Clinical Trials

Policy

Harvard Pilgrim reimburses contracted providers for services rendered during qualified clinical trials to the same extent those services are covered for members who are not enrolled in clinical trials and in accordance with state and federal mandates for coverage.

Policy Definition

A qualified *Clinical Trial* must provide a reasonable expectation that a member's participation will provide a medical benefit commensurate with the risk of participation, and not unjustifiably duplicate existing studies; be peer reviewed and approved by the National Institute of Health or other qualified entity and have a therapeutic intent; and be conducted at an academic medical center/affiliated facility with adequate patient volume and experienced staff qualified to assess the effect of the intervention on the member.

A qualified trial must meet the following criteria.

- Evaluates an item or service that falls within the Harvard Pilgrim benefit category
- Provides a reasonable expectation that the member's participation will provide a medical benefit
- Has defined selection criteria which the member must meet
- Has a therapeutic intent
- Enrolls members with a diagnosed disease
- Has desirable characteristics

Prerequisite(s)

Applicable Harvard Pilgrim referral, notification and authorization policies and procedures apply.
Refer to *Referral, Notification and Authorization* for more information.

HMO/POS/PPO

- A referral is required for HMO and in-network POS members for all specialist's care.
- Participating providers are required to notify Harvard Pilgrim of all inpatient admission.
- An authorization is required for home health service, selected elective surgical procedures and selected DME.

Open Access HMO and POS

For *Open Access HMO and Open Access POS* products, no referral is required to see a contracted specialist.

Harvard Pilgrim Reimburses[1]

HMO/POS/PPO

- Routine services rendered by contracted providers and supplies received as part of the qualified clinical trial when the member is enrolled in that trial
- Items or services required solely for the provision of the investigational item/service (e.g., the administration of a non-covered drug)
- Items or services needed for reasonable and necessary care resulting from the provision of the investigational service or item (e.g., treatment of a complication)

Reimbursement is provided for these services/supplies that are consistent with the study protocol and standard of care for someone with the member's diagnosis and would be covered if the member did not participate in the clinical trial.

Harvard Pilgrim Does *Not* Reimburse

HMO/POS/PPO

- Experimental, investigational or unproven treatment, drugs or devices that the trial is testing

- Items and services provided or covered by the clinical trial sponsor that are free of charge for any person enrolled in the trial
- Services that are inconsistent with accepted standards of care
- Services provided to primarily meet the needs of the trial including services that are typically covered but are being provided at a greater frequency, duration, or intensity than is medically necessary
- Services or items that are specifically excluded on member's Schedule of Benefits
- Services or items that would not be covered if a member was not enrolled in a clinical trial
- Non-health care items and services (e.g., food products, personal care services) required as a result of the member's enrollment in the clinical trial
- Costs of data collection and record-keeping that would not normally be required, other than for the clinical trial

Member Cost-Sharing

Services are subject to member out-of-pocket cost (e.g., copayment, coinsurance, deductible), as applicable. Harvard Pilgrim reimburses services to contracted providers when the service is a covered benefit. Benefits vary among employer groups. For benefit determination, call the Provider Service Center at 800-708-4414.

Provider Billing Guidelines and Documentation

Coding[2]

Code	Description	Comments
CPT 10004–99499	Integumentary, musculoskeletal, respiratory, cardiovascular, digestive, urinary, genital, nervous, eye and ocular adnexa, radiology, and pathology/lab system CPT codes	Refer to specific payment policy for appropriate billing guidelines
Rev Codes 020–96X	Revenue codes that may be applicable to clinical trial	
ICD-10 Code Z00.6	Encounter for examination for normal comparison and control in clinical research program	Use as third or subsequent diagnosis code

Related Modifiers

- 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
- If billing with other modifiers, use Q0 or Q1 in the second modifier fields

Related Policies

- Audit Policy
- Refer to payment policy relating to the specific service(s) rendered.

PUBLICATION HISTORY

04/30/05	original documentation
04/30/06	annual update; added FSEN notification and authorization requirements; revised FSEN reimburses/does not reimburse information; added prerequisite for HMO/POS/PPO authorization for home health care; minor language changes
04/30/07	annual review; added services rendered by contracted providers, minor language changes
04/30/08	annual review; clarification of non-covered services during clinical trials
03/15/09	annual review; no changes
03/15/10	annual review; no changes
03/15/11	annual review; minor edit to policy definition
01/01/12	removed First Seniority Freedom information from header
03/15/12	annual review; no changes

02/15/13	annual review; changed V70.5 to V70.7
03/15/14	annual review; no changes
06/15/14	added *Connecticut Open Access HMO* referral information to Prerequisites
03/15/15	annual review; no changes
06/15/15	added ICD-10 coding
03/15/16	annual review; updated related policies, administrative edits for clarification
03/15/17	annual review; administrative edits
01/01/18	updated Open Access Product referral information under Prerequisites
03/01/18	annual review; administrative edit
02/01/19	annual coding update
03/01/19	annual review; added related policy and updated Harvard Pilgrim does not reimburse item/services that are free of charge
03/02/20	annual review; no changes
03/01/2021	annual review; no changes

[1]This policy applies to the products of Harvard Pilgrim Health Care and its affiliates—Harvard Pilgrim Health Care of Connecticut, Harvard Pilgrim Health Care of New England, and HPHC Insurance Company—for services performed by contracted providers. Payment is based on member benefits and eligibility, medical necessity review, where applicable, and provider contractual agreement. Payment for covered services rendered by contracted providers will be reimbursed at the lesser of charges or the contracted rate. (Does not apply to inpatient per diem, DRG, or case rates.) HPHC reserves the right to amend a payment policy at its discretion. CPT and HCPCS codes are updated annually. Always use the most recent CPT and HCPCS coding guidelines.

[2]The table may not include all provider claim codes related to clinical trials.