Department: Health Services – Utilization Management	**Number:** HS-007
Title: Application of Medical Criteria and Medical Necessity Reviews	
Original Effective Date: 10/21/2024	**Latest Revision Date:** 12/30/2024

Purpose:

This policy establishes the guidelines and procedures for applying medical criteria and conducting medical necessity reviews for services requested by or on behalf of Sonder Health Plans ("SHP") members. The policy ensures that all medical necessity determinations are made in compliance with the Centers for Medicare & Medicaid Services ("CMS") regulations and applicable State of Georgia requirements, ensuring that members receive appropriate, high-quality care. This policy applies to all personnel involved in the Utilization Management ("UM") process, including but not limited to medical directors, UM nurses, case managers, and clinical reviewers. It pertains to all Medicare-covered services, including medical, surgical, diagnostic, and preventive care.

Definitions:

- **Adverse Determination:** a decision by the Plan to deny or limit coverage for a requested service or treatment based on a lack of medical necessity.
- **Expedited Determination:** a fast-tracked decision process required when a standard time frame could seriously jeopardize the life, health, or ability to regain maximum function of the member. Expedited decisions will be made within 72 hours of the request for items or services and within 24 hours for Part B Drugs.
- **Medical Criteria:** evidence-based guidelines, protocols, and standards that are used to determine whether the requested service, treatment, or procedure is clinically appropriate and necessary. These criteria include CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and other medical guidelines.
- **Medical Necessity:** refers to services or items that are reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body part, as defined by Section 1862(a)(1)(A) of the Social Security Act. *(Please also refer to Section I for definition by the State of Georgia)*
- **Organization Determination:** any decision made by the Plan regarding whether services or benefits requested by a member will be covered under the Plan.
- **Prior Authorization:** the process of obtaining approval from the Plan before providing specific services or treatments to confirm that they meet medical necessity criteria.
- **Representative:** an individual authorized by the enrollee to act on their behalf in filing requests for coverage, appeals, or grievances related to medical services.
- **Standard Determination:** a routine decision regarding coverage or services, typically processed within 14 calendar days of the request for items or services and within 3 calendar days for Part B Drugs.
- **Utilization Management (UM):** the process of reviewing and evaluating healthcare services provided to Medicare beneficiaries to determine whether they are medically necessary and appropriate, following established medical criteria and guidelines.

Policy Statement:

Consistent with CMS guidelines and its Dual Special Needs Program (DSNP) contract with the State of Georgia, SHP has established policies and procedures, that is, coverage rules, practice guidelines, payment policies, and utilization management, that allow for individual medical necessity determinations. SHP's staff will evaluate requests for medical services, treatments, and procedures using standardized medical criteria and guidelines to determine medical necessity. All determinations willwill be made in accordance with CMS requirements and, where applicable, Georgia state regulations.

Medical Necessity is defined as services that are reasonable and necessary for the diagnosis, treatment, and prevention of illness or injury, or to improve the functioning of a malformed body member, as per Section 1862(a)(1)(A) of the Social Security Act.

Medical Criteria used for decision-making will be based on CMS-approved guidelines, State of Georgia regulations applicable to HMOs and Medicare Advantage Plans, and evidence-based guidelines as documented below.

Application of Medical Criteria: Medical necessity reviews will use evidence-based guidelines that consider clinical appropriateness of the requested service, treatment, or procedure. Requests for services that do not meet the medical necessity criteria will be reviewed by a qualifid, SHP contracted or employed Medical Director or physician, and the member and treating provider will be notified of any denial based on lack of medical necessity.

Procedures:

I. **Medical Necessity Determinations**

A. Medical necessity reviews may be conducted before the service is provided (i.e., prior authorization), during (i.e., concurrent case review), or after the service is provided (i.e., claim review). In all of these circumstances, MA organizations will comply with the CMS requirements described below.

B. Medical necessity determinations will be based on:

i. **Review of Coverage and Benefit Criteria:** Coverage decisions are based on the coverage criteria described in Sections II and III below as well as in the member's benefit plan. SHP will not deny coverage for any basic benefits unless it aligns with these criteria.

ii. **Medical Necessity Assessment:**

1. HSD Staff will ensure that services or items provided are reasonable and necessary as required by CMS guidelines.
2. This means that services will be essential for diagnosing or treating a condition, injury, or illness; considered safe and effective; not experimental or investigation (unless approved by the Medical Director per policy HS-022); and considered appropriate, including the service's duration and frequency.

iii. **Review of Enrollee's Records:** The enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes.

iv. **Solicit Input from the Medical Director:** Where appropriate, HSD staff will involve SHP's Medical Director to ensure the clinical accuracy of organization determinations and reconsiderations.

v. **Exception for qualifying hospital stay.** SHP may elect to furnish, as part of its Medicare covered benefits, coverage of post-hospital SNF care in the absence of the prior qualifying hospital stay that would otherwise be required for coverage of this care.

C. Additional Considerations from the State of Georgia

i. "Medical necessity" or 'medically necessary' means healthcare services that a prudent physician or other healthcare provider would provide to a patient for the purpose of preventing, diagnosing, or treating an illness, injury, or disease or its symptoms in a manner that is:
   1. In accordance with generally accepted standards of medical or other healthcare practice;
   2. Clinically appropriate in terms of type, frequency, extent, site, and duration;
   3. Not primarily for the economic benefit of the health insurer or for the convenience of the patient, treating physician, or other healthcare provider; and
   4. Not primarily custodial care, unless custodial care is a covered service or benefit under the covered person's healthcare plan.

II. Coverage Criteria Sources

A. SHP uses CMS approved, nationally recognized criteria as well as evidence-based, clinically developed sources for policy and standards of care when making medical necessity determinations. Examples include:
   i. CMS National Coverage Determinations (NCDs): https://www.cms.gov/medicare-coverage-database/search.aspx
   ii. CMS Local Coverage Determinations (LCDs) (In absence of an LCD applicable to the Georgia service area, SHP may opt to apply coverage criteria from a Traditional Medicare Local Coverage Determination (LCD) that is not applicable to the service area): https://www.cms.gov/medicare-coverage-database/search.aspx
   iii. General coverage and benefit conditions included in Traditional Medicare regulations, unless superseded by laws applicable to MA plans. For example, use of guidance in CMS Medicare Benefit Policy manuals: https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms012673
   iv. SHP 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, such as those in InterQual or MCG Health guidelines. *(Also refer to the Use of SHP Internal Coverage Criteria section below)*
   v. For determining Part B drug requests, in addition to FDA labeled drug indications, SHP will also use one or more of the following CMS approved compendia:
      1. American Hospital Formulary Service-Drug Information (AHFS-DI) – indication is supportive.
      2. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium - indication is a Category 1 or 2A.
      3. Micromedex DrugDex® – indication is Class I, Class IIa, or Class IIb.
      4. Clinical Pharmacology – indication is supportive.
      5. Lexi-Drugs - indication is rated as “Use: Off-Label” and rated as “Evidence Level A”.

III. Use of SHP Internal Coverage Criteria

A. SHP 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.
B. What are Current, Widely used Treatment Guidelines?
   i. Those developed by organizations representing clinical medical specialties and refers to guidelines for the treatment of specific diseases or conditions.
   ii. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort 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.

C. Coverage Criteria Not Fully Established
    i. Coverage criteria are not fully established when:
        1. Additional, unspecified criteria are needed to interpret or supplement general provisions to determine medical necessity consistently.
        2. SHP will demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.
    ii. NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD; or
    iii. There is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria.

D. Publicly Accessible:
    i. For internal coverage policies, SHP will provide in a publicly accessible way the following:
        1. The internal coverage criteria in use and a summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations.
        2. A list of the sources of such evidence.
        3. An explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. When coverage criteria are not fully established SHP will identify the general provisions that are being supplemented or interpreted and explain how the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

IV. Use of Algorithms or Artificial Intelligence for Coverage Decisions

A. Key Definitions (Per CMS Guidance):
    i. Algorithms:
        1. Algorithms can imply a decisional flow chart of a series of if-then statements (i.e., if the patient has a certain diagnosis, they should be able to receive a test), as well as predictive algorithms (predicting the likelihood of a future admission, for example).
    ii. Artificial Intelligence (AI):
        1. Artificial intelligence has been defined as a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments.
        2. Artificial intelligence systems use machine- and human-based inputs to perceive real and virtual environments; abstract such perceptions into models through analysis in an automated manner; and use model inference to formulate options for information or action.

B. Permissible Uses and Examples:
    i. An algorithm or software tool can be used to assist SHP in making coverage determinations, but it is the responsibility of SHP to ensure that the algorithm or artificial intelligence complies with all applicable rules for how coverage determinations by MA organizations are made, including those referenced in this policy.
    ii. SHP may only deny coverage for basic benefits based on coverage criteria that are specified in Medicare regulations or for other expressly permissible bases, such as network limitations or failure to comply with prior authorization requirements.
        1. Therefore, the algorithm or software tool should only be used to ensure fidelity with the posted internal coverage criteria which has been made public.
    iii. In an example involving a decision to terminate post-acute care services, an algorithm or software tool can be used to assist providers or SHP in predicting a potential length of stay, but that prediction alone cannot be used as the basis to terminate post-acute care services.

1. For those services to be terminated in accordance with CMS regulations, the patient will no longer meet the level of care requirements needed for the post-acute care at the time the services are being terminated, which can only be determined by re-assessing the individual patient's condition prior to issuing the notice of termination of services.

C. Prohibited Uses:
   i. SHP will base the decision on the individual patient's circumstances, so an algorithm that determines coverage based on a larger data set instead of the individual patient's medical history, the physician's recommendations, or clinical notes would not be compliant with CMS guidelines.
   ii. For inpatient admissions, algorithms or artificial intelligence alone cannot be used as the basis to deny admission or downgrade to an observation stay; the patient's individual circumstances will be considered against the permissible applicable coverage criteria under CMS regulations.
   iii. Because publicly posted coverage criteria are static and unchanging, artificial intelligence cannot be used to shift the coverage criteria over time. Predictive algorithms or software tools cannot apply other internal coverage criteria that have not been explicitly made public and adopted in compliance with the evidentiary standard in CMS regulations.

D. Additional Considerations:
   i. To address CMS' concern that algorithms and many new artificial intelligence technologies can exacerbate discrimination and bias, if SHP does utilize these technologies, it will ensure it addresses the nondiscrimination requirements of Section 1557 of the Affordable Care Act, which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities.
   ii. SHP will, prior to implementing an algorithm or software tool, ensure that the tool is not perpetuating or exacerbating existing bias, or introducing new biases.

V. Special Needs Plan

A. Consistent with CMS regulations, SHP has implemented evidence-based models of care, including appropriate networks of providers and specialists, designed to meet the specialized needs of its targeted enrollees for each of its special needs plans (SNPs). *Refer to SHP's Models of Care for additional information.*

VI. Standard Review Process

A. Initial Review

i. All requests for medical services, treatments, or procedures are initially reviewed by qualified UM personnel using CMS-approved guidelines and SHP's medical policies.
   a. If the service meets the defined medical necessity criteria, the request will be approved.
   b. If the request does not meet the criteria, it will be escalated to an SHP Medical Director/physician for additional review.

B. Medical Director Review

i. If SHP expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination will be reviewed by an SHP Medical Director or physician (or other appropriate health care professional) with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the Plan issues the organization determination decision.
ii. For cases that do not meet initial medical necessity criteria, the case will be reviewed by a SHP Medical Director or physician, who will apply their clinical expertise in addition to the relevant medical guidelines.
iii. The Medical Director may consult with the member's treating provider, if needed, to make an informed decision.

iv. If the request is denied, the treating provider will be given the opportunity to engage in a peer-to-peer review.

C. Notification of Determination

i. Standard Organization Determination: Enrollees, enrollees' representatives, and providers will be notified of the Plan's decision for requests for services or items within 14 calendar days of the request and within 3 calendar days for Part B Drugs. *Refer to HSD Policy HS-037 on Standard Organization Determinations for additional guidance.*

a. The request can be extended up to an additional 14 days for items or services (not Part B drugs) if (1) the enrollee requests the extension; (2) the extension is justified and in the interest of the enrollee due to the need for additional medical evidence from a noncontract provider that may alter the Plan's decision to deny an item or service; or (3) the extension is justified due to an extraordinary, exigent, or other non-routine circumstances and is in the interest of the enrollee.

b. Extensions may not be taken for a standard Part B drug request – a decision will be made within 72 hours after receipt of the request.

ii. Expedited Organization Determination: Enrollees, enrollees' representatives, and providers will be notified of the Plan's decision for requests for services or items within 3 calendar days of the request and within 24 hours for Part B Drugs. *Refer to HSD Policy HS-038 on Expedited Organization Determinations for additional guidance.*

a. This decision can be extended by up to an additional 14 days if more information is required for items or services (not Part B drugs).

b. Extensions may not be taken for expedited Part B drugs request – a decision will be made within 24 hours after receipt of the request.

iii. The notification will include the rationale for approval or denial and provide information about the appeal process, as required by CMS guidelines.

VII. Documentation Requirements

A. Clinical Documentation

i. All requests for services will include sufficient clinical documentation to support medical necessity of the requested service. This includes, but is not limited to, physician notes, diagnostic results, and treatment history.

B. Record Keeping

i. All medical necessity reviews and determinations will be documented in the member's record, including the criteria used, decision rationale, and any communications with the member or provider.

VIII. Appeals Process

A. Members and providers have the right to appeal any denial of services based on medical necessity.

B. Appeals will follow the process outlined in SHP's Appeals and Grievances Policies and Procedures and CMS regulations, including the required timeframes for standard and expedited appeals.

II. Responsibilities

A. Utilization Management Staff: responsible for the initial review of medical requests, applying medical criteria, and escalating cases to a physician for review when necessary.

B. Medical Director/Physician Reviewer:

i. Responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity.

ii. The medical director will be a physician with a current and unrestricted license to practice medicine inthe State of Georgia.

Attachment(s): N/A

Statutory Reference(s):

- **Federal:**
  - 42 CFR § 422.101 – Requirements Relating to Basic Benefits
  - 42 CFR § 422.112 – Access to Services
  - 42 CFR §422.566 – Organization Determinations and Medical Necessity Reviews
  - 42 CFR § 422.570 - Expediting Certain Organization Determinations
  - 42 CFR §422.572 – Timeframes and Notice Requirements for Expedited Organization Determinations
  - HPMS Memo "Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)" dated 02/06/2024.
  - Medicare Benefit Policy Manual (Publication 100-02)
  - Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, Section 10.16

- **Statutory (Georgia)**
  - Rules and Regulations of the State of Georgia, Section 120-2-58 Certification of Private Review Agents *(Note: As an insurer, SHP is considered a Private Review Agent)*
  - Georgia Code, Title 33, Chapter 46, Article 2, Prior Authorizations

Contract Reference(s):

- Medicare Advantage D-SNP Health Plan Agreement Between Georgia Department of Community Health and Sonder Health Plans, Inc.

Document Reference(s):

Related Policy(s): References will be updated as needed once policies are finalized.

- HS-022: Experimental Treatments and New Technologies
- HS-037: Standard Organization Determinations
- HS-038: Expedited Organization Determinations