Clinical Policy: Cell-Free Fetal DNA Testing

Reference Number: WA.CP.MP.84
Date of Last Revision: 11/21
Effective Date: 12/01/21

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Cell-free fetal DNA testing is a screening test of the woman's blood taken after 10 weeks of pregnancy. It measures the relative amount of free fetal DNA and indicates if the fetus is at increased risk of having Down syndrome (trisomy 21), Edwards syndrome (trisomy 18) and Patau syndrome (trisomy 13).

Policy/Criteria

I. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's instruction, that one cell-free fetal DNA test per pregnancy is **medically necessary** for members meeting all of the following criteria:
   A. Underwent pretest counseling, and
   B. Current pregnancy not a multiple gestation, and
   C. Current pregnancy >= 10 weeks and <= 22 weeks gestation at the time of the blood draw, and
   D. High risk for fetal aneuploidy as evidenced by one of the following:
      1. Maternal age >= 35 years at delivery, or
      2. Maternal history of a child affected with trisomy, or
      3. Abnormal ultrasound findings, or
      4. Positive test result for aneuploidy, including first trimester, sequential or integrated screen or quadruple screen, or
      5. A parent carrying a balanced Robertsonian translocation with increased risk of trisomy 13 or trisomy 21.

II. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's instruction, that cell-free fetal DNA testing for any indication not listed above, including the average risk population, is **not covered.**

III. Cell-free fetal DNA testing for additional chromosomal abnormalities other than trisomy 21, 18 or 13 is considered **not medically necessary**, including, but not limited to, other trisomies, aneuploidies or microdeletions.

Background

This policy is based on the Washington State Health Care Authority (HCA) instruction.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for

informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Codes that support medical necessity

CPT® Codes	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.

Codes that do not support medical necessity

CPT® Codes	Description
81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (e.g., DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood
81479	Unlisted molecular pathology procedure
0060U	Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed.	02/21	03/21
Annual review. Added "Effective Date". Added codes 0168U and 0060U. Separated code tables.	10/21	11/21
Removed deleted CPT 0168U. Moved code 0060U from the coding table supporting medical necessity to the table of codes that do not support medical necessity.	11/21	12/21

References

1. The American College of Obstetricians and Gynecologists Committee on Practice Bulletins-Obstetrics, Committee on Genetics, and Society for Maternal-Fetal Medicine. Practice Bulletin: Screening for Fetal Aneuploidy. Number 163, May 2016.
2. The American College of Obstetricians and Gynecologists Committee on Genetics and Society for Maternal-Fetal Medicine Publications Committee. Committee Opinion: Cell-free DNA screening for fetal aneuploidy. Number 640, September 2015. (Reaffirmed 2017)
3. Sayres L, et al. Cell-free fetal DNA testing: A pilot study of obstetric healthcare provider attitudes towards clinical implementation. Prenat Diagn. 2011 November; 31(11): 1070–1076. Doi:10.1002/pd.2835.
4. Palomaki GE, Messerlian GM, Halliday JV. Prenatal screening for common aneuploidies using cell-free DNA. In: UpToDate, Wilkins-Haug (Ed), UpToDate, Waltham, MA. Accessed April 4, 2018.

5. Skelly, A., Brodt, E., Junge, M., Kantner, S. (Aggregate Analytics). *Stem Cell Therapy for Musculoskeletal Conditions*. Washington Health Technology Assessment. February 17, 2020.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.