

EVH Clinical Guideline 2736.CC for Non-Invasive Genetic Testing During Pregnancy

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| Guideline Number: EVH_CG_2736.CC | <u>Applicable Codes</u> | |
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STATEMENT

General Information

- *It is an expectation that all members receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines, and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

INDICATIONS

CountyCare considers cell-free fetal DNA (cfDNA)-based prenatal screening for fetal aneuploidy (trisomy 13, 18, and 21) medically necessary as follows ^(1–3):

- For pregnant persons with a current single or twin gestation pregnancy with one or more of the following:
 - Are aged 35 years or older at delivery and/or donor oocyte aged 35 years or older
 - Have fetal ultrasound findings indicate an increased risk of Aneuploidy
 - Have a history of a prior pregnancy with a trisomy due to translocation
 - Have positive first- or second-trimester screening test results for Aneuploidy
 - Have parental balanced Robertsonian translocation with an increased risk of fetal Trisomy 13 or Trisomy 21
 - Require screening after pre-test counseling from a board-certified genetic counselor
 - Require fetal sex determination for singleton pregnancies at increased risk of a sex (X)-linked condition or congenital adrenal hyperplasia
 - Had serum screening produce a high-risk result earlier in the pregnancy and are declining invasive diagnostic testing

CountyCare considers genomic sequence analysis with cfDNA for fetal chromosomal microdeletion screening medically necessary when ⁽²⁾:

- There is a known family history of genetic disorders associated with chromosomal microdeletions
- Prenatal screening tests suggest a potential risk for chromosomal abnormalities

- Specific risk factors are identified during prenatal care, such as abnormal results from non-invasive prenatal testing (NIPT)

In members with a positive screen, providers should consider evaluation with a maternal fetal medicine specialist, genetic counseling, comprehensive ultrasound and diagnostic testing ⁽²⁾.

LIMITATIONS

Cell-free fetal DNA-based prenatal screening for fetal aneuploidy (trisomy 13, 18, 21) is considered not medically necessary as follows:

- For individuals not meeting the criteria above, including pregnancies involving 3 or more fetuses
- Twin pregnancies when the current pregnancy is affected by fetal demise, vanishing twin, or one or more anomalies detected in one or both of the twins
- For fetal sex determination without an increased risk of a sex (X)-linked condition or congenital adrenal hyperplasia
- Only one cell-free DNA testing will be covered per pregnancy.

Fetal chromosomal microdeletion(s) genomic sequence analysis is considered not medically as follows:

- For routine screening of all pregnancies
- There are no indications of potential chromosomal issues
- When alternative testing methods are more suitable

EXCLUSIONS

Due to insufficient evidence of efficacy, the following DNA-based noninvasive prenatal tests are unproven and not medically necessary:

- Genome-wide or exome-wide screening
- Early (prior to 10 weeks of gestation) testing
- Single gene disorders
- Tests that have not received approval from the Food and Drug Administration (FDA)

CODING AND STANDARDS

Codes

CPT codes covered if selection criteria are met:

| 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 |
| 81422 | Fetal chromosomal microdeletion(s) genomic sequence analysis (eg, DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood |
| 81479 | Unlisted molecular pathology procedure |
| 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 |

Applicable Lines of Business

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|-------------------------------------|--|
| <input type="checkbox"/> | CHIP (Children's Health Insurance Program) |
| <input type="checkbox"/> | Commercial |
| <input type="checkbox"/> | Exchange/Marketplace |
| <input checked="" type="checkbox"/> | Medicaid |
| <input type="checkbox"/> | Medicare Advantage |

POLICY HISTORY

| Date | Summary |
|-------------------|---|
| November 20, 2025 | <ul style="list-style-type: none"> This guideline replaces PA.249.CC Noninvasive Genetic Testing During Pregnancy Annual Review - Editorial changes to match the formatting and layout of the new template; added in-text citations; updated Indications, Limitations and Exclusions sections; removed Background section; replaced outdated References with updated References |

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

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REFERENCES

1. Hayes Knowledge Center. *Cell-Free DNA (CfDNA) [Formerly NIPS, NIPT] Screening for Fetal Trisomy 21, 18, And 13 In High-Risk Women.*; 2022.
<https://evidence.hayesinc.com/report/gti.cellfreewomen4313>
2. 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(2):100336. doi:10.1016/j.gim.2022.11.004
3. American College of Obstetricians and Gynecologists. Screening for Fetal Chromosomal Abnormalities: ACOG Practice Bulletin. *Obstetrics & Gynecology*. 2020;136(4):e48-e69. doi:10.1097/AOG.0000000000004084