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GAVIN NEWSOM
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TO: ALL INSURERS OF PRENATAL HEALTH CARE IN CALIFORNIA

FROM: GENETIC DISEASE SCREENING PROGRAM

This letter is to inform you about major changes to the California Prenatal Screening (PNS) Program that will impact the way you provide prenatal screening services to pregnant individuals in California. The Office of Regulations will notify all stakeholders of the Public Notice of the Proposed Action, which will include the date and time of the Public Hearing for the Prenatal Screening Program regulation package, DPH-23-005.

Effective **April 1, 2024**, the PNS Program will add sex chromosome aneuploidy (X, XXY, XYY, XXX) screening to its cell-free DNA (cfDNA) prenatal screening panel, in addition to the already available fetal autosomal trisomies (trisomy 21, trisomy 18, and trisomy 13) offered in the first and second trimesters of pregnancy.

- All PNS specimens collected on or after April 1, 2024 will be screened for sex chromosome aneuploidies (in addition to the already available autosomal trisomy screening).
- The cfDNA screening program will be available throughout pregnancy beginning at 10 weeks 0 days of gestation. The recommended time window for screening is through 21 weeks 0 days gestation so patients can receive all authorized follow-up services.
- The PNS Program will continue to make maternal serum alpha-fetoprotein (MSAFP) screening available from 15 weeks 0 days through 21 weeks 0 days of gestation to screen for neural tube defects.

Title 17 of California Code of Regulations (CCR) section 6527 requires clinicians to offer participation in the PNS Program to all pregnant individuals who enter prenatal by 21 weeks of gestation. However, pregnant individuals may choose not to participate, and they may choose to get cfDNA screening outside of the PNS Program.

Currently the PNS Program has contracted with four cfDNA laboratories to provide screening as part of the program: Natera, Quest Diagnostics, Revvity Omics, and Southern California Permanente Medical Group (Kaiser).

CCR section 6540 requires the participation fees shall be paid to the Department by the individual being tested or by any third party which is legally responsible for a participating individual's care, including any health care service plan, managed health



care plan, managed care plan, prepaid health plan or prepaid group practice health care service plan.

Effective July 1, 2024, the Department proposes a participation fee increase for cfDNA of \$112.00. The increase is expected to raise the fee from \$232.00 to \$344.00. The fee for Maternal Serum Alpha Fetoprotein (screening for neural tube defects) remains the same at \$85.00. The change in the participation fees will be reflected in the billing by adjusting the amount of the existing CPT Codes, as follows:

Diagnosis Code: Z36.0 – Encounter for Antenatal Screening of Mother

CPT Code: 81420 Fetal chromosomal aneuploidy autosomal trisomies (trisomy 21, 18, and 13) and sex chromosome aneuploidies (X, XXY, XYY, XXX) **\$344.00**

or;

PLA Code: 0327U Fetal aneuploidy autosomal trisomies (trisomy 21, 18, and 13) and sex chromosome aneuploidies (X, XXY, XYY, XXX) **\$344.00**

CPT Code: 82105 Alpha Fetoprotein, maternal serum **\$85.00**

Please note that the final fee increase amount will be determined in accordance with the rulemaking process and will be provided in the 2024-25 May Revision.

The California Department of Public Health (CDPH) Genetic Disease Screening Program is requesting insurance providers to update the procedure codes (CPT codes), rates as shown above in your Procedure Master File for the California Prenatal Screening Program under **Tax ID# 94-3402381** and National Provider Identifier (**NPI 1588712020**).

The participation fees cover: 1) the cost of the screening, and 2) authorized follow-up services at a state-contracted Prenatal Diagnosis Center if the screening result indicates an increased risk of a birth defect.

Title 17 of the California Code of Regulations (CCR) section 6540 requires the participation fees be paid to the Department by the individual being tested or by any third party which is legally responsible for the participating individual's care, including any health care service plan, managed health care plan, managed care plan, prepaid health plan or prepaid group practice health care service plan. The PNS Program is not subject to prior authorization, copayment, coinsurance, deductible, or any other form of cost sharing, required of covered families, whether they are insured through Medi-Cal or other in-state insurance plan providers. These services include both cfDNA and NTD prenatal screening tests provided through the PNS Program. For more information, please check Insurance Code §10123.184 and Health and Safety Code §1367.54 and §124977(b)(1).

Providers may continue to additionally offer other expanded prenatal screening options to their patients, when there is appropriate patient understanding about the benefits, limitations and alternatives of such testing. Expanded screening options are not currently included as services covered in the public health PNS Program and would be separately coded and billed to patients or insurance payers. Prenatal care providers may order prenatal screening tests from licensed clinical laboratories that do not have a contractual relationship with the state Prenatal Screening (PNS) Program. Prenatal care providers are still legally required to offer participation in the state PNS Program to their pregnant patients. Patients who chose not to participate in the state PNS Program can be referred to labs testing outside of the Program. The PNS Program makes comprehensive prenatal screening available for trisomies 13, 18 and 21, sex chromosome aneuploidies (X, XXY, XYY, XXX) and NTDs. Only state PNS Program participants who are determined to be high risk through screening will be eligible to free, program-provided, genetic counseling and diagnostic services at a state-contracted Prenatal Diagnosis Center.

Please visit the [PNS Program Information for Providers web page](https://bit.ly/PNS4Providers) (<https://bit.ly/PNS4Providers>) to stay up-to-date on current PNS Program information, materials and resources for providers. If you have any questions, please email the PNS Program at PNS@cdph.ca.gov. If you have any questions regarding invoices, please contact our Billing and Collection Unit at (800) 597-0832.

Thank you for partnering with CDPH/GDSP to provide prenatal screening to California's pregnant individuals.