Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines: **Comprehensive Genomic Profiling with FoundationOne® CDx or FoundationOne® Liquid CDx to Guide Cancer Treatment in Patients with Advanced Cancer**

Effective: March 1, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products;
☒ Tufts Health Plan Commercial products;
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);
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans;
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan;
☐ Tufts Health Unify* – OneCare Plan (a dual-eligible product);
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage;
☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product);
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product);
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product);

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

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

Overview

Advances in the understanding of the molecular basis of cancer over the past two decades have led to the development of therapies approved to treat cancers harboring specific genomic biomarkers.[1-2] As a result, precision oncology, the use of molecular biomarkers to aid in the diagnosis, prognosis or treatment of cancer, is now possible for multiple types of tumors.[3] Additionally, improvements in next-generation sequencing (NGS), a technology that enables massively parallel DNA sequencing, have led to the development of multi-gene panels. Gene panels can include only the most critical, clinically relevant portions of genes or can be comprehensive, containing coding and non-coding regions of genes, and even gene fusion detection.[4]

Comprehensive Genomic Profiling (CGP) refers to NGS-based molecular assays that provide additional insight beyond individual gene hotspots; CGP assays can help characterize the underlying mechanisms of disease and may identify genomically-matched treatment options such as a targeted therapy or immunotherapy. CGP typically involves sequencing of entire exonic regions of genes of interest (within a comprehensive gene panel or whole exome sequencing) and may also include selected intronic regions. CGP can detect multiple types of molecular alterations (i.e., single nucleotide variants (SNVs), small and large insertion and deletion mutations (INDELs), copy number alterations (CNAs), structural variants (SVs) and splice-site variants) in a single assay, and may be used to calculate microsatellite instability (MSI) status and tumor mutational burden (TMB).[4-5] In addition to guiding treatment selection, CGP may optimize clinical management by excluding the use of ineffective therapies,[6-8] determining eligibility for clinical trials for genomically-matched and biomarker-driven therapies[7,9] and by informing diagnosis and/or prognosis.[10-13] Given the rapid evolution of the field of precision

oncology, and the need to efficiently identify an optimal treatment plan, there is increasing support for an expanded, broad or comprehensive approach to molecular or genomic profiling for a growing number of advanced solid tumors.[3, 14-21]

Although tissue-based testing is considered the gold-standard approach to molecular testing, tissue may not always be available or feasible to obtain. When comparing tissue and liquid biopsy, there are considerations that may factor into clinical decision-making such as: when the tissue specimen is exhausted from prior testing, patient preference to avoid (or contraindication for) a repeat invasive biopsy, patient progression on therapy, and lack of an available biopsy site to obtain an adequate sample for testing. A number of NCCN Guidelines recommend liquid biopsy (plasma) testing in certain clinical circumstances.[14-15, 18-20, 22-25] Because studies have shown substantial concordance between cell free DNA (cfDNA)-based testing and tumor testing, in patients without tissue-based genomic test results, treatment may be based on actionable alterations identified in cfDNA.[3]

FoundationOne®CDx is a qualitative next-generation sequencing based *in vitro* diagnostic test that uses targeted high throughput hybridization-based capture technology for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor tissue specimens.[26]

FoundationOne® Liquid CDx is a qualitative next generation sequencing based *in vitro* diagnostic test that uses targeted high throughput hybridization-based capture technology to detect and report substitutions, insertions and deletions (indels) in 311 genes, rearrangements in four (4) genes and copy number alterations in three (3) genes. FoundationOne Liquid CDx utilizes circulating cell-free DNA (cfDNA) isolated from plasma derived from anti-coagulated peripheral whole blood of cancer patients collected in FoundationOne Liquid CDx cfDNA blood collection tubes included in the FoundationOne Liquid CDx Blood Sample Collection Kit. [27]

For additional information, refer to U.S. Food & Drug Administration List of Cleared or Approved Companion Diagnostic Devices. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools) | FDA

NOTE: Genetic and molecular diagnostic testing requests for members of Harvard Pilgrim Health Care Commercial and Tufts Health Public Plans are managed by Carelon Medical Benefits Management (Carelon). 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). Clinical coverage criteria below applies to Harvard Pilgrim Health Plan and Tufts Health Plan products as listed above.

Clinical Guideline Coverage Criteria

FoundationOneCDx *or* FoundationOneLiquidCDx may be authorized when all the following criteria are met:

1. The Member has either recurrent, relapsed, refractory, metastatic, or any stage III or stage IV cancer; and
2. The Member has decided to seek further cancer treatment.

Limitations

- Tufts Health Plan will not cover both FoundationOneCDx **and** FoundationOneLiquidCDx in the same member for same primary cancer diagnosis.

Codes

The following code(s) require prior authorization:

Table 1: CPT Codes

HCPCS® Codes	Description
0037U	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
0239U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations

The following ICD-10-CM codes are covered when Clinical Coverage Criteria are met:
R11461OTN | CMS [cms.gov] (zip file and applicable PLA code tab)

References:

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Approval And Revision History

November 16, 2022: Reviewed by the Medical Policy Approval Committee (MPAC), effective January 1, 2023

Subsequent endorsements date(s) and changes made:

- December 21, 2022: Reviewed by MPAC, renewed without changes
- February 3, 2023: Effective March 1, 2023, MNG is applicable to Tufts Health Together, Tufts Health RITogether and Tufts Health Direct.

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.