# Clinical Trials Payment Policy

Applies to the following Tufts Health Public Plans products:

☒Tufts Health Direct – Health Connector

☒Tufts Health RITogether – A RI Medicaid Plan

☒Tufts Health Together – Includes MassHealth Plan and Accountable Care Partnership Plans

☒Tufts Health Unify – OneCare Plan

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The following payment policy applies to Tufts Health Plan contracting providers who render services for Tufts Health Public Plans products.

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

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.

Tufts Health Plan covers routine costs for in-network services rendered during qualified clinical trials, in accordance with state and federal mandates for coverage.

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

## DEFINITION

A clinical trial is a prospective biomedical or health-related research study of human subjects designed to test new methods of screening, prevention, diagnosis, or treatment of disease. These studies are conducted by physicians and other health professionals in a controlled environment to help determine the safety and efficacy of biological products, devices, drugs, medical treatments, procedures, or therapies to improve health.

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

Routine, medically necessary services covered by the member's plan, are covered whether or not the services are related to 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

Tufts Health Plan recommends not billing the member for the coinsurance and/or deductible amount until the claim has processed so that the appropriate member responsibility can be determined. Both the provider's explanation of payment (EOP) and the electronic remittance advice (ERA) will reflect the member's responsibility amount. Refer to the medical and behavioral health benefit summary grids for additional information on covered services, deductibles, co-payments, or co-insurance.

## AUTHORIZATION/NOTIFICATION REQUIREMENTS

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

## 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.

Providers can bill for services rendered during a qualified clinical trial on a UB04 form using the appropriate CPT and HCPCS codes and modifiers. Providers may submit changes via HIPAA-compliant electronic formats.

Providers should use the ICD-10 code Z00.6 in conjunction with the primary ICD-10 diagnosis code when billing for inpatient or outpatient claims for services rendered during qualified clinical trials.

Tufts Health Plan does not routinely compensate any clinical trial procedure billed with modifier Q0 (investigational clinical service provided in a clinical research study that is in an approved clinical research study) or Q1 (routine clinical service provided in a clinical research study that is in an approved clinical research study) unless the required diagnosis to indicate participation in a clinical trial or research study is present on the claim.

Refer to the Clinical Trials: Routine Costs Medical Necessity Guidelines for a list of billable modifiers.

## ADDITIONAL RESOURCES

- CMS NCD 310.1

## DOCUMENT HISTORY

- September 2020: Added claim edits for modifiers Q0 and Q1 and removed from THPP Claim Edits grid
- July 2020: Updated general benefit information and billing instructions boiler plate language
- August 2018: Updated to reflect that prior authorization is not required for services rendered during qualified clinical trials; updated definition; removed modifiers and revenue codes; created one policy for all Public Plans products
- March 2018: Template updates
- February 2017: Template updates

## 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 your office/facility did not comply with this payment policy, Tufts Health Plan will expect your office/facility to refund all payments related to non-compliance. For more information about Tufts Health Plan's audit policies, refer to our 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.