NO. 91448-R9

CLINICAL TRIALS FOR SELF FUNDED GROUPS OPTING OUT OF PPACA

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policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community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 only applies to grandfathered self-funded plans that opt out of PPACA expanded clinical trials coverage. For the individual market, fully funded commercial groups, and non-grandfathered self-funded groups, please refer to the new Clinical Trials Medical Policy #91606. This policy is limited to oncology clinical trials and does not include clinical trials for other diagnoses.

Related policies:

- Clinical Trials Medical Policy #91606

SUMMARY OF CHANGES – R9

Additions:

- New Policy scope section
- New Medical/Professional Society Guidelines section
- New Government Regulations section listing applicable CMS NCDs or LCDs
- New FDA/Regulatory section

I. MEDICAL NECESSITY CRITERIA

Priority Health will cover routine patient care costs (defined below) for Phase II & III cancer clinical trials that meet the qualifications for "approved" or "deemed" clinical trials

below. This policy is limited to oncology clinical trials and does not include clinical trials for other diagnoses.

Additional coverage requirements include:

- Services must be pre-approved by Priority Health if out of network. Refer to individual plan documents to verify clinical trial coverage for self-funded products.
- If services can be provided in plan (e.g., labs and imaging studies), then the Priority Health will pay for those services in-plan only.
- 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.

Note: A Clinical Trials Coverage Reference Sheet (Appendix A) can be found at the end of this policy.

A. Qualifications Required For "Approved" or "Deemed Status" Clinical Trial Classification. A clinical research study will be considered worthy of support if all of the following apply:

    1. The institution/investigator/team performing the cancer clinical trial adheres to accepted Office of Human Research Protection (OHRP), National Institute of Health (NIH), Food and Drug Administration (FDA) procedural and ethical standards pertaining to conflict of interest and consistent protection of human subjects including:

        a. Thoroughness of an independent peer review for scientific validity, all aspects of the trial are conducted according to the appropriate standards of scientific integrity.
        b. Review and approval by an Institutional Review Board (IRB)
        c. Processes to identify, avoid, and disclose conflicts of interest
        d. Policies prohibiting payment for patient recruitment beyond reasonable reimbursement for administrative costs incurred, and
        e. Policies that prohibit any actions intended to inappropriately influence the review process.

    2. The IRB/institution has written policies to preclude investigators and team members directly responsible for patient selection in a clinical trial, the informed consent process and/or clinical management of a trial from any influence by material enrichment. These policies shall include review, oversight, and appropriate disclosure of potential conflicts of interest that may interfere with appropriate attention to patient care.
    3. The institution shall have policies that would prohibit censorship of clinical trial results by the industry sponsor.

        a. These policies prohibit the industry sponsor reviewer to change, amend or otherwise modify the published outcomes.
        b. These policies prohibit industry sponsor influence on the clinical trial's publication.

4. Treatment is provided with therapeutic intent. Thus, a protocol of the study must show that the principle purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes.
5. Treatment is being provided pursuant to an oncologic or malignant hematologic clinical trial sponsored or approved by one or more of the following:

    a. One of the National Institutes of Health (NIH)
    b. A NIH cooperative group, or a NIH center
    c. At, or under the auspices of, an NCI designated Comprehensive Cancer Center
    d. The Food and Drug Administration (FDA) in the form of an investigational new drug (IND) or new device (IDE) exemption
    e. The Department of Defense (DOD)
    f. The Department of Veterans Affairs (VA)
    g. Health Care Financing Administration (HCFA)
    h. Agency for Healthcare Research and Quality (AHRQ)
    i. Centers for Disease Control (CDC)
    j. A qualified non-governmental research entity as identified in guidelines issued by individual NIH Institutes for center support grants

6. The facility and personnel providing the treatment are capable of doing so by virtue of their experience or training.
7. The available clinical or pre-clinical data provide a reasonable expectation that the protocol treatment will be at least as efficacious as non-investigational therapy.
8. The member has received full disclosure by the research sponsor or principal investigator about the trial, its potential risks and benefits, and other treatment options. In addition, the member has signed an informed consent agreement to participate in the clinical trial. 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. Priority Health will provide coverage for placebo care, including surgery, for members participating in double-blind studies.

B. Health Plan Discretion

1. "Deemed status" may be granted to investigators or institutions when it determines that the investigator or institution follows and is committed to the principles represented in this policy.
2. "Deemed status" may be revoked if it is determined that the investigator or institution has abused its privileges or violated principles represented in this policy.
3. This policy only applies to grandfathered self-funded plans that opt out of PPACA expanded clinical trials coverage. Verify clinical trial coverage with the individual plan document. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.

C. Costs Associated with Cancer Clinical Trials

Coverage applies to members enrolled in qualifying therapeutic Phase II and Phase III clinical trials. Members receiving ad hoc investigational treatment are not covered.

All and any services covered for any participant by the sponsor of the clinical trial are not covered by Priority Health.

1. The routine patient care costs (conventional care) are covered as follows:

    a. Routine member care costs are items or services that are typically covered benefits when provided outside a clinical trial.
    b. Routine services include services that would be approved for coverage under this policy, even when delivered within the context of a clinical trial.
    c. Coverage for routine patient care costs incurred for drugs and devices provided to the member during the clinical trial provided that those drugs or devices have been approved for sale by the FDA, whether or not the FDA has approved the drug or device for use in treating the member's particular condition, and to the extent those drugs or devices are not provided or paid for by the sponsor of the clinical trial, or the manufacturer, distributor, or provider of that drug or device.
    d. The health plan's coverage of "routine costs" would not include non-FDA approved drugs or devices or unapproved medical procedures.
    e. Coverage would not include diagnostic tests that are performed for investigational purposes but not necessary for the patient's medical management.
    f. Routine patient care costs and any related trial costs are not covered for healthy volunteers.

2. The costs associated in the delivery of the investigational agent shall be borne by Priority Health.

    a. Services required solely for the provision of the investigational item shall be provided in accordance with the benefits of the member's plan. Coverage would include procedures, drugs or devices approved for coverage for any medical indication.
    b. The clinically appropriate monitoring of the effects of the item or service should be considered routine patient care costs.
    c. The prevention of complications of the item or service should be considered routine patient care costs.
    d. This coverage shall include payment for reasonable and medically necessary services necessary to administer the drug or use the device under evaluation in the clinical trial.

3. Costs of treating adverse side effects experienced during treatment should be borne by Priority Health. The health plan would be expected to cover medical care needed to treat any complications arising from the investigational service, when the medical services provided are otherwise covered under the member's contract.

D. Not covered services:

1. Clinical trials and associated routine patient care costs for Phase I and Phase II treatment trials for other disease pathophysiology are not covered.
2. Clinical trials and associated routine patient care costs for prevention trials, screening trials, diagnostic trials and quality of life trials are not covered.
3. Costs incurred for patient care generated specifically by the cancer clinical trial shall be borne by the clinical trial sponsor

    a. Costs for additional medication, laboratory studies, or diagnostic imaging.
    b. If the routine care item/service is not a covered benefit outside of the trial, it is not a covered benefit in association with the trial.
    c. Services beyond the scope of the member's contract are not covered.

4. Out of Plan services are not covered, unless approved in advance by Priority Health
5. Cost for travel and lodging is not covered.
6. The administrative costs of the study borne by the sponsoring organizations and include

    a. Data gathering
    b. Statistical study
    c. Regulatory requirements
    d. Contractual agreements
    e. Meetings and travel

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.

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

Definitions:

Coverage of cancer clinical trials is based on the American Society of Clinical Oncology's definition of patient oriented research:

> Clinical investigation in oncology is hypothesis-driven research that employs measurements in whole patients or normal human subjects, in conjunction with laboratory measurements as appropriate, on the subjects of clinical biology, natural history, prevention, screening, diagnosis, therapy or epidemiology of neoplastic disease.

Clinical trials are research studies designed to evaluate the safety and effectiveness of medical care. They are key to understanding the appropriate use of medical interventions of all types. All trials are based on a set of rules called a protocol. The protocol describes the characteristics of people who may be enrolled; the characteristics of people who may not participate; the length of the study; the schedule of tests, procedures, medications and dosages; and other study details.

Clinical trials are sponsored or funded by a variety of organizations or individuals such as physicians, medical institutions, foundations, voluntary groups, and pharmaceutical companies, in addition to federal agencies such as the National Institutes of Health (NIH). The research services and research medications/products received in most clinical trials should be free to the patient.

A. There are different types of clinical trials. They include:

1. Treatment trials which test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.
2. Prevention trials that look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vitamins, vaccines, minerals, or lifestyle changes.
3. Diagnostic trials that help determine better tests or procedures for diagnosing a particular disease or condition.
4. Screening trials that test the best way to detect certain diseases or health conditions.
5. Quality of life trials (or Supportive Care trials) which explore ways to improve comfort and the quality of life for individuals with a chronic illness.

B. After careful laboratory testing for safety and effectiveness, new therapies are evaluated in 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.

Every clinical trial in the U.S. must be approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits. An IRB is an independent committee of physicians, statisticians, community advocates, and others that ensures that a clinical trial is ethical and the rights of study participants are protected. All institutions that conduct or support biomedical research involving people must, by federal regulation, have an IRB that initially approves and periodically reviews the research.

The guidelines in this document are applicable to Phase II and Phase III clinical trials. Only those studies that have the potential of therapeutic benefit (Phase II and III) for patients will be considered for coverage.

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. 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 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

Special Note: This policy represents a voluntary cooperative effort of Michigan health plans, providers, and legislators.

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. American Society of Clinical Oncology. About Clinical Trials. Available at https://www.cancer.net/research-and-advocacy/clinical-trials/about-clinical-trials.
2. Good Clinical Trials Collaborative, Guidance for Good Randomized Clinical Trials, May 2022, https://www.goodtrials.org/guidance
3. National Institutes of Health. NIH Clinical Research Trials and You. Available at https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics

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