Clinical Trials Payment Policy

Applies to the following Tufts Health Plan products:

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

The following payment policy applies to Tufts Health Plan contracting inpatient and outpatient facilities.

In addition to the specific information contained in this policy, providers must adhere to the information outlined in the Professional Services and Facilities Payment Policy.

Note: Audit and disclaimer information is located at the end of this document.

POLICY
Tufts Health Plan covers routine costs for 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.

For coverage details, refer to the Clinical Trials: Routine Costs Medical Necessity Guidelines

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.

Note: There is no member responsibility for covered services for Tufts Health Plan SCO members.

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. For more information, refer to the Clinical Trials: Routine Costs Medical Necessity Guidelines.

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.

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 INSTRUCTIONS
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. For more information, refer to the Professional Services and Facilities Payment Policy.

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)

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1 Commercial products include HMO, POS, PPO, and CareLink® when Tufts Health Plan is the primary administrator.

2 Tufts Medicare Preferred and Tufts Health Plan SCO are collectively referred to in this payment policy as Senior Products.
• **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.

**COMPENSATION/REIMBURSEMENT INFORMATION**

Providers are compensated according to the applicable contracted rates and applicable fee schedules, regardless of the address where the service is rendered. For more information, refer to the [Professional Services and Facilities Payment Policy](#).

**Senior Products:** Effective for dates of service on or after May 1, 2022, Tufts Health Plan will deny CPT codes 33274 (transcatheter insertion or replacement of permanent leadless pacemaker) or 33275 (Transcatheter removal of permanent leadless pacemaker) if billed without modifier Q0, in accordance with CMS.

**DOCUMENT HISTORY**

- 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
- September 2017: Policy reviewed. No content changes.
- January 2017: Template updates
- September 2015: Template conversion, template updates
- June 2015: Template updates
- February 2015: Updated ICD-10 information, template updates
- December 2014: Added revenue codes 0681-0684, 0689, 1000-1002 accepted when submitted electronically without a corresponding CPT and/or HCPCS procedure code, template updates
- May 2014: Added policy about modifiers Q0 and Q1 effective for dates of service on or after July 1, 2014, template updates.
- November 2013: Policy created.

**AUDIT AND DISCLAIMER INFORMATION**

Tufts Health Plan reserves the right to conduct audits on any provider and/or facility to ensure 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, Tufts Health Plan will expect the provider/facility to refund all payments related to noncompliance. For more information about Tufts Health Plan's audit policies, refer to the Provider website.

This policy provides information on Tufts Health Plan claims adjudication processes. 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. Claims for services subject to authorization may be reviewed for accuracy and compliance with payment policies.

This policy applies to the Tufts Health Plan products, as identified in the checkboxes on the first page, and to CareLinkSM for providers in Massachusetts and Rhode Island service areas. Providers in the New Hampshire service area are subject to Cigna’s provider agreements with respect to CareLink members. This policy does not apply to the Private Health Care Systems (PHCS) network (also known as Multiplan). Tufts Health Plan reserves the right to amend a payment policy at its discretion.