

**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**

Tufts Health Plan covers routine costs for in-network services rendered during qualified clinical trials for cancer and other life-threatening conditions, in accordance with state and federal mandates for coverage, as described below and in accordance with the member's benefits.

---

**General Benefit Information**

Services and subsequent payment are pursuant to the member's benefit plan document. Member eligibility and benefit specifics should be verified prior to initiating services by logging on to the secure Provider [portal](#) or by contacting [Provider Services](#).

Tufts Health Plan will cover routine patient costs when medically necessary and consistent with the member's benefit if the member was not participating in a clinical trial.

Tufts Health Plan does not cover clinical trials under the following circumstances:

- Services, drugs, or items specifically excluded in the member's benefit plan document
- Services, drugs, or items that would not be covered if the member was not enrolled in a clinical trial

---

**Referral/Prior Authorization/Notification Requirements**

Certain procedures, items and/or services may require referral and/or prior authorization. While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you must confirm that prior authorization has been obtained. For more information, refer to the [Referral, Prior Authorization, and Notification Policy](#).

Prior authorization is not required for services rendered during qualified clinical trials. Providers will not routinely be required to submit documentation about the clinical trial to Tufts Health Plan. However, documentation may be requested at any time to confirm that the trial meets current standards.

All inpatient admissions require inpatient notification prior to services being rendered. The admitting physician or facility should submit an inpatient notification at the time of admission.

---

**Billing Instruction**

Unless otherwise stated, Tufts Health Plan follows industry-standard coding guidelines. Refer to current industry standard coding guidelines for a complete list of ICD, CPT/HCPCS, revenue codes, modifiers, and their usage. Providers may only bill the procedure code(s) in accordance with the applicable financial exhibits of their provider agreements and applicable fee

schedules.

Use of noncontracting 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, Tufts Health Plan may hold the ordering provider accountable for any inappropriate behavior on the part of the nonparticipating lab that has been selected.

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

- **Q1** (routine clinical service provided in a clinical research study that is in an approved clinical research study)
- **Q0** (investigational clinical service provided in a clinical research study that is in an approved clinical research study)

Tufts Health Plan does not compensate for any routine costs associated with a clinical trial unless either modifier Q0 or Q1 and a diagnosis indicating participation in a clinical trial/research study are on the claim.

Submit ICD-CM code **Z00.6** (encounter for examination for normal comparison and control in clinical research program) for professional, facility outpatient and/or facility inpatient claims with the primary diagnosis code consistent with the clinical trial indication.

**Senior Products:** CPT codes 33274 (transcatheter insertion or replacement of permanent leadless pacemaker) or 33275 (Transcatheter removal of permanent leadless pacemaker) must be billed with modifier Q0, in accordance with CMS.

---

## Compensation/Reimbursement Information

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

---

## Additional Resources

- [Clinical Trials: Routine Costs](#)

---

## Publication History

- May 2023: Annual policy review; added Tufts Health Public Plans applicability
- March 2022: Annual review; no changes
- February 2022: Added Senior Products applicability; added claim edit for CPT codes 33274 and 33275, effective for dates of service on or after May 1, 2022
- June 2018: Template updates

---

## 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.