TO: ALL INSURERS OF PRENATAL HEALTH CARE IN CALIFORNIA

FROM: GENETIC DISEASE SCREENING PROGRAM, CALIFORNIA PRENATAL SCREENING PROGRAM

This letter is to inform you of major changes to the California Prenatal Screening (PNS) Program and an increase to the participation fees as reflected in the Prenatal Screening Program regulation package, DPH-21-008E. 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.

Effective September 19, 2022, the PNS Program will make cell-free DNA (cfDNA) prenatal screening available to replace the biochemical screening for fetal autosomal trisomies (trisomy 21, trisomy 18, and trisomy 13) traditionally offered in the first and second trimesters of pregnancy.

- 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, now available from 15 weeks 0 days through 21 weeks 0 days of gestation to screen for neural tube defects.

Title 17 of the California Code of Regulations (CCR) section 6523 provides that: Only Department of Public Health (CDPH) approved prenatal screening laboratories shall offer or provide prenatal screening for birth defects that are included in the Department’s Prenatal Screening Program to California residents. Currently the state has contracted with four cfDNA laboratories: Natera, PerkinElmer, Quest Diagnostics, 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.
The change in the participation fees will be reflected in the billing by adjustment of the CPT Codes effective with a date of service on/after September 19, 2022 as follows:

Diagnosis Code: Z36 – Encounter for Antenatal Screening of Mother

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>81420</td>
<td>Fetal chromosomal aneuploidy (trisomy 21, 18, 13); or; PLA Code: 0327U Fetal aneuploidy (trisomy 13, 18, and 21)</td>
<td>$232.00</td>
</tr>
<tr>
<td>82105</td>
<td>Alpha Fetoprotein, maternal serum</td>
<td>$85.00</td>
</tr>
</tbody>
</table>

Therefore, only CDPH’s California Prenatal Screening Program will be authorized to bill insurance companies for cfDNA screening for the three fetal autosomal trisomies and/or MSAFP for neural tube defects.

Providers may continue to additionally offer other expanded prenatal screening options (not including trisomies 21, 18, and 13) 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.

As per CCR section 6540 (c), prenatal health facilities and/or care providers may charge third party payers or patients for reasonable costs for blood specimen collection (venipuncture) and handling which should not exceed $6.00.

Please visit the PNS Program Information for Providers web page (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.