NO. 91606-R5

CLINICAL TRIALS

Effective date: 03/01/2026 **Last reviewed**: 02/2026

Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This policy applies to the Individual Market, fully funded commercial groups, and non-grandfathered self-funded groups. Verify clinical trial coverage with the individual plan document for self-funded products.

For grandfathered self-funded groups that may have opted out of PPACA expanded clinical trials coverage, please refer to the Clinical Trials for Self-Funded Groups Opting Out of PPACA #91448.

For self-funded members: This policy does not apply to most ASO/Self-funded plans. Verify clinical trial coverage with the individual plan document.

For Priority Health Medicare coverage, please refer to CMS guidelines and Appendix A

Related policies:

- Clinical Trials for Self-Funded Groups Opting Out of PPACA #91448
- Experimental & Investigational Policy #91117.

I. MEDICAL NECESSITY CRITERIA

A. Covered Services

For members who meet coverage criteria, Priority Health will cover the routine patient cost associated with an approved clinical trial and will include all items and services consistent with the coverage provided in the plan or coverage that is typically covered for a member who is not enrolled in a clinical trial.

Coverage for routine patient care costs in a clinical trial may be a covered benefit as defined in the Patient Protection and Affordable Care Act (PPACA) when all of the following are met:

1. Member is eligible according to the trial protocol for the treatment of:

    a. Cancer, or
    b. Other life-threatening disease/condition defined as: a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

2. The referring health care professional is a participating health care provider and has concluded that participation in a trial would be appropriate for the eligible disease or condition or the member or the referring healthcare provider provides medical and scientific information establishing that participation in such trial would be appropriate.

3. The clinical trial is an approved trial. An approved clinical trial is defined as a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and meets one of the following:

    a. Federally funded trials. The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

        i. The National Institutes of Health.
        ii. The Centers for Disease Control and Prevention.
        iii. The Agency for Health Care Research and Quality.
        iv. The Centers for Medicare & Medicaid Services.
        v. The Department of Veterans Affairs.
        vi. The Department of Defense.
        vii. The Department of Energy
        viii. Cooperative group or center of any of the entities described above
        ix. A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants;

        Or

    b. The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration; or
    c. The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

4. Additional coverage requirements include:

a. Copies of pertinent documentation, including the trial protocol and the member's signed informed consent agreement, must be submitted to Priority Health to support the member's request for coverage.
b. If services can be provided in plan (e.g., labs and imaging studies), then Priority Health will pay for those services in-plan only.
c. Priority Health will only reimburse for service provided through clinical trials at the fee schedule paid to participating providers. The member may have additional expenses if the physicians and facility providing the services balance bill the member.
d. Depending on the type of clinical trial that a member may be enrolled in, the potential for case management services should be evaluated. Case or payment rates should be negotiated, and out of network payment agreements should be executed for care that is not contracted by Priority Health.
e. Out of network services are not covered, unless approved in advance by the health plan.

B. Non-Covered Services

The following are not covered in connection with an approved clinical trial:

1. The investigational item, device, or service, itself;
2. Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; or
3. A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

Note: A Clinical Trials Coverage Reference Sheet (Appendix A) can be found at the end of this policy and reflects coverage for all products.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
Home Use of Oxygen in Approved Clinical Trials 240.2.1 Routine Costs in Clinical Trials 310.1	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified

First Coast Service Options, Inc.	None identified
National Government Services, Inc.	None identified
Noridian Healthcare Solutions	None identified
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified

III. BACKGROUND

The National Institutes of Health defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Studies intended solely to refine measures are not considered clinical trials. Studies that involve secondary research with biological specimens or health information are not clinical trials.

Clinical trials are conducted in phases. The trials at each phase have a different purpose and help scientists answer different questions:

1. In Phase I trials, researchers test a new drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
2. In Phase II trials, the study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.
3. In Phase III trials, the study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
4. In Phase IV trials, post marketing studies delineate additional information including the drug's risks, benefits, and optimal use.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
US Department of Health and Humans Services: Office for Human Research Protections	Regulations, Policy & Guidance
World Health Organization	Guidance for best practices for clinical trials (2024)
Good Clinical Trials Collaborative	Guidance for Good Randomized Trials (2023)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

FDA Regulations Relating to Good Clinical Practice and Clinical Trials

Clinical Trials Guidance Documents

Guidance documents represent the agency's current thinking on the conduct of clinical trials, good clinical practice and human subject protection.

Guidance documents are not binding for FDA or the public. Guidance should be viewed as recommendations unless specific regulatory or statutory requirements are cited. An alternative approach may be used if the approach satisfies the requirements of the applicable statute and regulations.

VI. CODING

See also Priority Health Billing Policy No. 038 – Clinical Trials

ICD-10 Codes that may support medical necessity

Z00.6 Encounter for examination for normal comparison and control in clinical research program

Modifiers

Report the appropriate modifier for services reported as part of a clinical trial and include the 8 digit national clinical trial number (NCT.) Do not append modifiers to service lines that are unrelated to the clinical trial protocol.

Q0 Investigational clinical service provided in a clinical research study that is in an approved clinical research study

Q1 Routine clinical service provided in a clinical research study that is in an approved clinical research study

CPT/HCPCS/Revenue Codes

Reportable, no charge, no payment.

0624 FDA investigational devices

0256 Experimental drugs

Explanatory notes must accompany claims billed with unlisted codes.

Not covered:

G0293 Noncovered surgical procedure(s) using conscious sedation, regional, general, or spinal anesthesia in a Medicare qualifying clinical trial, per day

G0294 Noncovered procedure(s) using either no anesthesia or local anesthesia only, in a Medicare qualifying clinical trial, per day

S9988 Services provided as part of a Phase 1 clinical trial

S9989 Services provided outside of the United States of America (list in addition to code(s) for services(s))

S9990 Services provided as part of a Phase II clinical trial

S9991 Services provided as part of a Phase III clinical trial

S9992 Transportation costs to and from trial location and local transportation costs (e.g., fares for taxicab or bus) for clinical trial participant and one caregiver/companion

S9994 Lodging costs (e.g., hotel charges) for clinical trial participant and one caregiver/companion

S9996 Meals for clinical trial participant and one caregiver/companion

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

1. Good Clinical Trials Collaborative, Guidance for Good Randomized Clinical Trials, May 2022, https://www.goodtrials.org/guidance
2. National Institutes of Health. NIH Central Resource for Grants and Funding Information. NIH's Definition of a Clinical Trial. Available at https://grants.nih.gov/policy/clinical-trials/definition.htm (Accessed December 5, 2025).

APPENDIX A
CLINICAL TRIALS COVERAGE REFERENCE SHEET***

	Commercial Fully-funded	Commercial Self-funded	Medicare
Clinical Trials	Routine services* only, use *Clinical Trials Policy #91606*	Non-grandfathered groups: routine services only, use *Clinical Trials Policy #91606* Grandfathered groups opting out of PPACA: use *Clinical Trials for Cancer Policy #91448*	Original Medicare covers routine services for those trials that are Medicare approved. *Submit Medicare EOB with claim for payment of member cost share from PH plan.* If trial is not Medicare approved, there is no coverage under Original Medicare or Priority Health Medicare
IDE (Investigational Device Exemption) Trial: Category A Device	Never covered. Device and all services, including routine services, are not covered Use *Experimental & Investigational Policy #91117.* *Report on claim with $0 or $.01 as charge amount on claim line for device.*	Never covered. Device and all services, including routine services, are not covered. Use *Experimental & Investigational Policy #91117.* *Report on claim with $0 or $.01 as charge amount on claim line.*	Device is never covered. Routine care items and services in CMS-approved Category A IDE studies are covered by Priority Health Medicare. *Report on claim with $0 or $.01 as charge amount on claim line.*
IDE Trial: Category B Device	Routine services only; device not covered. ** Use *Experimental & Investigational Policy #91117.* *Report device on claim with $0 or $.01 as charge amount on claim line for device.*	Device and all services, including routine services, are not covered. ** Use *Experimental & Investigational Policy #91117. Submit claims with $0 or $.01 as charge amount on claim lines related to the trial services.*	All services, including the device, are covered by Priority Health Medicare
Clinical Studies Approved Under Evidence Development (CED)	Use *Experimental & Investigational Policy #91117* or other specific medical policy to determine coverage.	Use *Experimental & Investigational Policy #91117, or other specific medical policy,* and/or individual plan documents to determine coverage.	All care and services are covered by Priority Health Medicare per related NCD/LCD.

*Routine patient care costs are items or services that are typically covered benefits when provided outside a clinical trial. The clinical trial protocol may be needed to determine the specific services that are covered and excluded.

** Priority Health may, at its discretion, choose to cover the experimental device if the cost of that device is less than the non-experimental arm of the trial.

***For Medicaid/Healthy Michigan refer to section III “Application to Products”

Past review dates: 12/2013, 11/2014, 11/2015, 11/2016, 11/2017, 11/2018, 02/2019, 02/2020, 02/2021, 02/2023, 02/2024, 02/2025, 02/2026