Clinical Trials Payment Policy

Applies to the following Tufts Health Plan products:

☒Tufts Health Plan Commercial (including Tufts Health Freedom Plan)[1]

☐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 here, providers must adhere to the policy information outlined in the Professional Services and Facilities Payment Policy.

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

DEFINITION

Clinical trials are biomedical or health-related research studies that follow a predefined protocol.

POLICY

In accordance with Section 2709 of the Patient Protection and Affordable Care Act (ACA) upon group renewal, 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 website or by contacting Commercial 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. For more information, refer to the Clinical Trials: Routine Costs Medical Necessity Guidelines.

Members of Massachusetts-based employer groups and non-group plans[2]:

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.

Members of Rhode Island-based employer groups[3]:

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.
- Experimental or investigational services, drugs or items that are being investigated as an objective within the trial.

AUTHORIZATION/NOTIFICATION REQUIREMENTS

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.

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[1] Commercial products include HMO, POS, PPO, Tufts Health Freedom Plan, and CareLink℠ when Tufts Health Plan is the primary administrator.
[2] Massachusetts General Law (M.G.L), Chapter 175: Section 100L Clinical Trials
[3] M.G.L. Chapter: 257 of the Acts of 2002

BILLING INSTRUCTIONS

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.

DOCUMENT HISTORY

- 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 an office/facility did not comply with this payment policy, Tufts Health Plan will expect the office/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 CareLink℠ 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.