Medicare Medical Policy

PHA Medicare Medical Policy Development and Application

MEDICARE MEDICAL POLICY NUMBER: 50

Effective Date: 1/1/2024

Last Review Date: 11/2023

Next Annual Review: 11/2024

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

PURPOSE

The purpose of Providence Health Assurance (PHA) Medicare medical policies are to ensure consistent and clinically appropriate outcomes regarding the application of Centers for Medicare and Medicaid Services (CMS) guidance for medical necessity determinations of medical services provided to Medicare Advantage (MA) members. Of note, the terms "Medicare" or "Medicare policies" in the context of this document and Company Medicare medical policies collectively relates to coverage manuals and guidance published by Original Medicare, as well as policies, articles, newsletters, and other communications published by entities contracted with CMS (e.g., Medicare Administrative Contractors or MACs).

Medicare requires 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 Medicare policies, guidelines, and regulations to ensure PHA MA Medical Policy development is based on accurate and consistent review of CMS and associated entity (e.g., MAC) policies. In addition, this policy establishes a process for evidence-based review and medical necessity determination of services not addressed by a specific Medicare-based policy or guideline or when Medicare coverage policies are not considered to be fully established.

Medicare Advantage medical policies are generally expected to apply to the majority of Medicare Advantage plan members; however, the unique clinical details of an individual member's needs should also be considered to making a final medical necessity decision.

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

APPLICATION OF BENEFITS

PHA medical policies are based on the application of Medicare policies or a systematic review of the current evidence and serve as guidance for the administration of plan benefits. PHA medical policies neither constitute medical advice nor guarantee coverage. With the exception of certain supplemental benefits that may be offered, the scope and availability of Company MA plan benefits are determined in accordance with the applicable Medicare guidelines. While the Company strives to stay up-to-date with Medicare coverage guidance, Original Medicare and their contractors may change their policies at any time. Any conflict or variance between the terms outlined within Medicare guidelines and PHA Medicare medical policy will be resolved in favor of the currently published Medicare guidance. In the event of any conflict between the medical policy and Evidence of Coverage (EOC) language, the EOC language and member benefits will take precedence over PHA Medicare medical policies.

MEDICARE DEFINITION OF MEDICAL NECESSITY

Medicare has adopted the definition of medical necessity as outlined in the *Social Security Act, Section 1862(a)(1)(A)*, which reads as follows:

> "…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."[1]

Note the requirement that the service, item or technology be **both** medically reasonable **and** necessary. With limited exceptions (e.g., preventive services such as pap and mammograms), any medical services (e.g., procedures, durable medical equipment, devices, inpatient services, etc.) deemed not medically reasonable and necessary to treat an illness or injury or improve function of a malformed body member will not be covered. Medicare and its contractors may utilize a variety of evaluation methods for determining the medical necessity of a medical service, including, but not limited to the following[2,3]:

- Safety and efficacy
- Quality of evidence and the clinical significance of reported outcomes
- Clinical practice guidelines
- Input or consultations by experts, recognized authorities, and medical associations in the applicable field of interest

Medicare's medical necessity protocols should be applied regardless of whether the service is approved by Food and Drug Administration (FDA) or included in a Medicare Fee Schedule.

1. The issuance of a CPT/HCPCS code to a device or procedure does not in itself automatically imply the procedure is medically reasonable and necessary.[4] Coverage determinations also include medical services and technologies reported with an unspecified (unlisted) CPT or HCPCS code.
2. Approval by the FDA also does not automatically imply medical necessity of a service or item under Medicare. While the FDA determines safety and effectiveness of a device or drug, it does not establish medical necessity under the Medicare Program. Medicare may reference FDA determinations regarding safety and effectiveness, but it is Medicare or its contractors who evaluate services, procedures, drugs or technology to determine if they may be considered Medicare covered services or are reasonable and necessary for Medicare members under *§1862(a)(1)(A)*.

DEVELOPMENT OF A PHA MEDICARE MEDICAL POLICY

TOPIC SELECTION FOR POLICY DEVELOPMENT

Issues are selected for Medicare medical policy development through several mechanisms, including referrals from internal staff, the provider community, and our members. Examples of activity which may warrant new policy development include, but may not be limited to, the following:

- New national coverage determinations (NCDs), local coverage determinations (LCDs), or local coverage articles (LCAs) developed by Medicare or MACs;
- New diagnostic tests, therapeutic procedures or medical devices;
- Controversial medical technologies with respect to their clinical utility;
- Technologies with a high level of interest for members and/or providers.

Criteria Development for PHA Medicare Advantage Medical Policies

The development of a PHA Medicare Advantage Medical Policy is based on a hierarchy of coverage determination. To ensure PHA Medicare Advantage Medical Policies are aligned with Original Medicare coverage determinations, policies are based on Medicare coverage manuals and/or provisions, NCDs, LCDs, LCAs, and Medicare Learning Network (MLN) documents, when such are available. When no policy or guideline is available from any of the resources noted above, PHA Medicare medical policy may be based on an evidence-based commercial medical policy or medical utilization vendor.
According to the 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 Centers for Medicare and Medicaid Services (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,…"[5]

As such, the following policy hierarchy is used to guide medical necessity determination of all PHA Medicare medical policies:

MEDICARE-BASED REFERENCES AND RESOURCES

- **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.

  Examples of a CMS coverage manual which may be referenced includes the Medicare Benefit Policy Manual, the Medicare Claims Processing Manual, and the Medicare Managed Care Manual.

- **National Coverage Determinations (NCDs) and Final Decision Memorandums**

  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.

  "NCDs are developed by CMS to describe the circumstances for Medicare coverage nationwide for a specific medical service procedure or device. NCDs generally outline the conditions for which a service is considered to be covered (or not covered) and usually issued as a program instruction."[6] NCDs are binding for Medicare, Medicare Administrative Contractors (MACs), and Medicare Advantage Organizations (MAOs).[5,7,8]

Coverage policy found in NCDs also includes Medicare Final Decision Memorandums (Memos) for new or revised NCDs. According to CMS, "…the effective date for the NCD is the same date as the publication date of the final decision memorandum. Therefore, we have found it expedient and practical to include the NCD that is included in the Medicare National Coverage Determination manual in the final decision memoranda and to use that date as the effective date for Medicare coverage and payment purposes."[9]

Therefore, final decision memorandums (memos) that are published for new or revised NCDs may also be included in Company Medicare medical policies until the NCD is formally updated.

- **Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and Other Publications by a Medicare Contractor**

When no Medicare coverage manual/provision or NCD is available, or if further definition of a Medicare 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.

According to Medicare:

> "An LCD, as defined in §1869(f)(2)(B) of the Social Security Act (SSA), is a determination by a Medicare Administrative Contractor (MAC) respecting whether or not a particular item or service is covered on a contractor–wide basis in accordance with section 1862(a)(1)(A) of the Act."[10,11]

LCAs include billing and coding articles, response to comment (RTC) articles, as well as other types of educational documents.[12,13] According to Noridian:

> "The term "article" is used to describe any bulletin article, website article, educational handout or any other non-LCD document intended for public release that contains coverage/coding statements or medical review related billing or claims considerations.
>
> "Medicare contractors post articles into the Medicare Coverage Database (MCD). Articles address local coverage, coding or medical review related billing and claims considerations, and may include any newly developed educational materials, coding instructions or clarification of existing medical review related billing or claims policy."[14]

Noridian Healthcare Solutions (Noridian) Jurisdiction F (J-F) is the designated MAC contracted to cover the states of Oregon and Washington.

MACs with Exclusive Jurisdiction over a Medicare Item or Service

According to the Medicare Managed Care Manual (Chapter 4):

> "A MAC outside of the plan's service area sometimes has exclusive jurisdiction over a Medicare covered item or service. In some instances, one Medicare A/B MAC processes all of the claims for a particular Medicare-covered item or service for all Medicare

beneficiaries around the country. This generally occurs when there is only one supplier of a particular item, medical device or diagnostic test (for example; certain pathology and lab tests furnished by independent laboratories). In this situation, MA plans must follow the coverage requirements or LCD of the MAC that enrolled the supplier and processes all of the Medicare claims for that item, test or service."[15]

In addition, "Services for an enrollee from a provider outside the service area are covered based on the local coverage determinations of that provider's geographic location."[16] Therefore, the Company may reference local coverage policies and articles by Medicare contractors from other service areas when necessary to remain compliant with Medicare regulations.

NCDs, LCDs, and LCAs can be accessed from the Medicare Coverage Database (MCD) website, while Noridian-specific information can be found on Noridian's website.

- **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.[17]

IN THE ABSENCE OF MEDICARE-BASED COVERAGE CRITERIA

- **Commercial Medical Policies**

In the absence of a Medicare policy, Medicare guidelines allow for the MAO to apply an objective, evidence-based review to reach a coverage determination.[18] The Medicare Managed Care Manual (Chapter 4, §90.5) reads as follows:

> "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."[18]

According to the CMS Final Rule CMS-4201-F:

"MA plans must comply with national coverage determinations (NCD), local coverage determinations (LCD), and general coverage and benefit conditions included in Traditional Medicare laws. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare. When coverage criteria are not fully established in Medicare statute, regulation, NCD, or LCD, MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature."[19]

Medicare NCD, LCD, or general coverage criteria are considered not to be fully established when:

A. Additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently.
    a. The MAO must demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services;
B. Available NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD; or
C. There is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria.[20]

Therefore, in the absence of a Medicare policy guideline as described above which addresses the medical necessity of services, the Company's commercial medical policies may be used for medical necessity determinations.

- **Use of Independent Third-Party Proprietary Tools**

  For some services, when there is no NCD, LCD, coverage manual, or when available CMS criteria are not fully established, the Company may choose to not develop its own coverage criteria, but instead will use independent third-party, proprietary tools to ensure consistent coverage determination outcomes. Examples include, but may not be limited to, Carelon (formerly AIM), InterQual®, and eviCore.

Reminder: While Medicare Advantage medical policies are generally expected to apply to the majority of Medicare Advantage plan members, the unique clinical details of an individual member's needs should be considered and reviewed to make a final medical necessity decision.

APPROVAL PROCESS

Policy drafts are presented to the Medical Policy Committee for final approval. The Committee consists of physician medical directors and other professional staff from the Company service area.

CONTINUED MANAGEMENT OF PHA MEDICARE MEDICAL POLICIES

The Medicare Medical Policies are reviewed and updated annually at a minimum. Policies may be reviewed more often in the event new information is published by Medicare, Noridian or other MACs, or as new evidence that alters the clinical criteria becomes available.

In the event multiple independent review entity (IRE) overturns are received for a service with no Medicare-based policy or guideline, the Company may reconsider its coverage position based on the rationale of the IRE determination for medical necessity. While coverage position changes are not guaranteed, especially if evidence is lacking or if member safety is a concern, the Plan may choose to review the policy coverage position in the event of multiple IRE overturns received for the same service(s), same condition, same clinical circumstances, and when the IRE overturns are based on the same or similar clinical rationale.

Elements considered during the review of a policy's coverage position include, but may not be limited to, other IRE reviews and outcomes, overall claim and prior-authorization volumes, ratio of overturns vs. appeals, current clinical practice guidelines (CPGs) and recognized standards of care, other payer policies, current peer-reviewed evidence, and clinical input and feedback by physician medical directors and other professional staff.

Medicare medical policy revisions are also presented to the Medical Policy Committee for final vetting and approval.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
12/2022	Annual review (converted to new format 2/2023)
1/2024	Annual review, no change to existing content; add guidance from CMS-4201-F