Medical Necessity Guidelines: Genetic Testing: Gene Expression for Cancer of Unknown Primary (CUP)

Effective: October 21, 2020

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

Applies to:

COMMERCIAL Products

☒ Tufts Health Plan Commercial products; Fax: 617.972.9409

☒ Tufts Health Freedom Plan products; Fax: 617.972.9409

- CareLink℠ – 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

Gene expression testing for cancers of unknown primary (CUP) is used to aid in the diagnosis and treatment of metastatic cancers for which the site of primary remains uncertain or unknown after a complete medical work-up.

CLINICAL COVERAGE CRITERIA

Tufts Health Plan may authorize the coverage of a gene expression testing assay for CUP when the test is ordered by an oncologist and **ALL** of the following are met:

- The Member has the diagnosis of metastatic cancer
- Clinical evaluation has failed to identify the primary site (tissue of origin) of the cancer
- The pathology report is submitted to Tufts Health Plan for review
- Pathology examination of the tumor is not able to conclusively identify the primary site or has identified two or more possible primary sites

LIMITATIONS

Tufts Health Plan will not cover this test when used to confirm a diagnosis.

CODES

The following CPT/HCPCS codes require prior authorization:

Code	Description
81504	Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores (Pathwork® Tissue of Origin Test, Pathwork Diagnostics)

Code	Description
81540	Oncology (tumor of unknown origin), mRNA, gene expression profiling by real-time RT-PCR of 92 genes (87 content and 5 housekeeping) to classify tumor into main cancer type and subtype, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a probability of a predicted main cancer type and subtype (CancerTYPE ID, bioTheranostics, Inc.)
84999	Unlisted chemistry procedure (when used to describe a gene expression assay for cancer of unknown origin)

REFERENCES

1. Hayes, Inc. Pathwork® Tissue of Origin Test to Classify Cancer of Unknown Primary Origin. Hayes Genetic Test Evaluation. December 20, 2010
2. Hayes, Inc. Pathwork Tissue of Origin Test to Classify Cancer of Unknown Primary Origin. Hayes Genetic Test Evaluation. December 20, 2010 Update Search. December 5, 2011.
3. Laouri, M, Halks-Miller, M., Henner, D. & J Scott Nystrom. Potential clinical utility of gene-expression profiling in identifying tumors of uncertain origin. Personalized Medicine (2011)8(6), 615–622.
4. Hayes, Inc. CancerTYPE ID® (bioTheranostics Inc.) for Cancer of Unknown Primary (CUP). Hayes Genetic Test Evaluation. October 3, 2012.

APPROVAL HISTORY

July 11, 2012: Reviewed by the Integrated Medical Policy Advisory Committee for an effective date of October 1, 2012.

Subsequent endorsement date(s) and changes made:

- January 9, 2013: Reviewed by Integrated Medical Policy Advisory Committee (IMPAC), renewed without changes.
- April 24, 2013: Reviewed at Medical Technology Assessment Committee (MTAC); Subject name changed. Prior laboratory no longer available.
- January 1, 2014: New CPT code 81504 added
- September 30, 2014: Adopted by Tufts Health Plan – Network Health Commercial Plans and Tufts Health Plan – Network Health Medicaid Plans.
- November 19, 2014: Reviewed by IMPAC, renewed without changes
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- November 16, 2015: Reviewed by IMPAC, renewed without changes
- December 31, 2015: Coding updated. Per AMA CPT®, effective January 1, 2016 the following code(s) added: 81540
- November 9, 2016: Reviewed by IMPAC, renewed without changes
- December 14. 2016: Reviewed by IMPAC, renewed without changes
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- December 13, 2017: Reviewed by IMPAC, renewed without changes
- May 31, 2018: Code description updated
- September 12, 2018: Reviewed by IMPAC, renewed without changes
- October, 2018: Template and disclaimer updated
- September 18, 2019: Reviewed by IMPAC, renewed without changes
- October 16, 2019: Reviewed by IMPAC, renewed without changes
- September 16, 2020: Reviewed by IMPAC, renewed without changes
- September 24, 2020: Fax number for Unify updated
- October 21, 2020: Reviewed by IMPAC, renewed without changes

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.