CLINICAL MEDICAL POLICY	
Policy Name:	Clinical Trials
Policy Number:	MP-117-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	11/01/2025; 01/01/2025; 08/01/2023
Effective Date:	12/01/2025; 02/01/2025; 09/01/2023
Next Annual Review:	08/2026
Revision Date:	08/20/2025; 08/21/2024; 05/17/2023
Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 6

Policy History

Date	Action
12/01/2025	Provider Effective date
09/29/2025	PARP Approval
08/20/2025	QI/UM Committee review
08/20/2025	Annual Review: No changes to clinical criteria. Updated 'Reference Sources' section.
02/01/2025	Provider Effective date
10/07/2024	PARP Approval
08/21/2024	QI/UM Committee review
08/21/2024	Annual Review: No changes to criteria. Updated 'Reference Sources' section.
05/01/2024	Provider Effective date
02/24/2024	PARP Approval
01/17/2024	QI/UM Committee review
01/17/2024	Urgent Revision: Updated 'Procedures' section with PA DHS guidance. Updated 'Reference Sources' section.
09/01/2023	Provider Effective date
07/02/2023	PARP Approval
05/17/2023	QI/UM Committee review
05/17/2023	Policy initially developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ may provide coverage for routine patient care costs associated with qualifying clinical trials and the updated requirements under the medical-surgical benefits of the Company's Medicaid products .

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) – A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Clinical Trial - scientific investigations that compare the safety and efficacy of new, untested or non-standard treatments. Clinical trials are intended to improve clinicians' knowledge about a treatment and to improve clinical outcomes for future individuals. Improvement of health outcomes for individuals enrolled in clinical trials is a desirable but secondary consideration.

Procedures

An "approved clinical trial" is defined as: Phase I, Phase II, Phase III, or Phase IV clinical trial (see *Informational* section below), being conducted in relation to the prevention, detection or treatment of cancer or other life threatening disease or condition.

1. A qualifying clinical trial is a clinical trial in any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition and meets ALL of the following criteria:
    A. A treatment or intervention that is provided pursuant to an approved clinical trial that has been federally funded, authorized, or approved by ANY of the following institutions:
        1) The National Institutes of Health (NIH) including the National Cancer Institute (NCI); OR
        2) The United States Food and Drug Administration (FDA) in the form of an investigational new drug (IND) exemption; OR
        3) The United States Department of Defense (DOD); OR

4) The United States Department of Veterans Affairs (VA); OR
5) The Centers for Disease Control and Prevention (CDC); OR
6) Agency for Healthcare Research and Quality (AHRQ); OR
7) The Centers for Medicare and Medicaid Services (CMS); OR
8) The Department of Energy (DOE); OR
9) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants; AND

B. The proposed therapy must be reviewed and approved by the applicable qualified Institutional Review Board; AND
C. The available clinical or pre-clinical data indicate that the treatment or intervention provided pursuant to the approved cancer clinical trial will be at least as effective as standard therapy, if such therapy exists, and is anticipated to constitute an improvement in effectiveness for treatment, prevention, or palliation of cancer; AND
D. The facility and personnel providing the treatment are capable of doing so by virtue of their experience and training; AND
E. The trial consists of a scientific plan of treatment that includes specific goals, a rationale and background of the plan, criteria for patient selection, specific directions for administering therapy and monitoring patients, a definition of the quantitative measures for determining treatment response, and methods for documenting and treating adverse reactions. All such trials must have undergone a review for scientific content and validity, as evidenced by approval from on the federal entities identified above.

2. The routine costs that must be considered covered for an individual participating in a qualifying clinical trial are:
   - Any items or services provided to the individual under the qualifying clinical trial, including any items or services provided to prevent, diagnose, monitor or treat complications resulting from participation in the qualifying clinical trial, to the extent that the provision of such items or services to the patient would otherwise be covered outside the course of participation in the qualifying clinical trial under the medical benefit.
   - Any item or service required solely for the provision of the investigational item or service that is the subject of the qualifying clinical trial, including the administration of the investigational item or service.

3. The following items and services are considered not medically necessary:
   - The investigational item, device, or service itself
   - The costs of any non-health service that might be required for a person to receive the treatment or intervention (e.g., transportation, hotel, meals, and other travel expenses)
   - The costs of managing the research
   - 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
   - The costs which would not be covered under the patient's contractual benefits for non-investigational treatments
   - A service that is clearly inconsistent with the widely accepted and established standards of care for a particular diagnosis.

Note:

- If a healthcare provider is participating in an approved clinical trial, the patient may be required to participate in the trial through that participating healthcare provider, if the healthcare provider will accept the patient as a participant in the trial.
- Treatments that fall outside the designated class of approved clinical trials are not considered medically necessary.
- Coverage will be denied if a patient is participating in an approved clinical trial conducted outside of Pennsylvania. However, any routine costs, if provided by a Pennsylvania Medical Assistance enrolled provider, will be covered.
- Any conditions other than those listed as medically necessary will be denied.

4. The Pennsylvania Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial (MA 584) must be submitted with any clinical trial prior authorization request. Please see MAB-99-23-10 titled "Payment for Services Associated with Qualifying Clinical Trials" at FORMS AND PUBS OMAPFORMS AND PUBS OMAP

5. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

6. Highmark Wholecare will cover the routine costs of qualifying clinical trials including items or services that are typically provided absent a clinical trial (e.g., conventional care).

7. Place of Service
   The proper place of service for clinical trials is in the outpatient setting. Clinical trials are only eligible as an inpatient procedure in special circumstances, including, but not limited to, that conventional care is provided in the inpatient or other setting, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

Governing Bodies Approval

CMS
The Centers for Medicare and Medicaid Services (CMS) has published the following guidance:

- National Coverage Determination (NCD) Routine Costs in Clinical Trials (310.1)

Informational

Phases of Clinical Trials

- **Phase I trials:** Researchers test a drug or treatment in a small group of people (20–80) for the first time. The purpose is to study the drug or treatment to learn about safety and identify side effects.
- **Phase II trials**: The new drug or treatment is given to a larger group of people (100–300) to determine its effectiveness and to further study its safety.
- **Phase III trials**: The new drug or treatment is given to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it with standard or similar treatments, and collect information that will allow the new drug or treatment to be used safely.
- **Phase IV trials**: After a drug is approved by the FDA and made available to the public, researchers track its safety in the general population, seeking more information about a drug or treatment's benefits, and optimal use.
  (National Institutes of Health, 2022)

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

Reference Sources

Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) Routine Costs in Clinical Trials (310.1). Effective date July 9, 2007. Implementation date October 9, 2007. Accessed on April 25, 2023.

National Institutes of Health (NIH). NIH Clinical Trials and You. October 2022. Accessed on April 25, 2023.

American Cancer Society. Clinical Trials. State laws regarding insurance coverage. Accessed on April 25, 2023.

HealthCare.gov. Patient Protection and Affordable Care Act. Accessed on April 25, 2023.

PA Department of Human Services (DHS). Medical Assistance Bulletin Number 99-23-10. Effective date December 28, 2023. Accessed on January 5, 2024.