Screening for Fetal Aneuploidy, OB 14

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Effective Date	7/2023
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Coverage Policy	OB 14
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All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

Purpose:

This policy addresses Screening for Fetal Aneuploidy.

Description & Definitions:

Screening for Fetal Aneuploidy is Noninvasive prenatal testing (NIPT) or screening.

Noninvasive prenatal testing (NIPT) is a non-invasive screening tool for detecting fetal chromosomal abnormalities such as trisomy 21 (Down Syndrome), trisomy 18 (Edward Syndrome), and trisomy 13 (Patau Syndrome). Circulating cell-free fetal DNA (cfDNA) crosses the placenta and can be isolated in maternal plasma. As early as 8-10 weeks of gestation these fetal DNA fragments can comprise 6-10% of the total cell free DNA in maternal plasma. NIPT has been shown to be a highly accurate screening test with high sensitivity (99%) and specificity (99.5%), which can be used from 10 weeks in pregnancy to determine risk of trisomy 21. It can also be used to screen for the other common chromosomal aneuploidies, trisomy 18 (Edwards syndrome) and trisomy 13 (Patau syndrome). The positive predictive value and negative predictive value of NIPT varies by maternal age.

Maternal serum analysis for free ß-human chorionic gonadotropin (hCG) and pregnancy-associated plasma protein A (PAPP-A) levels may also be used to screen for fetal aneuploidy. This test is usually done between gestational weeks 11–14 and can be completed in a single combined test or in a multistep process. An ultrasound may be performed to measure nuchal translucency (thickness of the space between the back of the fetal neck and overlying skin). A second trimester screen of maternal serum may be performed independently or in conjunction with the first trimester screen. The results of these tests, and consideration of maternal age, are used to calculate specific risk for fetal chromosomal disorders. If these results demonstrate a significant probability of a fetal abnormality, invasive testing such as amniocentesis or chorionic villus sampling (CVS), may be performed. Maternal serum alpha-fetoprotein may also inform the fetal risk of neural tube defects.

For purposes of this policy, these various forms of hCG are considered interchangeable: free beta subunit of hCG, total hCG, or hyperglycosylated hCG (also known as invasive trophoblast antigen [ITA]).

Criteria:

Screening for Fetal Aneuploidy is considered medically necessary for **1 or more** of the following:

- Non-invasive prenatal testing (NIPT) to screen for fetal trisomy 13, 18 and 21 **once per pregnancy** is considered medically necessary for **1 or more** of the following tests:

    - Individual has a viable pregnancy after 10 weeks but prior to 20 weeks gestation.
    - Individual has a viable pregnancy after 20 weeks gestation when prenatal ultrasound findings demonstrate fetal anomalies consistent with trisomy 13, 18, or 21.
- First-trimester nuchal translucency (NT) testing alone (without serum analyte screening) is considered medically necessary for **ALL of the following**:
    - Individual is pregnant with more than one fetus.
    - When performed in a setting of demonstrated ultrasound credentialing and ongoing quality monitoring.

Screening for Fetal Aneuploidy is considered **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- Noninvasive prenatal testing (NIPT) including but not limited to the following:
    - screening for a sex-chromosome aneuploidy
    - vanishing twin syndrome
    - screening for other chromosomal disorder other than those specified above
    - screening for microdeletions
    - single-gene disorders
    - whole genome NIPT
    - when used to determine genetic cause of miscarriage (e.g., missed abortion, incomplete
    - abortion)
    - screening for non-medical traits (e.g., biologic sex)
- Noninvasive screening schemes for fetal aneuploidy including but not limited to the following:
    - First-trimester serum analyte testing (hCG and PAPP-A) alone without NT measurement
    - First-trimester ultrasound assessment of the nasal bone
    - First-trimester maternal plasma levels of follistatin-related gene protein
    - First-trimester maternal serum A disintegrin and metalloprotease 12 (ADAM12-S) level
    - First-trimester maternal serum anti-Mullerian hormone level
    - First-trimester maternal serum placental growth factor level
    - Maternal fetal-derived circular RNA (circRNAs)
    - Maternal plasma microRNA
    - Ultrasound evaluation of the right subclavian artery (RSA)

Coding:

Medically necessary with criteria:

Coding	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
81508	Fetal congenital abnormalities, biochemical assays of two proteins (PAPP-A, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score
81509	Fetal congenital abnormalities, biochemical assays of three proteins (PAPP-A, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score
81510	Fetal congenital abnormalities, biochemical assays of three analytes (AFP, uE3, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score

81511	Fetal congenital abnormalities, biochemical assays of four analytes (AFP, uE3, hCG [any form], DIA) utilizing maternal serum, algorithm reported as a risk score (may include additional results from previous biochemical testing)
81512	Fetal congenital abnormalities, biochemical assays of five analytes (AFP, uE3, total hCG, hyperglycosylated hCG, DIA) utilizing maternal serum, algorithm reported as a risk score

Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

Reviewed Dates:

- 2024: April

Effective Date:

- July 2023

References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

(2023). Retrieved Mar 13, 2023, from MCG 26th Edition: https://careweb.careguidelines.com/ed26/index.html

Code of Federal Regulations. National Archives and Records Administration. 2024. Retrieved 3.25.24. https://www.ecfr.gov/search?flag=invalid_reference&search%5Bquery%5D=Fetal+congenital

U.S. Food and Drug Administration. Laboratory Developed Tests. 1.18.2024. Retrieved 3.26.24. https://www.fda.gov/medical-devices/in-vitro-diagnostics/laboratory-developed-tests

Hayes. A symplr Company. Evidence Analysis. Cell-Free DNA (cfDNA) [Formerly NIPS, NIPT] Screening for Fetal Rare Autosomal Trisomies. 12.1.2023. Retrieved 3.26.24. https://evidence.hayesinc.com/report/gti.nipshigh4047

Hayes. A symplr Company. Evidence Analysis. Cell-Free DNA (cfDNA) (Formerly NIPS, NIPT) Screening for Fetal Chromosomal Copy Number Variants. 3.15.2024. Retrieved 3.26.24. https://evidence.hayesinc.com/report/gti.nipsmicro4046

Hayes. A symplr Company. Evidence Analysis. Cell-Free DNA (cfDNA) [Formerly NIPS, NIPT] Screening for Fetal Trisomy 21, 18, and 13 in Low-Risk Women with Singleton Pregnancy. 4.25.23.Retreived 3.26.24. https://evidence.hayesinc.com/report/gti.nips4037

Centers for Medicare and Medicaid Services. Billing and Coding: Molecular Pathology and Genetic Testing. A58917. 1.1.2024. Retrieved 3.26.24. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58917

Commonwealth of Virginia. Department of Medical Assistance Services. Provider Manuals Library. 2024 DMAS. Retrieved 3.26.24. https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=non-invasive%20prenatal%20testing&gsc.sort=

Commonwealth of Virginia. Department of Medical Assistance Services. Procedure Fee Files & CPT Codes. 2024. Retrieved 3.26.2024. https://www.dmas.virginia.gov/for-providers/rates-and-rate-setting/procedure-fee-files-cpt-codes/#searchCPT

National Comprehensive Cancer Network. Search result. 2024. Retrieved 3.26.24. https://www.nccn.org/search-result?indexCatalogue=nccn-search-index&searchQuery=Fetal%20Aneuploidy

Carelon (formerly AIM) : Prenatal Testing using Cell-free DNA 2024-03-17. Retrieved 3.26.24. https://guidelines.carelonmedicalbenefitsmanagement.com/prenatal-testing-using-cell-free-dna-2024-03-17/

MCG Informed Care Solutions. 27th Edition. Noninvasive Prenatal Testing (Cell-Free Fetal DNA) - Aneuploidy Testing. ACG: A-0724 (AC). Retrieved 3.26.24. https://careweb.careguidelines.com/ed27/index.html

American College of Obstetrics and Gynecologist. Screening for Fetal Chromosomal Abnormalities. Number 226. October 2020. Retrieved 3.26.2024. https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/screening-for-fetal-chromosomal-abnormalities

American College of Medical Genetics and Genomics (ACMG). 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). 2.2023. Retrieved 3.26.24. https://www.gimjournal.org/article/S1098-3600(22)01004-8/fulltext

Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

Keywords:

Fetal Congenital Abnormalities Risk Score Panel, Noninvasive prenatal testing, nuchal translucency, trisomy 18, trisomy 13, trisomy 21, Edwards syndrome, Patau syndrome, ß-human chorionic gonadotropin, hCG