# **Genetic Counseling and Screening**

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This section contains information about genetic counseling and screening for pregnant individuals and newborns.

# **Genetic Testing for Pregnant Medi-Cal Patients**

Information about the California Prenatal Screening Program must be offered to patients seen before the 20th completed week of gestation. Prenatal screening tests are used to detect Down Syndrome (trisomy 21), trisomy 18, trisomy 13, neural tube defects and other specified birth defects. The Prenatal Screening Program consists of cell-free DNA (cfDNA) to screen for autosomal trisomies after 10 weeks of gestation, and maternal serum alpha-fetoprotein (MSAFP) in the second trimester.

# Ordering Literature, Forms and Supplies

Prenatal care providers should order California prenatal screening testing through the CalGenetic Portal.

Once electronic orders are submitted, providers must print the electronic order and consent form on the electronic order and consent stationery. For more information about how to order Prenatal Screening Program supplies, call 1-866-718-7915. Prenatal Screening Program supplies can also be ordered on the <a href="Prenatal Screening Program">Prenatal Screening Program</a> webpage of the California Department of Public Health (CDPH) website.

**Note:** Supplies for cfDNA screening tests are not provided by the California Prenatal Screening Program. Information on how to contact state-contracted cfDNA brands for supplies can also be found on the <a href="Prenatal Screening Program">Prenatal Screening Program</a> webpage of the CDPH website.

# Prenatal Screening: Authorization/Billing Requirements

Genetic Disease Screening Program (GDSP) authorizes all services and procedures as a result of a positive prenatal screening test at no additional cost to the patient or the provider. 
«Only GDSP can authorize and reimburse providers for additional services rendered to recipients with positive prenatal screening results.» Reimbursement for prenatal screening cannot be made to other providers.

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«Prenatal screening, which includes CPT® codes 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) or PLA Code 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), and CPT code 82105 (alpha fetoprotein [AFP]; serum), is reimbursable only once for recipients in the first and/or second trimester of pregnancy, including recipients with Presumptive Eligibility for Pregnant People (PE4PP) benefits. Recipients with positive screen results also may receive specialized follow-up services and diagnostic tests that are authorized only through GDSP.>>

Reimbursement will be limited to one of the following Noninvasive Prenatal Tests per pregnancy: PLA code 0327U or CPT code 81420 or CPT code 81507. Concurrent or repeat use of these services during the same pregnancy is not covered unless there is documentation of medical necessity.

If the prenatal screening results are negative and the recipient then requires follow-up services and diagnostic tests, claims submitted for the following procedures must 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 recipient).

#### **Prenatal Screening 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 Screening Documentation Requirements for Medical Necessity**

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

- Patient failed to understand the prenatal screening consent form.
- Patient's risk on her prenatal screening result is higher than her chronologic age.
- Patient has an abnormal ultrasound and is offered an amniocentesis or chorionic villus sampling procedure.
- Patient 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.
- Patient has significant anxiety regarding her risk of a genetic defect despite a negative prenatal screen.
- Patient will be 35 years old at the time of delivery and remains concerned regarding her 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.

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## **Prenatal Testing for Cystic Fibrosis**

CPT code 81220 (CTFR [cystic fibrosis transmembrane conductance regulator] gene analysis; common variants [eg, 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 <u>only</u> to the provider types listed below, and <u>only</u> 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 1 year of age or younger. Code S3620 is not reimbursable for recipients older than age 1 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, <u>must</u> 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**

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 code HCPCS 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 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 – \$160, five hours – \$180 and six hours – \$200.
- 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.

Services are no longer limited to once-in-a-lifetime. 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
<b>((</b>	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
<b>&gt;&gt;</b>	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.