Genetic testing: prenatal cell-free DNA testing

These services may or may not be covered by your HealthPartners plan. Please see your plan documents for your specific coverage information. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage.

Administrative Process

Other common names for this testing include: Non-invasive Prenatal Testing (NIPT), Cell-free Fetal DNA Testing (cffDNA).

Prior authorization is not required for the following:

- Prenatal Cell-free DNA testing for
  - Chromosome 13, 18, 21, X and Y Aneuploidies
  - Microdeletions
  - Single-gene disorders
- Maternal Serum Screening (MSS)

Prior authorization is required for the following services:

- Testing that is associated with a procedure code listed in "Box A", below.

Tests that require prior authorization will be reviewed for medical necessity of the testing as a whole. That is, a single coverage decision will apply to all of the tests, services, and/or procedure codes associated with the genetic test, whether they are requested/billed together or separately.

Box A: Genetic testing procedure codes that require prior authorization
Molecular pathology procedures, Tier 2 or unlisted (CPT 81400-81408, 81479)
Unlisted multianalyte assays (CPT 81599)
Any other listed or unlisted laboratory/pathology CPT code when it is used in association with a genetic test.

Prior authorization is not applicable for some tests as they are considered investigational/experimental. The provider and facility will be liable for payment unless:

1. The provider notifies the member that a specific service has been determined by HealthPartners to be investigational/experimental; and
2. The member signs a waiver agreeing to pay for the specific non-covered service being rendered; and
3. The claim has been billed with a GA modifier indicating such. If the member has signed a waiver agreeing to pay for the specific service then the member will be liable for payment.

Policy Reference Table

If available, codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive.

Coverage Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes
Prenatal Cell-free DNA Testing for Chromosome 13, 18, 21, X and Y Aneuploidies	Vasistera (Natera)	0327U	O09, O28, O30, O35, Q90-Q99, Z34, Z36.0
	Panorama Prenatal Panel (with or without twin zygosity testing) (Natera)	81420, 0060U (twin zygosity only)	
	Harmony Prenatal Test (BioReference Laboratories)	81507	
Non-invasive Prenatal Screening (NIPS) for Fetal RhD Genotyping	UNITY Fetal RhD™ NIPT (add on) (Billion to One)	81403	O36.0
	Fetal RhD NIPT (Natera)	81479	
Prenatal Cell-free DNA Testing for Microdeletions	Panorama Extended Panel (Natera)	81422	O09, O28, O35, Q90-Q99, Z34, Z36.0
	MaterniT21 Plus Core + ESS (LabCorp)		

	Prequel Prenatal Screen: Microdeletions (Myriad Genetics)		
Prenatal Cell-free DNA Testing for Single-gene Disorders	Vistara Single-Gene NIPT (Natera)	81302, 81404, 81405, 81406, 81407, 81408, 81442	O09, O28, O30, O35, Q90-Q99, Z34, Z36.0
	PreSeek Non-invasive Prenatal Gene Sequencing Screen (Baylor Genetics, LLC)		
	UNITY Fetal Antigen NIPT	0488U	
	UNITY Fetal Risk Screen	0489U	
Maternal Serum Screening (MSS)	First Trimester Maternal Screen, Serum (Mayo Clinic Laboratories)	81508	O09, O28, O30, O35, Q90-Q99, Z34, Z36.0
	Quad Screen (Quest Diagnostics)	81509, 81510, 81511, 81512	
	Serum Integrated Screen, Part 2 (Quest Diagnostics)		
	Penta Screen (Quest Diagnostics)	81512	

Coverage

Prenatal Cell-free DNA Testing for Chromosome 13, 18, 21, X and Y Aneuploidies

1. Prenatal cell-free DNA testing for chromosome 13, 18, 21, X and Y aneuploidies may be considered **medically necessary** when:
   - A. The member has a singleton or twin pregnancy, **and**
   - B. The member has not previously had cell-free DNA screening in the current pregnancy.
2. Prenatal cell-free DNA testing for Chromosome 13, 18, 21, X and Y aneuploidies is considered **investigational** for all other indications.

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Prenatal Cell-free DNA Testing for Fetal RhD Genotyping

1. Prenatal cell-free DNA testing for fetal RhD genotyping is considered **medically necessary** when:
   - A. The member is pregnant, **and**
   - B. The member is confirmed to be RhD negative, **and**
   - C. The member is not planning to undergo amniocentesis, **and**
   - D. The member's practice setting is experiencing RhIg shortages.
2. Prenatal cell-free DNA testing for fetal RhD genotyping is **investigational** for all other indications.

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Prenatal Cell-free DNA Testing for Microdeletions

1. Prenatal cell-free DNA testing for microdeletions and microduplications is considered **investigational**.

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Prenatal Cell-free DNA Testing for Single-gene Disorders

2. Prenatal cell-free DNA testing for mutations associated with single gene disorders is considered **investigational**.

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Maternal Serum Screening (MSS)

1. Maternal serum screening for aneuploidy using no more than one of the following one time per pregnancy is considered **medically necessary**:
   - A. First trimester screening (free or total beta-HCG and PAPP-A)
   - B. Second trimester screening (hCG, msAFP, uE3, and DIA)
   - C. Integrated, stepwise sequential, or contingent sequential screening
   - D. Penta screen (hCG, msAFP, uE3, DIA, ITA)

Definitions

Prenatal Cell-free DNA Testing is a screening test that is used to determine the risk of specific genetic disorders by analyzing traces of cell-free DNA (cfDNA) in a pregnant woman's blood.

Sequencing tests use 1 of 2 general approaches to analyze cell-free DNA. The most widely used technique to date uses massively parallel sequencing (MPS; also known as next-generation or “next gen” sequencing). The second general approach uses the single nucleotide polymorphism (SNP) method.

Singleton pregnancy is a pregnancy with one fetus.

Twin zygosity testing is used to predict the degree of genetic similarity within each pair (i.e., monozygotic versus dizygotic). Monozygotic (genetically identical twins) are at a higher risk for pregnancy complications, such as twin-twin transfusion syndrome (TTTS).

Products

This information is for most, but not all, HealthPartners plans. Please read your plan documents to see if your plan has limits or will not cover some items. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage. These coverage criteria do not apply to Medicare Products. For more information regarding Medicare coverage criteria or for a copy of a Medicare coverage policy, contact Member Services at 952-883-7272 or 1-877-778-8384.

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