Clinical Policy: Medical Necessity Guidelines

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Description
Medical necessity guidelines and related definitions.

Policy/Guidelines
PA Health & Wellness® (PHW), an affiliate health plan of Centene Corporation®, will use the following guidelines to make medical necessity decisions (numbered in order of significance) on a case-by-case basis, based on the information provided on the participant's health status:

A. Federal law (e.g., National Coverage Determinations (NCD), Local Coverage Determinations (LCD), and Medicare Coverage Articles for programs under Federal oversight such as Medicare);
B. Pennsylvania State law/guidelines (e.g., when State requirements trump or exceed federal requirements);
C. PHW clinical policy;
D. If no PHW clinical policy exists, then the nationally recognized decision support tool InterQual® Clinical Decision Support Criteria is used (See **Attachment I** for currently adopted Licensed InterQual Criteria);
E. In the case of no guidance from A-E, additional information that the PHW Medical Director will consider, when available, includes:
    1. Reports from peer reviewed medical literature, where 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 allowed to make denial decisions:	
Provider Type	**Denial Decision**
Physicians, all types	Medical, behavioral healthcare, pharmaceutical, dental, chiropractic, vision, and therapy denials
Dentists	Dental denials

Definitions
Unless defined differently by the participants' Benefit Plan Contract or the applicable provider agreement, PHW uses the following definitions:

A. **Medically necessary**, or medical necessity, as defined in the PA Community Health Choices Agreement is compensable under the Medical Assistance Program and meets any one of the following standards:
   1. Will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
   2. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
   3. Will assist a Participant to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Participant and those functional capacities that are appropriate for Participants of the same age.
   4. Will provide the opportunity for a Participant receiving LTSS to have access to the benefits of community living, to achieve person-centered goals, and live and work in the setting of his or her choice.

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 not inferior to 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 rational (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 participant 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 participant'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 participant 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 participant is not discharged (due to, e.g., a transportation problem, DME not delivered to the home, staff too busy to discharge the participant, provider did not come in to write discharge order, the participant 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

Background

PHW clinical policies are intended to be reflective of current scientific research and clinical thinking. They are developed with oversight of board-certified physicians and practitioners, reviewed on an annual basis for appropriateness and approved by the PHW Utilization Management Committee (UMC).

PHW utilizes the resources of the Centene® clinical policy department and the Clinical Policy Committee (CPC) for ongoing review of current scientific research and clinical thinking. The CPC is composed of physicians and other medical and operational representatives, as appropriate, from Centene Corporate and each Centene affiliated Plan to assist in the identification of need, development, review, revision, and approval of clinical policy. The PHW Chief Medical Director participates in the CPC. 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
- Guidelines used in the authorization of drugs included on a Plan prior authorization list
- Clinical/medical guidelines or information used in pre- or post-service review

PHW reviews and edits the CPC approved policies to ensure compliance with Pennsylvania regulations and the CHC Agreement, prepares them for adoption by PHW as a PHW-specific clinical policy, and brings them to the PHW UMC for approval. All prior authorization policies are submitted to the state for review and approval prior to their effective date, annually, and as needed for update or revision as defined in the PARP requirements of the Agreement.

PHW complies with and utilizes PA DHS QM/UM-8 Prior Authorization Review (PARP), Annual Submission and Quarterly Updates guideline and specifications to maintain adherence to CHC Agreement language related to development of, review and update, approval and adoption of Prior Authorization policies (Attachment II- #500-17-08 QM/UM-8 Prior Authorization Review (PARP), Annual Submission and Quarterly Updates). PHW designated staff from Medical Management and Pharmacy are responsible for quarterly review of Centene CPC updates, revision as applicable to PHW Medical and Pharmacy Prior Authorization polices, and submission to both the state via Docushare and the appropriate PHW Quality Committee. Once approved, the policy will be updated on the PHW internet site.

InterQual criteria are proprietary and cannot be publicly published and/or distributed. On an individual participant 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.

McKesson Corporation is the owner/licensor of the InterQual Clinical Decision Support Criteria and related software. McKesson 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 McKesson 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.

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Attachments
Attachment I PHW 2017 Licensed Proprietary Products  PA.MP.68_Attachment I_ PHW 2017 Licer Attachment II- #500-17-08 QM/UM-8 Prior Authorization Review (PARP), Annual Submission and Quarterly Updates  QM UM _8 Prior Authorization_FINAl

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. http://www.nationalacademies.org/hmd/~/media/8D03963CAEB24450947C1AEC0CAECD85.ashx.
2. Lembitz A, Clarke TJ. Clarifying "never events" and introducing "always events". Patient Saf Surg. 2009; 3:26.
3. McKesson Corporation InterQual® criteria.
4. National Committee for Quality Assurance. NCQA Standards and Guidelines for the Accreditation of Health Plans 2014.
5. National Quality Forum. Serious reportable events in healthcare 2006 update: A consensus report.
6. Steinberg, EP, Tunis, S, Shapiro, D. Insurance coverage for experimental technologies. Health Affairs, 1995 Vol. 14:4.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed	11/17	