Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Genetic Testing – Cell-Free DNA Screening for Fetal Trisomy

Effective: November 1, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☒ No ☐
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; 800-232-0816
☒ Tufts Health Plan Commercial products; 617-972-9409

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
☐ Tufts Health One Care – A dual-eligible product; 857-304-6304

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-972-9409
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-972-9409
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-972-9409

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

The human body has 23 distinct chromosome pairs or copies. Trisomy 21, 18 or 13 is defined as having 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 as a result of a previous ultrasound evaluation or serum screening test, a family history of aneuploidy, prior pregnancy involving fetal aneuploidy or a biological parent who carries a relevant Robertsonian translocation.

It is strongly recommended, but not required, that individuals receive counseling prior to screening to discuss the potential benefits, limitations, and risks . Genetic counseling may benefit individuals with positive screening test results. Noninvasive prenatal tests require prior authorization and may be covered when performed at a contracting laboratory.

Clinical Guideline Coverage Criteria

The Plan may authorize maternal blood sampling of cell-free fetal DNA screening for trisomy 21, 18, and 13 for the following:

1. The member has a singleton or twin pregnancy; **and**

2. Documentation supports the recommendation for cell-free fetal DNA screening based on clinical scenario and family history

The Plan additionally may authorize maternal blood sampling of cell-free fetal DNA screening for trisomy 21, 18, and 13 for the following:
1. The member has a singleton or twin pregnancy; **and**
2. Testing is done in follow up to abnormal maternal serum screen and diagnostic testing is declined; **or**
3. There is a pregnancy with multiple anomalies and diagnostic testing is not possible

Note: For prenatal genetic testing not included in this guideline, refer to applicable Medical Necessity Guidelines:
1. Genetic Testing: Prenatal Diagnosis, Carrier Screening
2. 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:
1. Testing solely for identification of fetal sex
2. **Expanded** non-invasive prenatal testing (NIPT) panels
3. Screening for copy number variants (e.g., 22q11.2, Cri-du-chat, whole genome, microdeletions, etc.)
4. Screening for autosomal trisomies other than 13, 18 and 21
5. Prenatal cell-free DNA testing for single gene conditions
6. Prenatal cell-free DNA testing for twin zygosity (e.g., 0060U)
7. Concurrent screening for aneuploidy using multiple screening tests is considered not medically necessary

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

Code	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. Cell-Free DNA (CfDNA) [Formerly NIPS, NIPT] Screening For Fetal Trisomy 21, 18, And 13 In High-Risk Women. Published February 16, 2018. Updated February 11, 2022. April 19, 2021. Accessed August 19, 2025.
2. American College of Obstetricians and Gynecologists' Committee on Clinical Consensus-Obstetrics, Gantt A; Society for Maternal-Fetal Medicine, et al. Obstetric Care Consensus #11, Pregnancy at age 35 years or older. Am J Obstet Gynecol. 2023;228(3):B25-B40. doi:10.1016/j.ajog.2022.07.022
3. Screening for Fetal Chromosomal Abnormalities: ACOG Practice Bulletin Summary, Number 226. *Obstet Gynecol*. 2020;136(4):859-867. doi:10.1097/AOG.0000000000004107
4. American College of Obstetricians and Gynecologists (ACOG). NIPT summary of recommendations. 2025. Available at: https://www.acog.org/advocacy/policy-priorities/non-invasive-prenatal-testing/current-acog-guidance. Accessed August 19, 2025.
5. Cell-Free DNA (cfDNA) [Formerly NIPS, NIPT] Screening for Fetal Rare Autosomal Trisomies. Hayesinc.com/login [via subscription only]. Published December 21, 2021. Updated. December 9, 2024. Accessed August 19, 2025.
6. Cell-free DNA (cfDNA) screening for fetal trisomy 21, 18, and 13 in women with twin pregnancies. Hayesinc.com/login [via subscription only]. Published July 21, 2021. Updated August 23, 2024. Accessed August 18, 2025.
7. Cell-free DNA (cfDNA) screening for fetal trisomy 21, 18, and 13 in low-risk women with singleton pregnancies. Hayesinc.com/login [via subscription only]. Published August 19, 2021. Updated June 14, 2024. Accessed August 19, 2025.
8. Moise Jr. KJ, MD. RhD alloimmunization in pregnancy: Overview. Accessed by subscription only July 19, 2022. RhD alloimmunization in pregnancy: Overview – UpToDate

9. Dungan JS, Klugman S, Darilek S, et al. Noninvasive prenatal screening (NIPS) for fetal chromosome abnormalities in a general-risk population: An evidence-based clinical guideline of the American College of Medical Genetics and Genomics (ACMG). Genetics in Medicine. 2023;25(8):100874.
10. Dungan JS, Klugman S, Darilek S, et al. Noninvasive prenatal screening (NIPS) for fetal chromosome abnormalities in a general-risk population: An evidence-based clinical guideline of the American College of Medical Genetics and Genomics (ACMG). Genet Med. 2023;25(2):100336. doi:10.1016/j.gim.2022.11.004
11. US Food & Drug Administration. Genetic non-invasive prenatal screening tests may have false results: FDA safety communication. 2022.
12. Palomaki G. Prenatal screening for common fetal aneuploidies: Cell free DNA test. UpToDate.com/login [via subscription only]. Published February 14, 2025.. Accessed August 19, 2025.
13. Yan X, Ding K, Zhang X, Zhang S, Peng H, Zhang Y. Analysis of prenatal diagnosis and pregnancy outcomes for rare autosomal trisomies detected by non-invasive prenatal testing in 33,079 cases. BMC Med Genomics. 2025 Feb 7;18(1):29. doi: 10.1186/s12920-025-02099-3. PMID: 39920731; PMCID: PMC11806773.
14. Yang S, Zhuang Y, Li J, Fu X. Expanded non-invasive prenatal testing offers better detection of fetal copy number variations but not chromosomal aneuploidies. PLoS One. 2025 Jan 24;20(1):e0312184. doi: 10.1371/journal.pone.0312184. PMID: 39854358; PMCID: PMC11759987.

Approval And Revision History

June 26, 2020: Fax number for Unify updated.

Subsequent endorsement date(s) and changes made:

- 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.
- January 18, 2023: Reviewed by MPAC. For effective date April 1, 2023, MNG name change from Cell-Free DNA Testing for Fetal Trisomy. Remove genetic counseling requirement.
- July 19, 2023: Reviewed by MPAC, renewed without changes, effective September 1, 2023
- October 19, 2023: Reviewed by MPAC, renewed without changes.
- November 29, 2023: Clarified Limitation #1 with addition of term “solely” for identification of fetal sex.
- November 2023: Unify name changed to One Care effective January 1, 2024
- July 22, 2024: Reviewed by MPAC. Addition of criteria regarding testing when “diagnostic testing declined or not possible”, effective September 1, 2024.
- August 30, 2024: Reviewed by MPAC, renewed without changes, effective October 1, 2024
- November 21, 2024: Reviewed by MPAC, removed language about risk factors from overview and criteria section, updated references, effective January 1, 2025.
- September 17, 2025. Reviewed by MPAC, annual review no changes, effective November 1, 2025. References updated.
- October 21, 2025: Fax number for Senior Care Options, Tufts Medicare Preferred HMO and Tufts Medicare Preferred PPO updated; language for Carelink removed; Harvard Pilgrim Health Care Stride Medicare Advantage removed as an applicable product from the template

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.