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Medical Necessity Determination Policy for Medicare-Covered Services Without Established Criteria

PURPOSE:

The purpose of this policy is to ensure that The Health Plan's medical necessity determinations are evidence-based, transparent, and consistent. It provides a framework for evaluating coverage requests for Medicare basic benefits when no established clinical criteria exist.

This policy reaffirms The Health Plan's commitment to ensuring that enrollees receive timely and appropriate access to medically necessary care, while adhering to clinically sound utilization management practices. It outlines the criteria and documentation required for individualized determinations, in alignment with the reasonable and necessary provisions defined in Section 1862(a)(1) of the Social Security Act (SSA) and Chapter 13, Section 13.5.4 of the Medicare Program Integrity Manual.

POLICY:

For Medicare Advantage (MA) medical necessity determinations, The Health Plan adheres to all Traditional Medicare coverage and benefit conditions, unless superseded by Medicare Advantage-specific regulations.

The Health Plan does not approve or deny Medicare-covered services based on internal, proprietary, or external clinical criteria unless explicitly recognized in Medicare coverage policies. When applicable Medicare Part A or Part B benefits lack established coverage criteria, this policy provides a structured approach to determine whether a service is reasonable and necessary for the enrollee.

This policy applies to medical necessity reviews at all stages of care, including:

- Pre-service (Prior Authorization) – Before the service is provided.
- Concurrent Review (Case Management) – During ongoing treatment.
- Post-service (Claims Review) – After the service has been delivered.

By following this policy, The Health Plan ensures consistent, evidence-based determinations that align with Medicare standards and enrollees' medical needs.

Coverage Indications, Limitations, and/or Medical Necessity:

When determining whether an item or service is reasonable and necessary for an individual member, The Health Plan follows the procedures outlined below. These determinations prioritize enrollee access to medically necessary services while aligning with CMS's definition of "reasonable and necessary" as stated in Section 1862(a)(1)(A) of the Social Security Act (SSA) and Chapter 13, Section 13.5.4 of the Medicare Program Integrity Manual.

Medical necessity determinations are based on individualized clinical assessments, including:

- The enrollee's medical history.
- Physician recommendations.
- Clinical documentation and supporting notes.

Denials cannot be made solely based on:

- Generalized inferences about enrollees with similar diagnoses.
- Utilization data that does not account for an individual's specific clinical circumstances.

The Health Plan ensures that all medical necessity decisions are compliant with applicable laws, regulations, and national/local coverage, payment, and coding policies — avoiding conflicts with statutory Medicare requirements.

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 for diagnosing or treating an illness or injury

For a service to be considered reasonable and necessary, there must be clear evidence that it meets the following criteria:

- Safe and effective for the intended use.
- Not experimental or investigational (Exception: Routine costs of qualifying clinical trial services that meet the Clinical Trials NCD are considered reasonable and necessary).
- Appropriate in duration, frequency, and setting, meaning:
    - It aligns with accepted standards of medical practice for diagnosing or treating the patient's condition or improving function.

- It is provided in a setting appropriate to the patient's medical needs and condition.
- It is ordered and delivered by qualified personnel.
- It meets, but does not exceed, the patient's medical needs.
- It is at least as beneficial as an existing, available, and medically appropriate.

Application to Medicare Advantage (MA) Plans

Medicare Advantage (MA) plans are required to:

- Cover all basic benefits outlined in Traditional Medicare regulations.
- Adhere to NCDs and LCDs relevant to their service area.

When Medicare statutes, regulations, NCDs, or LCDs do not fully define coverage criteria, MA plans may establish internal coverage policies based on:

- Widely accepted treatment guidelines
- Peer-reviewed clinical literature
- Publicly available medical evidence

This approach ensures that coverage determinations remain evidence-based, clinically sound, and aligned with Medicare's statutory framework.

Coverage criteria are considered incomplete when:

A. Additional criteria are required to interpret or supplement general provisions for consistent medical necessity determinations.
B. NCDs or LCDs provide flexibility for coverage beyond the specified indications.
C. No applicable Medicare statute, regulation, NCD, or LCD exists to define coverage criteria.

In these cases, Medicare Advantage (MA) plans may develop internal criteria to guide medical necessity decisions. However, the development of internal clinical criteria must:

- Adhere to regulatory requirements.
- Involve subject matter experts, including researchers, physicians, and data analysts.
- Undergo review and approval by the Utilization Management (UM) Committee before implementation.

The Health Plan recognizes that Medicare coverage criteria do not account for every possible clinical scenario in which a basic benefit may be requested. To bridge these gaps, The Health Plan has adopted internal coverage criteria for services where Medicare guidance is incomplete and where recurring clinical needs can be anticipated. However, due to the complexity of medical conditions, diverse patient histories, and the continuous evolution of medical treatments and technologies,

There may still be requests for services that lack both Medicare criteria and an established internal policy. In such cases, The Health Plan will evaluate coverage based on individual medical necessity determinations, ensuring that decisions remain aligned with evidence-based medicine and Medicare's statutory framework.

Rationale for Coverage Criteria

Developing service-specific internal policies requires significant time and resources. To address gaps where coverage criteria do not specify all possible circumstances for a basic benefit, The Health Plan has established this policy to provide a structured approach for interpreting "reasonable and necessary" (R&N) provisions, as outlined in the Medicare Program Integrity Manual. This ensures coverage decisions are made without creating barriers to care that would be inconsistent with Traditional Medicare access.

This policy does not override or bypass existing Medicare coverage criteria or internal clinical policies. It applies exclusively to cases where fully established Medicare or internal criteria do not exist. By implementing this policy, The Health Plan ensures consistent, evidence-based medical necessity determinations while remaining compliant with Section 1852(g)(1)(A) of the Social Security Act, which mandates that Medicare Advantage organizations have procedures in place for timely health service determinations.

Medical Director Decision-Making Expectations

- The Health Plan expects its Medical Directors to make informed, professional determinations about which services should be covered.
- These decisions must be based on clinical evidence that supports whether a service is reasonable and necessary under Medicare guidelines.
- Ultimately, the enrollee, in consultation with their physician, decides whether an item or service is appropriate for their health needs.
- The benefits of this policy—outlined below—outweigh potential risks, including those related to delayed or denied access to services.

Key Benefits of This Policy:

A. Case-by-Case Medical Necessity Evaluation
    - Ensures that each enrollee's unique clinical situation is considered.
    - Reduces unjustified denials by requiring documented evidence to support whether a service is reasonable and necessary.

B. Balancing Safety & Access to Innovation
    - Facilitates quicker access to new and emerging treatments while prioritizing patient safety.
    - Incorporates research-based safeguards to mitigate potential unknown or unexpected risks of new medical technologies.

C. Medical Directors Must Perform Rigorous Clinical Reviews
    - Establishes a high standard for decision-making, requiring a thorough analysis of all available clinical data.
    - Focuses on Medicare populations, who often have multiple comorbidities and

require higher-acuity treatments.

D. Greater Transparency for Providers & Enrollees
    - Ensures coverage decisions are based on clear, specific information, reducing confusion and uncertainty for enrollees and providers.

E. Alignment with Medicare Administrative Contractors (MACs)
    - CMS recognizes MAC coverage criteria and evidence summaries as best practices for ensuring transparent and consistent decision-making.
    - Aligning with these standards enhances compliance and reliability in coverage determinations.

Procedures:

1. **Coverage Criteria Hierarchy** - The Health Plan will determine if established criteria exists for the requested basic benefit:

- If Medicare criteria (NCDs, LCDs, or regulations) are available, they will be applied.
- If Medicare criteria does not exist, internal coverage criteria will be used.
- If neither Medicare nor internal coverage criteria exist, the request will be assessed based on reasonable and necessary (R&N) standards.

2. **Evidence Presentation**

- **Review Process**: The Health Plan will review requests and supporting documentation to determine if additional information is needed. If so, The Health Plan will follow its outreach process to obtain the required details. See Outreach for Information to Support Coverage Decisions for the outreach process.
- **Minimum Required Information**: Requests must include sufficient details to:
    - Identify the applicable Medicare benefit category (e.g., physician services, durable medical equipment, diagnostic tests, drugs, biologics, inpatient medical services, etc.).
    - Explain the relevance, expected clinical outcome, and medical benefit of the requested service.
    - Provide a comprehensive explanation of the item or service, including its design, purpose, and method of use.
- **Required Clinical Documentation**: Supporting documentation should include:
    - Physician orders for care and treatment
    - Medical diagnoses and history relevant to the request.
    - Progress notes detailing the enrollee's response to prior treatments.
    - Lab / test results and other relevant medical evidence.
- **Justification & Peer-Reviewed Evidence**: Requests must be supported by published, peer-reviewed literature demonstrating clinical benefit and general acceptance in the medical community. Acceptable evidence includes:

        - Randomized controlled trials (RCTs), cohort studies, or systematic reviews / meta-analyses with clear and consistent results, published in a peer-reviewed journal.
        - CMS-recognized clinical literature that meets Medicare's standards for demonstrating R&N.
    - **Limitations on Evidence Consideration**:
        - General acceptance must extend beyond a small group of healthcare providers.
        - Proprietary information that is not pubicly accessible will not be considered.

3. **Evidentiary Content** - Each medical necessity review will include a comprehensive summary detailing:

    - Description of the item or service.
    - Specific evidence and date considered.
    - Scientific rationale supporting the decision.
    - When applicable, The Health Plan may:
        - Consult external healthcare professionals and summarize their opinions.
        - Reference FDA regulatory status if relevant to the request.

4. **Evidence Analysis and Determination**

    - Compliance Check: All determinations must align with applicable statutes, regulations, and Medicare policies.
    - Medical Necessity Review: The review will assess:
        - The enrollee's medical history, diagnosis, functional status, and other supporting documentation.
        - Whether the requested service is reasonable and necessary under Medicare standards.
        - If the service is being provided in the appropriate setting and coded correctly.

5. **Criteria for Reasonable and Necessary (R&N)** - 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 is consistent with 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 servcies.
    - Apropriateness: The service must be appropriate based on:
        - Duration, frequency, and setting of care.
        - Ordering and administration by qualified personnel.
        - Avoidance of service primarily for the convenience of the patient, provider, or supplier.
    - Benefit Comparison: The service should provide at least equal or greater clinical benefit compared to available medically appropriate alternatives.

6. **Approval** - A request will be approved if it:

- Falls within a Medicare-covered benefit category.
- Is not statutorily excluded.
- Meets R&N criteria based on clinical documentation and medical necessity review.
- If approved, the entire medically necessary course of treatment will be authorized.

7. **Denial or Adverse Determination** - If the evidence does not support R&N, coverage cannot be authorized. Per Section 1862(a)(1)(A) of the Social Security Act (SSA), Medicare payment may be denied if the requested service:

- Is not generally accepted by the medical community as safe and effective for the condition or setting.
- Lacks proven safety and efficacy based on peer-reviewed literature.
- Is considered experimental and investigational.
- Is not medically necessary for the specific patient.
- Is furnished at an inappropriate level, duration, or frequency.
- Does not align with accepted medical standards.
- Is provided in an inappropriate setting based on the patient's medical condition.

8. **Notification of Determination** - The Health Plan will follow Medicare Timeliness of UM Decisions & Notifications (Part C Organizational Determinations) policy to inform the enrollee and provider of its determination.

Sources of Information:

- The Health Plan developed this policy using the following authoritative sources to ensure that medical necessity determinations align with Traditional Medicare standards:
    - Social Security Act §1862 - Governs Medicare coverage exclusions and the "reasonable and necessary" standard.
    - Medicare Program Integrity Manual, Chapter 13 - Establishes guidelines for medical review and coverage determinations.
    - Centers for Medicare and Medicaid Services (CMS), 88FR22120 - Utilization Management Requirements - Clarifications of Coverage Criteria for Basic Beneifts and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools ([22185-22217], Published April 12, 2023).
    - Centers for Medicare and Medicaid Services (CMS), CMS-3284-N - Medicare Program: Revised Process for Making National Coverage Determinations.
    - Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services (HHS), 86FR2987 - Published January 14, 2021.
    - Centers for Medicare and Medicaid Services (CMS), Department of Health and

All Revision Dates

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