

# Clinical Policy: Medical Necessity Criteria

Reference Number: CP.CPC.05

Date of Last Revision: 06/23

[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:* 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

Health plans affiliated with Centene Corporation® will use the following guidelines to make medical necessity decisions (listed in order of significance) on a case-by-case basis, based on the information provided on the member/enrollee's health status:

- A. Federal law for federal programs such as Medicare (e.g., National Coverage Determinations (NCD), Local Coverage Determinations (LCD), and Medicare Coverage Articles) or state law/guidelines (e.g., when state requirements trump federal requirements, such as for Medicaid, or exceed federal requirements);\*
- B. Plan-specific clinical policy (including plan-specific clinical policies in InterQual® as custom content);
- C. Centene clinical policy (including Centene clinical policies in InterQual as custom content);
- D. If no Plan- or Centene-specific clinical policy exists, then nationally recognized decision support tools such as InterQual Clinical Decision Support Criteria are used;
- E. In the case of no guidance from A through E, additional information that the applicable health plan Medical Director will consider, when available, includes:
  1. Reports from peer reviewed medical literature, from which a higher level of evidence and study quality is more strongly considered in determinations;
  2. Professional standards of safety and effectiveness recognized in the United States for diagnosis, care, or treatment;
  3. Nationally recognized drug compendia resources such as Facts & Comparisons®, DRUGDEX®, and The National Comprehensive Cancer Network® (NCCN®) Guidelines
  4. Medical association publications, such as those from American Society of Addiction Medicine, American College of Obstetricians and Gynecologists, etc.;
  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), Hayes Technology Assessment, Cochrane Reviews, National Institute for Health and Care Excellence (NICE), etc.;
  6. Published expert opinions, including in UpToDate;
  7. Opinion of health professionals in the area of specialty involved;
  8. Opinion of attending provider in case at hand.

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\* Note: Federal law may affect state and federal programs (e.g. Women's Health and Cancer Rights Act, Affordable Care Act), superseding any other criteria. However, this is taken into consideration in corporate clinical policies and state regulations.

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 physician, 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. Surgery on wrong body part
  2. Surgery on wrong patient
  3. Wrong surgery on patient
  4. Retained foreign body after surgery
  5. Death/disability associated with intravascular air embolism
  6. Death/disability associated with incompatible blood
  7. Death/disability associated with hypoglycemia
  8. Stage 3 or 4 pressure ulcers after admission
  9. Death/disability associated with electric shock
  10. Death/disability associated with a burn incurred within facility
  11. Death/disability associated with a fall within facility
  12. Various surgical site infections, i.e., following coronary artery bypass graft, bariatric surgery, or certain orthopedic procedures, etc.

## **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

## CLINICAL POLICY

### Medical Necessity Criteria

InterQual criteria are proprietary and cannot be publicly published and/or distributed. On an individual member/enrollee basis, the specific criteria document used to make a medical necessity determination can be made available upon request. Registered providers can obtain the appropriate InterQual criteria by logging into the secure provider portal. The InterQual criteria can be submitted with the authorization request to help expedite the process.

Change Healthcare is the owner/licensor of the InterQual Clinical Decision Support Criteria and related software. Change Healthcare has prepared this work for exclusive use of its licensees of software applications embodying the clinical content. This work contains confidential and trade secret information of Change Healthcare 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	06/13	06/13
Added definitions for experimental/investigational, carve-out days, and serious adverse events; information about clinical policy committee	08/13	10/13
Move LCD from #2 to #1 in Policy section	07/14	10/14
Added Plan specific policy under Policy/Criteria Converted into new template	10/15	10/15
Added Medicare Coverage Articles under criteria A. Redefined experimental/investigational per Health Net definition and added definition of not medically necessary and not investigational. Added footnote that the types of practitioners able to make a coverage denial may be mandated by specific states.	09/16	09/16
Clarified in provider/denial decision table that these are denial decisions <i>allowed</i> to be made by a given provider, instead of <i>requiring</i> a certain provider. Added PT as a denial decision allowed to be made by an MD.	09/17	09/17
Added that Centene clinical policy includes Centene custom content criteria in InterQual.	06/18	06/18
Specified that state-specific InterQual custom content is included in plan-specific clinical policy.	03/19	
Renumbered the policy from CP.MP.68 to CP.CPC.05. Changed references of McKesson to Change Healthcare. Added a note in description that this policy may not be referenced in denial letters as the sole criteria for adverse determinations. Added advanced practice registered nurses and doctoral-level Board-Certified Behavioral Analysts to provider type table.	04/19	06/19
Specified that doctoral-level Board-Certified Behavioral Analysts are needed for appeals and not all denials.	08/19	
Edits approved by the behavioral health subcommittee: Applied Behavior Analysis denials and appeals can be completed by doctoral-	10/19	09/19

Reviews, Revisions, and Approvals	Revision Date	Approval Date
level board-certified behavior analysts, doctoral-level clinical psychologists, child and adolescent psychiatrists		
Removed UpToDate from list of resources to use when no guidance is available in A through E in Policy/Criteria F.5, and added to F6 under “published expert opinion.” References reviewed and updated.	05/20	06/20
In F.4., added examples of medical associations, such as ASAM and ACOG.	10/20	
Updated Section F., adding “12.” referring to “various surgical site infections” found on CMS (added reference). Added reference to CP.MP.36 Experimental Technologies. Changed “review date” in the header to “date of last revision” and “date” in the revision log header to “revision date.” References reviewed and updated.	06/21	06/21
Annual review completed. Definition section C. and D. replaced “or” with a semi-colon. Background updated to reflect InterQual “criteria” and not “SmartSheets.” Minor wording changes in the background with no clinical significance. References reviewed and updated.	06/22	06/22
Annual review. Included “state law/guidelines...” under A and reworded for clarity. Added a note stating Federal law may affect state and federal programs (e.g. Women’s Health and Cancer Rights Act, Affordable Care Act), superseding any other criteria, but that it is taken into consideration in corporate clinical policies and state regulations. Removed MCG from D. and background. Minor wording changes in background with no clinical significance. Replaced all instances of “member” with “member/enrollee”. References reviewed and updated. Internal specialist review.	06/23	06/23

## References

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5. Steinberg EP, Tunis S, Shapiro D. Insurance coverage for experimental technologies. *Health Aff (Millwood)*. 1995;14(4):143 to 158. doi:10.1377/hlthaff.14.4.143
6. National Academies of Sciences, Engineering, and Medicine. *Essential Health Benefits: Balancing Coverage and Cost*. Appendix G: Medical necessity. Institutes of Medicine. Washington, DC: The National Academies Press, 2012 <https://doi.org/10.17226/13234>.
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