Health Management Department Policy

Title: **Medical Necessity Criteria**
Applies To: **Generations Advantage and US Family Health Plan**
Effective Date: 3/6/2013 Last Revised 10/2023

PURPOSE

This standard specifies the hierarchy of the clinical criteria, policies, and guidelines at Martin's Point Health Care (MPHC) used to determine medical necessity.

This standard also describes the procedures used to develop, approve, and apply medical necessity criteria to requests made under the MPHC health plans (Generations Advantage and US Family Health Plan).

DEFINITION

MPHC will apply objective and evidence-based criteria and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services.

MPHC defines medical necessity as the following:

Items and services must be established as safe and effective to be considered medically necessary. That is, the items and services must be:

- Consistent with the symptoms of diagnosis of the illness or injury under treatment
- Necessary for and consistent with, generally accepted professional medical standards of care (e.g., not experimental or unproven)
- Not furnished primarily for the convenience of the member or of the provider or supplier, and
- Furnished at the most appropriate level of care that can be provided safely and effectively to the member

MPHC supports the utilization management staff with explicit, written clinical review criteria and review procedures. MPHC adopts medical necessity criteria in accordance with a hierarchy of clinical evidence as follows:

Generations Advantage:

- Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs)
- Centers for Medicare & Medicaid Services (CMS) Local Coverage Determinations (LCDs)
- Medicare Benefit Policy Manual*
- Current evidence in widely used treatment guidelines and clinical literature** (See 42 CFR § 422.101(b)(6) Martin's Point Healthcare utilizes MCG Care Guidelines: Ambulatory Care, Inpatient & Surgical Care, General Recovery Care, Home Care, Recovery Facility Care, Chronic Care
- MPHC internally developed clinical guidelines

*Medicare Benefit Policy Manual Chapter 15-50.4.1 allows for the approval of a drug if it is being used according to the FDA-approved labeling. Additionally, Chapter 15-50.4.5 allows for the off-label use drugs and biologicals in an anti-cancer chemotherapeutic regimen if use is supported by either one or more of the acceptable compendia or in peer-reviewed medical literature with clinically meaningful outcomes.

** "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peerreviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question. "

US Family Health Plan:

- TRICARE Program Manuals
- MCG Care Guidelines: Ambulatory Care, Inpatient & Surgical Care, General Recovery Care, Home Care, Recovery Facility Care, Chronic Care
- MPHC internally developed clinical guidelines

If none of the above sources addresses the service being requested, MPHC uses the following sources to help determine medical necessity:

- Knowledge Centers such as Hayes, Cochrane Grading, NCCN,
- National guidelines and consensus statements such as Medical Association Guidelines, United States Preventative Services Task Force (USPSTF), National Institutes of Health (NIH), and clinical statements from the Agency for Healthcare Research and Quality (AHRQ)
- Statistically robust, well-designed randomized controlled trials and cohort studies
- Large multisite observational studies
- Single-site observational studies
- Independent Review Entities - examples include Advanced Medical Reviews (AMR) and MCMC

In making a determination that a drug, device, medical treatment, or procedure has moved from the status of unproven to the position of nationally accepted medical practice, MPHC uses the following hierarchy of reliable evidence (as defined in 32 CFR 199:2):

1. Well-controlled studies of clinically meaningful endpoints, published in refereed medical literature
2. Published formal technology assessments
3. Published reports of national professional medical associations
4. Published national medical policy organization positions
5. Published reports of national expert opinion organizations

The hierarchy of reliable evidence of proven medical effectiveness, established by items 1 through 5, is the order of the relative weight given to any particular source. With respect to clinical studies, only those reports and articles containing scientifically valid data and published in the refereed medical and scientific literature shall be considered as meeting the requirements of reliable evidence.

Specifically, not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence, or personal profession opinions. Also not included in the meaning of reliable evidence is the fact that a provider or a number of providers have elected to adopt a drug, device, medical treatment, or procedure as their personal treatment or procedure of choice or standard of practice.

PROCEDURE

The Utilization Management (UM) Committee chaired by the Health Plan Medical Director provides initial/ annual review and approval of all medical necessity criteria and clinical guidelines.

When the high level of specialty or complexity of the criteria warrants it, or when the UM Committee structure lacks representation of a particular specialty, MPHC obtains external specialty review from non-network physicians, other appropriately licensed providers, or an independent review entity.

Review of the adopted criteria / clinical guidelines ensures that:

- Appropriate providers with current knowledge relevant to the criteria/ clinical guidelines were involved when the organization or entity developed the criteria/ clinical guidelines.
- The criteria/ clinical guidelines derive from current clinical principles and standards of practice
- Actively practicing physicians, and other providers with current knowledge relevant to the criteria/ clinical guidelines evaluate at least annually and update when necessary.

MPHC intends that all medical necessity decisions be made in a consistent and impartial manner.

Medical necessity review criteria/ clinical guidelines do not replace clinical judgment; they serve as guidelines in a structured review process. As such:

- Whenever possible, MPHC's utilization and care management programs use evidence-based clinical criteria and guidelines that are applicable to services provided in a variety of settings.
- Upon request, MPHC makes the clinical criteria/ guidelines available to providers, facilities rendering services, and members so that they may understand the basis of a medical necessity decision.
- MPHC notifies all network practitioners of the availability of criteria in the provider manual.
- Clinical staff use the criteria/ clinical guidelines during first-level medical necessity reviews and has the authority to approve requests that meet the criteria for the applicable service.

  During first-level review, if information submitted does not meet criteria and clinical staff is unable to approve, he or she tasks the case to the physician advisor for review.

When making a decision, the physician advisor considers individual medical needs (e.g., age, comorbidities, complications, progress of treatment, psychosocial situation, home environment), available treatment options, and delivery system limitations, such as available skilled nursing facilities, home care agencies and hospitals).

- If a staff member believes criteria are not met, but individual member needs or delivery system limitations exist that could influence the decision, he or she initiates a discussion with the physician advisor.
- Utilization management clinical staff and physicians meet regularly to evaluate determinations and problem cases.
- Non-clinical staff assist clinical staff by requesting clinical information and medical records for the services requiring prior authorization.
- Non-clinical staff collect the clinical information submitted by the requesting providers and transfer the case to the Utilization Management Review Nurse or other licensed staff for clinical review.

MONITORING MPHC measures the consistency of criteria / guideline application via inter-rater reliability reviews (IRR) and through audit processes.

SOURCES (Regulatory and Accreditation)

- 32 CFR 199:2
- 42 CFR §§ 422.101(b),(c)
- 42 CFR § 422.202(b)
- NCQA, 2023-2024 Health Plan Standards - UM
- Centers for Medicare and Medicaid Services, *Medicare Managed Care Manual,* Chapter 4, section 10
- TRICARE Program Manuals – 2021 Edition (T-5)
- Medicare Benefit Policy Manual

Note: This replaces GA517, effective 9/1/2012. This policy was formerly known as FGM002.

This replaces FG012-02 effective 3/25/19.

As of 3/11/2020: Policy changed to Guideline.

As of 8/9/2021: Changed to a standard for naming convention.

As of 10/24/23: Naming convention changed to policy.

APPROVALS		
	Rebekah Dube, Pharm.D. Vice President Clinical Programs	Date: 9/24/2015
	Utilization Management Committee	Date: 3/25/2019
	Utilization Management Committee	Date: 4/29/2020
	Utilization Management Committee	Date: 4/12/2021
	Utilization Management Committee	Date: 5/31/2022
	Utilization Management Committee	Date: 2/22/2023
	Utilization Management Committee	Date: 10/31/2023

REVIEW/ REVISION DATES	
5/2012	
3/2013	
4/2014	
5/2015	
3/2019	
3/2020	
4/2020	
4/2021	
8/2021	

5/2022: Revised to be clearer that UM Committee reviews and approves clinical guidelines and criteria, updated spelling, added MCMC to examples of IRO's, and specified which edition of TRICARE manuals is being used under sources.	Tracy Howard – Director Health Management
1/2023: Revised to add Medicare Benefit Policy Manual under GA hierarchy and sources	Tracy Howard – Director Health Management
10/2023: Revised to reflect CMS changes to Final Rule, Changed to Policy for naming convention	Tracy Howard – Director Health Management Matthew Toohey – Health Plan Medical Director Alicia Siani – General Legal Counsel
4/2024: Revised to update years for NCQA Standards and TRICARE Program Manuals in Sources	Tracy Howard – Director Health Management