Clinical Policy: Medical Necessity Criteria

Reference Number: MC.CP.CPC.05
Date of Last Revision: 01/26 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Medical necessity criteria and related definitions.

Note:

- See *CP.CPC.05 Medical Necessity Criteria* for the medical necessity criteria hierarchy for lines of business other than Medicare.
- This policy may not be referenced in denial letters as the sole criteria for adverse determinations. The denial notification must reference the specific medical necessity criterion used to make the denial decision.

Policy/Criteria
Medicare health plans affiliated with Centene Corporation® and Centene Advanced Behavioral Health will use the following guidelines to make medical necessity decisions on a case-by-case basis, based on the information provided on the member/enrollee's health status that includes the medical history, physician recommendations and clinical notes.

If guidance exists from a source in the hierarchy above a subsequent step, the source earlier in the list should be used.

A. Federal law and regulations, sub-regulatory guidance, National Coverage Determinations (NCD), Local Coverage Determinations (LCD), Local Coverage Articles (LCA), Medicare policy manuals and other CMS guidance. When these do not constitute full coverage criteria, as defined below, criteria from sources in D-F may be used. Coverage criteria are not fully established when any of the following are met:[1]
   1. Additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently. The MA [Medicare Advantage] organization must demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services;
   2. NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD; or
   3. There is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria;
B. Centene clinical policy adopted by Medicare plans (including clinical policies in InterQual as custom content), or American Society of Addiction Medicine (ASAM; including the ASAM Criteria Navigator in InterQual) criteria for care related to substance use disorder (SUD), as applicable;
C. Nationally recognized decision support tools such as InterQual Clinical Decision Support Criteria;

D. In the case of no medical necessity/coverage criteria provided from sources A through C above, additional information that the applicable health plan Medical Director will consider, when available, includes any of the following:
   1. Current, widely-used treatment guidelines developed by organizations representing clinical medical specialties, such as those from American College of Obstetricians and Gynecologists and the National Comprehensive Cancer Network®, etc.
   2. Reports from peer reviewed medical literature meeting any of the following:[1]
      a. Large, randomized controlled trials;
      b. Prospective cohort studies with clear results specifically designed to answer the relevant clinical question;
      c. Large systematic reviews or meta-analyses summarizing the literature of the specific clinical question;
   3. Professional standards of safety and effectiveness recognized in the United States for diagnosis, care, or treatment;
   4. Nationally recognized drug compendia resources such as Facts & Comparisons®, DRUGDEX®;
   5. Government-funded or independent entities that assess and report on clinical care decisions and technology such as Agency for Healthcare Research and Quality (AHRQ) and National Institute for Health and Care Excellence (NICE), etc.

Only appropriate practitioners can make the decision to deny coverage of a requested service based on medical necessity guidelines. Practitioner types appropriate for making the following types of denial decisions include*:

Provider Type	Denial Decision
Physicians, all types	Medical, behavioral healthcare, pharmaceutical, dental, chiropractic, vision, and physical therapy denials
Doctoral-level clinical psychologists or certified addiction-medicine specialists	Behavioral healthcare denials
Doctoral-level board-certified behavioral analysts, doctoral-level clinical psychologists, child and adolescent psychiatrists	Applied Behavioral Analysis denials and appeals
Pharmacists	Pharmaceutical denials
Dentists	Dental denials
Chiropractors	Chiropractic denials
Physical therapists	Physical therapy denials
Advanced practice registered nurses (such as nurse practitioners and clinical nurse specialists)	Requests within the scope of the license, when acting as independent practitioners in accordance with the state practice act or regulation

*State mandates may alter which practitioner types are appropriate for denial decisions.

Definitions

Unless defined differently by the member/enrollees' Benefit Plan Contract or the applicable provider agreement, the Health Plan uses the following definitions:

A. **Medically necessary** or medical necessity shall mean health care services that a health care provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing, or treating an illness, injury, disease, or its symptoms, and that are:
   1. In accordance with generally accepted standards of medical practice;
   2. Clinically appropriate, in terms of type, frequency, extent, site, and duration, and considered effective for the patient's illness, injury, or disease; and
   3. Not primarily for the convenience of the patient, physician, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury, or disease.

   Medically necessary health care services may not include experimental and/or investigational technologies or carve-out days. For further information, please refer to CP.MP.36, Experimental Technologies.

B. **Generally accepted standards of medical practice** means standards that are based upon credible scientific evidence published in peer-reviewed medical literature recognized by the medical community at large or otherwise consistent with the standards set forth in policy issues involving clinical judgment.

C. **Experimental and/or investigational technologies** are defined as any drugs, procedures, treatments, devices, supplies, and other health care services ("Service") that are any of the following:
   1. It is currently the subject of active and credible evaluation (e.g., clinical trials or research) to determine:
      a. Clinical efficacy;
      b. Therapeutic value or beneficial effects on health outcomes;
      c. Benefits beyond any established medical based alternatives.
   2. It does not have final clearance from applicable governmental regulatory bodies (such as the US Food and Drug Administration "FDA") and unrestricted market approval for use in the treatment of a specified medical condition or the condition for which authorization of the Service is requested and is the subject of an active and credible evaluation.
   3. The most recent peer-reviewed scientific studies published or accepted for publication by nationally recognized medical journals do not conclude, or are inconclusive in finding, that the Service is safe and effective for the treatment of the condition for which authorization of the Service is requested.

D. **Not medically necessary and not investigational**: evaluations and clinical recommendations that are assessed according to the scientific quality of the supporting evidence and rationale (e.g., national medical associations, independent panels, or technology assessment organizations). A service is considered not medically necessary and not investigational when:
   1. There are no studies of the service described in recent, published peer-reviewed medical literature;
   2. There are no active or ongoing credible evaluations being undertaken of the service which has previously been considered not medically necessary;

3. There is conclusive evidence in published peer-reviewed medical literature that the service is not effective;
4. There are no peer-reviewed scientific studies published or accepted for publication by nationally recognized medical journals that demonstrate the safety and efficacy of the use of the service;
5. It is contraindicated.

E. In relation to inpatient stays, **carve-out days** are defined as non-medically necessary inpatient hospital days that occur during an approved admission (i.e., the inpatient stay was prolonged unnecessarily). Examples of circumstances giving rise to a carve-out day(s) include, but are not limited to:
   1. A day in which a member/enrollee meets concurrent inpatient criteria, and needs a service during the stay (e.g., imaging, surgery, etc.), but the service is not performed on the earliest possible date for reasons unrelated to the member's/enrollee's clinical condition (e.g., MRI machine is down, operating room time is not available, patient is bumped off schedule, or a specialist did not come in to perform a consult, etc.);
   2. A day that is solely "social" in nature (e.g., the member/enrollee is waiting for foster placement, discharge instructions, etc.);
   3. A day at the end of a stay in which discharge criteria are met but the member/enrollee is not discharged (due to, e.g., a transportation problem, DME not delivered to the home, staff too busy to discharge the member/enrollee, provider did not come in to write discharge order, the member/enrollee is waiting for a SNF placement, etc.).
   4. A day of care that is, or appears to be, necessitated by quality of care issues or largely preventable issues [e.g., complication due to wrong medication dose, central line-associated blood stream infections (which can include PICC lines and both tunneled and non-tunneled central lines), ventriculitis or meningitis in a patient with a reservoir who is receiving taps in place of a shunt and who is 2000 grams or greater in weight; infections with resistant hospital flora such as MRSA (methicillin-resistant Staphylococcus aureus) or VRE (vancomycin-resistant enterococcus), etc.].

F. The terms "**never events,**" "**serious reportable events,**" and "**non-reimbursable serious hospital-acquired conditions**" all refer to serious adverse events occurring in facilities that are largely preventable and of concern to both the public and to health care providers. Based on the benefit plan contract, the event and services resulting directly from a never event may not be a covered benefit and/or may be non-reimbursable. Examples of such events include:
   1. Death/disability associated with intravascular air embolism
   2. Death/disability associated with hypoglycemia
   3. Stage 3 or 4 pressure ulcers after admission
   4. Death/disability associated with electric shock
   5. Death/disability associated with a burn incurred within facility
   6. Various surgical site infections, i.e., following coronary artery bypass graft, bariatric surgery, or certain orthopedic procedures, etc.
   7. Death caused by self-inflicted injurious behavior if any of the following apply:
      a. While in a health care setting;
      b. Within 7 days of discharge from inpatient services;
      c. Within 7 days of discharge from emergency department (ED);

   d. While receiving or within 7 days of discharge from the following behavioral health care services: Day Treatment/Partial Hospitalization Program (PHP)/Intensive Outpatient Program (IOP), Residential, Group Home, and Transitional Supportive Living;
8. Homicide of any individual served receiving care, treatment, and services while on site at the organization or while under the care or supervision of the organization;
9. Homicide of a staff member, visitor, or vendor while on site at the organization or while providing care or supervision to individuals served;
10. Any intrapartum maternal death;
11. Severe maternal morbidity (leading to permanent harm or severe harm);
12. Sexual abuse/assault of any individual served receiving care, treatment, and services while on site at the organization or while under the care or supervision of the organization;
13. Sexual abuse/assault of a staff member, visitor, or vendor while on site at the organization or while providing care or supervision to individuals served;
14. Physical assault (leading to death, permanent harm, or severe harm) of any individual served receiving care, treatment, and services while on site at the organization or while under the care or supervision of the organization;
15. Physical assault (leading to death, permanent harm, or severe harm) of a staff member, visitor, or vendor while on site at the organization or while providing care or supervision to individuals served;
16. Surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong (unintended) procedure for a patient regardless of the type of procedure or the magnitude of the outcome;
17. Discharge of an infant to the wrong family;
18. Abduction of any individual served receiving care, treatment, and services;
19. Any elopement (that is, unauthorized departure) of an individual served from a staffed around-the-clock care setting (including the ED), leading to death, permanent harm, or severe harm to the individual served;
20. Administration of blood or blood products having unintended ABO and non-ABO (Rh, Duffy, Kell, Lewis, and other clinically important blood groups) incompatibilities, hemolytic transfusion reactions, or transfusions resulting in death, permanent harm, or severe harm;
21. Unintended retention of a foreign object in a patient after an invasive procedure, including surgery;
22. Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter);
23. Fluoroscopy resulting in permanent tissue injury when clinical and technical optimization were not implemented and/or recognized practice parameters were not followed;
24. Any delivery of radiotherapy to the wrong individual served, wrong body region, unintended procedure, or >25% above the planned radiotherapy dose
25. Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct care of the individual served caused by equipment operated and used by the organization. To be considered a sentinel event, equipment must be in use at the time of the event; staff do not need to be present;
26. Fall in a staffed-around-the-clock care setting or fall in a care setting not staffed around the clock during a time when staff are present resulting in any of the following:

a. Any fracture;
b. Surgery, casting, or traction;
c. Required consult/management or comfort care for a neurological (for example, skull fracture, subdural or intracranial hemorrhage) or internal (for example, rib fracture, small liver laceration) injury;
d. A patient with coagulopathy who receives blood products as a result of the fall
e. Death or permanent harm as a result of injuries sustained from the fall (not from physiologic events causing the fall).

Background

Centene clinical policies are intended to be reflective of current scientific research and clinical practice and judgment. They are developed with oversight of board-certified physicians and practitioners, reviewed on an annual basis for appropriateness, and approved by the Centene Clinical Policy Committee (CPC). The CPC is composed of physicians and other medical and identification of need, development, revision, and/or review of clinical policy. Clinical policies include medical, behavioral health, medical pharmacy benefits, durable medical equipment and devices. These policies include but are not limited to:

- New and emerging technologies
- New uses for existing technologies
- Clinical guidelines for the evaluation and treatment of specific conditions
- Criteria used in the authorization of drugs included on a Plan prior authorization list
- Clinical/medical criteria or information used in pre- or post-service review

InterQual Decision Clinical Support criteria ("InterQual Criteria") are proprietary. Optum is the owner/licensor of the InterQual Criteria and related software. Optum has prepared InterQual Criteria for exclusive use of its licensees of software applications embodying the clinical content. This work contains confidential and trade secret information of Optum and is provided to licensees who have an existing license agreement in force only under the time-limited license as provided under that license agreement. Licensee and any recipient thereunder shall use the clinical content in accordance with the terms and conditions of the license agreement.

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed; adapted from CP.CPC.05.	08/25	08/25
Added that the information considered for case-by-case review includes the medical history, physician recommendations and clinical notes. References updated.	01/26	01/26

References

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