Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Guardant360 CDx

Effective: November 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

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 Plan-- A dual-eligible product; 857-304-6304

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-972-9409
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-972-9409
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-972-9409

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

Guardant360 CDx is a liquid biopsy test that analyzes circulating tumor DNA (ctDNA) from the blood sample of an individual with advanced solid tumor. Guardant CDx is an FDA-approved companion diagnostic test used to identify actionable biomarker(s) to allow informed treatment decision regarding the benefit of related FDA-approved targeted therapies.

All genetic testing requires prior authorization. Refer to the following Medical Necessity Guidelines for genetic/molecular diagnostic testing not addressed within this guideline:

- Comprehensive Genomic Profiling with FoundationOne® CDx or FoundationOne® Liquid CDx to Guide Cancer Treatment in Patients with Advanced Cancer
- Breast Cancer Index
- Genetic and Molecular Diagnostic Testing
- Genetic and Molecular Diagnostic Testing for Tufts Health Direct, Tufts Health Together, Tufts Health RITogether, Tufts Health One Care
- Genetic Testing: BRCA1 and BRCA2; Hereditary Breast, Ovarian and Pancreatic Cancer
- Genetic Testing: Cell-Free DNA Screening for Fetal Trisomy
- Genetic Testing: Gene Expression for Cancer of Unknown Primary
- Genetic Testing: Prenatal Diagnosis, Carrier Screening
- Human Leukocyte Antigen Genotyping
- Human Leukocyte Antigen Genotyping for Tufts Health Direct, Tufts Health Together, Tufts Health RITogether, Tufts Health One Care
- Preimplantation Genetic Testing (PGT)

Clinical Guideline Coverage Criteria

The Plan may authorize Guardant 360 CDx testing for non-small cell lung cancer (NSCLC) or breast cancer in the initial diagnostic setting when **ALL** the following criteria are met:

1. Pathologic confirmation of locally advanced or metastatic NSCLC or breast cancer; **and**
2. Member has not had previous somatic testing that may have identified the genetic variant required to prescribe medication under consideration; **and**
3. Guardant 360 CDx is FDA-approved companion diagnostic test for medication being considered and testing is required per FDA drug label indications; **and**
4. Tumor biopsy cannot be obtained (e.g., the Member is not medically fit for invasive sampling) **or** tissue obtained with biopsy is insufficient for molecular analysis to identify/assess recommended biomarkers.

Limitations

The Plan will not cover:

1. CDx 360 for indications not listed in Clinical Coverage Criteria
2. Circulating tumor DNA testing should not be used in lieu of histologic tissue testing when criteria above is not met.
3. ctDNA testing is not medically necessary when the Member meets criteria for treatment being considered without the need for additional testing (e.g., individual meets criteria based on known genetic results or biomarker status is not required.

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

Code	Description
0242U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements

References:

1. Leighl NB, Page RD, Raymond VM, et al. Clinical Utility of Comprehensive Cell-free DNA Analysis to Identify Genomic Biomarkers in Patients with Newly Diagnosed Metastatic Non-small Cell Lung Cancer. *Clin Cancer Res*. 2019;25(15):4691-4700. doi:10.1158/1078-0432.CCR-19-0624.
2. Palmero R, Taus A, Viteri S, et al. Biomarker Discovery and Outcomes for Comprehensive Cell-Free Circulating Tumor DNA Versus Standard-of-Care Tissue Testing in Advanced Non-Small-Cell Lung Cancer. *JCO Precis Oncol*. 2021;5:93-102. doi:10.1200/PO.20.00241.
3. Aggarwal C, Thompson JC, Black TA, et al. Clinical Implications of Plasma-Based Genotyping With the Delivery of Personalized Therapy in Metastatic Non-Small Cell Lung Cancer. *JAMA Oncol*. 2019;5(2):173-180. doi:10.1001/jamaoncol.2018.4305.
4. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Accessed September 1, 2025. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools) | FDA.
5. Gray J, Thompson JC, Carpenter EL, Elkhouly E, Aggarwal C. Plasma Cell-Free DNA Genotyping: From an Emerging Concept to a Standard-of-Care Tool in Metastatic Non-Small Cell Lung Cancer. *Oncologist*. 2021;26(10):e1812-e1821. doi:10.1002/onco.13889.
6. NCCN Clinical Practice Guidelines in Oncology. 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.
7. Bidard FC, Kaklamani VG, Neven P, et al. Elacestrant (oral selective estrogen receptor degrader) Versus Standard Endocrine Therapy for Estrogen Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative Advanced Breast Cancer: Results From the Randomized Phase III EMERALD Trial. *J Clin Oncol*. 2022;40(28):3246-3256. doi:10.1200/JCO.22.00338
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9. National Comprehensive Cancer Network, NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines); Breast Cancer, (Version 4. 2025). April 17, 2025. Accessed September 1, 2025. breast.pdf (nccn.org).
10. Overview of the approach to metastatic breast cancer. UpToDate.com/login [via subscription only]. Published

February 7, 2025. Accessed August 21, 2025.
11. Personalized, genotype-directed therapy for advanced non-small cell lung cancer. UpToDate.com/login [via subscription only]. Published August 19, 2025. Accessed August 21, 2025.
12. Sorbini M, Carradori T, Togliatto GM, Vaisitti T, Deaglio S. Technical Advances in Circulating Cell-Free DNA Detection and Analysis for Personalized Medicine in Patients' Care. Biomolecules. 2024 Apr 19;14(4):498. doi: 10.3390/biom14040498. PMID: 38672514; PMCID: PMC11048502.
13. Carr DJ, Welch HG. Assessing the Clinical Utility of Liquid Biopsies Across 5 Potential Indications From Therapy Selection to Population Screening: A Review. JAMA Intern Med. 2023 Oct 1;183(10):1144-1151. doi: 10.1001/jamainternmed.2023.3603. PMID: 37639262.
14. Choucair K, et. al. Liquid Biopsy-based Precision Therapy in Patients with Advanced Solid Tumors: A Real-world Experience from a Community-based Oncology Practice. Oncologist. 2022 Mar 11;27(3):183-190. doi: 10.1093/oncolo/oyac007. PMID: 35274713; PMCID: PMC8914479.
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Approval And Revision History

August 10, 2022: Reviewed by the Medical Policy Approval Committee (MPAC).

Subsequent dates and changes made:

- December 21, 2022: Reviewed by MPAC, renewed without changes.
- June 21, 2023: Reviewed by MPAC. Added breast cancer indication for testing, effective August 1, 2023
- November 16, 2023: Reviewed by MPAC, renewed without changes.
- November 2023: Rebranded Unify to One Care
- October 2, 2024: Administrative update.
- November 21, 2024: Reviewed by MPAC, renewed without changes, effective January 1, 2025.
- September 17, 2025. Reviewed by MPAC, annual review no changes, effective November 1, 2025. References updated.
- October 21, 2025: Fax number for Senior Care Options, Tufts Medicare Preferred HMO and Tufts Medicare Preferred PPO updated; language for Carelink removed; Harvard Pilgrim Health Care Stride Medicare Advantage removed as an applicable product from the template

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.