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 will apply. (Refer to Referral, Notification and Authorization for more information.)

HMO/POS/PPO
• Referral required for HMO and in-network POS members for all specialists care.
• Participating providers are required to notify Harvard Pilgrim of all inpatient admission.
• Authorization required for home health service, selected elective surgical procedures and selected DME.

Exception: For the Connecticut Open Access HMO product, no referral is required to see a contracted specialist.

Harvard Pilgrim Reimburses

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 covered by the clinical trial sponsor.
• 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.

(continued)
• 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 subject to applicable member out-of-pocket cost (e.g., copayment, coinsurance, deductible).

**Provider Billing Guidelines and Documentation**

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT 10021–99499</td>
<td>Integumentary, musculoskeletal, respiratory, cardiovascular, digestive, urinary, genital, nervous, eye and ocular adenexa, radiology, and pathology/lab system CPT codes</td>
<td>Refer to specific payment policy for appropriate billing guidelines</td>
</tr>
<tr>
<td>Revenue Codes 020–96X</td>
<td>Revenue codes that may be applicable to clinical trial</td>
<td></td>
</tr>
<tr>
<td>ICD-9 Code V70.7</td>
<td>Examination of participant in clinical trial</td>
<td>Use as third or subsequent diagnosis code</td>
</tr>
</tbody>
</table>

**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**

• Refer to payment policy relating to the specific service(s) rendered.
• Maine State Mandate Title 24-A Subsection 4310 (effective 1999).
• Massachusetts General Law 176 Subsection 4P (effective 01/01/03).
• New Hampshire Revised State Annotated 415:18-1 (effective 01/01/01).

**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

1This policy is in reference to HPHC, HPHC-NE, and HPHC Ins. Co. products for services performed by contracted providers. Payment is based on member benefits and eligibility, medical necessity review, where applicable, and HPHC 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.

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