

Subject:	Clinical Research Studies (Clinical Trials)		
Policy Number:	PO-RE-171v1		
Effective Date:	07/01/2026	Last Approval Date:	05/18/2026

I. Policy Description

This policy establishes reimbursement guidelines for services associated with member participation in clinical research studies (clinical trials), in accordance with applicable New York State Department of Health (NYS DOH), Centers for Medicare & Medicaid Services (CMS), and Affordable Care Act (ACA) requirements.

A clinical trial is a research study conducted to evaluate new medical treatments, procedures, or drugs to determine their safety and effectiveness. These studies are a critical stage in clinical research and may involve voluntary participation by members.

Healthfirst reimburses covered services and routine patient care costs associated with clinical trials, subject to the member’s benefit plan and line of business (LOB). Coverage and reimbursement vary by product type.

The information below applies to the following lines of business:

• Child Health Plus (CHP)	• Essential Plan (EP)
• Integrated Benefit Dual Plan (IB-Dual)	• Managed Long Term Care Plan (MLTCP – Senior Health Partners)
• Medicaid Managed Care (MMC)	• Medicaid Advantage Plus/MAP (CompleteCare)
• Medicare Advantage HMO	• Qualified Health Plan (QHP)
• Medicare PPO	• Personal Wellness Plan (HARP)

Definition

Clinical Trial: A research study involving human participants designed to evaluate medical, surgical, or behavioral interventions.

Routine Patient Care Costs: Items and services typically covered under a member’s benefit plan that are provided in connection with a clinical trial.

Covered Services: Services eligible for reimbursement under the member's benefit plan, including routine costs associated with clinical trial participation.

Life-Threatening Condition:

A disease or condition where:

- The likelihood of death is high unless the course of the disease is interrupted; or
- The condition has potentially fatal outcomes where survival is a key endpoint (per 21 CFR 312.81(a))

A. General Reimbursement Guidelines

Healthfirst will reimburse clinical trial-related services when all of the following are met:

- The member is enrolled in a qualifying or approved clinical trial
- The services are covered under the member's benefit plan
- The services qualify as routine patient care costs or other covered services
- Claims are submitted with appropriate coding, including clinical trial modifiers (e.g., Q0, Q1)

Non-Covered Services

Healthfirst does not reimburse:

- Investigational drugs, devices, or services (unless otherwise covered under the benefit)
- Services performed solely for research or data collection
- Services provided free of charge by the study sponsor
- Non-healthcare or administrative research-related costs

B. Line of Business (LOB) Reimbursement Guidelines

1. Medicaid Managed Care / HARP

Coverage Overview

- Coverage is governed by NYS Medicaid and CMS guidance
- Routine costs for qualifying clinical trials may be reimbursed

Reimbursement Policy

Healthfirst will reimburse:

- Routine patient care costs and other covered services where applicable.

Experimental / Investigational Services

- Covered on a case-by-case basis
- May be eligible for external appeal under Public Health Law §4910 when:
 - The service was denied as experimental/investigational
 - The member has a life-threatening or disabling condition
 - No effective covered alternative exists
 - A qualified physician recommends the service or clinical trial

2. Medicare Advantage (MA), Medicare PPO, MAP/CompleteCare

Coverage Overview

- Medicare covers routine costs of qualifying clinical trials

Reimbursement Policy

Healthfirst will:

- Cover applicable cost-sharing (coinsurance and deductibles per CMS rules)
- Reimburse covered services and routine costs

Covered Routine Costs Include

- Standard services provided outside a clinical trial
- Services required to administer investigational items
- Monitoring and prevention of complications
- Diagnosis and treatment of complications

Non-Covered

- Investigational items/services (unless otherwise covered)
- Services performed solely for research/data collection

Clinical Trial Requirements

- Must fall within a Medicare benefit category
- Must have therapeutic intent
- Must meet CMS clinical trial qualification criteria

3. Integrated Benefit Dual Plan (Dual Eligible Members)

Coordination of Benefits

- Medicare = primary payer
- Medicaid = secondary payer

Medicaid may cover:

- Member cost-sharing
- Additional covered services based on Medicaid benefits

4. Child Health Plus (CHP), and Commercial

Coverage Overview

- ACA requires coverage of routine patient costs for approved clinical trials

Reimbursement Policy

Healthfirst will reimburse:

- Routine patient care costs and other covered services consistent with the member's benefit plan

Approved Clinical Trial Requirements

- Phase I–IV clinical trials
- Related to cancer or life-threatening conditions
- Federally funded, approved, or FDA-reviewed

Non-Covered

- Investigational items/services
- Research-related administrative costs
- Services not covered under the member's benefit

C. Billing and Documentation Requirements

Providers must:

- Submit claims using:
 - Clinical trial modifiers (Q0, Q1)
 - Appropriate diagnosis and procedure codes
- Clearly distinguish:
 - Covered services (routine costs)
 - Non-covered research-related services
- Maintain documentation supporting:
 - Clinical trial qualification
 - Member eligibility
 - Covered service determination

D. Adjudication and Appeal Process

1. Reimbursement for Clinical Trial services will be determined based on the provider's scope of services and the reimbursement rates outlined in the provider's contract with Healthfirst.
2. Claims submitted by providers that do not adhere to this policy will be denied or rejected. It is the responsibility of the provider to ensure claims are coded accurately.
3. This policy applies only to the line(s) of business (LOB) identified at the beginning of the policy and does not apply to other LOBs. For policies applicable to other lines of business, please visit www.hfproviders.org.
4. This policy is a provider resource for understanding Healthfirst's reimbursement guidelines. It does not guarantee coverage or payment. Final reimbursement decisions depend on benefit coverage, state/federal mandates, medical necessity, and provider contract.
5. Claims submissions will be subject to timely filing requirements, as set forth in the provider contract with Healthfirst and in the Healthfirst Provider Manual. *Refer to: Healthfirst Provider*

Manual Subsection 17, “Claims Inquiries, Corrected Claims, Claim Reconsideration, and Appeal Process” in this section.

For any questions or further clarification regarding this policy, providers are encouraged to reach out to their designated contact within our organization

II. Applicable Codes

Code	Description	Comment

III. Definitions

Term	Meaning

IV. Related Policies

Policy Number	Policy Description
N/A	N/A

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Procedure codes appearing in Reimbursement Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Reference Materials

CMS National Coverage Determination (NCD) – Clinical Trials (310.1)
CMS Medicaid Guidance – Mandatory Coverage of Routine Costs (SMD #21-005)
Medicaid Clinical Trial Attestation Form
New York State Public Health Law Article 49 (External Appeals)
Affordable Care Act – Clinical Trial Coverage (42 USC 300gg-8)
Medicare Claims Processing & Clinical Trial Billing Guidance

VI. Revision History

Revision Date	Summary of Changes

Disclaimer

Healthfirst’s claim edits follow national industry standards aligned with CMS standards that include, but are not limited to, the National Correct Coding Initiative (NCCI), the National and Local Coverage Determination (NCD/LCD) policies, appropriate modifier usage, global surgery and multiple procedure reduction rules, medically unlikely edits, duplicates, etc. In addition, Healthfirst’s coding edits incorporate industry-accepted AMA and CMS CPT, HCPCS and ICD-10 coding principles, National Uniform Billing Editor’s revenue coding guidelines, CPT Assistant guidelines, New York State-specific coding, billing, and payment policies, as well as national physician specialty academy guidelines (coding and clinical). Failure to follow proper coding, billing, and/or reimbursement policy guidelines could result in the denial and/or recoupment of the claim payment.

This policy is intended to serve as a resource for providers to use in understanding reimbursement guidelines for professional and institutional claims. This information is accurate and current as of the date of publication. It provides information from industry sources about proper coding practice. However, this document does not represent or guarantee that Healthfirst will cover and/or pay for the services outlined. Reimbursement decisions are based on the terms of the applicable evidence of coverage, state and federal requirements or mandates, and the provider’s participation agreement. This includes the determination of any amounts that Healthfirst or the member owes the provider.

