Medical Necessity Guidelines:
Genetic Testing: Maternal Tests for Fetal Trisomy

Effective: September 16, 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

OVERVIEW

The human body has 23 distinct chromosome pairs or copies. Trisomy 21, 18 or 13 means there are three copies of either chromosome 21, 18 or 13, instead of two. Noninvasive prenatal laboratory testing analyzes circulating cell-free DNA from a maternal blood sample which detects increases of chromosome material associated with trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome), or trisomy 13 (Pateau syndrome); and, in some cases may eliminate the need for a more invasive test such as amniocentesis and chorionic villus sampling (CVS). Currently, noninvasive prenatal tests may be covered with contracting Laboratories using this Medical Necessity Guideline.

CLINICAL COVERAGE CRITERIA

Tufts Health Plan covers maternal blood sampling of cell-free fetal DNA testing for trisomy 21, 18, and 13 when the following criteria is met:

- I. Criterion A, B **or** C is met:
  A. The Member is of advanced maternal age, defined as age 35 or over at the time of delivery
  B. The Member has fetal aneuploidy screening test results including maternal serum screening (elevated free beta-hCG) and/or an ultrasound evaluation (nuchal translucency) indicating the possibility of trisomy 21, 18, or 13
  C. The Member has a family history or prior pregnancy involving fetal aneuploidy

AND

- II. There is documentation of genetic counseling by an MD geneticist, an independent board-certified genetic counselor or an MD of appropriate expertise.

LIMITATIONS

Tufts Health Plan will not cover testing that has not been proven to be effective, including:

- Cell-free fetal DNA testing for indications other than those listed in above clinical coverage criteria
- **Expanded** non-invasive prenatal testing (NIPT) panels; refer to the Noncovered Investigational Services list for additional information

CODES

The following CPT/HCPCS codes listed below may be used for this testing.

Codes	Description
81420	Fetal chromosomal aneuploidy (e.g., trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21
81507	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy

Note: For other prenatal genetic tests, refer to the Medical Necessity Guidelines for Genetic Testing: Prenatal, Preconception.

REFERENCES

1. Hayes, Inc. MaterniT21™ Noninvasive Prenatal Test for Trisomy 21 (Down Syndrome). Hayes Genetic Test Evaluation. December 22, 2011. Last accessed January 20, 2017.
2. Palomaki GE, Deciu C, Kloza EM, Lambert-Messerlian GM et al. DNA sequencing of maternal plasma reliably identifies trisomy 18 and trisomy 13 as well as Down syndrome: an international collaborative study. Genetics in Medicine. 2012 Mar; 14(3):296-305.
3. Palomaki GE, Kloza EM, Lambert-Messerlian GM. Et al. DNA sequencing of maternal plasma to detect Down syndrome: an international clinical validation study. Genetics in Medicine. 2011 Nov, 13(11):913-20.
4. Hayes, Inc. Noninvasive Prenatal Testing (NIPT) Hayes Genetic Test Evaluation. March, 5 2015. Last Accessed September 20, 2017.

APPROVAL HISTORY

July 11, 2012: Reviewed by the Integrated Medical Policy Advisory Committee (IMPAC) for effective date of October 1, 2012

Subsequent endorsement date(s) and changes made:

- November 28, 2012: Reviewed by IMPAC. The title of the Medical Necessity Guideline was changed from the former 'MaterniT21™ Plus' to 'Maternal Tests for Fetal Trisomy' as there are other tests such as Verifi™. Both are commercially available laboratory tests with companies Sequenom Center for Molecular Medicine and Verinata Health, Inc. respectively. These are currently contracted with Tufts Health Plan. In addition, a link was added for access to the Medical Necessity Guideline 'Genetic Testing: Prenatal, Preconception'.
- October 9, 2013: Reviewed by IMPAC, renewed without changes.
- December 11, 2013: Reviewed by IMPAC, prior authorization will no longer be required effective April 1, 2014. Coding updated with new CPT code 81507, effective January 1, 2014.
- August 1, 2014: The names of additional tests covered, when the guidelines of this Medical Necessity Guideline are met, were added for reference. Genetic Testing: Maternal Tests for Fetal Trisomy includes guidelines for the following tests: Harmony™ Prenatal Test, Panorama™ Prenatal Test, MaterniT21™ PLUS, and Verifi™Prenatal Test.
- September 30, 2014: Adopted by Tufts Health Plan – Network Health Commercial Plans and Tufts Health Plan – Network Health Medicaid Plans.
- October 8, 2014: Reviewed by IMPAC, renewed without changes.
- November 19, 2014: Reviewed by IMPAC, renewed without changes.
- December 31, 2014: Coding updated. Per AMA CPT®, effective January 1, 2015 the following CPT® code added: 81420.
- 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. Coverage Guidelines for documentation of genetic counseling added. CPT 84999 removed.
- 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.
- May 10, 2017: Reviewed by IMPAC, limitation added for 'Expanded Non-Invasive Prenatal Testing (NIPT)' including a link to the Noncovered Investigational List.

- October 11, 2017: Reviewed by IMPAC, renewed without changes
- December 13, 2017: Reviewed by IMPAC, renewed without changes
- July 25, 2018: Reviewed by IMPAC, renewed without changes
- September 12, 2018: Reviewed by IMPAC. Added genetic counseling by "an MD of appropriate expertise" to guidelines for documentation of genetic counseling.
- October 2018: Template and disclaimer updated
- July 17, 2019: Reviewed by IMPAC, renewed with no changes
- September 18, 2019: Reviewed by IMPAC, renewed without changes
- May 20, 2020: Reviewed at IMPAC. Limitation added, "Cell-free fetal DNA testing for indications other than those listed in clinical coverage criteria. Clarification to formatting.
- June 17, 2020: Reviewed by IMPAC, renewed without changes.
- June 26, 2020: Fax number for Unify updated.
- September 16, 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.