Genetic Counseling and Screening

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This section contains information about genetic counseling and screening for eligible Medi-Cal members, including pregnant individuals and newborns.

‹‹Non-Invasive Prenatal Screening Tests for Pregnant Medi-Cal Members

Providers may order cell-free DNA (cfDNA) testing to screen for fetal chromosomal aneuploidies and maternal serum alpha-fetoprotein (MSAFP) testing to screen for neural tube defects (NTDs) through the California Prenatal Screening Program, administered by the Genetic Disease Screening Program (GDSP) at the California Department of Public Health (CDPH), or from a Medi-Cal enrolled licensed clinical laboratory.

California Prenatal Screening Program

California Code of Regulations (CCR), Title 17, Section 6527 requires clinicians to offer information about participation in the California Prenatal Screening Program to all pregnant individuals before 21 weeks 0 days of gestational age. Through state-contracted laboratories, the California Prenatal Screening Program provides:

- cfDNA testing to screen for autosomal trisomies (such as trisomy 21, trisomy 18 and trisomy 13) and sex chromosome aneuploidies (such as monosomy X, trisomy X, XXY and XYY) starting at 10 weeks 0 days of gestational age, and
- MSAFP to screen for NTDs from 15 weeks 0 days through 21 weeks 0 days of gestational age.

For members who choose to participate in the California Prenatal Screening Program:

Providers are referred to the California Prenatal Screening Program website for detailed test information, how prenatal screening tests should be ordered from state-contracted laboratories, recommended gestational ages for when each screening test should be performed, and contraindications to cfDNA testing that are specific to manufacturers' tests.

Providers should submit prenatal screening test orders electronically through the CalGenetic Portal and then print the consent and order confirmation onto label stationery provided by GDSP. For information on how to order supplies, including stationery, testing supplies and literature, call 1-866-718-7915 or order through the California Prenatal Screening Program Ordering Supplies Online website. Note that testing kit supplies for cfDNA screening tests are not provided by the California Prenatal Screening Program. Information on how to order testing kits from state-contracted cfDNA laboratories can be found at the Ordering Supplies Online website or CalGenetic Portal Resources website.››

‹‹When a member receives a positive or inconclusive test result for prenatal screening tests performed through the California Prenatal Screening Program's state-contracted laboratories, GDSP authorizes and reimburses follow-up services, such as genetic counseling and diagnostic testing, only at state-approved Prenatal Diagnosis Centers. GDSP does not authorize or reimburse follow-up services for positive or inconclusive test results when the prenatal screening tests are performed at Medi-Cal enrolled licensed clinical laboratories that are outside of the California Prenatal Screening Program (for example, non-state-contracted laboratories). Additional information can be found on the California Prenatal Screening Program website.

Medi-Cal Coverage of Prenatal Screening and Follow-Up Tests

Non-Invasive Prenatal Screening Tests

Non-Invasive Prenatal Screening Codes

Code	Description	Can Be Provided by GDSP (CA Prenatal Screening Program)	Can Be Provided by Medi-Cal Enrolled Clinical Labs	Medi-Cal Covered Benefit	TAR Required for Initial Test During Pregnancy
0327U	Fetal aneuploidy (trisomy 13, 18, and 21), DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy, includes sex reporting, if performed	Yes	Yes	Yes	No
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	Yes	Yes	Yes	No››

‹‹**Non-Invasive Prenatal Screening Codes (continued)**

Code	Description	Can Be Provided by GDSP (CA Prenatal Screening Program)	Can Be Provided by Medi-Cal Enrolled Clinical Labs	Medi-Cal Covered Benefit	TAR Required for Initial Test During Pregnancy
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	No	Yes	Yes	No
82105	Alpha-fetoprotein (AFP); serum	Yes	Yes	Yes	No

Billing Information for Non-Invasive Prenatal Screening Tests

Non-invasive prenatal screening tests include cfDNA testing (CPT® code 81420 or CPT code 81507 or PLA code 0327U) and MSAFP testing (CPT code 82105), which are reimbursable only once per pregnancy, including for members with Presumptive Eligibility for Pregnant People (PE4PP) benefits. Providers may order non-invasive prenatal screening tests through GDSP's California Prenatal Screening Program or through Medi-Cal enrolled licensed clinical laboratories.

Reimbursement will be limited to one of the following cfDNA prenatal tests per pregnancy: CPT code 81420 or CPT code 81507 or PLA code 0327U. Concurrent or repeat use of these cfDNA tests during the same pregnancy is not covered unless providers submit a *Treatment Authorization Request* (TAR) with documentation of medical necessity.››

‹‹Prenatal Screen Follow-Up and Diagnostic Testing

Medi-Cal covers follow-up services and diagnostic tests for positive or inconclusive prenatal screening test results received through Medi-Cal enrolled licensed clinical laboratories (outside of the California Prenatal Screening Program).

If prenatal screening test results (either through the California Prenatal Screening Program or through Medi-Cal enrolled licensed clinical laboratories) are negative and the member then requires follow-up services and diagnostic tests for other medical reasons, Medi-Cal covers the following procedures when submitted claims include a statement of medical necessity in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) or on an attachment (if billed up to 12 weeks after a negative prenatal screening test, for the same member).

Prenatal Screen Follow-Up and Diagnostic Testing Codes››

CPT Code	Description
59000	Diagnostic amniocentesis
76946	Ultrasonic guidance for amniocentesis, imaging supervision and interpretation
82106	Alpha-Fetoprotein, amniotic fluid
88261	Chromosome analysis; count 5 cells, 1 karyotype, with banding
88262	Chromosome analysis; count 15 – 20 cells, 2 karyotypes, with banding
88263	Chromosome analysis; count 45 cells for mosaicism, 2 karyotypes, with banding
88267	Chromosome analysis, amniotic fluid or chorionic villus, count 15 cells, 1 karyotype, with banding
88269	Chromosome analysis, in situ for amniotic fluid cells, count cells from 6 – 12 colonies, 1 karyotype, with banding
88280	Chromosome analysis; additional karyotypes, each study

Note: Refer to “CLIA Number: Billing for Pathology” in the *Pathology: An Overview of Enrollment and Proficiency Testing Requirements* section of the appropriate Part 2 manual for important laboratory billing information.

‹‹Prenatal Screen Follow-Up and Diagnostic Testing Documentation Requirements for Medical Necessity››

The statement of medical necessity should indicate one of the following:

- Member failed to understand the prenatal screening consent form.
- Member's risk on their prenatal screening result is higher than their chronologic age.
- Member has an abnormal ultrasound and is offered an amniocentesis or chorionic villus sampling procedure.
- Member is discovered to have a risk for a prenatally detectable genetic or chromosomal abnormality, metabolic disease, or neural tube defect not known at the time of the prenatal screen.
- Member has significant anxiety regarding their risk of a genetic defect despite a negative prenatal screen.
- Member will be 35 years old at the time of delivery and remains concerned regarding their risk of a genetic defect.

Collecting Blood Specimens

Providers who collect blood specimens as part of the procedure may bill Medi-Cal for this part of the service using CPT code 99000 (handling and/or conveyance of specimen). When billing for this procedure, use ICD-10-CM diagnosis code Z36.0 (encounter for antenatal screening for chromosomal anomalies) or Z36.2 (encounter for other antenatal screening follow-up) and write "Prenatal Screening" on the *Description* line (Box 43)/*Additional Claim Information* field (Box 19).

For patients who are Medi-Cal recipients, or Medi-Cal presumptive eligible, providers are to record the current Medi-Cal ID number accurately in *Section 3* (Billing Information) on the *Laboratory Requisition Form* (CDPH 4091 or CDPH 4092) submitted to GDSP.

Prenatal Screening Ultrasounds

Ultrasounds performed in conjunction with the California Prenatal Screening Program are separately reimbursable. Providers should refer to the *Pregnancy: Early Care and Diagnostic Services* section of the appropriate Part 2 manual for information.

Prenatal Testing for Cystic Fibrosis

CPT code 81220 (CTFR [cystic fibrosis transmembrane conductance regulator] gene analysis; common variants [for example, ACMG/ACOG guidelines]) is reimbursable for cystic fibrosis prenatal testing when billed as follows:

- When CPT code 81220 is used to bill for the purpose of cystic fibrosis screening, providers must document in the diagnosis field of the claim one of the ICD-10-CM diagnosis codes:
  - Z31.430
  - Z31.440
  - Z31.5
  - Z34.00 thru Z34.03
  - Z34.80 thru Z34.83
  - Z34.90 thru Z34.93
  - O09.00 thru O09.93
- CPT code 81220 is not reimbursable when billed with code 81224, for the same date of service, recipient and provider, but may be billed separately with the appropriate National Correct Coding Initiative (NCCI) associated modifier.
- Fetal testing is reimbursable using the recipient's Medi-Cal identification number if "fetal specimen" and medical justification is documented in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) or on a claim attachment. Failure to document these tests will result in claim denial.
- Cystic fibrosis screening is reimbursable for the father only if he is a Medi-Cal recipient. Providers must document in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) or on a claim attachment, "patient screen positive/partner sample his recipient number" and ICD-10-CM code Z31.440, or the claim will be denied.
- Cystic fibrosis screening is a once-in-a-lifetime procedure, which cannot be overridden with a *Treatment Authorization Request* (TAR).
- CPT code 81220 is reimbursable for PE recipients with aid code 7G.

Newborn Metabolic Screening Panel

Newborn metabolic screening tests for metabolic disorders may be reimbursable only to the provider types listed below, and only when HCPCS code S3620 is billed with modifier 90 (*California Code of Regulations*, Title 17, Section 6500):

- Physicians
- Hospital outpatient departments
- Laboratories
- Certified nurse midwives
- Certified nurse practitioners
- Outpatient clinics
- Out-of-state providers
- California Children's Services (CCS)/Genetically Handicapped Persons Program (GHPP)

The newborn metabolic screening panel (code S3620) is a once-in-a-lifetime procedure for infants one year of age or younger. Code S3620 is not reimbursable for recipients older than age one and cannot be billed twice. The cost of repeat tests is included in the initial reimbursement.

Health professionals providing newborn care, as well as certified nurse midwives, must obtain a *Newborn Screening Specimen Collection Form* (CDPH 4409), a California Newborn Screening Specimen Collection Card, and receive a screening laboratory assignment and laboratory provider number from the Genetic Disease Branch (GDB). Additional information and updates can be obtained by contacting GDB at:

Newborn Screening Section
Genetic Disease Branch
California Department of Public Health
850 Marine Bay Parkway, F-175
Mail Stop 8200
Richmond, CA 94804
(510) 412-6213; FAX: (510) 412-1559

Chorionic Villus Sampling

CPT code 59015 (Chorionic Villus Sampling [CVS], any method) is reimbursable when billed with the following provisions:

- CVS should be performed only by a physician experienced in this procedure. The physician performing a CVS procedure should be able to provide to prospective patients the rate of miscarriage that the physician has experienced for this procedure.
- Genetic counseling should include:
  - A full comparison of the risks and benefits of amniocentesis versus CVS.
  - That the overall risk for transverse limb deficiencies from CVS is 0.03 percent – 0.10 percent (1/3000 – 1/1000) and that the current data indicates no increased risk for limb deficiencies after amniocentesis performed at 15 – 18 weeks gestation.
  - That CVS cannot detect most neural tube defects. Therefore, a maternal serum alpha-Fetoprotein (AFP) to screen for neural tube defects should be offered at 15 – 20 weeks gestation and if positive (approximately 1.5 percent of cases) would need to be followed up by amniocentesis to rule out this genetic abnormality. This second procedure would have risks separate from the previous CVS.

For amniocentesis performed within 10 weeks after a CVS, providers must include medical documentation in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) on the claim about the previous results of the CVS including but not limited to one of the following:

- Placental mosaicism
- Tissue culture failure
- Maternal cell contamination
- An elevated maternal serum AFP level

Genetic Counseling and Screening

Medi-Cal covers genetic counseling and screening for all eligible Medi-Cal members as outlined in this policy.

Physicians who are board-certified in clinical genetics may apply for and receive a separate category of service (COS) and reimbursement code for genetic services.

Providers cannot use HCPCS code S0265 (genetic counseling, under physician supervision, each 15 minutes) for genetic services unless they have been approved by Medi-Cal through the genetic provider credentialing process. Each clinical geneticist (physician) in the practice may obtain this approval.

The physician must bill using an individual National Provider Identifier (NPI), not a billing NPI number issued to a group practice. No other person or facility (for example, hospital or clinic) may bill for genetic counseling services provided by the approved physician. However, a physician may submit claims for the services of a genetic counselor who is working under his/her supervision.

Medi-Cal coverage of genetic counseling and consultation services is as follows:

- Billing HCPCS code S0265 may be billed for the first two hours (eight 15-minute units) without submission of additional documentation. The first eight units are reimbursed at $15 per unit, for a total reimbursement of $120 for two hours.
- Any subsequent time is reimbursed at $5 per unit, up to a maximum of 24 units and requires submission of the consultation note as a claim attachment for payment of time beyond two hours. Reimbursement for three hours would be $140, four hours equals $160, five hours equals $180 and six hours equals $200.
- HCPCS code S0265 cannot be billed with another Evaluation and Management (E&M) code on the same day, whether by the same or another provider, unless the other visit is for a different medical indication. The reason for the second visit should be entered in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) of the claim.
- Services may include review of pertinent medical records, pre-clinic visit and consultation as required; complete examination of the patient or affected child (complete physical examination may not be required for counseling services [for example, infant deaths due to congenital anomalies or family with cystic fibrosis or muscular dystrophy]); examination of siblings, parents and/or other relatives, if indicated; complete pedigree and complete history; determination of likely diagnosis, confirmation of the diagnosis by interpretation of laboratory tests, documentation of natural history of the disease and evaluation of prognosis and recurrence risks; conveyance of information to patient or family and written report to the referring physician.

HCPCS code S0265 may be billed up to four times per year, per recipient.

Legend

Symbols used in the document above are explained in the following table.

Symbol	Description
‹‹	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
››	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.