Clinical Policy: Medical Necessity Criteria

Reference Number: LA.CPC.05
Date of last revision: 11/2021 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
Louisiana Healthcare Connections 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's health status:

A. Federal law (e.g., National Coverage Determinations (NCD), Local Coverage Determinations (LCD), and Medicare Coverage Articles for Federal programs such as Medicare);
B. State law/guidelines (e.g., when State requirements trump or exceed federal requirements);
C. Plan-specific clinical policy (including plan-specific clinical policies in InterQual® as custom content);
D. Louisiana Healthcare Connections clinical policy (including Louisiana Healthcare Connections clinical policies in InterQual® as custom content);
E. If no Plan- or Louisiana Healthcare Connections-specific clinical policy exists, then nationally recognized decision support tools such as InterQual Clinical Decision Support Criteria or MCG (formerly Milliman Care Guidelines®) 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®, DRUGDEX®, and The National Comprehensive Cancer Network® (NCCN®) Guidelines
    4. Medical association publications;
    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, Up-To-Date, Cochrane Reviews, National Institute for Health and Care Excellence (NICE), etc.;
    6. Published expert opinions;
    7. Opinion of health professionals in the area of specialty involved;
    8. Opinion of attending provider in case at hand.

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, Louisiana Healthcare Connections 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 LA.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, *or*
   b. Therapeutic value or beneficial effects on health outcomes, *or*
   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, *or*
   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, *or*
   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, *or*
   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. 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

Louisiana Healthcare Connections 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 Clinical Policy Committee. The Clinical Policy Committee is composed of physicians and other medical and operational representatives, as appropriate, 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 SmartSheet™ by logging in to the secure provider portal. The InterQual SmartSheet can be submitted with your authorization request to help expedite the process.

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The MCG guideline(s) and products are not intended to be used without the judgment of a qualified health care provider with the ability to take into account the individual circumstances of each patient's case.

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Converted corporate to local policy.	08/15/2020	
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.	11/11/2021	

References

1. American Medical Association (AMA). Statement of the AMA to the Institute of Medicine's Committee on Determination of Essential Health Benefits. January 14, 2011.
2. Lembitz A, Clarke TJ. Clarifying "never events" and introducing "always events". Patient Saf Surg. 2009;3:26.
3. Change Healthcare InterQual® criteria.
4. MCG (formerly Milliman Care Guidelines®) guidelines.
5. National Committee for Quality Assurance. NCQA Standards and Guidelines for the Accreditation of Health Plans 2014.
6. National Quality Forum (NQF). Serious reportable events in healthcare 2011 update: A consensus report, Washington, DC: NQF; 2011
7. Steinberg, EP, Tunis, S, Shapiro, D. Insurance coverage for experimental technologies. Health Affairs, 1995 Vol. 14:4.
8. CMS.gov. Centers for Medicare and Medicaid Services. Hospital-Acquired Conditions. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions