MEDICAL POLICY	Definition: Medically Reasonable and Necessary (Medical Necessity) (Medicare Only)
Effective Date: 12/1/2022	Medical Policy Number: 360
 12/1/2022	Medical Policy Committee Approved Date: 11/2022
Medical Officer Date	

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Medicare Only

MEDICARE POLICY CRITERIA

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.

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: Medical Necessity (All Lines of Business Except Medicare))*

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:
	  ○ 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;
	  ○ Furnished in a setting appropriate to the patient's medical needs and condition;
	  ○ Ordered and furnished by qualified personnel;
	  ○ One that meets, but does not exceed, the patient's medical need; and
	  ○ 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.

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

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, as long as the MAO applies an objective, evidence-based process, using authoritative evidence[5], as indicated in the relevant Company Medicare 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).

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)*. 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. *(Medicare Claims Processing Manual, Ch. 23, §30 A)* 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 Company Medicare Medical Policy *(Clinical Trials, Studies and Registries (Medicare Only),* 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.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

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.

CROSS REFERENCES

Medical Policy

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

Reimbursement Policy

- Plan-Directed Care, UM35

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]