STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Non-Invasive Prenatal Testing for Aneuploidy Using Cell Free DNA
LAB-007

Iowa Medicaid Program:	Claim Prepay	**Effective Date:**	10/20/2017
Revision Number:	5	**Last Rev Date:**	1/19/2024
Reviewed By:	Medicaid Medical Director	**Next Rev Date:**	1/17/2025
Approved By:	Medicaid Clinical Advisory Committee	**Approved Date:**	10/19/2018

Description

National guidelines recommend that all pregnant members be offered screening for fetal chromosomal abnormalities called aneuploidies (defined as an abnormal number of chromosomes) before 20 weeks of gestation, regardless of age. There are numerous limitations to standard screening for these disorders using maternal serum and fetal ultrasound. Noninvasive prenatal testing (NIPT) analyzing cell-free fetal DNA (cfDNA) in maternal serum is a potential complement or alternative to conventional serum screening.

Fetal chromosomal abnormalities occur in approximately 1 in 160 live births. Trisomy 21 or Down syndrome is the most common chromosomal aneuploidy and is the driving force for current maternal serum screening programs.

Standard aneuploidy screening involves combinations of maternal serum markers and fetal ultrasound done at various stages of pregnancy. The detection rate for various combinations of noninvasive testing ranges from 60 to 96 percent when the false-positive rate is set at 5 percent. When tests indicate a high risk of trisomy syndrome, direct karyotyping of fetal tissue obtained by amniocentesis or chorionic villous sampling (CVS) is required to confirm the diagnosis.

Both amniocentesis and CVS are invasive procedures and have procedure-associated risk including fetal injury, fetal loss (miscarriage), and infection. The cfDNA test provides excellent performance for members with successful testing (at least 99 percent of Down syndrome pregnancies are detected with a screen-positive rate less than 1 per 1000, less than 0.1 percent). However, it is still considered a screening test due to infrequent false positive and false-negative results. An invasive procedure (e.g., amniocentesis or CVS) and subsequent karyotyping or microarray analysis are considered the gold standard diagnostic tests and should be offered to members who are screen positive by cfDNA testing.

Criteria

Claim pre-pay review is required.

cfDNA-based prenatal screening for fetal aneuploidy (trisomy 13, 18, and 21) is considered medically necessary when **BOTH** the following have been met:

1. The member has received genetic counseling from a qualified health professional; **AND**
2. Members with a current single gestation pregnancy.

cfDNA-based prenatal screening for fetal aneuploidy (trisomy 13, 18, and 21) is NOT medically necessary for twin or multiple gestation pregnancies due to limited or inconsistent scientific evidence (Evidence level B per ACOG Guidelines).

The following indications are considered investigational:

1. cfDNA screening for fetal sex chromosome aneuploidies.
2. cfDNA screening for microdeletions.

Coding

The following list of codes is provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS/CPT code is inappropriate.

CPT	Description
81420	Fetal chromosomal aneuploidy (eg, 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.

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual and as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by

national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

EncoderPro Optum360.

Noninvasive Prenatal Testing (Cell-Free Fetal DNA) - Aneuploidy Testing ACG: A-0724 (AC) MCG Health Ambulatory Care 24th Ed.

Palomaki GE. Messerlian GM. Halliday JV. Prenatal screening for common aneuploidies using cell-free DNA. UpToDate. Topic last updated Oct 15, 2020.

Screening for Fetal Chromosomal Abnormalities ACOG Practice Bulletin Number 226 October 2020.

Rink BD. Norton ME. Screening for fetal aneuploidy. Seminars in Perinatology 2016;40(1):35-43. DOI: 10.1053/j.semperi.2015.11.006.

Quad Screens. University of Wisconsin Health. OBGYN. 2020 University of Wisconsin Hospitals and Clinics Authority.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
Signature			

Change Date	Changed By	Description of Change	Version
Signature			

Change Date	Changed By	Description of Change	Version
1/19/2024	CAC	Annual review.	5
Signature William (Bill) Jagiello, DO			
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1/20/2023	CAC	Annual review.	4
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Criteria Change History (continued)

Change Date	Changed By	Description of Change	Version
1/21/2022	CAC	Annual review	3
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
1/15/2021	CAC	All sections updated.	2
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
10/19/2018	Medical Director		1
Signature C. David Smith, MD			