Harvard Pilgrim Health Care | TUFTS Health Plan

Point32Health companies

Payment Policy:
Clinical Trials

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products
☒ Tufts Health Plan Commercial products

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan
☒ Tufts Health One Care – A dual-eligible product

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO) (a dual-eligible product)
☒ Tufts Medicare Preferred HMO/PPO (Medicare Advantage products)

Policy

Point32Health 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.

Prerequisites

Applicable Point32Health referral, notification, and authorization policies may apply. Refer to the appropriate sections within the Provider Manuals for more information.

General Benefit Information

Services are pursuant to the member's benefit plan documents and are subject to applicable member out-of-pocket cost (e.g., copayment, coinsurance, deductible). Member eligibility and benefit specifics should be verified prior to initiating services.

Use of non-contracted labs may have the unintended consequence of subjecting the member to unnecessary services not ordered by the treating provider or other unreasonable financial exposure. In such circumstances, Point32Health may hold the ordering provider accountable for any inappropriate behavior on the part of the nonparticipating lab that has been selected.

Point32Health Reimburses

- 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)
- Items or services required solely for the provision of the investigational item/ service (e.g., the administration of an experimental drug)
- Routine services rendered by contracted providers and supplies received as part of the qualified clinical trial that the member is enrolled in

Point32Health Does *Not* Reimburse

- Costs of date collection and record-keeping that would not normally be required, other than for the clinical trial
- 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

- 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
- Services or items that are specifically excluded in member's benefit plan documents
- Services or items that would not be covered if a member was not enrolled in a clinical trial
- 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 that are inconsistent with accepted standards of care

Provider Billing Guidelines and Documentation

Providers are reimbursed according to the applicable contracted rates and fee schedules.

ICD-10 Code
The diagnosis code below must be reported with the primary ICD-10 diagnosis code consistent with the clinical trial indication.

Code	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program

Required Modifiers
The following modifiers (for professional and facility outpatient claims) are item/service specific and constitute medically necessary routine patient care or treatment or complications arising from a member's participation in a qualified clinical trial.

Modifier	Description
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 field.

Related Policies and Resources

Clinical Policies

- Clinical Trials: Routine Costs

Publication History

05/01/2026: Annual policy review; administrative edits
04/01/2025: Annual policy review; administrative edits
05/01/2024: Policy moved to new template; includes all lines of business

Background and Disclaimer Information

This policy applies to the products of Harvard Pilgrim Health Care and Tufts Health Plan and their affiliates, as identified in the check boxes on the first page for services performed by contracted providers.

Payment is based on member benefits and eligibility on the date of service, medical necessity review, where applicable, and the provider's network participation agreement with the Plan. As every claim is unique, this policy is neither a guarantee of payment, nor a final indication of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization, and utilization management requirements (when applicable), adherence to Plan policies and procedures, and claims editing logic. An authorization is not a guarantee of payment.

Point32Health reserves the right to amend a payment policy at its discretion. CPT and HCPCS codes are updated as applicable; please adhere to the most recent CPT and HCPCS coding guidelines.

We reserve the right to conduct audits on any provider and/or facility to ensure accuracy and compliance with the guidelines stated in this payment policy. If such an audit determines that a provider/facility did not comply with this payment policy, Harvard Pilgrim Health Care and Tufts Health Plan will expect the provider/facility to refund all payments related to noncompliance.