Medical Necessity
Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Medical Necessity		
MNG #: 045	☒ **SCO** ☒ **One Care** ☒ **MA Medicare Premier** ☒ **MA Medicare Value** ☒ **RI Medicare Preferred** ☒ **RI Medicare Value** ☒ **RI Medicare Maximum**	**Prior Authorization Needed?** ☒ **Yes (always required)** ☐ **Yes (only in certain situations. See this MNG for details)** ☐ **No**
Benefit Type: ☒ **Medicare** ☒ **Medicaid**	**Approval Date:** 11/05/2020;	**Effective Date:** 04/01/2021;
Last Revised Date: 10/07/2021;10/14/2021; 4/19/2022; 7/13/2023; 10/10/2024	**Next Annual Review Date:** 11/05/2021; 10/14/2022; 4/19/2023; 7/13/2024; 10/10/2025	**Retire Date:**

OVERVIEW:
According to Medicare, medical necessity or medically necessary healthcare services or supplies are [those that are] needed for the diagnosis or treatment of [one's] illness, injury, medical condition, disease, or its symptoms, and that meet accepted standards of medicine. These services or supplies are provided for the diagnosis, direct care, and treatment of [one's] medical condition (e.g., improve a patient's current condition, maintain the patient's current condition, or prevent or slow further deterioration of the patient's condition), meet the standards of good medical practice in the local area, and are not mainly for the convenience of the individual nor [one's] healthcare professional designee.

The purpose of this medical necessity guideline (MNG) is to provide healthcare professionals, utilization reviewers, and members guidance on the definition and application of medical necessity for making individualized coverage determinations. Requests for healthcare services or products that require prior authorization should be accompanied with clear documentation of medical necessity. Supporting documentation should include justification on how the requested services align with generally accepted standards of medical practice. This may include credible scientific evidence in reputable peer-reviewed medical literature, physician or healthcare provider specialty society recommendations, and other relevant factors specific to the member.

The definition of medical necessity is important, but it is equally essential to understand how the concept is applied in the medical necessity determination process. For more information on the process of conducting medical necessity reviews, refer to SOP #121 Medical Necessity Review and Service Decisions. When applying the MNG for medical necessity, it is important to note that: (1) the MNG is intended to clarify specific medical information that Commonwealth Care Alliance (CCA) needs to determine medical necessity, that (2) it is not intended to replace or supersede clinical decision-making, and that (3) the definition or application of medical necessity should not emphasize cost and resource utilization above quality and clinical effectiveness.

DEFINITIONS:
Clinical Literature (or credible scientific evidence): Literature, published in a peer-reviewed journal, that describe research that is specifically designed to answer a relevant clinical question. The following are types of credible scientific research:

- Large volume, randomized, multi-center, controlled trials with long-term follow-up; or
- Large volume, multi-center, prospective cohort studies with clear results; or
- Large systematic reviews or meta-analyses which quantify the degree of reproducibility of results summarizing the literature pertaining to the specific clinical question.

Deluxe (in the context of Durable Medical Equipment): Aesthetic feature of an upgraded item of medical equipment that is also considered an excess component.

Excess Component (in the context of Durable Medical Equipment): An item, feature, or service, which is in addition to, or is more extensive and/or more expensive than the item that is reasonable and necessary under Medicare's coverage requirements.

Experimental, Investigational or Unproven Services (EIS): Experimental, investigational, or unproven services may refer to but are not limited to a drug, test, procedure, treatment, device, or equipment that remains under study, as its absolute risk is unestablished. Further study is required to determine the safety, effectiveness, toxicity, maximum tolerated dose, and efficacy of the EIS. It is generally not the standard therapy and, therefore, is not accepted by the professional medical community.

Generally Accepted Standards of Medical Practice: Standards that are based on credible scientific evidence, that are published in peer-reviewed medical literature, and are generally recognized by the relevant medical community, physician, specialty society recommendations, views of the medical practitioners practicing in relevant clinical areas, and other relevant factors.

Healthcare Services or Supplies (also known as Items and Services): Medical care or related goods and services, including behavioral health services and long-term services and supports (LTSS) provided to members.

Healthcare Professional Designee: Qualified and licensed healthcare professional designated to assist in the decision-making process.

Medical necessity guidelines (MNGs): Medical policies that are developed to publish what services are covered, and to provide a better understanding of the basis upon which coverage decisions are made. MNGs are only developed for select preventive, therapeutic, or diagnostic services that have been found to be safe and proven effective for a defined population, or in specific clinical circumstances.

Not Medically Necessary: Items and services that do not meet the definition of medical necessity. According to CMS, Medicare does not pay for medically unreasonable and unnecessary services and supplies to diagnose and treat a Medicare patient's condition. This includes, but is not limited to, the following:

- Hospital-provided services that, based on the patient's condition, could have been provided in a lower-cost setting, like the patient's home or nursing home; or
- Hospital services exceeding Medicare length of stay limits; or
- Evaluation and management services exceeding those considered medically reasonable and necessary; or
- Excessive therapy or diagnostic procedures; or
- Unrelated screening tests, exams, and therapies where the patient has no symptoms or diagnoses, except

certain screening tests, exams, and therapies; or
- Unnecessary services based on the patient's diagnosis.

Prior Authorization: Prior assessment that must be conducted to evaluate whether the service requested is deemed medically necessary and meets the specific requirements outlined in the health plan's documents. It is based on information provided (e.g., letter of medical necessity, medical records, etc.) to determine whether the proposed services meet the clinical requirements for medical necessity, which includes appropriateness, effectiveness, and level of care.

Upgrade (in the context of Durable Medical Equipment): An item with features that go beyond what is medically necessary.

Widely used Treatment Guidelines: Guidelines that are for the treatment of specific diseases or conditions, and that have been developed by organizations representing clinical medical specialties.

DECISION GUIDELINES:

Clinical Coverage Criteria:

Commonwealth Care Alliance will follow the Centers for Medicare and Medicaid Services (CMS) definition of medical necessity and will cover items or services that are reasonable and necessary under 1862(a)(1)(A) of the Social Security Act. According to CMS in the Program Integrity Manual, an item or service is considered to be reasonable and necessary if there is evidence to support that it is all of the following (1 through 4):

1. Safe and effective; and
2. Not experimental or investigational; *The exception to this criterion is routine costs of qualifying clinical trial services. Please refer to MNG #104 Clinical Trials, Routine Patient Care Costs for more information*; and
3. Appropriate, including the duration, frequency, and cost-effectiveness, that is considered appropriate for the item or service, in terms of whether it is:
    a. Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the member's condition or to improve the function of a malformed body member; and
    b. Furnished in a setting appropriate to the member's medical needs and condition; and
    c. Ordered and furnished by qualified personnel; and
    d. One that meets, but does not exceed, the member's medical need; and
    e. At least as beneficial, comparable in effect/availability/suitability, and no more costly than an existing and available medically appropriate alternative.

    AND
4. The items and services meet the CMS definition of medically necessary, as defined as healthcare services and supplies, that are:
    a. Proper and needed for the diagnosis or treatment of the member's medical condition; and
    b. Provided for the diagnosis, direct care, and treatment of the member's medical condition; and
    c. Meet the standards of good medical practice in the local area; and
    d. Not mainly for the convenience of the member, their doctor, or their healthcare professional designee.

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LIMITATIONS/EXCLUSIONS:

Commonwealth Care Alliance will not cover any items or services that are considered to not be medically necessary or reasonable. This includes, but is not limited to, any of the following (1 through 10).

1. Hospital-provided services that, based on the patient's condition, could have been provided in a lower- cost setting, like the patient's home or nursing home;
2. Hospital services exceeding Medicare length of stay limits;
3. Evaluation and management services exceeding those considered medically reasonable and necessary;
4. Excessive therapy or diagnostic procedures;
5. Related to durable medical equipment, any upgrade, excess component, or deluxe feature or item that is requested for aesthetic reasons or added convenience. Requests for a more expensive service or item may be considered when the additional expense is for an added feature that is medically necessary in a given case. In this circumstance, the request may be reviewed on an individual case-by- case basis and will require review from a CCA medical director to determine the medical necessity and clinical appropriateness.
6. Unrelated screening tests, exams, and therapies where the patient has no symptoms or diagnoses, except certain screening tests, exams, and therapies;
7. Unnecessary services based on the patient's diagnosis;
8. Items or services that are not covered as per a CMS national coverage determination (NCD), are not covered by a Medicare Local Coverage Determination (LCD) for the CCA plans' area of operations, and are not covered by a Medicaid regulation or guideline;
9. Items or services that are not based on current evidence in widely used treatment guidelines or clinical literature;
10. Items or services that are considered to be experimental and/or investigational and have not been proven to be safe and effective.

NOTE: For more information, please refer to MNG #010 Experimental and Investigational Services.

Disclaimer

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses evidence based InterQual© criteria, when available, to review prior authorization requests for medical necessity. This Medical Necessity Guideline (MNG) applies to all CCA Products unless a more expansive and applicable CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), or state-specific medical necessity guideline exists. Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis by considering the individual member's health care needs. If at any time an applicable CMS LCD or NCD or state-specific MNG is more expansive than the criteria set forth herein, the NCD, LCD, or state-specific MNG criteria shall supersede these criteria.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. This Medical Necessity Guideline is subject to all applicable Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

This Medical Necessity Guideline is not a rigid rule. As with all CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised,

however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity [(supporting literature (full text preferred) should be attached to the request)], or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

REFERENCES:

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2. Centers for Medicare & Medicaid Services, Publication 100-04, Medicare Claims Processing Manual, Chapter 30, Financial Liability Protections, Sections 40.2.2(C) Routine Notice Prohibition, Effective date: 12/20/2023. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c30.pdf
3. Centers for Medicare & Medicaid Services, Publication 100-08, Medicare Program Integrity Manual, Chapter 13, Local Coverage Determinations, Section 13.5 LCD Content, Effective date: 02/12/2019. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c13.pdf
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Investigational-Services-MNG-07.13.24.P.010.pdf
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REVISION LOG:

REVISION DATE	DESCRIPTION
10/10/2024	PA always required. Revised Overview, Definitions, and formatting; Updated document to revised MNG Template/Format. Updated references. Otherwise editorial.
12/31/23	Utilization Management Committee approval
06/06/2023	Cost-effectiveness added to the language referencing appropriate[ness] of what is medically necessary.

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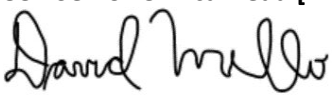
05/30/2023	The overview section was updated to include the context of the definition of medical necessity, the purpose of the MNG, and provides a reference to the process in making medical necessity determinations. Added the definitions section and the following terms: EIS, Generally accepted standards of medical practice, Healthcare services or supplies, Healthcare professional designee, Medical necessity guideline, Not medically necessary, and Prior authorization. The Clinical coverage criteria was updated to include safety, effectiveness, and not EIS. The format of the criteria was updated in the normal numbering convention. Added the Limitations and Exclusions section to include items and services considered to be non-covered. Updated the regulatory references.

APPROVALS:

David Mello	Senior Medical Director, Utilization Review and Medical Policy
CCA Senior Clinical Lead [Print]	**Title [Print]**
	10/10/2024
Signature	**Date**
Nazlim Hagmann	Chief Medical Officer
CCA CMO or Designee [Print]	**Title [Print]**
	10/10/2024
Signature	**Date**