RULE-MAKING ORDER
PERMANENT RULE ONLY

CR-103P (December 2017)
(Implements RCW 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: June 26, 2020
TIME: 10:17 AM

WSR 20-14-057

Agency: Health Care Authority

Effective date of rule:

Permanent Rules

☒ 31 days after filing.

☐ Other (specify) _____ **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: The agency (HCA) is updating this rule to further implement full integration of behavioral health in HCA's Medicaid program by replacing the term "mental health" with "behavioral health." This change will ensure clarity that clients receiving behavioral health services under HCA's Medicaid fee-for-service program receive appropriate notices and opportunities for hearings based on adverse benefit decisions resulting from prior authorization.

Citation of rules affected by this order:

New:
Repealed:
Amended: 182-501-0165
Suspended:

Statutory authority for adoption: RCW 41.05.021, 41.05.160

Other authority:

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 20-11-003 on May 8, 2020 (date).

Describe any changes other than editing from proposed to adopted version: None

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Web site:
Other:

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	____	Amended	____	Repealed	____
Federal rules or standards:	New	____	Amended	____	Repealed	____
Recently enacted state statutes:	New	____	Amended	____	Repealed	____

The number of sections adopted at the request of a nongovernmental entity:

	New	____	Amended	____	Repealed	____

The number of sections adopted on the agency's own initiative:

	New	____	Amended	____	Repealed	____

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	____	Amended	1	Repealed	____

The number of sections adopted using:

Negotiated rule making:	New	____	Amended	____	Repealed	____
Pilot rule making:	New	____	Amended	____	Repealed	____
Other alternative rule making:	New	____	Amended	1	Repealed	____

Date Adopted: June 26, 2020	**Signature:** 
Name: Wendy Barcus	
Title: HCA Rules Coordinator	

AMENDATORY SECTION (Amending WSR 15-15-053, filed 7/9/15, effective 8/9/15)

WAC 182-501-0165 Medical and dental coverage—Fee-for-service (FFS) prior authorization—Determination process for payment. (1) This section applies to fee-for-service (FFS) requests for medical or dental services and medical equipment that:

(a) Are identified as covered services or early and periodic screening, diagnosis, and treatment services; and

(b) Require prior authorization by the medicaid agency.

(2) The following definitions and those found in chapter 182-500 WAC apply to this section:

"Controlled studies" - Studies in which defined groups are compared with each other to reduce bias.

"Credible evidence" - Type I-IV evidence or evidence-based information from any of the following sources:

- Clinical guidelines
- Government sources
- Independent medical evaluation (IME)
- Independent review organization (IRO)
- Independent technology assessment organizations
- Medical and hospital associations
- Policies of other health plans
- Regulating agencies (for example, the Federal Drug Administration or Department of Health)
- Treating provider
- Treatment pathways

"Evidence-based" - The ordered and explicit use of the best evidence available (see "hierarchy of evidence" in subsection (6)(a) of this section) when making health care decisions.

"Health outcome" - Changes in health status (mortality and morbidity) which result from the provision of health care services.

"Institutional review board (IRB)" - A board or committee responsible for reviewing research protocols and determining whether:

(1) The rights and welfare of human subjects are adequately protected;

(2) The risks to people are minimized and are not unreasonable;

(3) The risks to people are outweighed by the potential benefit to them or by the knowledge to be gained; and

(4) The proposed study design and methods are adequate and appropriate in the light of stated study objectives.

"Independent review organization (IRO)" - A panel of medical and benefit experts intended to provide unbiased, independent, clinical, evidence-based reviews of adverse decisions.

"Independent medical evaluation (IME)" - An objective medical examination of the client to establish the medical facts.

"Provider" - The person who is responsible for diagnosing, prescribing, and providing medical, dental, or ((~~mental~~)) behavioral health services to agency clients.

(3) The agency authorizes, on a case-by-case basis, requests described in subsection (1) of this section when the agency determines the service or equipment is medically necessary as defined in WAC 182-500-070. The process the agency uses to assess medical necessity is based on:

(a) The evaluation of submitted and obtainable medical, dental, or ((~~mental~~)) behavioral health evidence as described in subsections (4) and (5) of this section; and

(b) The application of the evidence-based rating process described in subsection (6) of this section.

(4) The agency reviews available evidence relevant to a medical, dental, or ((~~mental~~)) behavioral health service or equipment to:

(a) Determine its efficacy, effectiveness, and safety;

(b) Determine its impact on health outcomes;

(c) Identify indications for use;

(d) Evaluate pertinent client information;

(e) Compare to alternative technologies; and

(f) Identify sources of credible evidence that use and report evidence-based information.

(5) The agency considers and evaluates all available clinical information and credible evidence relevant to the client's condition. The provider responsible for the client's diagnosis, or treatment, or both, must submit with the request credible evidence specifically related to the client's condition including, but not limited to:

(a) A physiological description of the client's disease, injury, impairment, or other ailment;

(b) Pertinent laboratory findings;

(c) Pertinent X-ray and/or imaging reports;

(d) Individual patient records pertinent to the case or request;

(e) Photographs, or videos, or both, if requested; and

(f) Objective medical/dental/((~~mental~~)) behavioral health information such as medically/dentally acceptable clinical findings and diagnoses resulting from physical or ((~~mental~~)) behavioral health examinations.

(6) The agency uses the following processes to determine whether a requested service described in subsection (1) is medically necessary:

(a) **Hierarchy of evidence - How defined.** The agency uses a hierarchy of evidence to determine the weight given to available data. The weight of medical evidence depends on objective indicators of its validity and reliability including the nature and source of the evidence, the empirical characteristics of the studies or trials upon which the evidence is based, and the consistency of the outcome with comparable studies. The hierarchy (in descending order with Type I given the greatest weight) is:

(i) Type I: Meta-analysis done with multiple, well-designed controlled studies;

(ii) Type II: One or more well-designed experimental studies;

(iii) Type III: Well-designed, quasi-experimental studies such as nonrandomized controlled, single group pre-post, cohort, time series, or matched case-controlled studies;

(iv) Type IV: Well-designed, nonexperimental studies, such as comparative and correlation descriptive, and case studies (uncontrolled); and

(v) Type V: Credible evidence submitted by the provider.

(b) **Hierarchy of evidence - How classified.** Based on the quality of available evidence, the agency determines if the requested service is effective and safe for the client by classifying it as an **"A," "B," "C,"** or **"D"** level of evidence:

(i) **"A" level evidence:** Shows the requested service or equipment is a proven benefit to the client's condition by strong scientific literature and well-designed clinical trials such as Type I evidence

or multiple Type II evidence or combinations of Type II, III or IV evidence with consistent results (An "A" rating cannot be based on Type III or Type IV evidence alone).

(ii) **"B" level evidence:** Shows the requested service or equipment has some proven benefit supported by:

(A) Multiple Type II or III evidence or combinations of Type II, III or IV evidence with generally consistent findings of effectiveness and safety (A **"B"** rating cannot be based on Type IV evidence alone); or

(B) Singular Type II, III, or IV evidence in combination with agency-recognized:

(I) Clinical guidelines;

(II) Treatment pathways; or

(III) Other guidelines that use the hierarchy of evidence in establishing the rationale for existing standards.

(iii) **"C" level evidence:** Shows only weak and inconclusive evidence regarding safety, or efficacy, or both. For example:

(A) Type II, III, or IV evidence with inconsistent findings; or

(B) Only Type V evidence is available.

(iv) **"D" level evidence:** Is not supported by any evidence regarding its safety and efficacy, for example that which is considered investigational or experimental.

(c) **Hierarchy of evidence - How applied.** After classifying the available evidence, the agency:

(i) Approves **"A"** and **"B"** rated requests if the service or equipment:

(A) Does not place the client at a greater risk of mortality or morbidity than an equally effective alternative treatment; and

(B) Is not more costly than an equally effective alternative treatment.

(ii) Approves a **"C"** rated request only if the provider shows the requested service is the optimal intervention for meeting the client's specific condition or treatment needs, and:

(A) Does not place the client at a greater risk of mortality or morbidity than an equally effective alternative treatment;

(B) Is less costly to the agency than an equally effective alternative treatment; and

(C) Is the next reasonable step for the client in a well-documented tried-and-failed attempt at evidence-based care.

(iii) Denies **"D"** rated requests unless:

(A) The requested service or equipment has a humanitarian device exemption from the Food and Drug Administration (FDA); or

(B) There is a local institutional review board (IRB) protocol addressing issues of efficacy and safety of the requested service that satisfies both the agency and the requesting provider.

(7) Within fifteen days of receiving the request from the client's provider, the agency reviews all evidence submitted and:

(a) Approves the request;

(b) Denies the request if the requested service is not medically necessary; or

(c) Requests the provider submit additional justifying information. The agency sends a copy of the request to the client at the same time.

(i) The provider must submit the additional information within thirty days of the agency's request.

(ii) The agency approves or denies the request within five business days of the receipt of the additional information.

(iii) If the provider fails to provide the additional information, the agency will deny the requested service.

(8) When the agency denies all or part of a request for a covered service or equipment, the agency sends the client and the provider written notice, within ten business days of the date the information is received, that:

(a) Includes a statement of the action the agency intends to take;

(b) Includes the specific factual basis for the intended action;

(c) Includes reference to the specific WAC provision upon which the denial is based;

(d) Is in sufficient detail to enable the recipient to:

(i) Learn why the agency's action was taken; and

(ii) Prepare an appropriate response.

(e) Is in sufficient detail to determine what additional or different information might be provided to challenge the agency's determination;

(f) Includes the client's administrative hearing rights;

(g) Includes an explanation of the circumstances under which the denied service is continued or reinstated if a hearing is requested; and

(h) Includes examples(s) of "lesser cost alternatives" that permit the affected party to prepare an appropriate response.

(9) If an administrative hearing is requested, the agency or the client may request an independent review organization (IRO) or independent medical examination (IME) to provide an opinion regarding whether the requested service or equipment is medically necessary. The agency pays for the independent assessment if the agency agrees that it is necessary, or an administrative law judge orders the assessment.