SHARP Health Plan

Clinical Policy

SUBJECT: CLINICAL POLICIES – Experimental and Investigative **POLICY NUMBER: HS-CP-MA-E1** **EFFECTIVE DATE: December 17, 2025** **SERVICE/PRODUCT LINE: MEDICARE– MEDICAL**	Product Line (check all that apply): ☐ All ☐ Group HMO ☐ Individual HMO ☐ PPO ☐ POS ☒ Medicare ☐ N/A

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. All reviewers must first identify member eligibility, and all decisions of this clinical policy are subject to current state and/or federal law. This 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.

II. REGULATORY:

A. Medicare Managed Care Manual, Chapter 4, §10.7.2 – Payment for Investigational Device Exemption (IDE) Studies.
B. Medicare Benefit Policy Manual, Chapter 14, §20 – Food and Drug Administration (FDA)-Approved Investigational Device Exemption (IDE) Studies.
C. Medicare Program Integrity Manual, Chapter 13, §13.5.4 – Reasonable and Necessary Provisions in LCDs.

III. DESCRIPTION:

Title XVIII of the Social Security Act SSA 1862(a) (1) (A) prohibits Medicare coverage for items and services which are not "reasonable and necessary" for the diagnosis and treatment of an injury or illness or to improve the functioning of a malformed body part. Medical necessity cannot be established if the safety and effectiveness of a device is unknown.

The following Clinical Policy- Experimental and Investigative Services – applies to the Medicare Advantage Plan (Sharp Advantage) administered by Sharp Health Plan (Plan) and / or its delegates. The purpose of this policy is to outline the Plan requirements for coverage of experimental/investigative services.

Experimental and investigational procedures, items, and medications are considered not reasonable and necessary. Investigational Device Exemption (IDE) studies are only covered when the Medicare coverage requirements are met. Routine costs associated with Medicare approved Clinical Trials is Medicare's financial responsibility.

Investigational Device Exemption (IDE) Studies

Category A Device Category

A (experimental) device refers to a device for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective. The Medicare Advantage Organization (MAO) is responsible for payment of Routine Care Items and Services in CMS approved Category A IDE studies that are covered by the MAC with jurisdiction over the MA plan's service area. CMS will not approve Category A devices because they are statutorily excluded from coverage.

Note: The local MAC(s) with jurisdiction over the MA plan's service area determines coverage of IDE studies. CMS finalized changes to the IDE regulations (42 CFR § 405 Subpart B), effective January 1, 2015. A listing of all CMS approved Category A IDE studies and Category B IDE studies is posted on the CMS Coverage website located at http://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html and published in the Federal Register.

Category B Device

Category B (nonexperimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type. MAOs are responsible for payment of claims related to members' participation in Category B IDE studies that are covered by the MAC with jurisdiction over the MA plan's service area. The MAO is responsible for payment of Routine Care Items and Services in CMS-approved Category B IDE studies. The MAO is also responsible for CMS-approved Category B devices.

Note: The local MAC(s) with jurisdiction over the MA plan's service area determines coverage of IDE studies. CMS finalized changes to the IDE regulations (42 CFR § 405 Subpart B), effective January 1, 2015. A listing of all CMS approved Category A IDE studies and Category B IDE studies is posted on the CMS Coverage website located at http://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html and published in the Federal Register.

IV. DEFINITIONS:

A. Life-threatening condition: Disease or condition where the likelihood of death is high unless the course of the disease is interrupted; or disease or condition with potentially fatal outcomes, where the end point of clinical intervention is survival.

B. Immediately life-threatening disease or condition" means a stage of disease in which there is a reasonable likelihood that death will occur within a matter of months.

C. Seriously debilitating disease: Diseases or conditions that cause major irreversible morbidity.

D. Experimental and Investigational drugs and devices: Considered experimental if the FDA has not issued a specific indication or NDC number for the specific drug or device. The Off-Label Use of an FDA approved prescription drug is not considered an experimental/investigational service, for example, using an FDA approved drug for a condition, disease or diagnosis not approved by the FDA.

E. Experimental and Investigational treatment: Includes experimental and investigational drugs and devices, medical and surgical treatments, and procedures.

F. Experimental and Investigational medical and surgical treatments and procedures: Considered experimental if they are in clinical trials phase of development and are not yet considered to be standard of care by nationally recognized technology assessment organizations, specialty societies and/or medical review organizations.

G. Terminal Illness: Refers to an incurable or irreversible condition that has a high probability of causing death in less than one year.

H. Food Drug Administration (FDA): The FDA is an agency within the U.S. Department of Health and Human Services. It oversees medical products, food and new drugs (among other duties) to protect the public health by assuring safety, effectiveness and quality of these products. Examples are cosmetics, dietary supplements and products that give off radiation, biologics, prescription drugs, veterinary products, medical devices, etc.

I. Category A (Experimental) Device: This is a classification assigned by the Food and Drug Administration (FDA) in which there are still questions of safety and effectiveness regarding a device. These devices are generally novel, first of-a-kind technologies in which the absolute risk of the device type has not been established.

J. Category B (Non-experimental/investigational) Device: This is a classification assigned by the Food and Drug Administration in which the initial questions of safety and effectiveness of that device type have been resolved, for example, FDA premarket approval or clearance has been obtained.

K. Category III codes (or T codes): The American Medical Association (AMA) developed Category III CPT codes to track the utilization of emerging technologies, services and procedures. The assignment of a Category III code description does not establish a service or procedure as safe, effective, or applicable to the clinical practice of medicine, unless there is an NCD, LCD or a Medicare coverage article exist.

L. Coverage with Evidence Development (CED) is a Medicare provision that allows for the coverage of items or services only when they are provided in the context of approved clinical studies. This process requires the collection of additional clinical data to evaluate the effectiveness of the treatment or technology. The goal of CED is to generate data on the utilization and impact of the item or service evaluated in the National Coverage Determination (NCD), ensuring that Medicare beneficiaries receive appropriate care while supporting research and innovation in healthcare.

V. MEDICAL NECESSITY:

A. An experimental or investigational treatment may be considered medically necessary when ALL the following conditions are met:

1. Member has a life threatening or seriously debilitating condition, **AND**
2. Standard treatments covered by the Plan have not been effective in improving the member's condition or would not be medically appropriate, **AND**
3. The proposed experimental or investigational treatment is likely to be more beneficial than any available standard treatments(s) for the member's condition, supported by member's clinical or pre-clinical data, **AND**
4. A statement of the evidence relied upon to recommend the proposed treatment, which includes a copy of two peer-reviewed medical and scientific publications (as defined in section VII E. below), on which the recommendation is based, and a statement of why standard therapy is not beneficial, ineffective, or inappropriate has been submitted Plan physician, **AND**
5. The certifying Physician is a plan provider and is board certified or board eligible and qualified to treat the member's condition.

B. An experimental or investigational treatment may be considered medically necessary for an **immediately life-threatening condition** when all the following are met:

1. A member has tried all Food and Drug Administration (FDA) approved treatment options for the disease or condition, **AND**
2. Has not been accepted to participate in the nearest clinical trial to his or her home for the immediately life-threatening disease or a Plan provider has certified that member is unable to participate in a clinical trial due to the member's current condition or state of disease for the investigational drug, **AND**
3. The member has given written informed consent stating they understand the risks of taking the investigational drug, **AND**
4. The investigational drug must have already been through a phase one (1) clinical trial.

C. Clinical Studies Approved Under Coverage with Evidence Development (CED)
1. All studies seeking Medicare coverage under CED should be registered with ClinicalTrials.gov.
2. Registrants at ClinicalTrials.gov should submit a standardized set of data elements to describe the study design, eligible populations, outcome measures, and other parameters

and results.

3. MAOs are responsible for payment of items and services in CMS approved CED studies unless CMS determines that the significant cost threshold is exceeded for that item or services

VI. NOT MEDICALLY NECESSARY:

Investigational and experimental treatments not meeting the above criteria are not medically necessary and are not covered.

VII. PROCESS/PROCEDURES:

A. All requests for coverage of Experimental and Investigative Treatment will be reviewed by the delegated Plan Medical Group (PMG) or by the Plan according to its regular and appropriate utilization management process, administered consistent with the Plan benefit and provided in a manner that limits disruptions in care per Health and Safety Code 1363.5.

B. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this guideline. This Policy provides assistance in determining coverage under the member's benefit plan.

C. The terms of a member's benefit plan summary defined in the evidence of coverage document may differ from the standard benefit plans upon which this guideline is based. In the event of a conflict, the member's specific benefit document supersedes these guidelines.

D. If the proposed treatment is part of a clinical trial, this policy does not apply.

E. Any request for experimental or investigational treatment will be reviewed by the Plan according to its regular and appropriate utilization management process and administered consistent with the Plan benefit and regulations.

F. Terminally ill members who have been denied experimental or investigational treatment are entitled to attend a conference to review the denial information provided to them regarding a service denied as Experimental or Investigational. The process for this is described in Plan policy and procedure titled Appeal Conference for Terminally Ill Member and is consistent with applicable law for terminally ill individuals.

G. In addition, terminally ill members who have been denied experimental or investigational treatment are entitled to apply to the DMHC for an independent medical review. The process for this is described in Plan policy and procedure titled Independent Medical Review and is consistent with applicable law for terminally ill individuals.

H. To be considered Medical and Scientific evidence for the purposes of this policy, documents must meet one or more of the criteria below:

1. Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts; or

2. Peer-Reviewed literature that meet the criteria of the NIH National Library of Medicine for Index Medicus, Medline, etc. **or** The Cochrane Library, **or**

3. An accepted indication for treatment of cancer in one of the following standard reference compendia, for drugs approved by the FDA for treatment of cancer e.g. The National Comprehensive Cancer Network Drugs & Biologics Compendium, The Thomson Micromedix DRUGDEX, The Elsevier Gold Standard's Clinical Pharmacology, Medical journals recognized by the Secretary of HH, **or**
4. Any of the reference compendia approved in Section 1370.4 of the California Health and Safety Code, such as NCCN or Micromedex, **or**
5. Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes e.g., USDHHS, Federal Agency for Healthcare Research and Quality, NIH, National Cancer Institute, National Academy of Sciences, Center for Medicare, and Medicaid Services, etc., **or**
6. Peer-reviewed abstracts accepted for presentation at major medical association meetings.

I. For immediately life- threatening disease must meet above criteria in V. B.

Any request for health care services, supplies, treatments, items, procedures, drug therapies, or devices that are not covered in a National Coverage Determination (NCD), or Local Coverage Determination (LCD), or otherwise specified "covered" in the Medicare benefit manuals or other transmittals and/or have an unspecified code will have to be reviewed for medical necessity.

VIII. CODES: N/A

IX. REFERENCES:

A. Medicare Managed Care Manual, Chapter 4, §10.7.2 – Payment for Investigational Device Exemption (IDE) Studies.
B. Medicare Managed Care Manual; Chapter 4; Section 90.5; Effective 01/01/2015; Creating new Guidance; Viewed online at MCM Chapter 4 (cms.gov).
C. Medicare Benefit Policy Manual, Chapter 14, §20 – Food and Drug Administration (FDA)-Approved Investigational Device Exemption (IDE) Studies.
D. Medicare Program Integrity Manual, Chapter 13, §13.5.4 – Reasonable and Necessary Provisions in LCDs.
E. Medicare Claims Processing Manual 100-4, Chapter 32, Sections 68 & 69; Effective date: 1/1/15; Accessed via Internet site Medicare Claims Processing Manual (cms.gov)
F. Centers for Medicare and Medicaid Services Coverage with Evidence Development Guidance Document August 7, 2024
G. Centers for Medicare and Medicaid Services: Medicare Coverage Related Investigational Device Exemption (IDE) Studies

X. REVISION HISTORY:

Date	Modification (Original, Reviewed or Revised)
12/17/2025	Added CED coverage
12/18/2024	Original

Approved by: _____ Date: 12/17/2025
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