

PROVIDENCE HEALTH ASSURANCE MEDICAL POLICY FOR MEDICARE ADVANTAGE	Centers for Medicare & Medicaid Services (CMS) Medical Policy Manual	
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Purpose

The purpose of this Providence Health Assurance (PHA) CMS Medical Policy Manual is to provide guidance regarding the application of Medicare CMS policy for medical necessity determination of medical services provided by Medicare Advantage (MA) Plans. CMS requires that MA Plans provide the same medical benefit as Original Medicare to MA members for medical services specifically addressed by CMS. This manual establishes the hierarchy of application of CMS policy documents to ensure PHA MA Medical Policy development is based on accurate and consistent review of CMS policies. In addition, this manual establishes a process for evidence-based review and medical necessity determination of services not addressed by CMS policy.

This policy manual and hierarchy of coverage determination does not apply to Medicaid members.

Application of Benefits

PHA Medical Policies, based on the application of CMS policies or a systematic review of the current evidence, serve as guidance for the administration of plan benefits. PHA medical policies neither constitute medical advice nor guarantee coverage. The scope and availability of CMS plan benefits are determined in accordance with the applicable CMS guidelines. Any conflict or variance between the terms outlined within CMS guidelines and PHA Medical Policy will be resolved in favor of the currently published CMS guidelines.

Definition of Medical Necessity

CMS has adopted the definition of medical necessity as outlined in the Social Security Act, Section 1862(a)(1)(A) regarding exclusions from coverage for secondary payers, which states:

“...Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services, ... (which) are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”²

Therefore, any medical services deemed by CMS benefit guidelines as not reasonable and necessary to treat an illness or injury or improve function of a malformed body member will not be covered. CMS may utilize a variety of evaluation methods for determining the medical necessity of a medical service,

including, but not limited to the following:

- Safety and efficacy
- Quality of evidence and the clinical significance of reported outcomes
- Clinical practice guidelines
- Input from licensed clinical specialist

CMS medical necessity determinations should be applied regardless of whether the service is approved by Food and Drug Administration (FDA) or addressed in a CMS Fee Schedule. This application of coverage determination includes medical services which may be reported with an unspecified CPT or HCPCS code.

Development of a PHA CMS Medical Policy

The development of a PHA CMS Medical Policy is based on a hierarchy of coverage determination. To ensure PHA CMS Medical Policies are aligned with Original Medicare coverage determinations, policies are based on Medicare coverage manuals and/or provisions, CMS National Coverage Determinations (NCDs), CMS Local Coverage Determinations (LCDs), CMS Local Coverage Articles (LCAs), CMS Medicare Learning Network (MLN) documents, and feedback from Independent Review Entity (IRE) input, when available. When no input is available from any of the resources noted above, PHA Medical Policy may be based on the evidence-based commercial Medical Policy.

Per the CMS Medicare Managed Care Manual (Chapter 4):

“...(A)n item or service classified as an original Medicare benefit must be covered by every MA plan if:

- Its coverage is consistent with general coverage guidelines included in original Medicare regulations, manuals and instructions (unless superseded by written CMS instructions or regulations regarding Part C of the Medicare program);
- It is covered by CMS’ national coverage determinations...; or
- It is covered by written coverage decisions of local Medicare Administrative Contractors (MACs) with jurisdiction for claims in the geographic area in which services are covered under the MA plan...”³

As such, the following policy hierarchy is used to guide medical necessity determination of all PHA CMS-based Medical Policies:

- **CMS Coverage Manuals and Provisions**

CMS coverage manuals/provisions may be used as the basis for medical policy development to determine the medical necessity of medical services.

The CMS Medicare Program Integrity Manual (Chapter 13) indicates the following:

“Coverage provisions in interpretive manuals are instructions that are used to further define when and under what circumstances items or services may be covered (or not covered).

The contractor shall apply coverage provisions in interpretive manuals to claims that are selected for review. When making claim determinations, contractors shall not deviate from these coverage provisions if absolute words such as "never" or "only if" are used. Requirements for prerequisite therapies listed in coverage provisions in interpretive manuals (e.g., "conservative treatment has been tried, but failed") shall be followed when deciding whether to cover an item or service.”⁵

An example of a CMS coverage manual is the CMS Medicare Managed Care Manual (Chapter 4) which addresses coverage of transplant providers and service locations:

“If the local providers of transplants, within the normal community patterns of care for transplants, are not willing to cover transplants for MA enrollees at a mutually agreed upon payment rate, then the MA plan must offer transplants through alternative transplant providers.”⁶

- **National Coverage Determinations (NCDs)**

When no CMS coverage manual/provision is available, or if further definition of a CMS coverage manual/provision is required, then an NCD may be used as the basis for medical policy development to determine the medical necessity of medical services.

Per the CMS Medicare Program Integrity Manual (Chapter 13):

“The NCDs are developed by CMS to describe the circumstances for Medicare coverage nationwide for an item or service. NCDs generally outline the conditions for which an item or service is considered to be covered (or not covered) under §1862(a) (1) of the Act or other applicable provisions of the Act. NCDs are usually issued as a program instruction. Once published in a CMS program instruction, an NCD is binding on all Medicare carriers/DMERCS, FIs, Quality Improvement Organizations (QIOs, formerly known as Peer Review Organizations or PROs), Program Safeguard Contractors (PSCs) and beginning 10/1/01 are binding for Medicare+Choice organizations. NCDs made under §1862(a)(1) of the Act are binding on Administrative Law Judges (ALJ) during the claim appeal process. (See 42 CFR 405.732 and 42 CFR 405.860).

The contractor shall apply NCDs when reviewing claims for items or services addressed by NCDs. When making individual claim determinations, contractors have no authority to deviate from NCD if absolute words such as "never" or "only if" are used in the policy.

National Coverage Determinations should not be confused with "National Coverage Requests" or "Coverage Decision Memoranda".”⁵

- **Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs)**

When no CMS coverage manual/provision or NCD is available, or if further definition of a CMS coverage manual/provision or NCD is required, then an LCD and accompanying LCA, may be used as the basis for medical policy development to determine the medical necessity of medical services.

Per the Medicare Coverage Database:

“FIs, Carriers, and Medicare Administrative Contractors (MACs) are Medicare contractors that develop and/or adopt LCDs. Medicare contractors develop LCDs when there is no National Coverage Determination (NCD) or when there is a need to further define an NCD. The guidelines for LCD development are provided in Chapter 13 of the Medicare Program Integrity Manual. A local policy may consist of two separate, though closely related documents: the LCD and an associated article. The LCD only contains reasonable and necessary language. Any non-reasonable and necessary language a Medicare contractor wishes to communicate to providers may be done through the article. At the end of an LCD that has an associated article, there is a link to the related article and vice versa.”¹

Per the CMS Medicare Program Integrity Manual (Chapter 13):

“An LCD is a decision by a Medicare administrative contractor (MAC) whether to cover a particular item or service on a MAC-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (i.e., a determination as to whether the item or service is reasonable and necessary). The difference between LMRPs (Local Medical Review Policy) and LCDs is that LCDs consist of only “reasonable and necessary” information, while LMRPs may also contain benefit category and statutory exclusion provisions.”⁵

Multiple MACs

Per the CMS Medicare Managed Care Manual (Chapter 4):

“A regional MA plan that chooses to adopt a uniform coverage policy must select one of the A/B MACs with jurisdiction in the plan service area and apply the policies of that A/B MAC uniformly to all enrollees of the plan...

Regional MA plans may not select local coverage policies from more than one A/B MAC...”³

- **Medicare Learning Network® (MLN)**

*When no CMS coverage manual/provision, NCD, or LCD/LCA is available, MLN Matters® Articles may be used as the basis for medical policy development to determine the medical necessity of medical services.*⁷

- **Commercial Medical Policies**

When no CMS coverage manual/provision, NCD, LCD/LCA, or MLN guideline is available, then the health plan commercial medical policy may be used to determine the medical necessity of medical services.

In the absence of a CMS policy which addresses the medical necessity of a given medical service, generally or for a specific condition, CMS guidelines allow for the Medicare Advantage organization (MAO) to apply an objective, evidence-based review to reach a coverage determination.³ Per CMS Medicare Managed Care Manual (Chapter 4, 90.5):

“In coverage situations where there is no NCD, LCD, or guidance on coverage in original Medicare manuals, an MAO may adopt the coverage policies of other MAOs in its service area. However, if the MAO decides not to use coverage policies of other MAOs in its service area, the MAO:

- Must make its own coverage determination;
- Must provide CMS an objective evidence-based rationale relying on authoritative evidence such as:
 - Studies from government agencies (e.g. the FDA);
 - Evaluations performed by independent technology assessment groups (e.g. BCBSA); and
 - Well-designed controlled clinical studies that have appeared in peer review journals; and
- In providing its justification, the MAO may not use conclusory statements with no accompanying rationale.”³

Therefore, in the absence of a CMS policy guideline as described above which addresses the medical necessity of services, approved, commercial medical policies will be used for medical necessity determinations. See the PHP UM150 guidelines regarding the health plan’s medical policy development process.⁴

- **Independent Review Entity (IRE)**

When no CMS coverage manual/provision, NCD, LCD/LCA, or MLN guideline is available, then input from independent review entity, such as MAXIMUS⁸, may be used to review the medical necessity of medical services.

In the absence of a CMS policy which addresses the medical necessity of a given medical service, generally or for a specific condition, CMS guidelines allow for the Medicare Advantage organization (MAO) to apply an objective, evidence-based review to reach a coverage determination.³ However, in the event the Plan receives multiple IRE overturns, the plan will review its coverage stance based on the IRE determination of medical necessity. In general, the following algorithm will be applied:

The PHA Medical Policy coverage review will occur under the following circumstances:

- Two IRE overturns are received for the same services, same condition, same clinical circumstances, and the overturns are based on the same clinical rationale.
- Three IRE overturns are received for the same service and the condition, clinical circumstances and rationale are similar.

Elements considered during a review of coverage stance will include:

- Claims/PA data (overturns vs. approvals vs. denials; costs, LOB)
- Current Clinical practice guidelines
- Other payer policies
- Current peer-reviewed evidence
- Clinical input

Review of the elements noted above will be vetted at the PHA Medical Directors meeting and a final coverage decision, including an update to the Medicare Advantage medical policy will be presented at the Medical Policy Committee meeting for final vote and approval.

References

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