use '24' or other designated appropriate place of service code for a freestanding ASC.
- All line items must be submitted on one claim. Do not bill separate procedures on multiple claim forms.

ASC facility fee services

Unless otherwise specified in the contract, the maximum allowable is intended to include, but not limited to the following:

- Intraocular lenses for insertion during or after cataract surgery
- Administrative functions such as scheduling or cleaning, utilities and rent
- Anesthetic and any materials, disposable or re-useable, needed to administer anesthesia
- Implants, including but not limited to the following: screws, plates, anchors, pins, and wires
- Nursing, technical staff, orderlies and others involved in patient care connected to the procedure, intravenous therapy, and other related services
- Use of facility, including operating room, recovery and/or short stay rooms, prep areas, and use of waiting rooms and lounges created for patients and relatives
- Diagnostic testing such as urinalysis, blood hemoglobin or hematocrit, pre-operative chest x-ray, and therapeutic items and services directly related to the procedure/service

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- Drugs (including take home), biologicals (blood), surgical dressings, supplies, splints, casts, appliances, non-custom braces, disposable infusion pain control pump, and equipment related to the provision of care

Services not included in the ASC facility fee

Unless otherwise specified in the contract, these items should be billed separately from the facility fee with appropriate Healthcare Common Procedure Coding System (HCPCS) or CPT coding.

- Ambulance services
- Custom braces (e.g., leg, arm, back and neck)
- Services furnished by an independent laboratory
- Physician or other individually contracted provider services, including anesthesia
- The sale, lease or rental of durable medical equipment to ASC patients for use in their homes
- Prosthetic devices defined as those items that are permanent replacements to existing body parts, including artificial legs, arms and eyes. Invoices are to be submitted upon request. Shipping and handling are not separately reimbursed.

Physician charges

The physician charge is the fee for performing the surgery and related diagnostic and therapeutic services. This includes the administration or the supervision of the administration of local anesthesia or IV sedation. The professional fees are billed separately by the performing physician. The facility and performing physician codes must be the same.

Hospice

Hospice services provide medical, nursing, and emotional care when a cure is no longer possible. Hospice care is provided by a coordinated team of professionals and may include a:

- Nurse
- Physician
- Therapist
- Social worker
- Home health aid
- Bereavement counselor

Hospice services may need pre-authorization for medical necessity.

Submitting claims

- Submit claims electronically in an ANSI 837I claim format and submit it once every month.
- Include all charges for each month on one claim. Do not overlap calendar months or years.

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Billing guidelines

Current revenue codes and the services they include are listed below. The revenue codes are subject to change.

0651- Routine home care (per diem) includes:

- Dietary counseling
- Medical equipment and supplies
- 24-hour on-call medical management
- Grief counseling with patient and family
- Physical, occupational and speech therapy
- All visits by nurses, chaplains, MSW's and HHA volunteers
- All medicine pertaining to terminal illness, including pain management

0652 - Continuous home care (per hour)

- The patient needs at least 8 hours of skilled nursing care at home
- The caregiver cannot cope or when patient needs intensive short-term care

0655 - Inpatient respite care (per diem)

- The patient is in a SNF

0656 - Inpatient hospice care (per diem)

- The patient is hospitalized for pain control

0659 - Other hospice care

- Use this code for in-home respite care (per hour)

Hourly non-skilled care provided to patient when respite is needed for the caregiver.

Services not Included in hospice care

The following services are not included. They should be billed separately by the performing provider:

- Surgery
- Tube Feedings
- Physician services
- Blood transfusions
- Ambulance services
- Diagnostic radiology
- Drugs not related to the terminal illness
- Chemotherapy and radiation (other than when used for pain control)
- IV's and intravenous medications necessary for pain or symptom management

Treatment plans

Treatment plans and progress notes may be requested for selected patients. We reserve the right to review past records and claims submissions. The fully documented treatment plans must include:

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- Physician prescription or referral
- Appropriate and legible chart note documentation

The treatment plan should describe in detail the specific hospice services to be provided to the patient. Progress reports and/or notes which support the following status of the patient:

- The diagnosis or diagnoses must support the level of care provided.
- Medical necessity of the care provided must be demonstrated and may be subject to review.
- Procedures performed must be within the scope of license as defined by either the Revised Code of Washington, Washington Administrative Code or the governing Quality Assurance Commission.

Skilled nursing facilities
Skilled nursing facilities (SNF) care for individuals requiring rehabilitative services and/or the daily attention of nurses. SNF care is for patients that no longer need all of the medical support provided by a hospital but need more skilled care than they would have at home or in a nursing home.

SNFs may be referred to as transitional care units, extended care facilities, nursing homes or sub-acute facilities.

Admissions require pre-authorization to determine medical necessity, treatment plan, length of stay, as well as requiring ongoing concurrent reviews. It is the responsibility of the SNF to ensure that a pre-authorization is in place and completed upon admission.

Physician Certification and Recertification requirements
According to the Washington Administrative Code (WAC) 388-97-1260 at **apps.leg.wa.gov/WAC/default.aspx?cite=388-97-1260**, the skilled nursing facility must ensure that the resident is seen by a physician, whenever necessary. In addition except as specified in the Revised Code of Washington (RCW) 74.42.200 at **apps.leg.wa.gov/RCW/default.aspx?cite=74.42.200**, a physician must personally approve in writing a recommendation that an individual be admitted to a skilled nursing facility.

The skilled nursing facility must also ensure that except as specified in RCW 74.42.200, the medical care of each resident is:

- Supervised by a physician
- When the attending physician is unavailable, another physician supervises the medical care of the residents
- Physician services are provided 24 hours per day, in case of emergency.

The physician must:

- Write, sign and date the progress notes at each visit, including all orders
- Review the resident's total program of care, including medications and treatments, at each federally required visit in Medicare and Medicare/Medicaid certified facilities.

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Notice of Medicare Non-Coverage (NOMNC) form

Our network SNF and home health providers with Medicare contracts are expected to deliver the NOMNC according to CMS guidelines at least two days before the last day of covered SNF or home health services for Medicare members. The NOMNC informs our members of the date they no longer meet criteria for SNF or home health care and describes their appeal rights.

We will request the clinical documentation to support continued SNF or home health care three to five days before the current authorization period ends. Based on our review, we will notify you of our determination as follows:

- If we determine that continued SNF or home health care is appropriate, we will send notification of the new authorized dates.
- If we determine that the patient no longer meets the criteria for SNF or home health coverage, we will prepare the patient-specific NOMNC and send it to you with our determination. **It is your responsibility to deliver the NOMNC to the patient or his or her authorized representative at least two days prior to the last day of coverage.**

Please follow these steps to ensure that the NOMNC is delivered in compliance with the requirements:

1. The SNF or home health agency discusses discharge with the patient and family or authorized representative informing them of the last covered day of services, and presents the NOMNC provided by Regence.

2. The patient or authorized representative signs page 2 of the NOMNC. If the patient is unable to sign and the SNF or home health agency is working with an authorized representative who is unable to be present that day, the SNF or home health agency may issue the NOMNC by telephone. For a telephonic notice to be valid, the documentation on the NOMNC must include all of the following:

   - The name of the staff person initiating the contact
   - The name of the representative contacted by phone
   - The date and time of the telephone contact
   - The telephone number called
   - A notation that full appeal rights were given to the representative

   The date of the telephone conversation is the date of the receipt of the notice. The facility or agency must confirm the telephone contact by sending written notice to the authorized representative on that same date.

3. Copies of the completed NOMNC are:
   - Given to the patient or the authorized representative who signed the NOMNC
   - Placed in the patient's medical record at the SNF or home health agency

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- Faxed to Regence at 1 (855) 240-6498 as soon as possible after the form is signed

NOMNCs can be issued early to accommodate a weekend or to provide a longer transition period. After delivery of the NOMNC, the patient may choose to appeal the decision. They must contact the Quality Improvement Organizations (QIO) to request a review no later than noon on the day before services are to end. The QIO appeal decision will generally be completed within 48 hours of the patient's request. Please be prepared to provide documentation to us quickly to assist the QIO review process.

Provider responsibility for failure to deliver a valid NOMNC: Medicare Advantage providers are responsible for the delivery of the NOMNC. **Effective January 1, 2020, if a QIO or Regence determines that you did not deliver a valid NOMNC to a beneficiary or that requested records were not returned by a stated deadline, you will be financially liable for continued services until two days after the beneficiary receives valid notice, or until the effective date of the valid notice, whichever is later.** You must supply all information, including medical records, requested for the QIO appeal to Regence.

Home health

Home health encompasses a broad spectrum of both health and social services delivered to the recovering, disabled or chronically ill person in the home environment. These services include:

- Nutritional services
- Medical social services
- Therapy services (e.g., physical, occupational, speech)
- Traditional professional nursing and home care aide services

Generally, home health is appropriate whenever a person needs assistance that cannot be easily or effectively provided only by a family member or friend on an ongoing basis, for a short or long period of time.

Home health care is subject to the following limitations:

- The patient's condition must be serious enough to require hospitalization in the absence of home health care.
- The patient must be homebound, which means that leaving the home could be harmful to him or her or would involve a considerable and taxing effort.

Please verify the patient's eligibility and benefits. Home health services may require pre-authorization for medical necessity. Pre-authorization is required for Medicare Advantage patients' subsequent episodes of treatment beginning with the 61st day of home health care. (Pre-authorization is not required for the 60 consecutive days of home health care.) *Note*: Effective January 1, 2020, an episode will be defined as a period of 30 consecutive days, not by the number of visits.

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Billing guidelines

The following services can be performed by any of the following professionals, if they are employees of and billed by an approved home health agency:

- Certified aide
- Speech therapist
- Registered nurse
- Physical therapist
- Nutritionist/Dietician
- Master social worker
- Occupational therapist
- Licensed practical nurse

A written treatment plan and the signature of the attending physician must be on file at the home health agency.

A home health agency can submit claims for supplies and home medical equipment that are eligible for reimbursement. The treatment plan should describe in detail the specific services to be provided to the patient.

Claims Submission

All claims must be submitted electronically on an ANSI 837I (Institutional) claim format and include the revenue code and appropriate CPT/HCPCS code as indicated below.

Revenue code	Procedure code	Description
551	CPT 99500-99507, 99511, 99512 and 99600	Skilled nursing visit
552	HCPCS S9123	Hourly skilled nursing services
552	HCPCS S9124	Hourly LPN care
571	HCPCS 99509	Home health aide visit
572	HCPCS S9122	Hourly home health aide or CNA care
561	HCPCS S9127	Medical social services per diem
421	HCPCS S9131	Physical therapy per diem
431	HCPCS S9129	Occupational therapy per diem
441	HCPCS S9128	Speech therapy per diem
581	HCPCS S9470	Nutritionist visit
691	CPT 99509	Palliative care home health aide visit
691	CPT 99510	Palliative care medical social services visit

Note: Reimbursement for supplies is included in the payment amounts listed in your Agreement. Supplies shall not be considered eligible for additional reimbursement.

Submitting claims

- CPT/HCPCS codes with descriptions reading “per hour” will be reimbursed as one unit of service per day.
- The date of service should be the date of drug administration - not the date of shipment.
- Include all charges for each month on one claim. Do not overlap calendar months or years.

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- When billing for drugs use the National Drug Code (NDC) number and appropriate "J" code.
- There are certain infusion medications that require prior-authorization by us. Please refer to our drug formulary for the most current list.
- Charges for sales tax are not eligible for benefit consideration, except durable medical equipment defined by Washington state Senate Bill 6273 at **apps.leg.wa.gov/billinfo/summary.aspx?year=2010&bill=6273**.
- Retail drugs will not be reimbursed through the infusion therapy contract. Claims for retail drugs must be submitted through our pharmacy drug care program.

Treatment plans

Treatment plans and progress notes may be requested for selected patients. We reserve the right to review past records and claims submissions. We require fully documented treatment plans to include:

- Physician prescription or referral
- Appropriate and legible chart note documentation
- Progress reports and/or notes which support the status of the patient should include:
  - The diagnosis or diagnoses must support the level of care provided.
  - Medical necessity of the care provided must be demonstrated and may be subject to review.
  - Procedures performed must be within the scope of license as defined by either the Revised Code of Washington, Washington Administrative Code or the governing Quality Assurance Commission.

Pre-authorization

Pre-authorization requests should be submitted five to seven days before the subsequent episode begins. Requests should include the original Outcome and Assessment Information Set (OASIS) and the completed medication reconciliation form, both signed by the physician.

Medicare Advantage home health agencies

The Medicare Advantage home health program aligns reimbursement with quality for our Medicare Advantage home health agencies. The program is based on the CMS Quality of Patient Care Star Ratings in Medicare Home Health Compare. Medicare Home Health Compare is available at **medicare.gov/homehealthcompare/search.html**.

Quality ratings and reimbursement will be reviewed annually. Notification to agencies of changes to the percentage of Medicare allowable will be provided by October 1 each year for a January 1 effective date. Reimbursement rates will be based on an agency's Quality of Patient Care Star Ratings for the period ending each July based on the previous calendar year's data. Payment continues to be based on a percentage of the current CMS Home Health Prospective Payment System (PPS) fee schedule.

Home Health Quality Program Reimbursement		
CMS Star Rating	**Regence Quality Rating**	**%CMS Allowable**
4.5 to 5 Stars	Excellent	105%

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3.5 to 4 Stars	Good	85%
1.5 to 3 Stars	Adequate	75%
1 Star	Poor	70%

Note: If a home health agency has a Poor quality rating for two consecutive years, we will evaluate continued participation for the agency and may determine that terminating participation is appropriate.

Notification requirements for Medicare Advantage home health agencies
Home health agencies are required to provide written notification to Medicare patients before reducing or terminating an item and/or service and when home health services are ending.

In accordance with Medicare guidelines, home health agencies are responsible for issuing the following beneficiary rights and protections notices to Medicare patients when required:

- *Home Health Change of Care Notice* (HHCCN) Form CMS-10280
- *Advance Beneficiary Notice of Noncoverage* (ABN) Form CMS-R-131
- *Notice of Medicare Non-coverage* (NOMNC) Form CMS-10123 (See instructions under Skilled nursing facilities above)
- *Detailed Explanation of Non-coverage* (DENC) Form CMS-10124

These forms are available on the CMS website at: **cms.gov/Medicare/Medicare-General-Information/BNI**.

Home infusion therapy
Home infusion therapy allows patients to receive vital fluids and medications without the inconvenience or costs of a hospital visit. These services may be provided by any agency that is dually licensed as a pharmacy and a home health agency.

Home Infusion Therapy services are not allowable for days when a patient is in an inpatient facility.

Infusion services and/or administrative drugs may require pre-authorization. The patient must have a written prescription and plan of care. The provider should always sign changes in infusion therapy, including the dose and frequency of medication.

Wastage policy
Medicine mixed and delivered to the patient but not used must be billed by using the J code with modifier JW and the National Drug Code (NDC) number.

Per diem rate includes
- Lab draws
- Setup and disposal
- Administrative overhead
- Clinical pharmacy services
- Delivery of medication and supplies

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- Pharmacy compounding and dispensing fees
- Intravenous solutions, diluents and compounding ingredients
- Equipment (e.g., IV pumps, poles), ancillary medical supplies (e.g., syringes, tubing) and nursing supplies (e.g., catheter care kits, catheter-flushing solutions, dressings)

Nursing services include:

- Pharmacokinetic dosing
- Compounding of medication
- Patient/caregiver educational activities
- Monitoring for potential drug interaction
- Pharmacy assessment and clinical monitoring
- Review and interpretation of patient test results
- Medication profile set-up and drug utilization review
- Comprehensive knowledge of vascular access systems
- Development and implementation of pharmaceutical care plans
- Home visit by a health care professional in a single 24-hour period
- Recommendation of dosage or medication changes based on clinical findings
- Coordination of care with physicians, nurses, the patient and his or her family, other providers and caregivers
- Patient discharge services, including communication with other medical professionals and closing of the medical record
- Sterile procedures including intravenous admixtures, clean room upkeep, vertical and horizontal laminar flow hood certification and all other biomedical procedures necessary for a safe environment

Growth hormones

All growth hormones must be pre-authorized, and a contracted growth hormone provider must render all services.

Durable medical equipment and prosthetic devices

Durable medical equipment (DME) can enhance the quality of life for those in need of services by providing durable medical equipment and supplies. Rehabilitation products are a necessity for anyone who has been involved in any minor or serious injury or condition such as a stroke. For those whose injuries are less severe, DME needs may include items such as crutches, canes and walkers.

DME refers to equipment that is:

- Able to withstand repeated use
- Appropriate for use in the home
- Primarily and customarily used to serve a medical purpose
- Not generally useful to a person in the absence of illness or injury

The provider agrees to provide medical equipment, orthotic devices, prosthetic appliances and other medically necessary supplies to Regence's members who submit a physician's

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prescription to secure such equipment or supplies. Such medical equipment and supplies shall be immediately available in the provider's warehouse. Items not routinely available shall be delivered to the patient as rapidly as possible, not to exceed two calendar days unless delayed by the manufacturer. The provider shall obtain pre-authorization from Regence prior to providing certain medical equipment in accordance with Regence's published policy as amended from time to time.

The provider also agrees to the following additional responsibilities:

- Accept orders for medical equipment, related products and services on a 24-hour basis.
- Provide free delivery and installation of medical equipment and related products ordered for or furnished to patients.
- If requested by Regence, perform in-service training for Regence's employees on the medical equipment and related products and supplies.
- Maintain an adequate inventory of medical equipment and related products and supplies including economical models that meet the patient's needs and quality standards.
- Provide installation by people properly trained and qualified to do so.
- Ensure that all equipment has been maintained to manufacturer's specifications and standards and that records are available to confirm this.
- Meet or exceed all applicable standards in the Joint Commission Accreditation Manual for Home Care.

The provider agrees that the maintenance, replacement or repair of medical equipment and other items and supplies shall be available as follows:

- If a patient's life is threatened by a sudden equipment malfunction, emergency services are available 24 hours a day, seven days a week.
- If the performance and intended use of the equipment is affected by a sudden malfunction, services for repair or replacement are available 24 hours a day, seven days a week.
- If the performance and intended use of the equipment is not affected by a sudden malfunction, services for assessment, repair or replacement (when applicable) are available within five business days.
- Emergency backup systems for electrical equipment are provided either through a manual means or a self-contained battery integral to the equipment.
- The medical equipment, items and supplies are safe, sanitary and working as intended for use in the patient's home. The provider will complete a written assessment at the time of delivery and ensure that the medical equipment, items or supplies are appropriate for use within the patient's home.

The provider shall provide education appropriate to the medical equipment, items and/or supplies provided and shall document ongoing education of the patient, family members and care givers, including but not limited to the following:

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- Written instructions in terms the patient and family can reasonably understand, which includes but is not limited to the care, storage, handling and therapeutic use of the medical equipment, items and supplies
- Written instructions regarding when and how to contact the provider for maintenance and/or repair
- Documentation of the patient's and/or patient's family's receipt and understanding of the above required education and their demonstrated ability to operate the equipment safely and appropriately
- Verbal and written instructions regarding emergency procedures
- Provide at a minimum, a one-year warranty for purchased medical equipment, orthotic devices and prosthetic appliances (this does not supersede or replace any manufacturer's warranty)

The provider shall be responsible for servicing, at no additional charge, all rented medical equipment. The provider shall provide warranty services for purchased medical equipment, orthotic devices and prosthetic appliances limited to the manufacturer's warranty. Repairs and replacements covered by warranties are not eligible for reimbursement. Any maintenance or repair performed on the medical equipment shall not be billed to Regence unless pre-approved by Regence.

Least costly items and services: The provider shall provide or arrange for the provision of the least costly items and services appropriate to the member's needs and safety. Exceptions must be discussed and approved by Regence and the patient prior to delivery of the item or service.

Dispensing codes
Dispensing codes are not eligible for separate reimbursement.

Oxygen equipment rental-only reimbursement
Our DME exhibits specify that life-sustaining oxygen equipment is eligible for reimbursement based on rental periods only. Reimbursement exceeding the rental allowable rate is not provided for equipment purchased by the member.

If the member purchases the equipment, DME providers should obtain a member consent form signed by the member that specifies that neither the DME provider nor the Company is financially responsible in excess of one month's rental allowable amount.

For more information, refer to our reimbursement policy *Durable Medical Equipment Purchase and Rental Limitations* (Administrative #131).

Oxygen and Oxygen Equipment
The fee schedule amount for oxygen system rentals is a monthly allowance and will include all equipment, oxygen, accessories, supplies, maintenance and repairs. The provider will include the appropriate modifier identifying the amount of oxygen prescribed.

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We reserve the right to determine if an item should be rented or purchased on an individual item basis according to the medical recommendations of physicians and the determination of our appropriate employees or agents who may review such recommendations.

Sales tax

In compliance with Washington state Senate Bill (SB) 6273 at **http://apps.leg.wa.gov/billinfo/summary.aspx?year=2010&bill=6273**, our payment to providers for eligible prescribed durable medical equipment or mobility enhancing equipment claims includes the sales tax or use a tax calculation.

Please note the following billing information:

- A separate line item should appear on claims for the sales tax or tax calculation.
- Use HCPCS S9999 *Sales tax* when submitting claims. The tax should be based on the equipment's allowable amount listed in our fee schedules.

Our payment to the provider will include the tax in the payment. Providers must then remit the tax to the Department of Revenue.

Rental/purchase guidelines

Rental

- Rental is paid up to the purchase price
- Use Modifier RR with HCPCS codes to indicate rental
- Repairs required on rented equipment are not separately reimbursable
- One unit of service equals one month's rental, with the exception of HCPCS B4034, B4035, B4036, E0277, E0935, and E2402 where one unit of service equals one day's rental

Purchase

- Use Modifier NU if purchasing new DME equipment
- Use Modifier UE if purchasing used DME equipment
- The outstanding dollars are paid toward the purchase price

We will only reimburse up to the purchase price regardless of when the decision to purchase is made.

Additional modifiers

When appropriate, use the following modifiers when billing for DME services. If more than one modifier is used, place the modifier in the first position or directly after the procedure and/or HCPCS code.

- Modifier AW *Items furnished in conjunction with surgical dressings*
- Modifier KM *Replacement of facial prosthesis including new impression/moulage*
- Modifier KN *Replacement of facial prosthesis using previous master model*

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Shipping and handling
Shipping and handling charges are not eligible for separate reimbursement.

Repairs and modifications
If the purchased equipment is not covered by the manufacturer's warranty, we allow one month's rental fee for loaner equipment while the equipment is being repaired or serviced.

All claims for repairs and servicing are subject to review and approval to ensure charges do not exceed the purchase price.

Replacement
If an item needs to be replaced, the referring physician must submit a new prescription and the supplier must indicate the condition of the present equipment on the prescription. Claims for replacement are subject to our review and approval.

Customization
When it is necessary for a manufacturer, factory or supplier to create an item to fit a specific patient, it is considered a custom item. Custom items must be purchased rather than rented and medical necessity criteria must be met.

Back-up DME
Back-up DME items are not eligible for separate reimbursement.

Deluxe products/upgrades
The patient may choose to upgrade from a standard product. We will only reimburse up to the allowable amount for the standard product.

It is the responsibility of the provider to inform the patient that there are standard products available that meet medical necessity. The patient must sign a waiver indicating that he or she has been informed of his or her responsibility for any outstanding balance prior to ordering the product or before the product is delivered. If the patient does not sign a waiver, the outstanding balance will be a provider write-off.

Providers should use HCPCS S1001 *Deluxe item, patient aware (list in addition to code for basic item)* when billing for the cost in excess of the standard product. The signed waiver must accompany the bill and be on file if a health care service requests the waiver at a future date.

Pre-authorization
Pre-authorization may be required. View our pre-authorizations lists, forms and submission information.

Orthoses
Custom-made, functional orthotics are covered when they are medically necessary to treat a condition of the foot, ankle or leg. Prefabricated, supportive, accommodative and digital orthotics are not covered on most of our products.

Billing guidelines
- Indicate the units of service

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- Use HCPCS codes to bill for the orthoses

Note: Reimbursement for HCPCS orthotic codes include the cost of orthoses, cast impression and materials.

Fitting or adjustment
Adjustment and/or fitting of orthoses and prosthetics is not covered. This service is included in the cost of the device.

Repair and/or replacement
The repair and/or replacement of an orthotic or prosthetic device may be allowed, based on the patient's benefit. Please use the appropriate HCPCS or CPT code when submitting a claim for repair or replacement.

Prosthetic Devices
For purposes of this document, the definition of prosthetic devices (other than dental) is: A device which replaces all or part of an internal body organ (including contiguous tissue) or replaces all or part of the function of a permanently inoperative or malfunctioning internal body organ.

A prescription must be on file and the prescribing physician's name must be submitted on the claim. Pre-authorization may be required.

DME documentation requirements for Medicare Advantage Plans
Providers must follow CMS criteria for durable medical equipment (DME) for our Medicare Advantage Plan members. This includes using appropriate Certificates of Medical Necessity (CMN) or other forms.

Criteria, documentation requirements, CMN forms and instructions for completing the forms are available in chapter 4 of the Supplier Manual at **https://www.noridianmedicare.com/eula.php?t=/dme/news/manual/chapter4.html** from Noridian Administrative Services, LLC. Noridian has also made several documentation checklists at **https://www.noridianmedicare.com/dme/coverage/checklists.html**, available for various DME, to help ensure compliance with the requirements.

Ambulance
Our standard member contracts state that, the service of a licensed ambulance company will be provided, when medically necessary and if other means of transportation would endanger the patient's health. The purpose of the transportation cannot be for personal or convenience reasons. Ambulance services are provided when the ambulance is used to transport the patient, to the nearest accredited hospital where adequate facilities for treatment are available.

Levels of Ambulance Services
- Cabulance is used when the patient is medically stable and does not require the use of a stretcher.
- Air ambulance service is medically necessary when the use ground ambulance would endanger the patient's health.

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- Basic Life Support means non-invasive emergency medical services and provides transportation by stretcher, plus equipment and staff.
- Advanced Life Support means invasive emergency medical services with specialized life-sustaining equipment and (usually) radiotelephone contact with a physician or hospital.

Air Ambulance Services

Claims for air transportation are reimbursed according to the patient's benefits as described in the member contract. Medical necessity must be established. It is not covered when done for convenience. Transportation must be to the nearest hospital equipped to provide the necessary treatment.

Transportation by air is considered medically necessary when:

- There are multiple orthopedic fractures.
- There is a high potential for rapid medical decliner.
- The patient's condition is considered life threatening.
- The point of pick-up is inaccessible by land vehicles.
- There are great distances or other factors involved in transporting the patient to the nearest appropriate medical services.
- Other factors include but are not limited to; the time of day and imminent danger of limb loss if other modes of transportation are used.

Note: Air transport is not considered medically necessary for routine medical visits or for returning home or to another hospital when services can be provided at the present hospital.

Cabulance Services

Cabulance services are available for non-emergent transport of medically stable patients who cannot otherwise use private transportation without endangering their safety. Eligible services include:

- Medically stable patients via wheelchair with portable oxygen, a non-active IV, hep lock, Foley catheter or NG tube.
- A patient who is non-ambulatory, medically stable and requires movement by wheelchair or the patient is ambulatory but requires assistance to transfer.

Typical uses

- Transfer to a medical facility for special treatment
- The purpose of transportation is not for personal or convenience reasons.
- From a hospital or skilled nursing facility to home when other transportation is not medically feasible.
- When transportation is medically necessary, if other means of transportation would endanger the patient's health.

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Billing guidelines

Proper Use of 'V' Codes

Ambulance claims should be billed using valid ICD 'V' diagnosis codes in the second position when it is necessary and appropriate. The 'V' codes are used to define the external cause of morbidity and cannot be billed as the primary diagnosis.

Example: For injuries incurred from a driver in a motor vehicle accident, the symptom ICD-10 S62.90xA *Unspecified Fracture of unspecified wrist and hand, initial encounter for closed fracture* would be listed as the primary diagnosis. ICD-10 V48.5xxA *Car driver injured in noncollision transport accident in traffic, initial encounter* would be listed as secondary.

Use the appropriate 'V' code that best represents the accident type. This allows us to identify the responsible party and process the claim without delay.

Name and Address of Facility Where Services Were Rendered

Include the "From" location and the "To" location.

- If the "From" or "To" location is not a hospital or care facility, enter the street address.
- If the "From" or "To" location is a hospital or care facility, enter the name of the facility only. Do not enter the address.

This information should be entered in the narrative field of the electronic claim format.

Services Not Typically Covered

The following is a list of examples of services not normally covered. This list is not a complete list of plan exclusions or a determination of medical necessity:

- Charges for the return and pickup of staff
- Ambulance calls where the patient is not transported to a medical facility
- Ground ambulance transportation for patients during an inpatient hospital stay initiated in a DRG payment methodology (e.g., a patient is transported to another facility for a MRI because there was no MRI equipment available at the DRG hospital where the patient is currently hospitalized). Contact your provider consultant for a list of DRG hospitals.
- Transportation to a clinic or provider's office
- Transportation for personal or convenience reasons including but not limited to:
- Moving the patient closer to home
- Moving the patient to receive treatment from his or her provider (i.e., if the provider does not have admitting privileges at the first hospital)

Note: When in the course of transporting a patient to a hospital, the ambulance stops at the provider's office, the claim will be reviewed for medical necessity.

Urgent Care Clinics

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Urgent care is a category of walk-in clinics focused on the delivery of ambulatory care in a dedicated medical facility outside of a traditional emergency room. Urgent care centers primarily treat injuries or illnesses requiring immediate care, but not serious enough to require an emergency room visit. Urgent care clinics are distinguished from similar ambulatory health care centers, such as emergency rooms and convenient care clinics, by the scope of conditions treated and available facilities on-site.

Urgent care clinics can only submit professional claims electronically via an ANSI ASC X12N 837P Health Care Claim Transaction using the Place of Service Code 20 (POS -20).

Qualifying Criteria for categorization as an Urgent Care Clinic

Availability and capability

- The facility accepts walk-in patients of all ages for a broad spectrum of illness, injury and disease.
    - Hours: During weekdays and evenings and at least one weekend day.
    - Appointments: Not needed.
- The facility has access to rapid diagnostic testing (including labs and radiology), on-site injectable medications for emergent needs, and transfer or admission arrangements with local hospitals.

Building and equipment

- The facility has at least one exam room and separate waiting area.
- The following equipment is available (and the staff are trained to use this equipment):
    - Automated external defibrillator (AED) or standard defibrillator
    - Oxygen and emergency breathing equipment
    - Drug cart with some emergency medications

Staffing

- A licensed physician (MD/DO) has been designated as the facility's medical director and is responsible for overall clinical quality.
- All medical care is provided under the direction or supervision of a physician who accepts responsibility for that care.
- Any paraprofessionals who assist in providing care (e.g., RN) are appropriately licensed.
- Licensed providers are able to:
    - Perform pulse oximetry, cardiac monitoring, and advanced cardiac life support in an emergency, while 911 is called.
    - Obtain and read an EKG and X-ray.
    - Administer oral, intramuscular, and intravenous medication and fluids.
    - Perform minor procedures (e.g., suturing, cyst removal, incision, drainage, splinting)

Licensure and compliance

- The facility is licensed by the state in which it is located, if the state requires such licensure.
- The facility complies with applicable federal, state, and local laws and regulations.

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If your clinic meets the criteria above and is interested in being designated as an Urgent Care Clinic, please contact your provider consultant.

Retail Clinics

Retail Clinics, sometimes referred to as convenient care clinics, are a category of walk-in clinics focused on the delivery of ambulatory care in a retail setting, such as a supermarket or pharmacy location outside of a traditional dedicated medical facility. Retail Clinics provide convenient access to care for preventive health services. Retail Clinics also provide care for minor illnesses and injuries for which immediate care is desired but not medically required and that are not serious enough to require an urgent care or emergency room visit. Retail Clinics are distinguished from similar ambulatory health care centers, such as urgent care and emergency rooms, by the scope of conditions treated and available services on-site.

Retail Clinics should only submit professional claims electronically via an ANSI ASC X12N 837P Health Care Claim Transaction using the Place of Service Code 17 (POS 17).

<u>Qualifying Criteria for categorization as a Retail Clinic</u>

Availability and capability

- The clinic accepts walk-in patients for minor illness, injury and disease. Age ranges may vary by clinic (e.g. 18 months or older).
    - Hours: During weekdays and evenings and at least one weekend day
    - Appointments: Not needed
- The clinic has access to Point of Care "CLIA" waived lab testing, the ability to send out for lab services and write prescriptions for medications routinely within the scope of services provided.

Building and equipment

- The clinic has at least one exam room and a separate waiting area.

Staffing

- A licensed physician (MD/DO) provides oversight or supervision of a Retail Clinic and is responsible for insuring clinic Policy and Procedures are in place with a dedicated team of medical professionals.
- An advance practice provider (ARNP, PA) provides treatment of patient in the Retail Clinic and is responsible for following the Policies and Procedures while providing the best care within those guidelines.
- Any paraprofessionals who assist in providing care (e.g., medical assistants) are appropriately licensed.
- Licensed providers are able to:
    - Obtain samples from venipuncture and/or non-venipuncture lab tests
    - Perform point of care testing, such as rapid strep, urinalysis and conjunctivitis testing
    - Administer immunizations including travel vaccinations, following a pre-travel health evaluation
    - Write prescriptions for medications to treat minor illnesses and injuries that fall within the Retail Clinic scope of service

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Licensure and compliance

- The clinic is licensed by the state in which it is located, if the state requires such licensure.
- The clinic complies with applicable federal, state and local laws and regulations.
- Joint Commission Accreditation is preferred.

If your clinic meets the criteria above and is interested in being designated as a Retail Clinic, please contact your provider consultant.

Behavioral Health

Contracting Service Requirements

The following Contracting Service Requirements and should assist behavioral health facilities in understanding our minimum requirements for each level of service in the delivery of mental health and chemical dependency services.

Notes:

- The assumption for all levels of care is that the facility is licensed for that level in the state where services are rendered.
- It is understood that all treatment will be developed to meet the member's individual needs. Guidelines regarding the frequency and types of therapy sessions are suggested minimal expectations.

Mental Health, Inpatient (MHIP) level of care

- Psychosocial assessment completed within 24 hrs of admit
- Psychiatric evaluation and History and Physical completed within 24 hours of admit
- Psychiatric visits need to occur daily or at least 5 out of 7 days per week
- 24-hour nursing staff on site (RN or LPN/LVN)
- Chemical Dependency evaluation within first 48 hours, including UA
- Discharge planning and development of treatment plan begins within 24 hours
- Individual Therapy twice weekly
- Group Therapy at least once daily
- Family Therapy once weekly, twice weekly for children only. Family therapy for children and adolescents is scheduled within 24 hours of admission
- Seven (7) day post hospital follow up appointment is scheduled before discharge

Mental Health, Residential Treatment Center (MHRTC) level of Care

- Must stay overnight and be involved in structured activities 8 hours a day, 5 days per week
- All therapy must be provided by or supervised by a licensed clinician
- Psychiatric evaluation within 48 hours of admit by psychiatrist or Advanced Practice Nurse
- Chemical Dependency assessment within 48 hours of admit, including UA
- Psychiatric visits need to occur at least once per week
- 24-hour nursing staff on site (RN or LPN/LVN)

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- Discharge planning and development of treatment plan begins within 72 hours
- Individual Therapy at least weekly
- Group Therapy at least once daily
- Family Therapy once weekly, twice weekly for children only. Family therapy for children and adolescents is scheduled within 24 hours of admission
- Designated physician medical director
- Availability of a medical physician for history and physicals and ongoing medical problems
- Availability of psychiatrist for evaluation as needed
- School provided on site for children
- Seven (7) day post hospital follow up appointment is scheduled before discharge

Mental Health Partial Hospitalization Program (MHPHP) level of care

- Minimum of 12-20 hours per week
- Services greater than 5 days per week must demonstrate clinical need
- Psychosocial assessment within 24 hours of admit
- Psychiatric evaluation completed within 48 hours of admit by psychiatrist or Advanced Practice Nurse, unless stepping down
- Chemical Dependency assessment within 48 hours of admit
- Psychiatric visits need to occur at least once weekly
- Individual Therapy at least weekly
- Group Therapy at least once daily
- Family Therapy once weekly, twice weekly for children only. Family therapy for children and adolescents is scheduled within 24 hours of admission
- Discharge planning and development of treatment plan begins within 72 hours
- Designated physician medical director
- Availability of a medical physician for history and physicals and ongoing medical problems

Mental Health Intensive Outpatient Program (MHIOP) level of care

- All treatment provided by state licensed or state certified professionals (or supervised by)
- Services occur at least 2 hours per day, 3 days per week (6 hours minimum per week, 9 hours maximum)
- Psychiatric evaluation completed at the beginning of treatment, unless member is stepping down
- Family therapy component required for children and adolescents
- Discharge planning and development of treatment plan begins within 72 hours

Chemical Dependency, Inpatient or Detoxification (CDIP) level of care

- Psychosocial assessment and CD assessment within the first 24 hours
- Medical evaluation (including relevant labs) and History and Physical within first 24 hours
- Physician visits 7 days per week including med management for withdrawal symptoms

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- 24-hour nursing staff on site (RN or LPN/LVN)
- Discharge planning and development of treatment plan begins within 24 hours

Chemical Dependency, Inpatient Rehabilitation (CDIP Rehab) level of care

- Authorization occurs when the member has: significant co-morbid psychiatric condition that needs to be monitored, significant medical condition that needs to be monitored, in addition to significant withdrawal symptoms. The degree of supervision needed is higher than CDRTC level of care
- Must stay overnight and be involved in structured activities 8 hours a day, 5 days per week
- 24-hour nursing staff on site (RN or LPN/LVN)
- Medical evaluation (including relevant labs) and History and Physical within first 48 hours, unless stepping down
- Availability of psychiatrist for evaluation as needed
- All treatment provided by state licensed or state certified professionals (or supervised by)
- Individual Therapy at least weekly
- Group Therapy daily
- Family Therapy once weekly
- Seven (7) day post hospital follow up appointment is scheduled before discharge

Chemical Dependency, Residential Treatment Center (CD RTC) level of care

- Must stay overnight and be involved in structured activities 8 hours a day, 5 days per week
- 24-hour nursing staff on site (RN or LPN/LVN)
- Medical evaluation (including relevant labs) and History and Physical within first 48 hours, unless stepping down
- Availability of psychiatrist or Advanced Practice Nurse for evaluation as needed- this is not required
- School completed on site for children
- All treatment provided by state licensed or state certified professionals (or supervised by)
- Facility must be licensed as a Residential facility in the state treatment is delivered
- Individual Therapy at least weekly
- Group Therapy daily
- Family Therapy once weekly, twice weekly for children only. Family therapy for children and adolescents is scheduled within 24 hours of admission
- Seven (7) day post hospital follow up appointment is scheduled before discharge

Chemical Dependency Partial Hospitalization Program (CDPHP) level of care

- All treatment provided by state licensed or state certified professionals (or supervised by)
- Services provided minimum of 3 hours a day, 5 days per week
- Services greater than 5 days per week must demonstrate clinical need

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- Psychosocial assessment and Chemical Dependency assessment within 48 hours of admit
- Availability of psychiatrist or Advanced Practice Nurse for evaluation if needed
- Random drug screens throughout treatment as needed
- Individual Therapy at least weekly
- Group Therapy at least once daily
- Family Therapy once weekly, twice weekly for children only. Family therapy for children and adolescents is scheduled within 24 hours of admission

Chemical Dependency Intensive Outpatient Program (CDIOP) level of care

- All treatment provided (or supervised) by state licensed or state certified professionals
- Services occur at least 3 hours per day, 3 days per week (9 hours minimum per week)
- Chemical Dependency evaluation completed at the beginning of treatment, unless member is stepping down

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Regence Oregon and Utah | Regence Idaho and select counties of Washington

NOTE: This policy has been revised. The revised policy will be effective December 1, 2020. To view the revised policy, click here.

Medical Policy Manual Medicine, Policy No. 152

Extracorporeal Membrane Oxygenation (ECMO) for the Treatment of Cardiac and Respiratory Failure in Adults

Effective: January 1, 2020

Next Review: September 2020
Last Review: November 2019

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Extracorporeal Membrane Oxygenation (ECMO) is a complex treatment which utilizes a modified cardiopulmonary bypass circuit for temporary life support as a treatment for reversible cardiac and/or respiratory failure.

MEDICAL POLICY CRITERIA

Note: This policy does not address the use of ECMO in children or neonates, which may be considered medically necessary. In addition, this policy does not address the use of short-term extracorporeal support, including ECMO, such as during surgical procedures. The Policy Guidelines section below includes information regarding weaning and/or discontinuation of ECMO.

I. Extracorporeal Membrane Oxygenation (ECMO) in adults (18 years or older) may be considered **medically necessary** as a treatment of respiratory or cardiac failure that is potentially reversible when both of the following criteria I.A. and I.B. are met:

   A. At least one of the following criteria is met:

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1. Hypoxic respiratory failure despite maximal lung-protective ventilation (see Policy Guidelines) as demonstrated by any one or more of the following:
    a. Murray Lung Injury Score three or higher (see Policy Guidelines for Murray Lung Injury Score); or
    b. PaO2/FiO2 of less than100 mm Hg on fraction of inspired oxygen (FiO2) greater than 90%; or
    c. Inability to maintain airway plateau pressure (Pplat) less than 30 cm H2O despite a tidal volume of four to six mL/kg ideal body weight (IBW); or
    d. Oxygenation Index greater than 30: Oxygenation Index equals FiO2 times 100 times MAP divided by PaO2 mm Hg. [FiO2 times 100 equals FiO2 as percentage; MAP equals mean airway pressure in cm H2O; PaO2 equals partial pressure oxygen in arterial blood].
2. Respiratory failure despite maximal lung-protective ventilation (see Policy Guidelines) as demonstrated by any one of the following:
    a. Significant hypercapnea despite high Pplat (greater than 30 cm H_2O); or
    b. A pH of less than 7.20 due to significant uncompensated hypercapnia
3. Severe air leak syndromes including, but not limited to:
    a. Significant tracheal airway injuries; or
    b. An air-leak or broncho-pleural fistula that prevents adequate ventilation with lung-protective ventilation (see Policy Guidelines) strategies.
4. Refractory cardiogenic shock as demonstrated by one of the following:
    a. Inadequate tissue perfusion manifested as hypotension and low cardiac output despite adequate intravascular volume; or
    b. Shock which persists despite volume administration, inotropes and vasoconstrictors, and intra-aortic balloon counterpulsation.
5. Hypothermia with a core temperature of less than 28 degrees centigrade.
6. As a bridge to heart, lung or heart-lung transplantation.

B. None of the following contraindications are present:
1. Ventilation with high ventilator pressure (Pplat greater than 30 cm H2O) sustained throughout a seven day period and/or high FiO2 (greater than 80%) sustained throughout a seven day period; or
2. Signs of intracranial bleeding, or other major central nervous system injury without the potential to recover meaningful function; or
3. Presence of an irreversible, terminal illness; or
4. Cardiac decompensation and not meeting medical necessity criteria for heart transplant or ventricular assist device; or
5. Chronic organ failure without the potential to recover meaningful function; or
6. Prolonged CPR without adequate tissue perfusion; or

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7. Patient choice to decline extraordinary life support interventions. (see Policy Guidelines)

II. The continued use of Extracorporeal Membrane Oxygenation (ECMO) in adult patients meeting criteria I., is considered **not medically necessary** if any one or more of the following conditions are present for five or more days:

   A. Neurologic devastation determined by at least two physicians agreeing after evaluation, (including neurologic examination, head CT, and EEG), that the patient has sustained irreversible cessation of all functioning of the brain, including the brain stem and an outcome better than "persistent vegetative state" at six months is unlikely. At least one of these physicians should be a neurologist, neurosurgeon, and/or neuro-intensivist.

   B. End stage fibrotic lung disease confirmed by lung biopsy. The presence of end stage fibrotic lung disease is suggested by PA systolic pressures sustained at greater than 75% of systemic pressures.

   C. Hypotension and/or hypoxemia recalcitrant to all maneuvers which causes inadequate aerobic metabolism demonstrated by evidence of profound tissue ischemia [creatine phosphokinase (CPK), lactate, lactate to pyruvate (L/P) ratio, near-infrared spectroscopy (NIRS)].

   D. End-stage cardiac or lung failure without alternative long-term plan (i.e., ineligible for assist device and/or transplant).

III. The use of Extracorporeal Membrane Oxygenation (ECMO) in adult patients is considered **investigational** in all other situations, including but not limited to when the above criteria I. is not met.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

RESPIRATORY FAILURE REVERSIBILITY

The reversibility of the underlying respiratory failure is best determined by the treating physicians, ideally physicians with expertise in pulmonary medicine and/or critical care. Some of the underlying causes of respiratory failure which are commonly considered reversible are as follows:

- Acute respiratory distress syndrome (ARDS)
- Acute pulmonary edema
- Acute chest trauma
- Infectious and noninfectious pneumonia
- Pulmonary hemorrhage
- Pulmonary embolism
- Asthma exacerbation
- Aspiration pneumonitis.

MAXIMAL LUNG-PROTECTIVE VENTILATION

The American Thoracic Society/European Society of Intensive Care Medicine/Society of

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Critical Care Medicine Clinical Practice Guideline made the following recommendations regarding lung-protective ARDS ventilation management:[1]

- Low tidal volume ventilation (4-8 mL/kg of predicted body weight)
- Plateau pressure (pPlat) < 30 cm H_2O

Additional lung protective options include prone positioning[2] and neuromuscular blockade[3].

MURRAY LUNG INJURY SCORE

The Murray Lung Injury Score is a system for classifying the severity of respiratory failure. It was developed for use in ARDS, but has been applied to other indications.[4] This score includes four subscales, each of which is scored from 0 to 4. The final score is obtained by dividing the collective score by the number of subscales used. A score of 0 indicates no lung injury; a score of 1-2.5 indicates mild or moderate lung injury; and a score of 2.5 indicates severe lung injury, e.g. ARDS. Table 1 shows the components of the Murray scoring system.

Table 1: Murray Lung Injury Score

Subscale	Criteria	Score
Chest x-ray score	No alveolar consolidation Alveolar consolidation confined to 1 quadrant Alveolar consolidation confined to 2 quadrants Alveolar consolidation confined to 3 quadrants Alveolar consolidation in all 4 quadrants	0 1 2 3 4
Hypoxemia score	PaO_2/FiO_2 >300 PaO_2/FiO_2 225-299 PaO_2/FiO_2 175-224 PaO_2/FiO_2 100-174 PaO_2/FiO_2 ≤ 100	0 1 2 3 4
PEEP score (when ventilated)	PEEP ≤ 5 cm H_2O PEEP 6-8 cm H_2O PEEP 9-11 cm H_2O PEEP 12-14 cm H_2O PEEP ≥ 15 cm H_2O	0 1 2 3 4
Respiratory system compliance score (when available)	Compliance >80 mL/cm H_2O Compliance 60-79 mL/cm H_2O Compliance 40-59 mL/cm H_2O Compliance 20-39 mL/cm H_2O Compliance ≤ 19 mL/cm H_2O	0 1 2 3 4

CPAP – continuous positive airway pressure; FiO_2 – fraction of inspired oxygen; PaO_2 – partial pressure of oxygen in arterial blood; PEEP – peak end expiratory pressure.

In addition to the Murray Lung Injury Score, the Berlin Definition is gaining acceptance for classifying acute respiratory distress syndrome (ARDS).[5]

WEANING AND DISCONTINUATION OF ECMO

The Extracorporeal Life Support Organization (ELSO) has published guidelines regarding the weaning and discontinuation of ECMO.[6] The general ECMO guidelines indicate: "(e)xtracorporeal support is decreased as native organ function improves. When ECC [extracorporeal circulation] support is less than 30% of total, native heart or lung function may be adequate to allow coming off ECLS, and a trial off is indicated. Note: As long as ECC

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support is more than 30 to 50%, there is no indication to trial off, except in special circumstances such as uncontrolled bleeding. ECLS should be discontinued promptly if there is no hope for healthy survival (severe brain damage, no or heart or lung recovery, and no hope of organ replacement by VAD or transplant). The definition of irreversible heart or lung damage depends on the patient and the resources of the institution. In each case a reasonable deadline for organ recovery or replacement should be set early in the course."

In addition, ELSO has published specific weaning guidelines for cardiac failure:

Cardiac Failure

ELSO suggests the general guidelines summarized above should be used for weaning in cases of cardiac failure.[7] In addition, ELSO guidelines for Adult Cardiac Failure list the following for bridge to recovery, including for postcardiotomy, acute MI, and myocarditis:

1. Expect early signs of recovery within one week of support.
2. With evidence of improved aortic pulsatility and contraction on echocardiography, optimize inotropes and reduce flow to 50%, then 25% of adequate cardiac output.
3. Use echo to visualize ventricular function and major valvular pathology.
4. Clamp circuit and allow recirculation for trial period of 30 minutes to four hours.
5. Flush cannulae with heparinized saline continuously or flash from the circuit every 10 minutes to avoid cannula thrombosis.
6. If hemodynamics and oxygen delivery are adequate on less then maximum inotropic infusions, consider decannulation.

Respiratory Failure

Methods of weaning and discontinuing ECMO treatment may vary based upon a variety of factors, including but not limited to, individual patient clinical considerations and the current established practice of specialty ECMO centers. Weaning guidelines for respiratory failure used regionally include the following:[8]

1. Indications of recovery:
    a. Absence of signs of active inflammation and/or shock
    b. Reduced pressor requirements
    c. Improvements in laboratory findings, including white blood counts (WBCs), C-reactive protein (CRP), lactate, and base deficit
    d. Evidence of improving respiratory status on chest X-ray (CXR) arterial blood gases (ABGs) and ventilation parameters (compliance, etc.). A specific measure is the Cilley test: daily "step up" ABGs measuring responses to transient FiO_2 of 100% on vent.
    e. Evolution of negative fluid balance
    f. Decreasing sweep requirements

2. "Recruitment" measures may be considered:
    a. If effusions are present, consider draining effusions to improve functional residual capacity (FRC)
    b. Central venous pressure (CVP) < 9 and total body water (TBW) euvolemia with diuresis or continuous renal replacement therapy (CRRT)
    c. Regional atelectasis may be addressed with positional therapy
    d. Possible lightened sedation to encourage spontaneous breathing and coughing

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e. Bronchoscopy for pulmonary toilet
f. Ventilator settings to encourage recruitment, assuring mean arterial pressure (MAP) < 24

3. Consider a trial off ECMO when indications of recovery are present.

PATIENT CHOICE TO DECLINE EXTRAORDINARY LIFE SUPPORT INTERVENTIONS

Choices to decline extraordinary life support interventions may include, but is not limited to, the presence of an advanced directive, healthcare directive, Physician Orders for Life Sustaining Treatment (POLST), or Physician Orders for Scope of Treatment (POST) to indicate the patient or the patient's health care representative or agent has selected any of the following upon which life-sustaining support would be withheld or withdrawn:

- A Do Not Resuscitate (DNR, DNAR, No Code) order; or
- Allow Natural Death; or
- No CPR or advanced cardiac life support interventions; or
- An equivalent choice.

LIST OF INFORMATION NEEDED FOR REVIEW

REQUIRED DOCUMENTATION:

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and physical/chart notes
- Indication for the requested service
- Documentation of symptoms, associated diagnoses and treatments

CROSS REFERENCES

1. Ventricular Assist Devices and Total Artificial Hearts, Surgery, Policy No. 52

BACKGROUND

Extracorporeal Membrane Oxygenation (ECMO), also referred to as extracorporeal life support (ECLS), or extracorporeal lung assist (ELA), has been proposed as an alternative treatment for cardiac and respiratory failure in adult patients and is described by the Extracorporeal Life Support Organization (ELSO) as, "the use of a modified cardiopulmonary bypass circuit for temporary life support for patients with potentially reversible cardiac and/or respiratory failure. ECMO provides a mechanism for gas exchange as well as cardiac support thereby allowing for recovery from existing lung and/or cardiac disease."[9] ECMO is used for prolonged time periods (days to weeks) and involves removing a portion of the patient's blood, pumping it through a membrane oxygenator, removing carbon dioxide, rewarming the blood, and returning it to the patient. ECMO is a complex treatment requiring a specialized staff and specific equipment. The ELSO specialty group maintains a registry of detailed data from a voluntary international consortium of health care centers which utilize ECMO.[9]

Historically, ECMO has been used in neonatal and pediatric populations to treat respiratory failure related to a variety of respiratory diseases. The treatment may be used in newborn infants with neonatal respiratory distress due to congenital diaphragmatic hernia, meconium

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aspiration, hyaline membrane disease, pulmonary hypertension and pulmonary hypoplasia, and pneumonia with sepsis. ECMO is associated with a 55% survival rate in this subgroup and has become an accepted treatment for respiratory failure in pediatric and neonatal patients, despite the lack the randomized trials.[10-12]

With improvements in ECMO circuit technology and methods of supportive care, ECMO has been proposed as salvage therapy to prevent irreversible neurologic damage in adults with acute, reversible respiratory or cardiac failure. In critically ill adult patients, ECMO also may be considered a non-ventilatory treatment by which to avoid ventilator induced lung injury (VILI) associated with mechanical ventilation. In these situations, death would be imminent unless medical interventions can immediately reverse the underlying disease process or physiologic functions can be supported for long enough that normal reparative processes or treatment can occur (e.g., resolution of ARDS or treatment of infection) or other life-saving intervention can be delivered (e.g., provision of a lung transplant).

DISEASE-SPECIFIC INDICATIONS FOR ECMO

Venoarterial (VA) and venovenous (VV) ECMO have been investigated for a wide range of adult conditions that can lead to respiratory or cardiorespiratory failure, some of which overlap clinical categories (e.g., H1N1 influenza infection leading to ARDS and cardiovascular collapse), which makes categorization difficult. ARDS has been defined by consensus in the Berlin definition, which includes criteria for the timing of symptoms, imaging findings, exclusion of other causes, and degree of oxygenation.[5] However, in general, indications for ECMO can be categorized as follows:

- Acute respiratory failure due to potentially reversible causes. Acute respiratory failure refers to the failure of either oxygenation, removal of carbon dioxide, or both, and may be due to a wide range of causes. In these cases, ECMO is most often used as a bridge to recovery. Specific potentially reversible or treatable indications for ECMO may include ARDS, acute pneumonias, and a variety of other pulmonary disorders.

- Bridge to lung transplant. Lung transplant is used for management of chronic respiratory failure, most frequently in the setting of advanced chronic obstructive pulmonary disease (COPD), idiopathic pulmonary fibrosis, cystic fibrosis, emphysema due to alpha-1-antitrypsin deficiency, and idiopathic pulmonary arterial hypertension. In the end stages of these diseases, patients may require additional respiratory support while awaiting an appropriate donor. In addition, patients who have undergone a transplant may require retransplantation due to graft dysfunction after the primary transplant.

- Acute-onset cardiogenic or obstructive shock is defined as shock that is due to cardiac pump failure or vascular obstruction, refractory to inotropes and/or other mechanical circulatory support. Examples of this category include postcardiotomy syndrome (ie, failure to wean from bypass), acute coronary syndrome, myocarditis, cardiomyopathy, massive pulmonary embolism, and prolonged arrhythmias.

- ECMO-assisted cardiopulmonary resuscitation (E-CPR). ECMO can be used as an adjunct to CPR in patients who do not respond to initial resuscitation measures.

TECHNOLOGY DESCRIPTION

The basic components of ECMO include a pump, an oxygenator, sometimes referred to as a

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“membrane lung,” and some form of vascular access. Based on the vascular access type, ECMO can be described as VV or VA. VA ECMO has the potential to provide cardiac and ventilatory support.

More recently, these include ventilation support devices that provide oxygenation and removal of CO_2 without the use of a pump system or interventional lung assist devices (e.g., iLA® Membrane Ventilator, Novalung GmbH). These technologies are not the focus of this evidence review, but are described briefly because there is overlap in patient populations treated with extracorporeal carbon dioxide removal ($ECCO_2R$) and those treated with ECMO, and some studies have reported on both technologies.

In contrast to VA and VV ECMO, which use large-bore catheters and generally high flow through the ECMO circuits, other systems use pumpless systems to remove CO_2. These pumpless devices achieve $ECCO_2R$ via a thin double-lumen central venous catheter and relatively low extracorporeal blood flow. They have been investigated as a means to allow low tidal volume ventilator strategies, which may have benefit in ARDS and other conditions where lung compliance is affected. Although ECMO systems can effect CO_2 removal, dedicated $ECCO_2R$ systems are differentiated by simpler mechanics and the fact that they do not require dedicated staff.[13]

Venovenous ECMO

Technique

In venovenous extracorporeal membrane oxygenation (VV ECMO), the ECMO oxygenator is in series with the native lungs, and the ECMO circuit provides respiratory support. Venous blood is withdrawn through a large-bore intravenous line; oxygen is added and CO_2 removed, and oxygenated blood is returned to the venous circulation near the right atrium. Venous access for VV ECMO can be configured through two single lumen catheters (typically in the right internal jugular and femoral veins), or through one dual lumen catheter in the right internal jugular vein. In the femorojugular approach, a single large multiperforated drainage cannula is inserted in the femoral vein and advanced to the cavo-atrial junction, and the return cannula is inserted into the superior vena cava via the right internal jugular vein. Alternatively, in the bi-femoral-jugular approach, drainage cannulae are placed in both the superior vena cava and the inferior vena cava via the jugular and femoral veins, and a femoral return cannula is advanced to the right atrium. In the dual-lumen catheter approach, a single bicaval cannula is inserted via the right jugular vein and positioned to allow drainage from the inferior vena cava and superior vena cava and return via the right atrium.

Indications

VV ECMO provides only respiratory support, and therefore is used for conditions in which there is progressive loss in ability to provide adequate gas exchange due to abnormalities in the lung parenchyma, airways, or chest wall. Right ventricular (RV) dysfunction due to pulmonary hypertension that is secondary to parenchymal lung disease may sometimes be effectively treated by VV ECMO.

However, acute or chronic obstruction of the pulmonary vasculature (e.g., saddle pulmonary embolism) may require VA ECMO. There may be cases in which RV dysfunction due to pulmonary hypertension caused by severe parenchymal lung disease may be severe enough to require VA ECMO. In adults, VV ECMO is generally used only in situations in which all other

reasonable avenues of respiratory support have been exhausted, including mechanical ventilation with lung protective strategies, pharmacologic therapy, and prone positioning.

Venoarterial ECMO

Technique

In venoarterial extracorporeal membrane oxygenation (VA ECMO), the ECMO oxygenator is in parallel with the native lungs and the ECMO circuit provides both cardiac and respiratory support. In VA ECMO, venous blood is withdrawn and oxygen is added and CO_2 removed similar to VV ECMO, but blood is returned to the arterial circulation. Cannulation for VA ECMO can be done peripherally, with withdrawal of blood from a cannula in the femoral or internal jugular vein and return of blood through a cannula in the femoral or subclavian artery. Alternatively, it can be done centrally, with withdrawal of blood directly from a cannula in the right atrium and return of blood through a cannula in the aorta. VA ECMO typically requires a high blood flow extracorporeal circuit.

Indications

VA ECMO provides both cardiac and respiratory support. Thus, it is used in situations of significant cardiac dysfunction that is refractory to other therapies, when significant respiratory involvement is suspected or demonstrated, such as treatment-resistant cardiogenic shock, pulmonary embolism, or primary parenchymal lung disease severe enough to compromise right heart function. Echocardiography should be used before ECMO is considered or started to identify severe left ventricular dysfunction which might necessitate the use of VA ECMO. The use of peripheral VA ECMO in the presence of adequate cardiac function may cause severe hypoxia in the upper part of the body (brain and heart) in the setting of a severe pulmonary shunt.

MEDICAL MANAGEMENT DURING ECMO

During ECMO, patients require supportive care and treatment for their underlying medical condition, including ventilator management, fluid management, and systemic anticoagulation to prevent circuit clotting, nutritional management, and appropriate antimicrobials. Maintenance of the ECMO circuit requires frequent monitoring by medical and nursing staff and evaluation at least once per 24 hours by a perfusion expert.

ECMO may be associated with significant complications, which can be related to the vascular access required to the need for systemic anticoagulation, including hemorrhage, limb ischemia, compartment syndrome, cannula thrombosis, and limb amputation. Patients are also at risk of progression of their underlying disease process.

EVIDENCE SUMMARY

The ideal study design to evaluate the specific therapeutic effects of (VA) or venovenous (VV) extracorporeal membrane oxygenation (ECMO) for adult respiratory and cardiorespiratory conditions would be multicenter randomized controlled trials (RCTs) that compare ECMO with best standard therapy, such as mechanical ventilation. RCTs are needed to adequately control for confounding factors, evaluate adverse effects, safety, effectiveness and individual patient differences (age, condition, and severity of illness) compared to standard therapy. The RCT is the most rigorous and reliable study design for demonstrating a causal relationship between the therapy under investigation and the health outcomes of interest. Specifically,

questions regarding appropriate patient selection, standardization and duration of ECMO treatment and complication and survival rates, would be addressed. However, there are challenges in conducting RCTs to evaluate ECMO due to several factors, such as small patient populations and the urgent and emergent setting in which EMCO is typically utilized. Given these confounding factors, data from large randomized controlled trials are not expected in the near future.

Current guidelines for establishing causality require direct evidence which demonstrates that the effect of utilizing ECMO as a treatment of respiratory or cardiac failure in adults is greater than the combined influence of all confounding factors for the given condition.[14] Given that RCTs are unlikely, evidence from non-randomized trials may be considered when treatment with ECMO results in an improvement of symptoms which is so sizable that the health improvement rules out the combined effect of all other possible concurrent treatments or natural progression of the disease. Currently, there is limited evidence of this magnitude regarding patient selection, timing and therapeutic strategies in adult patients with respiratory or cardiac failure.[15,16] Therefore large studies with adequate follow-up are needed in order to validate appropriate patient selection criteria, treatment strategies and timing of ECMO use.

ECMO IN ADULTS WITH ACUTE RESPIRATORY FAILURE

The current evidence regarding ECMO in adult patients is primarily limited to nonrandomized studies with heterogenous patient populations, treated at various healthcare institutions with differing ECMO treatment protocols. In addition, ECMO technology and treatment protocols have evolved over the past several decades with the use of lung-protective ventilation systems.[15,16] Therefore, the following literature review focuses on systematic reviews and meta-analyses regarding the use of ECMO in adults in the past two decades.

Systematic Reviews and Technology Assessments

Aoyama (2019) reported results of a systematic review and meta-analysis analyzing mortality in ARDS patients following different lung protective ventilation strategies.[17] Included studies were limited to RCTs of interventions for adults with moderate to severe ARDS that used lung protective ventilation. A total of 25 RCTs were included evaluating nine interventions. Prone positioning and VV ECMO were found to have a statistically significant association with lower 28-day mortality compared with lung protective ventilation alone (prone positioning: risk ratio [RR], 0.69; 95% credible interval, 0.48-0.99; low quality of evidence; venovenous extracorporeal membrane oxygenation: RR, 0.60; 95% CI, 0.38-0.93; moderate quality of evidence).

Vaquer (2017) performed a systematic review and meta-analysis analyzing complications and hospital mortality associated with ARDS patients who underwent VV ECMO.[18] Twelve studies were included that comprised 1,042 patients with refractory ARDS. The pooled mortality at hospital discharge was 37.7% ($z = -3.73$; CI 95% = 31.8-44.1; $I2 = 74.2\%$; $p < 0.001$). This review included some H1N1 populations. H1N1 as the underlying cause of ARDS was determined to be an independent moderator of mortality.

In 2015 the Washington State Health Care Authority published a health technology assessment (HTA) for ECMO in adults.[19] Evidence of clinical efficacy of ECMO compared to conventional treatment included RCTs, good-quality comparative cohort studies, and good-quality systematic reviews. The review identified two RCTs, both of good quality. Among the 41 comparative cohort studies identified, 16 were of good quality, eight of fair quality and 17 of

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poor quality. The bulk of the good quality evidence was for pulmonary support, including two randomized control trials[20,21] and six observational studies. Based on the evidence, which was admitted to have significant limitations for some indications, and expert consensus, the committee determined that ECMO is effective for patients with severe life-threatening respiratory or cardiac dysfunction that is not responding to conventional management but is potentially reversible; as a bridging therapy for patients in pulmonary and/or cardiac failure for transplantation.

In 2015, Tramm published a Cochrane review on the use of ECMO for critically ill adults. The reviewers included RCTs, quasi-RCTs, and cluster RCTs that evaluated VV or VA ECMO compared with conventional respiratory and cardiac support.[22] Four RCTs were identified (Peek [2009][21], Morris [1994][23], Bein [2013][20], Zapol [1979][24]), which described below. Combined, the trials included 389 subjects. Inclusion criteria (acute respiratory failure with specific criteria for arterial oxygen saturation and ventilator support) were generally similar across studies. Risk of bias was assessed as low for the trials by Peek, Bein, and Zapol, and high for the trial by Morris. The reviewers were unable to perform a meta-analysis due to clinical heterogeneity across studies. The Morris and Zapol trials were not considered to represent current standards of care. The reviewers summarized the outcomes from these studies (findings described individually above). They concluded: “We recommend combining results of ongoing RCTs with results of trials conducted after the year 2000 if no significant shifts in technology or treatment occur. Until these new results become available, data on use of ECMO in patients with acute respiratory failure remain inconclusive.”

In 2015, Schmidt conducted a systematic review of studies reporting outcomes for extracorporeal gas exchange, including both ECMO and $ECCO_2R$, in adults with acute respiratory failure.[25] The review identified 56 studies, of which four were RCTs, seven were case-control studies, and 45 were case series. Two of the RCTs evaluated $ECCO_2R$ in ARDS patients, while the other two evaluated ECMO in ARDS. One RCT evaluating ECMO in ARDS was from the 1970s and was noted to have significant methodologic issues. The second RCT evaluating ECMO in ARDS was the CESAR trial (described above). The reviewers have reported that retrospective cohort studies of ECMO using more updated technology reported high rates (approximately 60%-80%) of short-term survival. The RCTs reporting on $ECCO_2R$ in ARDS patients included those by Morris (1994) and Bein (2013). As noted in the Randomized Controlled Trials section below, the Morris trial was stopped early due to futility. In the second RCT of $ECCO_2R$ in ARDS (Bein), the number of ventilator-free days did not differ significantly between groups.

In 2013, Zampieri , reports results of a systematic review and meta-analysis evaluating the role of VV ECMO for severe acute respiratory failure in adults.[26] The authors searched for RCTs and observational case-control studies with severity-matched patients that evaluated the use of ECMO in severe acute respiratory failure in adults. Three studies were included in the meta-analysis that comprised a total of 353 patients of whom 179 received ECMO, one RCT (CESAR trial,[27] described below) and two case control studies[28,29] with severity-matched patients. For the primary analysis, the pooled in-hospital mortality in the ECMO-treated group was not significantly different from the control group (odds ratio [OR], 0.71; 95% CI, 0.34 to 1.47; p=0.358). Both nonrandomized studies included only patients treated for H1Noneinfluenza A infection, which may limit their generalizability to other patient populations.

Also in 2013, Zangrillo , reported the results of a systematic review and meta-analysis that evaluated the role of ECMO for respiratory failure due to H1N1 influenza A infection in

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adults.[30] The meta-analysis included eight studies, all observational cohort studies, that included 1357 patients with confirmed or suspected H1N1 infection requiring ICU admission, 266 (20%) of whom were treated with ECMO. The median age of those receiving ECMO was 36 years, with 43% men. In 94% of cases, VV ECMO was used, with VA ECMO used only in patients presenting with respiratory and systolic cardiac failure or unresponsive to VV ECMO. The median ECMO use time was 10 days. Reported outcomes were variable across the studies, but in a random-effects pooled model, the overall in-hospital mortality was 27.5% (95% CI, 18.4% to 36.7%), with a median ICU stay of 25 days and an overall median length of stay of 37 days.

In 2013, Hirshberg conducted a review of evidence regarding ECMO use in critically ill adults with ARDS.[31] Studies included in the review were limited to the two most recent years' publications. A total of 12 case series and 12 review articles were considered in the assessment. Successful ECMO treatment of ARDS secondary to H1N1 was reported within the literature; however, studies were limited in the discussion of alternative modes of ventilation or other interventions. In addition, two national registry reports published conflicting conclusions regarding H1N1-related ARDS and ECMO treatment.[28,29] The authors made key observations, concluding:

- Increase in ARDS survival over time makes historical controls and comparisons to determine the efficacy of ECMO challenging and likely unreliable.
- Scientifically credible evidence to support the use of ECMO in the routine management of patients with ARDS is lacking.
- The use of ECMO as a salvage therapy in practice biases the interpretation of case series results.

Additional systematic reviews[32,33] were identified which also noted the heterogeneous nature of patients studied as well as a lack of well-designed randomized trials comparing ECMO to other therapies.

There are some older systematic reviews on H1N1-related respiratory distress/failure published prior to 2013 that will not be described in detail here.[34-36]

Randomized Controlled Trials

Combes reported the results of a 2018 French-sponsored RCT (NCT01470703) comparing the use of ECMO to conventional treatment for severe ARDS.[37] The ECMO group included 124 patients and the control group included 125. Sixty-day mortality was 35% and 46% in the ECMO and control groups, respectively, and the relative risk was 0.76 (confidence interval [CI] 0.55 to 1.04; p=0.09). From the control group, 35 patients who had refractory hypoxemia crossed over to the ECMO group. Of these, 20 (57%) died. Differences in frequency of complications between groups included a greater number of bleeding events leading to transfusions, more cases of severe thrombocytopenia, and fewer cases of ischemic stroke in the ECMO group. One limitation of this study involves the risk of bias due to crossover, such as carryover, period effects, and missing data. Another limitation of this study was the possible confounding factors associated with non-standardized treatment protocols between the two groups. The ECMO group underwent percutaneous venovenous cannulation and was given heparin in varying doses to achieve a targeted activated PTT time; the control group was not exposed to these variables. In contrast, the control group was exposed to ventilatory treatment, neuromuscular blocking agents, and prone positioning that differed from the comparative group, limiting the generalizability of any findings.

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In 2013, Bein reported results of the Xtravent study, which randomized patients with ARDS to a strategy of low tidal volume ventilation combined with $ECCO_2R$ (n=40) or a conventional ventilation strategy (n=39).[20] For the study's primary end point (28 and 60 ventilator-free days), there was no significant difference between treatment groups. However, the interventions evaluated are better characterized as pumpless extracorporeal lung assist devices (CO_2 removal only), making them less relevant to the evaluation of ECMO.

In 2010, Peek conducted an RCT and economic evaluation of conventional ventilatory support versus extracorporeal membrane oxygenation in adults with severe respiratory failure (CESAR trial).[27] Patients were 18-65 years old with severe, but reversible, respiratory failure (defined as a Murray score ≥ 3.0), or uncompensated hypercapnia with a pH < 7.20. The primary study outcome was death or severe disability at six-month follow-up. Secondary outcomes included: duration of ventilation, use of high frequency/oscillation/jet ventilation, use of nitric oxide, prone positioning, use of steroids, length of intensive care unit stay, and length of hospital stay - and (for ECMO patients only) mode (venovenous/veno-arterial), duration of ECMO, blood flow and sweep flow. Exclusion criteria were: high pressure (>30 cm H_2O for peak inspiratory pressure) or high FIO_2 (>0.8) ventilation for more than seven days; intracranial bleeding; other contraindication to limited heparinization; or any contraindication to continuation of active treatment. A total of 180 patients (90 in each arm) were randomized from 68 centers. Data from 87 patients in the conventional management (CM) group and 68 patients from the ECMO group were available at six-month follow-up. Authors reported significantly better mortality and disability rates in the ECMO arm compared to the CM arm six months after randomization, (33/90 [36.7%] versus 46/87 [52.9%] respectively). However, these outcomes included the 22 patients who were randomized to the ECMO treatment arm, but who never received ECMO due to death or improvement with conventional treatment. A comparison of patients actually treated with ECMO to those treated with CM did not result in a significant difference between groups [33/68 (49%) versus 46/87 (52.9%) respectively] at six-month follow-up. The study is further limited by a lack of standardized mechanical ventilation management in the CM group.

Two early small RCTs were identified that compared some form of extracorporeal support with standard care. They are described here briefly. In 1994, Morris reported the results of an RCT comparing a ventilator strategy of low-frequency positive-pressure ventilation (LFPPV) $ECCO_2R$ (ECCO2R; n=21) to standard care (n=19) in adults with ARDS.[23] In this trial, there was no significant difference in 30-day survival between groups (33% for LFPPV-ECCO2R patients vs 42% for conventional ventilation patients; p=0.8), although the trial was stopped early due to futility. The clinical practices in this trial are likely not representative of current practice. In a very early RCT, Zapol (1979)[24] compared mechanical ventilation with partial VA bypass (n=42) to conventional ventilation (n=48) in individuals with severe hypoxemic respiratory failure.

Nonrandomized Studies

Numerous nonrandomized comparative and non-comparative studies have been published regarding outcomes in patients treated with ECMO for cardiac or respiratory failure due to a variety of conditions. Several key nonrandomized comparative studies are reviewed below:

In 2009, Davies , published an observational series to characterize patients with influenza A (H1N1)-associated ARDS treated with ECMO.[38] A total of 61 patients with confirmed H1N1 influenza (n=53) or influenza A, not otherwise subtyped (n=8) and an additional 133 influenza patients treated with mechanical ventilation were included in the study. Compared to the 133

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patients who improved with conventional care, median days of mechanical ventilation were longer in patients treated with ECMO (18 [9-27] vs. 8 [4-14] days, p=0.001), median ICU days were higher (22 [13-32] vs. 12 [7-18] days; p=0.001) and ICU mortality was higher (23% vs. 9%; p=0.01). At the point of data assessment, 48 (71%) of the ECMO patients had survived to ICU discharge, 14 (21% mortality) had died, and six remained in the ICU. Of the 22 patients still remaining in the hospital, 16 had survived to ICU discharge. By comparison, the non-ECMO cohort had 13% mortality at the time of reporting, suggesting no observable benefit with ECMO treatment.

Additional nonrandomized studies regarding the use of ECMO for a variety of conditions have been published[39-48], with a majority of studies reporting an overall survival to discharge ranging from 50-68%[42,43,49-51] in patients with severe respiratory failure. Overall these publications suggest some survival benefit with ECMO treatment; however, these studies should be interpreted with caution due to the following limitations:

- Results from small sample sizes (n<100), limit the ability to rule out the role of chance as an explanation of study findings.
- Results from studies with short-term follow-up (hospital discharge) are not adequate to determine the durability of the treatment effect.
- A lack of comparison group, without which it is not possible to account for the many types of bias that can affect study outcomes.

Conclusion

Although evidence to establish standardized protocols regarding patient selection and treatment strategies is lacking, there is sufficient evidence to suggest the use of ECMO in patients with severe acute respiratory or cardiac failure may provide some survival benefit when the risks associated with mechanical ventilation are very high. Questions remain about the generalizability of findings from the CESAR trial and nonrandomized study results to other patient populations, and further clinical trials in more specific patient populations are needed.

ECMO IN ADULTS AS A BRIDGE TO TRANSPLANTATION

The evidence related to the use of ECMO as a bridge to transplantation consists of three large nonrandomized comparative studies and small case series ranging from 13 to 46 patients.[44,49,52-62] Some retrospective studies have compared outcomes for patients treated with and without ECMO preoperatively. Overall, these studies report success rates of 81-87%, and one-year survival rates of 74-100%. Adverse events reported in these series include: renal failure requiring temporary dialysis, pulmonary infections, sepsis, tracheostomy required, and distal digital ischemia. Since ECMO is generally determined to be medically necessary as a bridge to transplant, the published studies are not described in detail. Of note, three large studies are described below.

Fukuhara (2018) performed a retrospective analysis of the use of ECMO as a bridge to heart transplant in patients whose data were collected by the United Network of Organ Sharing (UNOS).[63] Of 25,168 recipients identified between 2003 and 2016, 104 were bridged with ECMO and 6,148 were bridged with a continuous-flow left ventricular assist device (CF-LVAD). Differences between the groups at baseline included younger age, more likely to have severely disabled functional status, shorter waitlist time, higher model for end-stage liver disease excluding international normalized ration (MELD-XI) score, and more frequent mechanical ventilation in the ECMO group as compared to the CF-LVAD group. Kaplan-Meier calculated

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estimated posttransplant survival was 73.1% and 93.1% in the ECMO and CF-LVAD groups, respectively at 90 days (p<0.001) and 67.4% and 82.4% in the ECMO and CF-LVAD groups, respectively at three years (p<0.001). Multivariable logistic and Cox regression analyses showed that for ECMO patients, the only contributor to both 90-day and three-year mortality was MELD-XI score. Limitations of this study include a difference in cohort size between the groups and a high rate of missing data.

In 2016, Schechter published a survival analysis comparing types of preoperative support prior to lung transplantation, using data from UNOS.[64] Included in the analysis were 12,403 adult lung transplantations from 2005 through 2013: 11,607 (94.6%) did not receive invasive support prior to transplantation, 612 (4.9%) received invasive mechanical ventilation (iMV) only, 119 (1%) received iMV plus ECMO, and 65 (0.5%) received ECMO only. Table 2 shows the cumulative survival for patients at six months, one year, and three years, by support prior to transplantation. Compared to patients with no invasive support, patients receiving iMV with or without ECMO had an increased mortality risk. The mortality of patients receiving ECMO alone was not significantly different from patients receiving no support at three years. A limitation of the study is related to the use of registry data, in that complications due to the bridge strategy and certain details such as equipment and technique of ECMO, are not available. In addition, underlying demographic differences are not represented in the comparisons.

Table 2. Cumulative Survival among Patients Undergoing Lung Transplantation, by Type of Support (Schechter 2016)

Support	N	6 Months	1 Year	3 Years
No support	11,607	89.4%	84.2%	67.0%
Invasive mechanical ventilation only	612	79.9%	72.0%	57.0%
Invasive mechanical ventilation plus ECMO	119	68.1%	61.0%	45.1%
ECMO only	65	75.2%	70.4%	64.5%

ECMO: extracorporeal membrane oxygenation.

In 2014, Jayarajan evaluated survival rates of ECMO and mechanical ventilation (MV) treatment as a bridge to heart-lung transplantation (HLT).[65] The primary study outcome was risk-adjusted all-cause mortality. Of 542 adult patients who received HLT between 1995-2011, 15 (2.8%) received ECMO and 22 (4.1%) received MV as a bridge to transplantation. At 30-day survival, the ECMO group had worse survival than the control group (patients who did not receive either ECMO or MV) (20% vs. 83.5%, respectively). Similar results were reported at 5-year survival (20% vs. 47.4%, respectively; p<0.001). Both ECMO (hazard ratio [HR]=3.820, p=0.003) and MV (HR=2.011, p=0.030) were independently associated with mortality. The authors concluded that HLT recipients receiving ECMO or MV as a bridge to transplantation had increased short and long-term mortality and that additional studies were needed in order to establish optimal treatment protocols and patient selection criteria for ECMO as a bridge to HLT.

ECMO IN ADULTS WITH REFRACTORY CARDIOGENIC SHOCK

Systematic Reviews

Wang (2018) reported the results of a meta-analysis of 20 observational studies of ECMO for postcardiotomy cardiogenic shock.[66] A total of 2,877 patients were included in the analysis. The pooled rates of one-year survival and midterm survival were 34.0% and 24.0%,

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respectively. Leg ischemia, redo surgery, renal failure, neurologic complications, and infection were reported in 18.0%, 14.0%, 50.0%, 57.0%, 16.0%, and 31.0% of patients, respectively. Commonly reported risk factors of in-hospital mortality were age >65 years, pre-ECMO or post-ECMO blood lactate, renal insufficiency, a longer duration of ECMO, and neurologic complications.

In 2015, Xie reported on a meta-analysis evaluating VA ECMO for cardiogenic shock and cardiac arrest that included observational studies and clinical trials with at least 10 adult patients.[33] Twenty-two studies, all observational, with a total of 1199 patients (12 studies [n=659 patients] with cardiogenic shock; five studies [n=277 patients] with cardiac arrest; five studies [n=263 patients] with both patient types) met inclusion criteria. Across the 16 studies (n=841 patients) that reported survival to discharge, the weighted average survival was 40.2% (95% CI, 33.9% to 46.7%). Across the 14 studies that reported 30-day survival, the weighted average survival was 52.8% (95% CI, 43.9% to 61.6%), with similar survival rates at three, six, and 12 months across studies that reported those outcomes. Across studies that reported on cardiogenic shock only, the weighted average survival to discharge was 42.1% (95% CI, 32.2% to 52.4%; I^2=79%). Across all studies, complications were common, most frequently acute kidney injury (pooled incidence, 47.4%; 95% CI, 30.2% to 64.9%; I^2=92%), followed by renal dialysis (pooled incidence, 35.2%; 95% CI, 23% to 47.4%; I^2=95%) and reoperation for bleeding (pooled incidence, 30.3%; 95% CI, 1.8% to 72.2%; I^2=98%). However, the authors noted that it is uncertain that the complications were entirely due to ECMO, given the underlying illness in patients who receive ECMO.

Nonrandomized Studies

Numerous nonrandomized comparative and non-comparative studies have been published regarding outcomes in patients treated with ECMO for refractory cardiogenic shock. Several key nonrandomized studies that are either large or comparative are reviewed below:

A 2018 retrospective case series reported by El Sibai reported outcomes of patients undergoing ECMO for cardiogenic shock. Of the 922 patients included in the study, 51.0% survived to hospital discharge. Mean length of stay was 21.8 days. An association was reported between increased mortality and respiratory diseases, genitourinary diseases, undergoing and echocardiogram, and presenting during seasons other than Fall. A decrease in mortality was associated with injury and poisoning, certain vascular procedures, and increased length of stay.

Aso (2016) analyzed 5263 patients from the Japanese Diagnosis Procedure Combination database who received VA ECMO during hospitalization.[67] Reasons for receiving VA ECMO included: cardiogenic shock (88%), pulmonary embolism (7%), hypothermia (2%), trauma (2%), and poisoning (1%). Among patients in the cardiogenic shock group, 33% died during VA ECMO, 40% died after weaning from VA ECMO, and 25% were discharged following weaning from VA ECMO. Multivariate logistic regression for in-hospital mortality showed an increased risk among patients 60 years of age and older, a BMI less than 18.5 kg, a BMI of 25 kg or more, ischemic heart disease, myocarditis, use of intra-aortic balloon pumping, use of continuous serial replacement therapy, and cardiac arrest.

Diddle 2015 reported on 147 patients (150 ECMO runs), treated with ECMO for acute myocarditis, who were identified from the Extracorporeal Life Support Organization database.[68] Patients in this group were relatively young (median age, 31 years) and were most often treated with VA ECMO (91%). Of the cohort, 101 (69%) were decannulated from

ECMO and 90 (61%) survived to discharge. In multivariable analysis, the occurrence of pre-ECMO cardiac arrest and the need for higher ECMO support at four hours were significantly associated with in-hospital mortality (OR, 2.4; 95% CI, 1.1 to 5.0; p=0.02 for pre-ECMO arrest; OR=2.8; 95% CI, 1.1 to 7.3; p=0.03 for increased ECMO support at four hours).

Chamogeorgakis (2013) conducted a retrospective chart review of patients with cardiogenic shock at a single center, comparing outcomes of 18 patients treated with a temporary miniaturized percutaneous ventricular assist device (mpVAD) with 61 patients who underwent ECMO.[69] The patient population was mostly male adults who had had myocardial infarction documented during the same hospital admission. Mean follow-up time was 14.3 months. No benefit from use of ECMO was found on in-hospital survival (ECMO 50.0% mp-VAD 49.2%), successful weaning off mechanical support (ECMO 33.3% mp-VAD 19.7%),or bridging to long-term support or transplant (ECMO 27.8% mp-VAD 31.1%).

Conclusion

The evidence on ECMO for refractory cardiogenic shock includes case series and case reports. The largest body of literature relates to the use of ECMO in the failure-to-wean from bypass population. For this indication, case series report some successful cases of weaning patients from ECMO in the setting of very high expected morbidity and mortality rates. However, without comparative studies, it is difficult to assess whether rates of weaning from bypass are better with ECMO than with standard care.

ECMO ASSISTED CARDIOPULMONARY RESUSCITATION

Systematic Review

In 2017, Debaty published a systematic review and meta-analysis on prognostic factors for patients receiving ECPR following out-of-hospital refractory cardiac arrest, to inform the decision of which patients benefit most from ECPR.[70] The search included literature through September 2016. Fifteen retrospective and prospective cohort studies were included (total N=841 patients). The overall rate of a favorable outcome following ECPR was 15%, though the range among the studies was wide (0% to 50%) due to heterogeneity of inclusion criteria, outcome definition, and compliance with protocol. Favorable outcomes occurred more frequently among patients with initial shockable cardiac rhythms, shorter low-flow duration, higher arterial pH, and lower serum lactate concentration on hospital admission. No significant differences were found when age, gender, and bystander CPR attempt were evaluated.

Nonrandomized Studies

Numerous nonrandomized comparative and non-comparative studies have been published regarding outcomes in patients treated with ECMO for cardiopulmonary resuscitation. Several key nonrandomized studies that are large or comparative are reviewed below:

Park (2014) developed a predictive score for survival to discharge using a series of 152 consecutive patients who received ECPR for in-hospital cardiac arrest.[71] In this series, in-hospital death occurred in 104 (68.4%) patients. Factors significantly associated with improved survival were an age of 66 years or less, the presence of an arrest rhythm of pulseless electrical activity or ventricular fibrillation or pulseless ventricular tachycardia, shorter CPR to ECMO time, higher initial mean arterial pressure, and higher Sequential Organ Failure Assessment scores. A score developed from these factors and evaluated in a test set generated from the initial sample using a bootstrap method was associated with a sensitivity

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and specificity of 89.6% and 75.0%, respectively, for predicting survival to discharge. This score may help select patients for ECMO, but further validation is needed.

Maekawa (2013) reported results from a prospective observational cohort of adult patients who underwent ECPR after prolonged conventional CPR after out-of-hospital cardiac arrest.[72] The study included 162 patients, 53 in the ECPR group and 109 in the conventional CPR group. After propensity score matching, 24 patients in each group were analyzed. The survival rate was higher in the matched ECPR group (29.2%) than in the matched conventional CPR group (8.3%; p=0.018).

In 2011, Shin compared ECPR with conventional CPR in adult patients who had undergone CPR for more than 10 minutes after witnessed in-hospital cardiac arrest.[73] Four hundred six patients were included, 85 who underwent ECPR and 321 who underwent conventional CPR. The cause of arrest was considered cardiac in most cases (n=340 [83.7%]) and noncardiac (secondary to respiratory failure or hypovolemia) in the remainder (n=66 [16.3%]). The decision to initiate ECPR was made by the CPR team leader. Typically, the ECMO device was available in the catheterization laboratory, coronary care unit, and operating room, and an ECMO cart was transported to the CPR site within 5 to 10 minutes during the day and within 10 to 20 minutes at night. After propensity score matching, 120 patient pairs were included; in the matched group, ECPR was associated with significantly higher rates of survival to discharge with minimal neurologic impairment (OR for mortality or significant neurologic deficit, 0.17; 95% CI, 0.04 to 0.68; p=0.012) and survival at six months with minimal neurologic impairment (hazard ratio [HR], 0.48; 95% CI, 0.29 to 0.77; p=0.003).

In contrast, in a single institution cohort of 122 patients with in-hospital cardiac arrest of cardiac origin with prolonged (>10 minutes) conventional CPR, Lin demonstrated no survival difference between patients who had return of spontaneous breathing after ECMO and those who had return of spontaneous circulation after conventional CPR.[74] After propensity score matching, 59 patients experienced return of spontaneous breathing after ECPR and 63 patients experienced sustained return of spontaneous circulation after conventional CPR. Acute coronary syndrome was the most common etiology of cardiac arrest, occurring in 73% of the ECPR patients and 50.9% of the conventional CPR patients. In the 27 ECPR response group, eight (29.6%) patients survived to discharge, while in the conventional CPR response group, five (18.5%) patients survived to discharge. In a multivariable model, ECPR was not associated with reduced mortality (adjusted HR=0.618; 95% CI, 0.325 to 1.176; p=0.413).

In an earlier prospective study, Chen (2008) compared ECPR with conventional CPR in adult patients who had undergone prolonged (>10 minutes) conventional CPR after in-hospital cardiac arrest of cardiac origin.[75] One hundred seventy-two patients were included, 59 in the ECPR group and 113 in the conventional CPR group. The decision to call the extracorporeal life-support team was made by the physician in charge. The average duration from the call to team arrival was five to seven minutes during the day and 15 to 30 minutes overnight. Survival to discharge occurred in 17 (28.8%) patients in the ECPR group and in 14 (12.3%) patients in the conventional CPR group. In a multivariable logistic regression model to predict survival at discharge, use of ECPR was associated with reduce risk of death before discharge (adjusted HR=0.50; 95% CI, 0.33 to 0.74; p=0.001).

Other noncomparative case series have described the use of ECPR for refractory cardiac arrest.[76-87] Overall, these studies suggest that ECPR is feasible, particularly for in-hospital cardiac arrests, although mortality rates are high.

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Conclusion

The most direct evidence related to the use of ECPR in cardiac arrest consists of several nonrandomized comparative studies, the largest of which consisted of 406 patients, most of which have demonstrated a survival benefit with ECPR. However, selection for ECMO in these studies was at the discretion of treating physicians, and treatment groups were not likely to be comparable. Multiple unanswered questions remain about the role of ECPR in refractory cardiac arrest, including appropriate patient populations, duration of conventional CPR, and assessment of futility.

ECMO IN ADULTS WITH OTHER CONDITIONS

Systematic Reviews

Biancari (2018) performed a systematic review and meta-analysis of patients requiring postcardiotomy VA-ECMO.[88] A total of 31 studies, 25 of which were considered good quality, were included in the analysis and with a total of 2,986 patients. The mean age of patients was 58.1 years. Hospital survival was 36.1%, which was not influenced by study quality. The mean duration of ECMO was not associated with hospital survival. The weaning rate from VA-ECMO, pooled rate of reoperation for bleeding, and major neurological event were 59.5%, 42.9%, and 11.3%, respectively. Rates of lower limb ischemia, deep sternal wound infection/mediastinitis, and renal replacement therapy were reported as 10.8%, 14.7%, and 47.1%, respectively. Patients stayed in the intensive care unit for a mean of 13.3 days. From the 11 studies that reported Kaplan-Meier estimates of one-year survival including operative deaths, the pooled one-year survival rate after postcardiotomy VA-ECMO was 30.9%. Limitations of this analysis include that many of the included studies were small and retrospective and used heterogeneous procedures.

In 2013, Lazzeri evaluated the use of ECMO to improve outcomes after refractory cardiac arrest (CA).[89] Authors concluded that analyses of the available observational studies were characterized by heterogeneity and controversial results. In addition authors noted, “the impact of ECMO implantation in CA patients can be considered a clinical challenge, since it is strictly linked to the ‘clinical selection of patients’”, as well as the technical skills and experience of the team. The study concluded that improved outcomes from the use of ECMO, in patients with refractory CA, could not be established but that, “…optimal utilization requires a dedicated local health-care organization and expertise in the field (both for the technical implementation of the device and for the intensive care management of these patients). A careful selection of patients guarantees optimal utilization of resources and a better outcome.”

In 2009, Cardarelli conducted a meta-analysis regarding the use of ECMO in adult patients in cardiac arrest or immediately after cardiopulmonary resuscitation (CPR).[36] Data was collected from observational studies published between: 1990-2007, and included 11 case series and nine case reports. A total of 135 patients were included in the analysis with a median age of 56 years (18-83). Overall survival to discharge in patients receiving ECMO was 40% (54 of 135 patients). Survival was notably improved in younger patients (17-41 years) and in patients where ECMO was used for short periods of time (0.875-2.3 days, odds ratio 0.2). Authors noted that major complications such as neurologic sequelae were not well described in the pooled studies.

Nonrandomized Studies

A 2018 study reported by Ro analyzed the outcomes of 71 venoarterial ECMO in adult patients with septic shock.[90] Of the 11 patients (15.5% of the total) that were successfully weaned from ECMO, five survived to discharge. This was compared to the rate of successful weaning in 253 cardiogenic shock patients receiving ECMO, which was 45.5% (p<0.001). Lactate levels, both pre- and six-hours-post-procedure, were significantly higher in the nonsurvivors (p=0.002).

In 2018, Huesch published a retrospective chart review of outcomes, length of stay, and discharge destination of adult patients treated with ECMO between 2007 and 2015.[91] From a review of Pennsylvania state-regulated hospitals, 2,948 consecutive patients admitted for respiratory, cardiac, cardiac arrest, or uncategorized based on administrative data were treated with ECMO. The average observed death rate was 51.7%. Of patients who survived, 14.6% went home to self-care and 15.2% went to home health care. Readmission was reported for 43.8% within one month and 60.6% within one year.

In 2017, Sauneuf evaulated patients admitted to the ICU for pheochromocytoma crisis. A total of 34 patients were included, 14 of whom received ECMO.[92] Ninety-day mortality was not significantly different between patients who were or were not treated with ECMO, despite the ECMO group having higher severity scores at admission.

Ramanathan analyzed data from the Extracorporeal Life Support Organization Registry database in 2017 of patients treated with ECMO for community-acquired pneumonia and in 2019 of patients treated with ECMO for adenoviral pneumonia.[93,94] Their data came from a >10-year period, over which time an increase in the number of patients treated with ECMO. Of the community-acquired pneumonia patients (a total of 1,055 patients),66% survived. Duration of mechanical ventilation prior to extracorporeal membrane oxygenation, lower arterial pressure, fungal pneumonia, and advancing age were all factors indicated as predictors of mortality via a multiple regression analysis. Of the adenoviral pneumonia patients (a total of 542 patients), overall mortality was 58% overall (307/529 patients), and when divided by age, 86.4% for neonates (108 of 125), 49% for children (158 of 327), and 49% for adults (41 of 83).

Dangers (2017) reported the outcomes from 105 patients implanted with venoarterial-ECMO for acute decompensated heart failure at one ICU.[95] One-year survival was 42%. Independent predictors of one-year mortality were determined with multivariable analyses to be pre-extracorporeal membrane oxygenation Sequential Organ Failure Assessment score of more than 11, idiopathic cardiomyopathy, cardiac disease duration greater than two-years pre-ECMO, pre-ECMO blood lactate greater than 4 mmol/L.

Other nonrandomized studies reported outcomes following ECMO for trauma[96], as a bridge to long-term left ventricular assist device[97], as post-cardiovascular surgery support[98], ischemic heart disease[99], and others[100].

ADVERSE EFFECTS OF ECMO IN ADULTS

Systematic Reviews

Thongprayoon (2019) performed a systematic review and meta-analysis on the incidence and mortality risk of acute kidney injury in patients receiving ECMO.[101] A total of 41 studies met the inclusion criteria, including 10,282 patients receiving ECMO. Studies were only included if they reported acute kidney injury using standard definitions including RIFLE (Risk, Injury, Failure, Loss of kidney function, and End-stage kidney disease) AKIN (Acute Kidney Injury Network), and KDIGO (Kidney Disease: Improving Global Outcomes) classifications, severe

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acute kidney injury requiring renal replacement therapy (RRT), and mortality risk of AKI among adult patients (age ≥ 18 years old) on ECMO. The pooled estimated incidence of acute kidney failure and severe acute kidney failure requiring RRT while on ECMO were 62.8% (95%CI: 52.1% to 72.4%) and 44.9% (95%CI: 40.8% to 49.0%), respectively. In patients receiving RRT for acute kidney injury, the pooled OR was 3.73 (95% CI, 2.21 to 4.99).

A 2018 systematic review by Fletcher-Sandersjöö analyzed the incidence, outcome, and predictors of ECMO-associated intracranial hemorrhage in adult patients. Twenty-five articles met inclusion criteria. In the included studies, the incidence of intracranial hemorrhage was between 1.8 and 21%. For patients who developed intracerebral hemorrhage, relative risk of mortality was 1.27 to 4.43 compared to those that did not.

In 2013, Zangrillo conducted a systematic review and meta-analysis regarding outcomes and complications related to ECMO.[102] Studies reporting complications and mortality in 100 or more patients were included in the analysis. The primary outcome was mortality at the longest follow-up date, while secondary outcomes were fatal and non-fatal complications. A total of 12 studies were included (1763 patients) with ECMO treatment utilized for acute respiratory failure, cardiogenic shock, or both. The most common ECMO-associated complications were as follows:

- renal failure requiring continuous venovenous hemofiltration (52%)
- bacterial pneumonia (33%)
- any bleeding (33%)
- oxygenator dysfunction requiring replacement (29%)
- sepsis (26%)
- hemolysis (18%)
- liver dysfunction (16%)
- leg ischemia (10%)
- venous thrombosis (10%)
- central nervous system complications (8%)
- gastrointestinal bleeding (7%)
- aspiration pneumonia (5%)
- disseminated intravascular coagulation (5%).

The overall mortality at 30-day follow-up was 54%, with 45% of fatal events occurring during ECMO and 13% occurring after ECMO.

In 2013, Cheng conducted a systematic review and meta-analysis evaluating complications related to ECMO treatment of cardiogenic shock or cardiac arrest in adult patients.[103] Studies reporting complication rates and including at least 10 patients were included for a total of 20 studies (1,866 patients). The pooled estimated complication rates with 95% confidence were as follows:

Complication	Pooled Estimated Complication Rate (%)	95% Confidence Interval
Acute kidney injury	55.6	35.5% to 74.0%
Renal replacement therapy	46.0	36.7% to 55.5%
Rethoracotomy for bleeding or tamponade in postcardiotomy patients	41.9	24.3% to 61.8%
Major or significant bleeding	40.8	26.8% to 56.6%
Significant infection	30.4	19.5% to 44.0%
Lower extremity ischemia	16.9	12.5% to 22.6%
Neurologic complications	13.3	9.9% to 17.7%
Fasciotomy or compartment syndrome	10.3	7.3% to 14.5%
Stroke	5.9	4.2% to 8.3%
Lower extremity amputation	4.7	2.3% to 9.3%

In addition, 17 studies reported survival to discharge with a pooled survival rate of 534 of 1,529 patients, ranging from 20.8%-65.4%. The authors concluded that, "[a]lthough ECMO can improve survival of patients with advanced heart disease, there is significant associated morbidity with performance of this intervention." Similar complication rates were reported in a 2014 review by Xie.[33]

Given the significant complications associated with ECMO, additional studies are needed which compare ECMO to other standard treatments, such as mechanical ventilation (MV), in order to better define appropriate patient selection criteria and treatment strategies in these high-risk patients.

Nonrandomized Studies

Numerous nonrandomized studies were identified which demonstrated that ECMO was associated with other serious complications[10,104], including, but not limited to: brachial plexus injury[105], thoracic complications (including bleeding and pneumothorax)[106-108], infection[109-112] (e.g. systemic, surgical site, respiratory tract, urinary tract), limb ischemia[113], neurological injury[114], abdominal compartment syndrome[115], groin lymphocele[116], and major vascular complications[117]. Furthermore, a recent analysis of ELSO database indicated that ECMO-related infections were higher in adults compared to children and neonates (30.6 vs. 20.8 vs. 10.1 infections per 1,000 ECMO days, respectively).[118]

PRACTICE GUIDELINE SUMMARY

AMERICAN THORACIC SOCIETY/EUROPEAN SOCIETY OF INTENSIVE CARE MEDICINE/SOCIETY OF CRITICAL CARE MEDICINE

In 2017, the American Thoracic Society/European Society of Intensive Care Medicine/Society of Critical Care Medicine Clinical Practice Guideline made recommendations on the use of mechanical ventilation in adult patients with acute respiratory distress syndrome (ARDS).[1] The guideline stated "Additional evidence is necessary to make a definitive recommendation for or against the use of extracorporeal membrane oxygenation in patients with severe ARDS." It went on to state "we recommend evidence-based use of lung-protective ventilation and early medical management for patients with severe ARDS before use of ECMO."

EXTRACORPOREAL LIFE SUPPORT ORGANIZATION

In 2014, the Extracorporeal Life Support Organization (ELSO)[9] published updated practice guidelines regarding the use of ECMO at specialty centers which highlighted the importance of institutional support, staff experience and implementation of specific procedures. However, these guidelines are not based on evidence or consensus, but rather intended to be used as a model for institutional requirements regarding appropriate ECMO use. ELSO authors noted, "[t]his guideline describes useful and safe practice, but these are not necessarily consensus recommendations. These guidelines are not intended as a standard of care…"

Adult Respiratory Failure

ELSO published guidelines regarding the use of ECMO for adult respiratory failure.[8] ELSO indicated ECMO could be considered in patients who met the following criteria:

1. In hypoxic respiratory failure due to any cause (primary or secondary) ECLS should be considered when the risk of mortality is 50% or greater, and is indicated when the risk of mortality is 80% or greater.
   a) 50% mortality risk is associated with a PaO_2/FiO_2 < 150 on FiO_2 > 90% and/or Murray score 2-3.
   b) 80% mortality risk is associated with a PaO_2/FiO_2 < 100 on FiO_2> 90% and/or Murray score 3-4 despite optimal care for six hours or more.
2. CO_2 retention on mechanical ventilation despite high Pplat (>30 cm H_2O)
3. Severe air leak syndromes
4. Need for intubation in a patient on lung transplant list
5. Immediate cardiac or respiratory collapse (PE, blocked airway, unresponsive to optimal care)

ELSO noted there are no absolute contraindications to ECMO; however, ELSO listed conditions associated with a poor outcome despite ECMO treatment in patients with adult respiratory failure:[8]

1. Mechanical ventilation at high settings (FiO_2 > .9, P-plat > 30) for7 days or more.
2. Major pharmacologic immunosuppression (absolute neutrophil count <400/mm3).
3. CNS hemorrhage that is recent or expanding.
4. Non recoverable comorbidity such as major CNS damage or terminal malignancy.
5. Age: …increasing risk with increasing age.

ELSO has published specific weaning guidelines for respiratory failure:[8]

Respiratory Failure Weaning

- Decrease flow in steps to 1L/min at sweep 100% OR decrease flow to 2L/min then decrease sweep FiO_2 to maintain SaO_2 > 95%.
- When SaO_2 stable on these settings, on VV [vein to vein], trial off by clamping sweep on vent rest settings PSV [pressure support ventilation] or CPAP 20 cm H_2O. If SaO_2 >95 and $PaCO_2$ <50 x 60 mins, come off.
- If $PaCO_2$ >50 stay on at low flow, go to selective CO_2 clearance mode.

Adult Cardiac Failure

ELSO published guidelines regarding the use of ECMO for adult cardiac failure due to cardiogenic shock.[7] ELSO indicated ECMO could be considered in patients who met the following criteria:

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1. Inadequate tissue perfusion manifested as hypotension and low cardiac output despite adequate intravascular volume.
2. Shock persists despite volume administration, inotropes and vasoconstrictors, and intraaortic balloon counterpulsation if appropriate.
3. Septic shock is an indication in some centers.

ELSO also listed contraindications for ECMO in patients with cardiac failure:

1. Absolute: Unrecoverable heart and not a candidate for transplant or VAD, advanced age, chronic organ dysfunction (emphysema, cirrhosis, renal failure), compliance (financial, cognitive, psychiatric, or social limitations), prolonged CPR without adequate tissue perfusion.
2. Relative: Contraindication for anticoagulation, advanced age, obesity.

AMERICAN HEART ASSOCIATION

In 2015, the American Heart Association (AHA) issued updated guidelines on cardiopulmonary resuscitation (CPR) and emergency cardiovascular care, which included a new systematic review of the evidence for ECPR and recommendations about the use of ECPR for adults with in- or out-of-hospital cardiac arrest.[119] The systematic review identified no RCTs evaluating ECPR for cardiac arrest and variability in the inclusion and exclusion criteria of the studies was noted, which potentially affects generalizability. The guidelines make the following recommendations related to ECPR:

> "There is insufficient evidence to recommend the routine use of ECPR for patients with cardiac arrest. In settings where it can be rapidly implemented, ECPR may be considered for select cardiac arrest patients for whom the suspected etiology of the cardiac arrest is potentially reversible during a limited period of mechanical cardiorespiratory support" (Class IIb, level of evidence C—limited data)."

SUMMARY

The research for extracorporeal membrane oxygenation (ECMO) for adult respiratory or cardiac failure has limitations. Despite these limitations, the research shows that ECMO for adult respiratory or cardiac failure improves health outcomes, including survival rates, compared to conventional therapy. Therefore, ECMO may be considered medically necessary as a treatment of respiratory or cardiac failure in adults when policy criteria are met.

Due to a lack of research and clinical practice guidelines, the use of ECMO is considered investigational when policy criteria are not met and in all other situations not specified in the policy criteria.

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CODES

Codes	Number	Description
CPT	33946	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-venous
	33947	;initiation, veno-arterial
	33948	;daily management, each day, veno-venous
	33949	;daily management, each day, veno-arterial
	33952	;insertion of peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed)
	33954	;insertion of peripheral (arterial and/or venous) cannula(e), open, 6 years and older
	33956	;insertion of central cannula(e) by sternotomy or thoracotomy, 6 years and older
	33958	;reposition peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed)
	33962	;reposition peripheral (arterial and/or venous) cannula(e), open, 6 years and older (includes fluoroscopic guidance, when performed)
	33964	;reposition central cannula(e) by sternotomy or thoracotomy, 6 years and older (includes fluoroscopic guidance, when performed)
	33966	;removal of peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older
	33984	;removal of peripheral (arterial and/or venous) cannula(e), open, 6 years and older
	33986	;removal of central cannula(e) by sternotomy or thoracotomy, 6 years and older
	33987	Arterial exposure with creation of graft conduit (eg, chimney graft) to facilitate arterial perfusion for ECMO/ECLS (List separately in addition to code for primary procedure)
	33988	Insertion of left heart vent by thoracici incision (eg, sternotomy, thoracotomy) for ECMO/ECLS

These criteria do not imply or guarantee approval. Please check with 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.

	33989	Removal of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS
ICD-9 PCS	39.65	Extracorporeal membrane oxygenation [ECMO]
ICD-10 PCS	5A15223	Extracorporeal Membrane Oxygenation, continuous
HCPCS	None	

Date of Origin: *July 2014*