Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Clinical Trials: Routine Costs

Effective: April 1, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☐ No ☒
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816

☒ Tufts Health Plan Commercial products; 617-972-9409

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055

☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404

☒ Tufts Health One Care – A dual-eligible product; 857-304-6304

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; 866-874-0857

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

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 a 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.

Clinical trials are conducted in phases that help answer different scientific questions.

- **Phase I trials** test a new drug or treatment for the first time to evaluate safety in a very small group of people.
- **Phase II trials** study an experimental drug or treatment to determine its effectiveness and further evaluate safety in a large group of people.
- **Phase III trials** confirm the drug or treatment effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely in larger groups of people
- **Phase IV trials** are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

Effective January 1, 2014, in accordance with Section 2709 of the Patient Protection and Affordable Care Act (ACA), the plan will provide coverage for 'routine costs' when a Member is a 'qualified individual' enrolled in an 'approved clinical trial':

- In general, routine patient costs for a qualified individual participating in a qualified clinical trial include all items and

services consistent with coverage that a Member would be eligible for if not enrolled in a clinical trial.

- A 'qualified individual' is someone who is eligible to participate in an 'approved clinical trial' according to the trial protocol and either the individual's doctor has concluded that participation is appropriate, or the participant provides medical and scientific information establishing that their participation is appropriate.
- An 'approved clinical trial' is a phase I, phase II, phase III or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition. A life-threatening disease or condition is defined as any disease or condition from which the likelihood of death is probable, unless the course of the disease or condition is interrupted.

There are several types of clinical trials that are eligible for coverage of routine costs:

1. Trials approved or funded by the:
    - National Institutes of Health (NIH)
    - Centers for Disease Control and Prevention (CDC)
    - Agency for Health Care Research & Quality (AHRQ)
    - Centers for Medicare & Medicaid Services (CMS)
2. Trials approved or funded by the below entities when the trial has been reviewed and approved through a system or peer review that the Secretary of Health and Human Services determines is comparable to the peer review system used by the NIH and assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review:
    - Department of Defense (DoD)
    - Department of Veteran Affairs (VA)
    - Department of Energy (DOE)
3. Trials approved or funded by centers or cooperative groups of the NIH, CDC, AHRQ, CMS, DOD, and/or VA.
4. Trials conducted under an investigational new drug application (IND) reviewed by the Food and Drug Administration.
5. Phase II, III, or IV clinical trials approved by a qualified institutional review board (IRB).

Clinical Guideline Coverage Criteria

PRIOR AUTHORIZATION IS NOT REQUIRED: Providers will not routinely be required to submit documentation about the clinical trial to the plan. However, documentation may be requested at any time to confirm that the trial meets current standards referenced below:

The 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.

Routine costs include:

1. Items or services typically provided absent a clinical trial (e.g., conventional care)
2. Items or services solely for the provision of the investigational item or service that are not statutorily excluded from coverage (e.g., cosmetic surgery)
3. Clinical monitoring for the effects of the investigational item or service
4. Prevention and management of complications
5. Items or services for reasonable and necessary care that may occur from the provision of an investigational service or item
6. For Massachusetts products only, in addition to the above, the actual costs of the device or drug used in a clinical trial that is intended to treat cancer in a patient who has been so diagnosed, when it is not paid for by the manufacturer, distributer, or provider of the drug/device[5]

Note: Point32Health supports inclusive enrollment of diverse populations in clinical trials.

Limitations

Routine costs do not include:

1. For Massachusetts products: the actual costs of the investigational, drug or device when paid for by the manufacturer, distributer, or provider of the drug/device[5]
2. For Rhode Island products: the investigational item, device, or service itself is not covered-regardless of manufacturer, distributor, or provider of the drug/device payment or nonpayment
3. For New Hampshire products: the cost of the investigational new drug or device that is not approved for market for any indication by the FDA[7]

4. Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the Member
5. Any item, service, or cost that is reimbursed or provided by the sponsors of the clinical trial
6. Non-health care services that a Member may receive as a result of being enrolled in the qualified clinical trial
7. A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis
8. Services or costs that are **not** covered under the Member's Evidence of Coverage (EOC)

Codes

The following code(s) are associated with this service:

Table 1: Modifier Codes

Table 1 contains modifiers 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.

Code	Description
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

*Note: Use for professional and facility outpatient claims.

Table 2: ICD-10 Code(s)

Table 2 contains the diagnosis code that must be reported with the primary ICD-10-CM diagnosis code consistent with the clinical trial indication.

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

Note: Use for professional, facility outpatient, and/or facility inpatient claims.

References:

1. Centers for Medicare and Medicaid Services. NCD Routine Costs in Clinical Trials (A49286). Medicare Coverage Database. Medicare Clinical Trial Policies | CMS. Effective date May 27, 2024. Accessed January 9, 2025.
2. Centers for Medicare & Medicaid Services. LCD for Clinical Trials (A52840). Medicare Coverage Database. Clinical Trials – Medical Policy Article (A52840) (cms.gov). Effective date October 1, 2015. Accessed January 9, 2025.
3. ClnicalTrials.gov website. Learn about clinical studies. https://clinicaltrials.gov/ct2/aboutstudies/learn#ClinicalTrials. Bethesda: U.S. National Library of Medicine. Accessed January 9, 2025.
4. The Patient Protection and Affordable Care Act (PPACA), Sec. 2709. March 23, 2010. Affordable Care Act, Health Care Law | HealthCare.gov. Accessed January 9, 2025.
5. Massachusetts General Law (M.G.L), Chapter 175: Section 110L Clinical Trials; definitions; coverage. General Law - Part I, Title XXII, Chapter 175, Section 110L (malegislature.gov). Accessed January 9, 2025.
6. Medicare Benefit Policy Manual, Chapter 14 - Medical Devices. § 20.2 Category B; http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.html. Accessed Jan 9, 2025.
7. New Hampshire General Law NH Rev Stat § 415:18-l Coverage Required for Qualified Clinical Trails. New Hampshire Revised Statutes Section 415:18-l (2023) - Coverage Required for Qualified Clinical Trials. :: 2023 New Hampshire Revised Statutes :: US Codes and Statutes :: US Law :: Justia, 2023.
8. Rhode Island General Law (RIGL) 27-20-60 Rhode Island General Law (RIGL) 27-20-60 Coverage for individuals participating in approved clinical trials. http://webserver.rilin.state.ri.us/Statutes/title27/27-20/27-20-60.HTM. Accessed January 9, 2025.
9. U.S. National Library of Medicine. National Institutes of Health. Clinical trial phases. Phases of Clinical Trials (nih.gov). Accessed January 9, 2025.

Approval And Revision History

October 21, 2020: Reviewed by IMPAC, renewed without changes

Subsequent endorsement date(s) and changes made:

- November 24, 2020: Fax number for Unify updated
- December 21, 2021: Reviewed by Medical Policy Approval Committee (MPAC), renewed without changes
- February 17, 2022: Freedom removed from template
- April 20, 2022: Reviewed by MPAC for integration purposes between Harvard Pilgrim Health Care and Tufts Health Plan with an effective date of June 1, 2022; added note for “Point32Health supports inclusive enrollment of diverse populations in clinical trials”.
- December 1, 2022: Reviewed by MPAC, renewed without changes
- June 21, 2023: Reviewed by MPAC, renewed without changes
- November 2023: Unify name changed to One Care effective January 1, 2024
- October 17, 2024: Reviewed by MPAC, renewed without changes effective December 1, 2024
- February 19, 2025: Reviewed by MPAC, clarified that Massachusetts requirements only apply to clinical trials intended to treat cancer and under Limitations, added new limitation for New Hampshire, effective April 1, 2025

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.