

<p>SUBJECT: CLINICAL POLICIES DEVELOPMENT</p> <p>POLICY NUMBER: HS-CP-MA-M5</p> <p>EFFECTIVE DATE: June 25, 2025</p> <p>SERVICE/PRODUCT LINE: MEDICARE – MEDICAL & BEHAVIORAL HEALTH</p>	<p>Product Line (check all that apply):</p> <p><input type="checkbox"/> All</p> <p><input type="checkbox"/> Group HMO</p> <p><input type="checkbox"/> Individual HMO</p> <p><input type="checkbox"/> PPO</p> <p><input type="checkbox"/> POS</p> <p><input checked="" type="checkbox"/> Medicare</p> <p><input type="checkbox"/> N/A</p>
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These guidelines are used in conjunction with the independent judgment of a qualified licensed physician and do not constitute the practice of medicine or medical advice. This Clinical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This Clinical Policy is not intended to recommend treatment for members. Members should consult with their treating provider in connection with diagnosis and treatment decisions.

When coverage criteria are not fully established by Medicare including but not limited to National Coverage Decisions (NCD), Local Coverage Decisions (LCD), Medicare Manuals and National Coverage Articles, Sharp Health Plan develops Clinical Policies that serve as recommendations for medical necessity decisions. Sharp Health Plan utilizes evidence-based guidelines from nationally recognized professional organizations, peer reviewed medical and scientific literature and evidence-based consensus statements, which are all based on generally accepted standards of care.

- I. **BENEFIT STATEMENT:** Any service reviewed and approved by this Sharp Health Plan Clinical Policy must be a covered benefit according to the member’s evidence of coverage (EOC). Since benefit plans vary in coverage and some plans may not provide coverage for certain services discussed in this clinical policy, decisions are subject to all terms and conditions of the applicable benefit plan. Benefit determinations should be based in all cases on the member’s contract benefits in effect at the time of service.
 - A. All reviewers must first identify member eligibility, and all decisions of this clinical policy are subject to current state and/or federal law. Clinical policy does not constitute plan authorization, nor is it an explanation of benefits. In the event of a conflict, a member’s benefit plan, EOC, always supersedes the information in the Clinical Policies.
 - B. Sharp Health Plan provides coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the plan’s service area.
 - C. Sharp Health Plan complies with CMS’s national coverage determinations and general coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare.
- II. **REGULATORY:** Social Security Administration (SSA) is the most authoritative non-EOC statutory source. It trumps regulations, rules, memos, and manuals. CMS is the regulatory body.
- III. **DESCRIPTION:** The purpose of this policy is to define the mechanism for the development, application, and maintenance of Sharp Health Plan (SHP) clinical policies consistent with criteria or guidelines supported by

clinical principles and relevant medical evidence.

IV. DEFINITIONS

- A. Sharp Health Plan clinical policies are developed by the Health Services Department under the direction of the Chief Medical Officer (CMO), or designee, and are used for determining the medical necessity related to utilization management activities.
- B. Plan clinical policies are developed based on evidence-based guidelines and/or the clinical indications for the medical service requested.

V. MEDICAL NECESSITY

- A. Medical necessity is determined by referring to Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), available on the CMS Medicare Coverage Database (MCD) website.
- B. Policies specific to Durable Medical Equipment (DME) are available through the vendor, which holds the Medicare Administrative Contract for California, currently Noridian.
- C. The MCD also includes Determination and Coverage Articles.
- D. CMS Manuals: sometimes manuals will address coverage criteria not addressed by NCDs.
- E. If an applicable NCD or LCD or other criteria from MCD does not exist, Plan/ PMG clinical staff refer to the hierarchy of criteria below in Process/Attachments.

VI. NOT MEDICALLY NECESSARY

- A. All services that do not meet the criteria in Medical Necessity A-E are considered not medically necessary.

VII. CODES: See MCD**VIII. PROCESS / ATTACHMENTS****B. PROCEDURE FOR CLINICAL POLICIES (CP) DEVELOPMENT-MEDICARE**

If an applicable NCD or LCD or other criteria from MCD does not exist, Plan/ PMG clinical staff use the following procedure for CP Development.

1. All Sharp Health Plan Clinical Policies shall be formulated based on relevant medical evidence using one or more of the following:
 - a) Guidelines from nationally recognized health care organizations,
 - b) Guidelines published by nationally recognized professional organizations,
 - c) Available protocols regarding use of drug, device, procedure or therapy adopted by academic institutions,
 - d) Peer reviewed medical and scientific literature,
 - e) A review of available studies on a particular topic,
 - f) Evidence-based consensus statements,
 - g) Expert opinions of health care professionals,
 - h) Input from Plan Medical Group (PMG) and/or other health plan Medical Directors to assist in determination of policy considerations to be applied that reflect the needs and characteristics of the local delivery system and local standards of care.

2. Plan clinical policies are created using Sharp Health Plan standard policy format which includes:
 - a) Title: Name of Clinical Policy,
 - b) Benefit Statement,
 - c) Regulatory,
 - d) Description: Brief Description of product, procedure, or service type,
 - e) Definition,
 - f) Medical Necessity/Indications (criteria) for the procedure, treatment, equipment, etc.,
 - g) Not Medically Necessary: Any limitations or exclusions,
 - h) Codes,
 - i) Process/Procedure,
 - j) References/comments: Any other pertinent information including references,
 - k) Revisions,
 - l) Attachments.

3. All Plan clinical policies are reviewed by the CMO, or designee, and presented to the Clinical Policy and Technology Advancement Committee (CPTAC) and then to the Quality Management Committee for final review and approval. Plan clinical policies are reviewed and updated annually based on current information. Policies may be retired and maintained as archived files when the topic is covered by nationally recognized evidence-based guidelines as defined above.

4. Clinical staff are notified about new Plan clinical policy development via e-mail and directed on how to access all Plan clinical policies, including NCDs, LCDs, MCG, Hayes Knowledge Center, NCCN, and Noridian policies, which are available via the Internet and SHP Intranet/Portal.

5. All clinical policies are made available to PMGs upon approval and to providers, enrollees, and the public upon request.

C. The hierarchy of guidelines used by Plan/PMG clinical staff is as follows:

(Move from top (1) to bottom (4) of each box)

Medical/Surgical	Behavioral Health
1. National Coverage Determinations (NCDs)	1. National Coverage Determinations (NCDs)
2. Local Coverage Determinations (LCDs), Noridian Policies (DME only if no NCD) including articles and CMS Manuals	2. Local Coverage Determinations (LCDs), Noridian Policies (DME only if no NCD) including articles and CMS Manuals
3. Sharp Health Plan Clinical Medicare Policies	3. Sharp Health Plan Clinical Medicare Policies

<p>4. National Comprehensive Cancer Network (NCCN) Guidelines for oncology; MCG Care Guidelines; Medication PBM Criteria; Food and Drug Administration (FDA)</p>	<p>4. MCG Care Guidelines or Magellan Care Guidelines: LOCUS/CALOCUS ASAM Medication PBM Criteria Food and Drug Administration (FDA)</p>
<p>5. Other guidelines and tools developed by third parties to assist in determining medical necessity and administering health benefits i.e.: Professional Associations</p>	<p>5. Other guidelines and tools developed by third parties to assist in determining medical necessity and administering health benefits i.e., Professional Associations</p>


IX. REFERENCES

- D. CMS Medicare Coverage Database website: <https://www.cms.gov/medicare-coverage-database/search.aspx> Accessed 04/18/2025.
- E. Medicare Managed Care Manual, Chapter 4, Section 90.2-90.5: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf> Accessed 04/18/2025.
- F. Code of Federal regulations: Sec. 422.101 (a) and (b), Sec. 422.202 (b); Both Accessed 04/18/2025.
- G. Centers for Medicare & Medicaid Services (CMS); Accessed 04/18/2025.
- H. Noridian Healthcare Solutions: <https://med.noridianmedicare.com/> Accessed 04/18/2025.
- I. California Health and Safety Code Knox-Keene Act 1367.01, 1363.5.

X. REVISION HISTORY

Date	Modification (Original, Reviewed or Revised)
04/01/2015	Original
03/23/16	Revised and Approved QMC
03/14/17	Revised and Approved QMC
03/14/18	Revised and Approved QMC
03/27/19	Reformatted and Updated
04/01/2015	Original
03/23/16	Revised and Approved QMC
03/14/17	Revised and Approved QMC
03/14/18	Revised and Approved QMC
3/27/19	New format
3/25/20	Reviewed
3/31/21	Updated, changed to clinical policy , added criteria in hierarchy
12/21/22	Updated references, formatting
9/27/23	Added Behavioral Health

3/27/24	Updated criteria hierarchy
6/26/24	Updated to add language from 422.101 (a)(b)
4/18/25	Updated references

Approved by:  Date: 6/25/25
Cary Shames, DO, CMO/VP