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MEMORIAL HERMANN HEALTH PLAN HOLDINGS, LLC POLICY

POLICY TITLE: **MHHP MEDM-MA 303 Medical Necessity Determinations**

PUBLICATION DATE: 05/26/2025
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VERSION: 1

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MEMORIAL HERMANN HEALTH SYSTEM
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POLICY

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POLICY PURPOSE:

To ensure that the Health Plan's coverage determination process for medical necessity is evidence-based, transparent, equitable and consistent, this policy provides guidance for evaluating individual medical necessity when a coverage request is made for an item or service covered under Medicare as a basic benefit without established clinical criteria. This coverage criteria outlines the information required for The Health Plan to make an individualized determination in accordance with the reasonable and necessary provisions defined in 1862(a)(1) of the Social Security Act (SSA) and Chapter 13, Section 13.5.4 of the Medicare Program Integrity Manual.

DEFINITIONS:

Basic Benefits – Services covered under Medicare Parts A and B, excluding hospice care and the cost of kidney acquisitions for transplant. The scope of basic benefits is defined by the limits and conditions on payment and coverage in the Traditional Medicare program. This includes specifications on who may deliver a service, the settings in which a service may be provided, criteria outlined in relevant National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs).

Centers for Medicare and Medicaid Services – The Centers for Medicare and Medicaid Services, the Federal agency within the Department of Health and Human Services (DHHS) that administers the Medicare program and oversees all Medicare Advantage Prescription Drug Plan (MAPD) and Prescription Drug Plan (PDP) organizations.

Experimental/Investigational – A service, piece of equipment, facility or supply, including drugs or drug usage, that has not been proven effective to the point that it has been accepted as standard medical practice for diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member by the general medical community, and/or does not have a beneficial effect on net health outcomes due to insufficient and inadequate clinical evidence. For most

Medicare coverage purposes, the term experimental has been used synonymously with the term investigational[1].

Hierarchy of coverage criteria – When making coverage determinations, review criteria is applied in the order outlined below:

a. Benefit conditions included in Traditional Medicare laws. The item or services must fall within at least one benefit category established in Section 1861 of the SSA. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare, such as payment criteria for inpatient admissions at 42 CFR 412.3, services and procedures designated as requiring inpatient care under 42 CFR 419.22(n), and requirements for payment of Skilled Nursing Facility (SNF) Care, Home Health Services under 42 CFR part 409, and Inpatient Rehabilitation Facilities (IRF) at 42 CFR 412.622(a).
b. General coverage and in Traditional Medicare laws unless superseded by laws applicable to The Health Plans. This includes coverage criteria published in the Code of Federal Registry, Internet Only Manuals, National Coverage Determinations (NCDs), and Local Coverage Determinations (LCDs) made by the Medicare Administrative Contractor with jurisdiction.
c. Internal coverage policy reviewed and approved by the Utilization Management Committee. This includes coverage policies as well as utilization management tools such as InterQual, among others, which provide coverage criteria to help guide medical necessity determinations.

SCOPE:

This policy applies to Memorial Hermann Health Plan Holdings, LLC Medicare plans. The Health Plan follows this policy to determine if a basic benefit is reasonable and necessary (R & N) for the enrollee when the basic benefit requested lacks applicable Medicare or internal coverage criteria. When applicable, this policy guides medical necessity reviews conducted for MA enrollees before the service is provided (pre-service/prior authorization), during treatment (concurrent review/case management), or after the service has been provided (post-service/claim for payment).

POLICY STATEMENT

The Health Plan is committed to ensuring that enrollees receive timely and appropriate access to medically necessary care, while The Health Plan applies utilization management practices that maintain clinically appropriate standards of care. The company does not deny a Medicare-covered item or service

[1] https://www.govinfo.gov/content/pkg/FR-1995-09-19/pdf/95-23132.pdf

based on internal, proprietary, or external clinical criteria not included in Traditional Medicare coverage policies, when such coverage policies exist.

Coverage Indications, Limitations, and/or Medical Necessity
When deciding whether an item or service is R&N for an individual enrollee, The Health Plan makes this medical necessity decision under the procedures outlined below and in a manner that most favorably provides access to services for the enrollee and aligns with CMS's definition of reasonable and necessary as outlined in Section 1862(a)(1)(A) of the SSA and Chapter 13, Section 13.5.4 of the Medicare Program Integrity Manual.
The Health Plan makes medical necessity determinations based on the enrollee's medical history, physician recommendations, and clinical notes and does not allow denials based solely on the reviewer's general inferences about enrollees with similar diagnoses or on general data related to utilization. The Health Plan shall ensure that all medical necessity determinations do not conflict with applicable statutes, rulings, regulations, and national/local coverage, payment, and coding policies.

General Provisions and Summary of Evidence
Medicare coverage is restricted to items and services that fall within a Medicare benefit category and are deemed reasonable and necessary (R&N) for diagnosing or treating an illness or injury[2]. To be R&N, there must be evidence the service is:

- Safe and effective; and
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services which meet the requirements of the Clinical Trials NCD are considered R&N); 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[3]

[2] https://www.ssa.gov/OP_Home/ssact/title18/1862.htm

[3] https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c13.pdf

The Health Plans are required to cover all basic benefits and adhere to the general coverage and benefit conditions included in Traditional Medicare regulations, as well as national and local coverage determinations (NCDs and LCDs) relevant to their service area. We may also reference a MAC's most applicable LCD to render an evidence-based and scientifically sound determination. When coverage criteria are not fully defined in Medicare statutes, regulations, NCDs, or LCDs, The Health Plans can establish internal coverage criteria based on current evidence from widely accepted treatment guidelines or publicly available clinical literature.

Coverage criteria are considered incomplete when:

1) additional criteria are needed to interpret or supplement general provisions for consistent medical necessity determinations;
2) NCDs or LCDs allow flexibility for coverage beyond specified indications; or
3) there is no applicable Medicare statute, regulation, NCD, or LCD providing coverage criteria.

In these cases, The Health Plans may develop internal criteria to guide medical necessity decisions[4]. Development of internal clinical criteria in accordance with regulatory requirements necessitates considerable time and plan resources. This includes researchers, physicians, data analysts and additional supporting staff who are instrumental in the policy development and convening the Utilization Management Committee to review and approve the proposed policy prior to its implementation.

The Health Plan acknowledges that Medicare coverage criteria are not fully established for every scenario in which basic benefit coverage might be requested. To address this, Apex has adopted internal coverage criteria for services where Medicare criteria are not fully established and where Apex can anticipate a need. However, due to the complexity of medical conditions, diverse enrollee medical histories, and the continuous advancements in medical care and treatment innovations, there may be requests to cover services lacking both Medicare criteria and an established clinical policy by The Health Plan.

Rationale for Coverage Criteria

Given the time required to develop service-specific internal policies, The Health Plan has established this policy to address gaps where coverage criteria cannot specify all possible circumstances for coverage of a basic benefit for an individual enrollee. This policy ensures that The Health Plan can interpret the general provision of R&N as defined in the Medicare Program Integrity Manual without creating barriers to care inconsistent with Traditional Medicare access.

This policy does not undermine or circumvent existing Medicare coverage criteria or existing internal clinical policies. This policy applies only to requests for services lacking fully established coverage criteria. This policy ensures

[4] https://www.ecfr.gov/current/title-42/section-422.101

consistency in determining the medical necessity of services eligible for coverage as a basic Medicare benefit when specific service criteria are not fully established by CMS or The Health Plan and supports The Health Plan' compliance with Section 1852(g)(1)(A) of the Act, which requires MA organizations to have procedures for timely determinations of whether an enrollee is entitled to receive a health service.

The Health Plan expects treating providers be comfortable stating their professional opinions about which services should and should not be covered for their patients and expects that they use clinical evidence to support their opinions. The Health Plan' medical necessity determinations assess whether the clinical evidence provided by treating providers supports that a service is R&N under the Medicare program. Ultimately, it is up to the enrollee, in consultation with their physician, to decide if an item or service is appropriate for their individual health circumstances. The clinical benefits of this policy, outlined below, outweigh any potential clinical harms, including those from delayed or decreased access to items or services.

1. Allows The Health Plan to evaluate R&N on a case-by-case basis, considering each enrollee's unique clinical situation. By assessing the risk-benefit profile for specific enrollees, it reduces the likelihood of coverage for services without documentation demonstrating that the service is reasonable and necessary.

2. Protects enrollee safety while facilitating quicker access to new and innovative services or technologies. While increasing access to new technologies, The Health Plan remains mindful of potential unknown or unexpected risks and requires research methodologies that can plausibly establish causality as a safeguard to address such situations. The Health Plan, in keeping with CMS expectations, considers the best available scientific and clinical evidence concerning the benefits and harms of various clinical items and services and apply the highest attainable level of expertise to evaluate such evidence.

3. Sets an expectation for initial or physician reviewers to conduct a thorough analysis of all available data, reducing the likelihood of arbitrary determinations. It emphasizes a robust review of clinical evidence, focusing on the Medicare population, which often has more comorbidities and requires higher acuity treatments.

4. Provides specific information needed to demonstrate that a service is R&N for the enrollee, reducing uncertainty among enrollees and providers regarding coverage decisions.

5. Aligns with coverage criteria and evidence summaries presented by Medicare Administrative Contractors (MACs), which CMS has identified as a best practice for public presentation of this information.

PROCEDURE

General Requirements

1. **Coverage Criteria Hierarchy:** The Health Plan will first determine if fully established criteria exist for the requested basic benefit.
    - If Medicare criteria are available, they will be applied.
    - If not, internal criteria will be used.
    - If neither is available, the following steps will be taken to assess R&N.
2. **Evidence Presentation:**
    - Review Process: The Health Plan will review requests and supporting documentation to determine if additional information is needed. When additional information is required, The Health Plan will follow its outreach process to obtain the needed information.
    - Minimum Information Required:
        - The request must convey the necessary information to:
            1. Identify the Medicare benefit category the item or service falls under (i.e., physician services, durable medical equipment and prosthetics, diagnostic test, drugs and biologics, inpatient hospital services, etc.).
            2. Understand the relevance, usefulness, clinical health outcome, or medical benefit expected from the item or service.
            3. Fully explain the design, purpose, and/or method, as appropriate, of using the item or service for which the request is made.
        - Clinical documentation that supports medical necessity may be expected to include physician orders for care and treatments, medical diagnoses, rehabilitation diagnosis (as appropriate), past medical history, progress notes that describe the beneficiary's response to treatments and his/her physical/mental status, lab and other test results, and other documentation supporting the beneficiary's need for the requested item or service.
        - When applicable i.e. an experimental, investigational or off-label use of a service or drug, the request must

include a justification supported by full copies of published, peer-reviewed evidence of clinical benefit and general acceptance by the medical community.

1. Clinical literature that CMS considers to be of high enough quality for the justification of demonstrating R&N include large, randomized controlled trials, cohort studies, or all-or-none studies with clear results, published in a peer reviewed 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 published in a peer-reviewed journal with clear and consistent results.
2. Acceptance by individual health care providers, or even a limited group of health care providers, does not indicate general acceptance of the item or service by the medical community.
3. Proprietary information not publicly accessible will not be considered.

3. **Evidentiary Content:**
    - Summary of Evidence: Each medical necessity review will include a summary of evidence supporting coverage or non-coverage, detailing:
        - Description of the item or service.
        - Identification of specific information considered.
        - Narrative of scientific evidence considered.
    - Expert Consultation: When applicable, The Health Plan will consult outside healthcare professionals and summarize opinions from those consultative healthcare professionals.
    - FDA-Regulated Items: Include information on FDA indications if applicable.
4. **Evidence Analysis and Determination:**
    - Compliance: Ensure determinations align with statutes, regulations, and coverage policies.

- Medical Necessity Review: The goal of medical review is to use the available documentation to determine whether the services are R&N, delivered in the appropriate setting, and coded correctly, when applicable. The reviewer shall review the enrollee's medical history, including diagnosis, conditions, and functional status, as reflected by medical record, and any other available documentation to render a determination.

5. **Criteria for Reasonable and Necessary:** The service under review will be 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. It consists of the symptoms of diagnosis of the illness or injury under treatment and all the following:
    - Safety and Effectiveness: The service must be safe, effective, and not experimental (except for qualifying clinical trial services).
    - Appropriateness: The service must be appropriate in terms of duration, frequency, and setting, and ordered by qualified personnel. The service is not to be furnished primarily for the convenience of the patient, the provider or supplier
    - Benefit Comparison: The service should be at least as beneficial as existing medically appropriate alternatives.
6. **Approve:** Confirm the item or service falls within a benefit category, is not excluded, and is R&N based on medical history and clinical notes. When R&N is demonstrated for a specific enrollee, authorize the service for the entire course of treatment determined to be medically necessary.
7. **Deny:** If evidence does not support R&N, coverage cannot be authorized. Section 1862(a)(1)(A) of the SSA provides the statutory basis for denying Medicare payment for certain types of care, items, services, and procedures that, while meeting all technical requirements for coverage, are not excluded by any other statutory clause. The criteria for denial under this section include:
    - Not Generally Accepted: The care, item, service, or procedure is not generally accepted by the medical community as safe and effective for the specific setting and condition for which it is used.

- Lack of Proven Safety and Efficacy: The care, item, service, or procedure has not been proven safe and effective based on peer-reviewed scientific literature.
- Experimental: The intervention is considered experimental.
- Not Medically Necessary: The care, item, service, or procedure is not medically necessary for the specific patient.
- Inappropriate Level, Duration, or Frequency: The care, item, service, or procedure is furnished at a level, duration, or frequency that is not medically appropriate.
- Not in Accordance with Accepted Standards: The care, item, service, or procedure is not furnished in accordance with accepted standards of medical practice.
- Inappropriate Setting: The care, item, service, or procedure is not furnished in a setting appropriate to the patient's medical needs and condition.

8. **Notification of the determination:** The Health Plan will follow its procedure to notify the enrollee and provider, when applicable, of its decision.

REFERENCES

The Health Plan considered the following evidence when developing this policy to assist reviewers in making medical necessity determinations consistent with Traditional Medicare:

1. Social Security Act §1862
2. 42 CFR Part 422
3. Medicare Program Integrity Manual, Chapter 13
4. Department of Health and Human Services (HHS), Medicare Program; Criteria and Procedures for Extending Coverage to Certain Devices and Related Services, 60 FR 48417. Published September 19, 1995.
5. Centers for Medicare & Medicaid Services (CMS), 88 FR 22120, 'Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools,' [22185-22217]. Published April 12, 2023.[5]

[5] https://www.federalregister.gov/documents/2023/04/12/2023-07115/medicare-program-contract-year-2024-policy-and-technical-changes-to-the-medicare-advantage-program

6. Centers for Medicare & Medicaid Services, CMS-3284-N, 'Medicare Program; Revised Process for Making National Coverage Determinations'. Published August 7, 2013.[6]
7. Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary", 86 FR 2987. Published January 1, 2021.[7]
8. Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary", 86 FR 62944. Published November 15, 2021.[8]

[6] https://www.cms.gov/medicare/coverage/determinationprocess/downloads/fr08072013.pdf

[7] https://www.federalregister.gov/documents/2021/11/15/2021-24916/medicare-program-medicare-coverage-of-innovative-technology-mcit-and-definition-of-reasonable-and#page-62958

[8] https://www.federalregister.gov/documents/2021/11/15/2021-24916/medicare-program-medicare-coverage-of-innovative-technology-mcit-and-definition-of-reasonable-and#page-62958