Medicare Medical Policy

Definition of Medically Reasonable and Necessary (Medical Necessity)

MEDICARE MEDICAL POLICY NUMBER: 360

Effective Date: 11/1/2023

Last Review Date: 10/2023

Next Annual Review: 10/2024

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

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

NOTE: With the exception of select Medicare-approved preventive (screening) benefits, Medicare requires all items and services rendered to members to be **both** medically reasonable **and** necessary to treat or diagnose an illness or injury.

Service	Medicare Guidelines
Medically Reasonable and Necessary (Medical Necessity)	I. Coverage determinations regarding medical necessity for Medicare Advantage Plan members are made in accordance with the applicable Centers for Medicare and Medicaid Services (CMS) payment policies, internet-only manuals (Benefit Policy Manual, Claims Processing Manual, etc.), National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs) and Articles (LCAs) and other Medicare-based guidance, when available. II. In the absence of Medicare coverage policies to guide medical necessity coverage determinations, the Company may make its own coverage determination following the following CMS guidance:[1] A. Objective evidence-based rationale relying on authoritative evidence must be used. Examples include: i. Studies from government agencies (e.g., the FDA); ii. Evaluations performed by independent technology assessment groups (e.g., BCBSA); and iii. Well-designed controlled clinical studies that have appeared in peer review journals; and B. The use of conclusory statements with no accompanying rationale (e.g., "It is our policy to deny coverage for this service.") cannot be used.

	III.	According to CMS, in order for a service, item, or medical technology to be considered medically necessary, it must be:[2] A. Safe and effective. B. Not experimental or investigational (exceptions may apply to select clinical trial or registry services which meet the requirements of the Clinical Trials National Coverage Determination [NCD] or Coverage with Evidence Development [CED] NCDs **and** when reported appropriately). (See Policy Guidelines) C. Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is: i. Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member; ii. Furnished in a setting appropriate to the patient's medical needs and condition; iii. Ordered and furnished by qualified personnel; iv. One that meets, but does not exceed, the patient's medical need; and *v.* At least as beneficial as an existing and available medically appropriate alternative.
	IV.	Services, procedures, or other medical technologies determined by the Company to be investigational (or experimental) are considered **not medically necessary** for Medicare members.
	V.	Out of network requests for services that are not covered (e.g., robotic or computer assisted orthopedic procedures – MAKO) are considered **not medically necessary** for Medicare members. *(See the Company medical policy for* Definition of Medical Necessity*)*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

MEDICAL POLICY

- Clinical Trials, Studies and Registries, MP233
- PHA Medicare Medical Policy Development and Application, MP50

REIMBURSEMENT POLICY

- Plan-Directed Care, UM35

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DEFINITIONS

The following guidelines and definitions may apply.

Centers for Medicare and Medicaid Services (CMS) glossary[3]	**Medically necessary:** "Services or supplies that: are proper and needed for the diagnosis or treatment of your medical condition, are provided for the diagnosis, direct care, and treatment of your medical condition, meet the standards of good medical practice in the local area, and aren't mainly for the convenience of you or your doctor."
Plan Medicare Advantage plan benefit documents (aka, Evidence of Coverage or EOC)	**Medically necessary:** "…the services, supplies, or drugs are needed for the prevention, diagnosis, or treatment of your medical condition and meet accepted standards of medical practice." "**Experimental** procedures and items are those items and procedures determined by Original Medicare to not be generally accepted by the medical community."
Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, §13.5.4 – Reasonable and Necessary Provisions in LCDs[2]	"Contractors shall determine if evidence exist to consider an item or service to be reasonable and necessary* if the contractor determines that the service is: • Safe and effective; • Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and

	• Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is: o Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member; o Furnished in a setting appropriate to the patient's medical needs and condition; o Ordered and furnished by qualified personnel; o One that meets, but does not exceed, the patient's medical need; and o At least as beneficial as an existing and available medically appropriate alternative." *Note this includes **both** medically reasonable **and** necessary.
Company policy for *Definition: Experimental/Investigational* (MP5)	Company policy use of the term "investigational" includes procedures, devices or technologies which: • Have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), ***or*** • Do not meet all of the Company's technology assessment criteria.
Medicare Claims Processing Manual, Chapter 23 – Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A[4]	Services which demonstrate a "lack of safety and efficacy" are considered experimental. Experimental services and devices are considered "not medically necessary" under Medicare.

GENERAL

The Company may reimburse medically reasonable and necessary (medically necessary) services for eligible Medicare Plan members when **all** of the following apply:

- The service or item must be a covered benefit; **and**
- Any applicable coverage criteria, including the guidelines noted above, are met; **and**
- The service or item is eligible for reimbursement under the specific provider contract; **and**
- No bundling or utilization edit (e.g., medically unlikely edits or MUEs) apply which would disallow separate payment.

The Company may perform preauthorization or retrospective review as determined to be appropriate to confirm the services rendered are medically reasonable and necessary. To complete these reviews,

medical records may be requested. When clinical documentation is requested, all pertinent information necessary to make a medical necessity determination must be included.

Since the Medicare Advance Beneficiary Notice of Non-coverage (ABN) form is **not** valid for Medicare Advantage members, prior to providing an item or service that may be non-covered because it is not medically necessary, a pre-service organization determination request must be submitted. The Company Reimbursement Policy *(Plan-Directed Care,* UM35*)* provides additional information regarding this process (see Cross References).

MEDICARE AND MEDICAL NECESSITY

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage. The following definition of medical necessity is the primary foundation of coverage under Medicare and it is found in the *Social Security Act, Section 1862(a)(1)(A)*:

> "…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."[5]

MEDICALLY REASONABLE AND NECESSARY (MEDICAL NECESSITY) COVERAGE DETERMINATIONS

Medicare Coverage Policies

Coverage determinations, including medical necessity, for Medicare Advantage Plan members are made in accordance with the applicable CMS payment policies, internet-only manuals (Benefit Policy Manual, Claims Processing Manual, etc.), National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs) and Articles (LCAs) and other Medicare-based guidance when available.

In the Absence of a Medicare Coverage Policy

As previously stated, only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. In the absence of Medicare coverage policies to guide the medical necessity of a given health care service, Medicare regulatory guidelines allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations.

During the MAO review, an evidence-based process must be used. This includes using authoritative evidence, such as studies performed by government agencies (i.e., the FDA), well-designed clinical studies that appeared in peer reviewed journals, and evaluations performed by independent technology assessment groups.[1] In addition to review of the quality of the body of studies and the consistency of the results, additional consideration may be given to determine if the evidence can be generalized to the Medicare population.

More information regarding the hierarchy used for Medicare Advantage medical necessity decision-making can be found in the Medicare medical policy for *PHA Medicare Medical Policy Development and Application* (MP50).

Investigational or Experimental Procedures and Services

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be "investigational." The term "investigational" is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]). "Investigational" (or "experimental") may also mean the procedure, device, or technology does not meet all of the Company's technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

According to Medicare, "If a service is not reasonable and necessary to treat illness or injury for any reason (including lack of safety and efficacy because it is an experimental procedure, etc.)" the service is considered noncovered.[4] Therefore, investigational procedures or services are considered "not medically reasonable or necessary" for Medicare Plan members.

Investigational Device Exemption (IDE) Studies, Clinical Trials, and Registries

Some services may be considered not medically necessary (or investigational) under either a Medicare Only or a Company policy, but may be eligible for coverage for Medicare Plan members if rendered within the context of a **Medicare-approved** IDE study, clinical trial, or registry. The separate Medicare medical policy *(Clinical Trials, Studies and Registries [Medicare],* MP233*)* provides additional information regarding these scenarios (see Cross References). Note that some clinical trials are paid by Original Medicare as the primary payor. Medicare member EOCs provide coverage information for these situations.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

CODES*		
CPT	None	
HCPCS	None	

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §90.5 – Creating New Guidance; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf [Last Cited 9/14/2022]
2. Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, §13.5.4 – Reasonable and Necessary Provisions in LCDs; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf [Last Cited 9/7/2022]
3. CMS Glossary; Available at: https://www.cms.gov/glossary
4. Medicare Claims Processing Manual, Chapter 23 – Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c23.pdf [Last Cited 9/21/2022]
5. Social Security Administration; Section 1862(a)(1)(A); Link: https://www.ssa.gov/OP_Home/ssact/title18/1862.htm [Last Cited 9/7/2022]

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
12/2022	New Medicare Advantage medical policy (converted to new format 2/2023) (updated title 8/2023)
11/2023	Annual review, no change to policy position, update language and Medicare citations