

# Clinical Policy: Medical Necessity Criteria

Reference Number: NC.CP.MP.05

Date of Last Revision: 08/2024

[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

It is the policy of Carolina Complete Health to 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'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. State law/guidelines, if otherwise applicable
- C. Plan-specific clinical policy (including plan-specific clinical policies in InterQual<sup>®</sup> as custom content) or state-mandated criteria such as Level of Care Utilization System (LOCUS)/Child and Adolescent Level of Care Utilization System (CALOCUS) or Early Childhood Service Intensity Instrument (ECSII), as applicable.
- D. Centene clinical policy (including Centene clinical policies in InterQual as custom content), American Society of Addiction Medicine (ASAM; including the ASAM Criteria Navigator in InterQual) criteria for care related to substance use disorder (SUD).
- E. If no Plan- or Centene-specific clinical policy exists, and the request is not related to care for SUD, then nationally recognized decision support tools such as InterQual Clinical Decision Support Criteria are used;
- F. In the case of no guidance from A-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 US for diagnosis, care, or treatment;
  3. Nationally recognized drug compendia resources such as Facts & Comparisons<sup>®</sup>, DRUGDEX<sup>®</sup>, and The National Comprehensive Cancer Network<sup>®</sup> (NCCN<sup>®</sup>) 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.

\* 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 psychiatrist.	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 members’ Benefit Plan Contract or the applicable provider agreement, the Health Plan uses the following definitions:

- A. **Medically necessary** or medical necessity is determined by generally accepted North Carolina community practice standards as verified by independent Medicaid consultants. As required by 10A NCAC 25A.0201, all medical services performed must be medically necessary and may not be experimental in nature. Furthermore, services should also be:
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, *or*
  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 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 clinical condition (e.g., MRI machine is down, operating room time is not available or patient is bumped off schedule, a specialist did not come in to perform a consult, etc.);
  2. A day that is solely "social" in nature (e.g., the member 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 is not discharged (due to, e.g., a transportation problem, DME not delivered to the home, staff too busy to discharge the member, provider did not come in to write discharge order, the member 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, a. 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. The Clinical Policy Committee is composed of physicians and other medical and operational representatives, as appropriate, from Centene Corporate and each Plan to assist in the 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 criteria are proprietary and cannot be publicly published and/or distributed. On an individual member 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 in to 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.

<b>Reviews, Revisions, and Approvals</b>	<b>Date</b>	<b>Approval Date</b>
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

Reviews, Revisions, and Approvals	Date	Approval Date
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 <b>appeals</b> and not all denials.	08/19	
Edits approved by the behavioral health subcommittee: Applied Behavior Analysis denials and appeals can be completed by doctoral-level board-certified behavior analysts, doctoral-level clinical psychologists, child and adolescent psychiatrists	10/19	09/19
Removed Up-To-Date from list of resources to use when no guidance is available in A-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	
Revised medical necessity definition language.	04/21	
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.” Policy name changed to NC.CP.MP.05. Minor wording changes in the background with no clinical significance. References reviewed and updated.	09/22	9/22
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 E 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.	08/23	08/23

Reviews, Revisions, and Approvals	Date	Approval Date
<p>Annual review. Updated language in B. to: State law/guidelines, if otherwise applicable;” In C., added “or state-mandated criteria such as the Level of Care Utilization System (LOCUS)/ Child and Adolescent Level of Care Utilization System (CALOCUS) or Early Childhood Service Intensity Instrument (ECSII), as applicable;”. Added ASAM and ASAM Navigator to C. Specified that D applies if the request is not for SUD treatment. Minor rewording for clarity. Updated list of “Never Events” in Definition F to include the Joint Commission’s list. Removed previous never events listed in 1-4 and 6 and 11 as they are otherwise stated in the Joint Commission’s list. Minor reformatting with no changes to policy. References reviewed and updated.</p>	08/24	08/24

**References**

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5. Steinberg EP, Tunis S, Shapiro D. Insurance coverage for experimental technologies. *Health Aff (Millwood).* 1995;14(4):143-158. doi:10.1377/hlthaff.14.4.143
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