Medical Necessity Guidelines: Guardant360 CDx

Effective: August 1, 2023

Prior Authorization Required
If REQUIRED, submit supporting clinical documentation pertinent to service request.

Applies to:

COMMERCIAL Products
☒ Tufts Health Plan Commercial products; Fax: 617.972.9409
• CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

TUFTS HEALTH PUBLIC PLANS Products
☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404
☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

SENIOR Products
• Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List
• Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

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 Unify
- 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 Unify
- Preimplantation Genetic Testing (PGT)
CLINICAL COVERAGE CRITERIA

The Plan may authorize Guardant 360 CDx testing for non-small cell lung cancer (NSCLC) 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:

- CDx 360 for indications not listed in Clinical Coverage Criteria
- Circulating tumor DNA testing should not be used in lieu of histologic tissue testing when criteria above is not met
- 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 CPT code(s) require prior authorization:

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0242U</td>
<td>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</td>
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REFERENCES

4. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools) accessed May 22, 2023. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools) | FDA.

**APPROVAL 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

**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.

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.

[Provider Services]