Harvard Pilgrim Health Care | TUFTS Health Plan

Point32Health companies

Medical Necessity Guidelines:

Genetic and Molecular Diagnostic Testing for Tufts Health Direct, Tufts Health Together, Tufts Health RITogether, and Tufts Health One Care

Effective: November 4, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation (electronically recommended or by fax)	Yes ☒ No ☐
Notification Required (Concurrent review may be required)	Yes ☐ No ☒

Applies to:

- Tufts Health Direct
- Tufts Health Together
- Tufts Health RITogether
- Tufts Health One Care

We recommend submitting prior authorization electronically. If you opt to submit prior authorization requests via fax, please refer to this reference chart for the appropriate fax number (varies by product).
For details on all our products, please visit the Our Plans page on our provider website. For additional Prior Authorization and Notification details on other lines of business not listed on our Medical Necessity Guidelines page, please also reference our Prior Authorization Resources page.

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

Genetic and molecular diagnostic testing is managed by Carelon Medical Benefits Management (Carelon). The Plan requires providers to obtain prior authorization for genetic and molecular testing through Carelon for members of Tufts Health Public Plans.

Ordering providers should contact Carelon to request clinical appropriateness review and obtain an authorization on or prior to the sample collection date and before scheduling or performing any genetic testing services. Failure to notify Carelon in advance of a service that requires prior authorization will result in payment denial. In this scenario, members may not be balance billed and are responsible only for their applicable copayments, and/or coinsurance.

Ordering providers may submit authorization review requests online 24/7 at www.providerportal.com or by phone by calling Carelon toll-free at: 833-342-1255 (Mon.– Fri., 8 a.m.– 5 p.m. EST).

HLA typing (CPT 81370-81383) continues to require prior authorization and is managed by Tufts Health Plan Precertification Dept. Refer to Medical Necessity Guidelines: HLA Genotyping for Tufts Health Direct, Tufts Health Together, Tufts Health RITogether, Tufts Health One Care.

Clinical Guideline Coverage Criteria

Using evidence-based criteria and guidelines, Carelon will review coverage requests and provide authorizations for genetic and molecular diagnostic testing. Refer to Carelon Clinical Appropriateness Guidelines for Genetic Testing and their associated codes at: https://providers.carelonmedicalbenefitsmanagement.com/point32health/

The following Genetic and Molecular Diagnostic services are included in the program:

- Reproductive Carrier Screening and Prenatal Diagnosis

- Preimplantation Genetic Testing, including embryo biopsy (CPT 89290,89291)
- Testing for Single-Gene and Multifactorial Conditions
- Chromosomal Microarray Analysis, Whole Exome Sequencing, and Whole Genome Sequencing
- Hereditary Cancer Susceptibility Testing
- Hereditary Cardiac Disease Testing
- Molecular Testing of Solid and Hematologic Tumors and Malignancies (Including tumor markers)
- Pharmacogenetic Testing

NOTE: For Tufts Health Direct, Tufts Health Together and Tufts Health RITogether members, refer to Medical Necessity Guidelines: Comprehensive Genomic Profiling with FoundationOne®CDx or FoundationOne®Liquid CDx to Guide Cancer Treatment in Patients with Advanced Cancer for Clinical Coverage Criteria used for FoundationOne CDx and FoundationOne Liquid CDx prior authorization requests. cgp-w-foundation-one (tuftshealthplan.com)

Genetic Counseling is not required for genetic testing authorization, with the exception of Whole Genome Sequencing (CPT 81425, 81426, 81427).

NOTE: For **Tufts Health RITogether only**, the following tests are covered with prior authorization when criteria is met. Submit request for authorization to Tufts Health Plan Precertification Department (Fax: 857.304.6304):

CPT 81538 (e.g., VeriStrat)

Predictive testing is considered medically necessary when member is a candidate for erlotinib therapy, and the following criteria are met:

1. The Member has confirmed diagnosis stage IIIB or stage IV nonsquamous non-small cell lung cancer (NSCLC); and
2. Wild-type EGFR negative, or EGFR mutation status is a tested unknown; and
3. The Member has disease progression after chemotherapy; and
4. The Member has ECOG performance status 0-2.

Limitation: VeriStrat test is covered ONCE per year

CPT 81539 (e.g., 4Kscore)

Testing is considered medically necessary when **ONE** of the following criteria are met:

1. The Member is:
    a. Member is 40 through 75 years of age; and
    b. Member is considered high risk (e.g., known or suspected germline mutation(s) in prostate cancer, including but not limited to BRCA2, BRCA1, ATM, CHEK2, PALB2, HOXB13, MLH1, MSH2, MSH6, PMS2, EPCAM, and TP53, personal and/or family cancer history that increases risk for prostate cancer, Black ethnicity, African American ethnicity); and
    c. Documentation of PSA >3 ng/mL, and/or very suspicious digital rectal exam (DRE) (e.g., nodules, induration, or asymmetry).
2. The Member is:
    a. Member is 76 to 80 years of age; and
    b. Documentation of PSA ≥4 ng/mL and/or very suspicious DRE (e.g., nodules, induration, or asymmetry)

Limitation: 4Kscore test is covered ONCE per year

CPT 0174U (e.g., LC-MS/MS Targeted Proteomic Assay) is considered medically necessary when the following criteria are met:

1. Member is a candidate for an FDA approved targeted therapy and the requested test is of proven clinical validity/utility to:
    a. Predict member response to the planned targeted therapy; or
    b. Identify contraindications or exclusions related to planned targeted therapy.

CPT 0490U, 0491U, 0492U, and 0513U (biomarker testing)

Testing is considered medically necessary when the test result will provide information that will be used to create a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision-making process. This efficacy test must be supported by medical and scientific evidence.

Documentation must include the following:

1. A face-to-face visit with the ordering healthcare professional within 30 days of submitting the request; **or**
2. Documentation that testing has been recommended by a Tumor Board or consulting specialist.

AND

3. The test result is needed to determine the appropriate treatment plan for the beneficiary; **or**
4. The test will confirm or rule out a diagnosis; **or**
5. The test result is needed to prevent, diagnose, monitor, or treat complications resulting from participation in a clinical trial.

NOTE: Requests for biomarker testing that is subject of a clinical trial or experimental protocol will be denied.

NOTE: For **Tufts Health Together and Tufts Health OneCare only,** the following tests are covered with prior authorization when the following criteria is met.

CPT 81514, 81515, 82233, 82234, 83884, 84393, 84394, 86581, 87513, 87564, 87594, 87626, 81335

Testing is considered medically necessary when the test result will provide information that will be used to create a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision-making process. This efficacy test must be supported by medical and scientific evidence.

Documentation must include the following:

1. A face-to-face visit with the ordering healthcare professional within 30 days of submitting the request; **or**
2. Documentation that testing has been recommended by a consulting specialist.

AND

3. The test result is needed to determine the appropriate treatment plan for the Member; **or**
4. The test will confirm or rule out a diagnosis; **or**
5. The test result is needed to prevent, diagnose, monitor, or treat complications resulting from participation in a clinical trial.

Limitations

The Plan will not cover genetic and molecular tests whose clinical utility is scientifically unproven. Refer to the Medical Necessity Guidelines: Noncovered Investigational Services.

Codes

As noted above, for a list of genetic testing CPT and HCPCS codes managed by Carelon, please refer to the Carelon Clinical Appropriateness Guidelines for Genetic Testing at:
https://providers.carelonmedicalbenefitsmanagement.com/point32health/

References:

1. Massachusetts Session Laws, Chapter 186 of the Acts of 2024, An Act Promoting Access To Midwifery Care And Out-Of-Hospital Birth Options (effective November 21, 2024). Available at: https://malegislature.gov/Laws/SessionLaws/Acts/2024/Chapter186. Last accessed December 4, 2024.
2. The Commonwealth of Massachusetts. MassHealth Independent Clinical Laboratory Manual. Subchapter 6: Service Codes. Transmittal Letter LAB-57. November 21, 2024.
3. 4Kscore Prostate Cancer Testing | BioReference Laboratories. Accessed April 17, 2023.
4. Gadgeel S, Goss G, Soria JC, et al. Evaluation of the VeriStrat® serum protein test in patients with advanced squamous cell carcinoma of the lung treated with second-line afatinib or erlotinib in the phase III LUX-Lung 8 study. *Lung Cancer*. 2017;109:101-108. doi:10.1016/j.lungcan.2017.05.010
5. Carbone DP, Salmon JS, Billheimer D, et al. VeriStrat classifier for survival and time to progression in non-small cell lung cancer (NSCLC) patients treated with erlotinib and bevacizumab. *Lung Cancer*. 2010;69(3):337-340. doi:10.1016/j.lungcan.2009.11.019
6. Rich P, Mitchell RB, Schaefer E, et al. Real-world performance of blood-based proteomic profiling in first-line immunotherapy treatment in advanced stage non-small cell lung cancer. *J Immunother Cancer*. 2021;9(10):e002989. doi:10.1136/jitc-2021-002989
7. Grossi F, Rijavec E, Genova C, et al. Serum proteomic test in advanced non-squamous non-small cell lung cancer treated in first line with standard chemotherapy. *Br J Cancer*. 2017;116(1):36-43. doi:10.1038/bjc.2016.387
8. National Comprehensive Cancer Network, NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines); Non-Small Cell Lung Cancer. (Version 7.2025). July 10, 2025. Accessed September 1, 2025.

https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
9. NCCN Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia. (Version 2.2025). January 27, 2025. Accessed September 1, 2025. https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf .

Approval And Revision History

July 20, 2022: Reviewed by Medical Policy Approval Committee (MPAC). Effective October 1, 2022, AIM Specialty Health® (AIM) will oversee medical necessity review for Tufts Health Public Plans.

Subsequent endorsement date(s) and changes made:

- November 16, 2022: Reviewed at MPAC. Effective 2/12/23, refer to Comprehensive Genomic Profiling with FoundationOne CDx™ or FoundationOne Liquid CDx to Guide Cancer Treatment in Patients with Advanced Cancer MNG for clinical coverage criteria applicable to TH Direct, TH Together and TH RITogether.
- December 28, 2022: Coding updated. Per AMA CPT®, effective January 1, 2023 the following code(s) added: 81418, 81441, 81449, 81451, 81456, 0355U, 0356U, 0362U, 0363U.
- February 3, 2023: Effective March 1, 2023, refer to Medical Necessity Guidelines: Comprehensive Genomic Profiling with FoundationOne CDx™ or FoundationOne Liquid CDx to Guide Cancer Treatment in Patients with Advanced Cancer for clinical coverage criteria applicable to Tufts Health Direct, Tufts Health Together and Tufts Health RITogether.
- April 1, 2023. Per AMA CPT®, effective April 1, 2023 the following code(s) added:0364U, 0368U, 0378U, 0379U, 0380U.
- April 19, 2023: Reviewed at MPAC. CPT codes 81538, 81539 and 0174U covered with prior authorization, RITogether only.
- June 21, 2023: Reviewed by MPAC. Prior authorization for chimerism (CPT 81267, 81268) removed, effective August 1, 2023
- July 1, 2023. Per AMA CPT®, effective July 1, 2023 the following code(s) added: 0388U, 0389U, 0391U, 0392U, 0396U, 0397U, 0400U, 0401U.
- July 19, 2023: Reviewed by MPAC; renewed without changes.
- October 1, 2023. Per AMA CPT®, effective October 1, 2023 the following code(s) added: 0403U, 0405U, 0409U, 0410U, 0411U, 0413U, 0414U, 0417U, 0419U.
- October 18, 2023: Reviewed by MPAC, renewed without changes.
- November 2023: Unify name changed to One Care effective January 1, 2024
- December 1, 2023: Reviewed and approved by the UM Committee, effective January 1, 2024
- January 1, 2024: Coding updated per AMA CPT, effective January 1, 2024, the following code(s) added: 81457, 81458, 81459, 81462, 81463, 81464.
- March 29, 2024: Coding updated per AMA CPT, effective April 1, 2024, the following codes added, 0448U, 0449U, 0439U, 0440U, 0441U, 0444U, 0445U, 0446U, & 0447U.
- June 13, 2024: Reviewed and approved by the UM Committee, effective July 1, 2024
- June 29, 2024: Coding updated per AMA CPT, codes 0471U added effective July 1, 2024
- September 30, 2024: Coding updated per AMA CPT, effective October 1, 2024, the following code(s) added: 0476U, 0477U, 0478U, O481U, 0485U, 0486U, 0487U, 0488U, 0489U, 0493U, 0494U, 0496U, 0497U, 0498U, 0499U, 0500U, 0506U, 0507U, 0508U, 0509U, and 0516U.
- December 18, 2024: Reviewed by MPAC. Prior authorization (CPT 81420) removed for Tufts Health Together and Tufts Health One Care effective November 21, 2024. Biomarker criteria added for Tufts Health RITogether to comply with Rhode Island mandate. The following codes added: 0490U, 0941U, 0942U, 0513U. References updated. Effective April 1, 2025.
- May 30, 2025: Coding updated per AMA CPT®, effective July 1, 2025, the following codes added: 0552U and 0554U. Harvard Pilgrim Health Care Stride Medicare Advantage removed as an applicable product from the template.
- August 20, 2025: Reviewed by MPAC. Per EOHHS mandate, criteria and prior authorization for Tufts Health Together and Tufts Health One Care added to codes 81514, 81515, 82233, 82234, 83884, 84393,84394, 86581, 87513, 87564, 87626, and 81335. Also, removed coding chart in back of guideline and added instructions to access Carelon for coding and criteria information. Effective date December 1, 2025.
- September 5, 2025: Fax number for Senior Care Options, Tufts Medicare Preferred HMO and Tufts Medicare Preferred PPO updated; language for Carelink removed.
- September 17, 2025. Reviewed by MPAC, annual review no changes, effective November 1, 2025. References updated.
- October 21, 2026: Reviewed by MPAC, annual review no changes, effective November 4, 2026. Administrative update, template updated.

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.