

<p><b>SUBJECT: CLINICAL POLICIES –CLINICAL TRIALS - MEDICARE</b></p> <p><b>POLICY NUMBER: HS-CP-MA-C1</b></p> <p><b>EFFECTIVE DATE: March 25, 2026</b></p> <p><b>SERVICE/PRODUCT LINE: MEDICARE – MEDICAL &amp; BEHAVIORAL HEALTH</b></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 by 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. Refer to the following:

1. National Coverage Determination (NCD) Routine Costs in Clinical Trials (310.1)
2. Medicare regulations in 42 CFR § 422.109(e) (1-5) and (f) (1-2). April 12, 2023.

§ 422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits; coverage of clinical trials and A and B device trials.

(e) *Clinical trials specified in NCD 310.1.*

(1) With the exception specified in paragraph (e)(3) of this section, original Medicare is responsible for coverage of MA enrollees participating in CMS-approved clinical trials to

include routine costs, as specified in NCD 310.1, and any coverage for the diagnosis or treatment of complications related to the clinical trial.

(2) MA enrollees are not charged traditional Medicare Part A and B deductibles for clinical trial coverage.

(3) MA plans are responsible for paying the difference between traditional Medicare cost-sharing incurred for qualifying clinical trial items and services and the MA plan's in-network cost-sharing for the same category of items and services.

(4) An enrollee's in-network cost-sharing portion must be included in the MA plan's maximum out-of-pocket calculation.

(5) MA plans may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create impediments to an enrollee's participation in a non-plan-sponsored clinical trial.

(f) Investigational Device Exemption (IDE) Category A and Category B

(1) MA plans are responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies that are covered under [§ 405.211\(a\) of this chapter](#).

(2) MA plans are responsible for coverage of CMS-approved Category B devices that are covered under [§ 405.211\(b\) of this chapter](#).

### III. DESCRIPTION

This policy defines the Sharp Health Plan (Plan) criteria for coverage of Medicare Clinical Trials.

### IV. DEFINITIONS

- A. An approved Clinical Trial is defined as a phase I, phase II, phase III, or phase IV clinical trial approved by an Institutional Review Board that is conducted for the prevention, detection, or treatment of cancer or other life-threatening disease or condition (defined as any disease from which the likelihood of death is probable unless the course of the disease or condition is interrupted) AND is ONE of the following:
1. A federally funded or approved trial (i.e., approved by the National Institutes of Health, (NIH), the federal Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Federal Centers for Medicare and Medicaid Services, the US Department of Defense, or the US Veterans' Administration) a qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants; or
  2. A clinical trial conducted under an FDA investigational new drug (IND) application of the United States Food and Drug Administration; or
  3. A drug trial that is exempt from the requirement of an FDA investigational new drug application.
  4. A clinical research study (also called a "clinical trial") is a way that doctors and scientists test new types of medical care, like how well a new cancer drug works. Certain clinical research studies

are approved by Medicare. Clinical research studies approved by Medicare typically request volunteers to participate in the study.

- B. A Qualified Individual is a Sharp Health Plan (Plan) member.
- C. Experimental and Investigational drugs and devices:
  - 1. Considered experimental if the FDA has not issued a specific indication or NDC number for the specific drug or device AND they are currently under investigation in a registered Clinical Trial.
  - 2. The Off-Label Use of an FDA approved prescription drug or device is not considered an experimental/investigational service if this off-label use is not currently being investigated in a registered Clinical Trial.
  - 3. Medicare classifies Investigational Device Exceptions (IDE) devices as Category A (Experimental) or Category B (Non-Experimental/Investigational).
    - a) Category A (Experimental) defined as safety/effectiveness not established.
    - b) Category B (Non-Experimental/Investigational) defined as sufficient evidence supports potential safety/effectiveness.

#### **V. MEDICAL NECESSITY**

- A. To be eligible for coverage under this policy, the member must be a Qualified Individual with active Plan membership in Sharp Medicare Advantage, and
- B. Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:
  - 1. The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, DME, diagnostic test) and is not statutorily excluded from coverage such as cosmetic surgery.
  - 2. The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
  - 3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group. AND
- C. The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:
  - 1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes.
  - 2. The trial is well-supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
  - 3. The trial does not unjustifiably duplicate existing studies.
  - 4. The trial design is appropriate to answer the research question being asked in the trial.
  - 5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;

6. The trial is in compliance with Federal regulations relating to the protection of human subjects;  
AND
  7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.
- D. For Category A and B Investigational Device Exceptions (IDE) :
1. Category A
    - a) Device: Not covered by Medicare (statutorily excluded).
    - b) Routine Care: Covered (e.g., standard services, services solely for provision/monitoring, and complication care).
    - c) MA Cost-Sharing: Processed under Original Medicare; the MA plan pays any difference between FFS Medicare and the plan's in-network cost-sharing. Member in-network cost-sharing applies to MOOP.
  2. Category B
    - a) Device: Covered by Medicare in CMS-approved Category B studies.
    - b) Routine Care: Covered consistent with NCD 310.1.
    - c) MA Cost-Sharing: Processed under Original Medicare with MA plan reconciliation as above.
- E. Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria. This process will require the principal investigator to enroll the trial in a Medicare clinical trials registry, currently under development.
- F. Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs because they have been deemed by AHRQ, in consultation with the other agencies represented on the multi-agency panel to be highly likely to have the above-listed seven desirable characteristics of clinical trials. The principal investigators of these automatically qualified trials do not need to certify that the trials meet the qualifying criteria but must enroll the trials in the Medicare clinical trials registry for administrative purposes, once the registry is established.
- G. Clinical trials that are deemed to be automatically qualified are:
1. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
  2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA;
  3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and
  4. Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification

process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status.

- H. Sharp Health Plan considers it medically necessary to cover Routine costs as defined in the NCD 310.1: Routine costs in clinical trials include:
1. Items or services that are typically provided absent a clinical trial (conventional care)
  2. Items or services required solely for the provision of investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
  3. Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.

#### **VI. NOT MEDICALLY NECESSARY**

- A. The investigational item or service, itself unless otherwise covered outside of the clinical trial.
- B. Items and services provided solely to satisfy data collection and analysis needs (protocol-induced costs) and that are not used in the direct clinical management of the member (e.g., monthly CT scans for a condition usually requiring only a single scan).
- C. Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.
- D. For non-covered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare only covers the treatment of complications arising from the delivery of the non-covered item and service and unrelated reasonable and necessary care. However, if the item or service is not covered by virtue of a national non-coverage policy in Pub. 100.03 NCD Manual, and is the focus of a qualifying clinical trial, the routine costs of the clinical trial will be covered by Medicare but the noncovered item or service, itself, will not.
- E. Travel, lodging and meals.

#### **VII. PROCESS/PROCEDURE**

- A. All requests for coverage of Clinical Trials will be reviewed by the delegated Plan Medical Group (PMG) or by the Plan according to its regular and appropriate utilization management process and administered consistent with the Plan benefit.
- 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 aids 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. Original Medicare covers most of costs for the covered services as part of the study, and any coverage for the diagnosis or treatment of complications related to the clinical trial.
- E. Members do not need SHP approval/prior authorization to participate.
- F. The providers that deliver care as part of the clinical research study do not need to be part of SHP's network of providers.

- G. SHP must pay the difference between traditional Medicare cost sharing incurred for qualifying clinical trial items and services and SHP’s in-network cost-sharing for the same category of items and services.
- H. An enrollee's in-network cost-sharing portion must be included in the MA plan's maximum out-of-pocket calculation.
- I. Using the authority found in §1142 of the Social Security Act (the Act) (cross-referenced in §1862(a)(1)(E) of the Act), the Agency for Healthcare Research and Quality (AHRQ) will convene a multi-agency Federal panel (the "panel") composed of representatives of the Department of Health and Human Services research agencies (National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), AHRQ, and the Office of Human Research Protection), and the research arms of the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics listed above. These criteria will be easily verifiable, and where possible, dichotomous. Trials that meet these qualifying criteria will receive Medicare coverage of their associated routine costs. This panel is not reviewing or approving individual trials. The multi-agency panel will meet periodically to review and evaluate the program and recommend any necessary refinements to the Centers for Medicare & Medicaid Services (CMS).

Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria. This process will require the principal investigator to enroll the trial in a Medicare clinical trials registry, currently under development.

Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs because they have been deemed by AHRQ, in consultation with the other agencies represented on the multi-agency panel to be highly likely to have the above-listed seven desirable characteristics of clinical trials. The principal investigators of these automatically qualified trials do not need to certify that the trials meet the qualifying criteria, but must enroll the trials in the Medicare clinical trials registry for administrative purposes, once the registry is established.

**VIII. ATTACHMENTS: N/A**

**IX. CODES:**

The following list(s) of procedure codes is provided for reference purposes only and may not be all-inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Inclusion of a code in this section does not guarantee that it will be reimbursed. The member specific benefit plan document and applicable laws that may require coverage for a specific service determine benefit coverage for health services.

<b>CPT Code</b>	<b>Description</b>
S9988	Services provided as a part of a phase I clinical trial
S9990	Services provided as a part of a phase II clinical trial
S9991	Services provided as a part of a phase III clinical trial
Modifier Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study
Modifier Q1	Routine clinical service provided in a clinical research study that is in an approved clinical research study

**X. REFERENCES**

- A. Medicare regulations in 42 CFR § 422.109(e)(1-5). Up to date 1/31/2015
- B. Medicare regulations in 42 CFR § 422.109(f)(1-2). Up to date 1/31/2015
- C. Medicare National Coverage Determination (NCD) 310.1 Routine Costs in Clinical Trials. Effective 5/27/2024
- D. Medicare Managed Care Manual chapter 4 section 10.7. Accessed 1/29/26

**XI. REVISION HISTORY**

<b>Date</b>	<b>Modification (Original, Reviewed or Revised)</b>
3/25/26	Revised, and updated Investigational Device Exemption section (f)
3/26/25	Revised, References updated
03/27/24	Original

<b>Approved by:</b> (Signature of VP /CMO) 	<b>Approval date:</b> 03/25/2026
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