Medical Necessity Guidelines:
Genetic Testing: Cell-Free DNA Testing for Fetal Trisomy

Effective: November 1, 2022

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

- 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

The human body has 23 distinct chromosome pairs or copies. Trisomy 21, 18 or 13 means there are three copies of chromosome 21, 18 or 13, instead of two. Noninvasive prenatal laboratory testing analyzes circulating cell-free DNA (cfDNA) from a maternal blood sample and can detect increases of chromosome material associated with trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome) and 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). cfDNA testing may be used as a primary screening test or as a secondary screening test in pregnancies considered high-risk as a result of a previous ultrasound evaluation or serum screening test, a family history of aneuploidy, prior pregnancy involving fetal aneuploidy or a parent who carries a relevant Robertsonian translocation. Genetic counseling may benefit individuals who have an increased chance of having a child with trisomy anomaly. Currently, noninvasive prenatal tests may be covered with prior authorization when performed at a contracting laboratory.

CLINICAL COVERAGE CRITERIA

1. The Plan may authorize maternal blood sampling of cell-free fetal DNA testing for trisomy 21, 18, and 13 when the Member has a singleton or twin pregnancy; and

2. Documentation is provided by an MD geneticist, a licensed genetic counselor or a physician with expertise in genetic counseling (e.g. obstetrician) and supports the recommendation for testing based on a review of risk factors, clinical scenario and family history

Note: For prenatal genetic testing not included in this guideline, refer to applicable Medical Necessity Guidelines;

- Genetic Testing: Prenatal Diagnosis, Carrier Screening
- Genetic and Molecular Diagnostic Testing

LIMITATIONS

The 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. Noncovered testing includes:

- Testing for identification of fetal sex
- **Expanded** non-invasive prenatal testing (NIPT) panels
- Screening for copy number variants (e.g., 22q11.2, Cri-du-chat, whole genome, microdeletions, etc.)
- Screening for autosomal trisomies other than 13, 18 and 21
- Prenatal cell-free DNA testing for single gene conditions
- Prenatal cell-free DNA testing for twin zygosity (e.g., 0060U)
- Concurrent screening for aneuploidy using multiple screening tests is considered not medically necessary

CODES

The following CPT/HCPCS codes require prior authorization:

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

REFERENCES

1. Hayes Clinical Utility Evaluation: Cell-Free DNA (CfDNA) [Formerly NIPS, NIPT] Screening F or Fetal Trisomy 21, 18, And 13 In High-Risk Women. April 19, 2021. Accessed at Hayes a symplr company by subscription only July 19, 2022.
2. Screening for Fetal Chromosomal Abnormalities: ACOG Practice Bulletin Summary, Number 226. (2020). *Obstetrics and gynecology*, *136*(4), 859–867. doi.org/10.1097/AOG.0000000000004107
3. American College of Obstetricians and Gynecologists: Summary of Recommendations; Current ACOG guidance. Accessed July 19, 2022. Current ACOG Guidance | ACOG
4. Hayes Clinical Utility Evaluation: Cell-Free DNA (cfDNA) [Formerly NIPS, NIPT] Screening for Fetal Rare Autosomal Trisomies. Accessed at Hayes a symplr company by subscription only July 19, 2022.
5. Hayes Clinical Utility Evaluation: Cell-free DNA (cfDNA) screening for fetal trisomy 21, 18, and 13 in women with twin pregnancies. Accessed at Hayes a symplr company by subscription only July 19, 2022.
6. Hayes Clinical Utility Evaluation : Cell-free DNA (cfDNA) screening for fetal trisomy 21, 18, and 13 in low-risk women with singleton pregnancies. Accessed at Hayes a symplr company by subscription only July 19, 2022.
7. Palomaki GE, PhD; Messerlian GM, PhD et. al. Prenatal screening for common aneuploidies using cell-free DNA. Accessed by subscription only UpToDate July 19, 2022.
8. Moise Jr. KJ, MD. RhD alloimmunization in pregnancy: Management. Accessed by subscription only UpToDate July 19, 2022.

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.
- June 16, 2021: Reviewed by IMPAC, renewed without changes.
- October 20, 2021: Reviewed by IMPAC for changes effective October 20, 2021. Updated name of MNG to Genetic Testing: Cell-Free DNA Testing for Fetal Trisomy, removed criterion point for maternal age, abnormal screening for aneuploidy, and family history of trisomy.
- July 20, 2022: Reviewed by Medical Policy Approval Committee (MPAC). For effective date November 1, 2022, prior authorization is required for all prenatal testing. MNG is applicable to THP-Commercial product only. Limitations section updated.

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