

CAUTION: Read the [ICD-9 Policy Holding Library](#) page about policy in this document.

Genetic Counseling and Screening

This section contains information about genetic counseling and screening for pregnant women 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, neural tube defects and other specified birth defects. The Prenatal Screening Program consists of five separate serum tests, depending on the timing of the test: PAPP-A and hCG in the first trimester, and alpha-fetoprotein (AFP), hCG, unconjugated estriol (uE3) and inhibin A in the second trimester. The addition of first trimester and integrated screening instead of second trimester screening alone increases the ability to predict which pregnant women have an increased risk of carrying a fetus with Down Syndrome and/or Trisomy 18.

Ordering Literature, Forms and Supplies

Literature, including Patient Information Consent booklets, Laboratory Requisition Forms (CDPH 4091, CDPH 4409 and CDPH 4092) and supplies may be ordered through the California Department of Public Health (CDPH), Genetic Disease Screening Program (GDSP), at the following address:

California Prenatal Screening Program
Genetic Disease Screening Program
Department of Public Health
850 Marine Bay Parkway, F175
Richmond, CA 94804
(510) 412-1441
Fax: (510) 412-1553

**Prenatal Screening:
Authorization/Billing
Requirements**

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 women with positive prenatal screening results. Reimbursement for prenatal screening cannot be made to other providers.

Prenatal screening, which includes CPT-4 codes 81508 (fetal congenital abnormalities, biochemical assays of two proteins [PAPP-A, hCG (any form)], utilizing maternal serum, algorithm reported as a risk score) or 81511 (fetal congenital abnormalities, biochemical assays of four analytes [AFP, uE3, hCG (any form), DIA] utilizing maternal serum, algorithm reported as a risk score) are reimbursable only once for women in the first and/or second trimester of pregnancy, including women with Presumptive Eligibility (PE) benefits and can include any combination of the five analytes. Women with positive screen results also may receive specialized follow-up services and diagnostic tests that are authorized only through GDSP.

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).

CPT-4

| <u>Code</u> | <u>Description</u> |
|-------------|--|
| 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 | count 15 – 20 cells, 2 karyotypes, with banding |
| 88263 | 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-4 code 99000 (handling and/or conveyance of specimen). When billing for this procedure, use ICD-9-CM diagnosis code V28.89 (other specified antenatal screening) and write "Prenatal Screening" on the *Description* line (Box 43)/*Reserved for Local Use* 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-4 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-4 code 81220 is used to bill for the purpose of cystic fibrosis screening, providers must document in the diagnosis field of the claim ICD-9-CM code V26.31 (testing of female for genetic disease carrier status) or ICD-9-CM code V26.34 (testing of male for genetic disease carrier status).
- CPT-4 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). 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-9-CM code V26.34, 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-4 code 81220 is reimbursable for PE recipients with aid code 7G.

**Newborn Metabolic
Screening Panel**

Newborn metabolic screening tests for metabolic disorders detectable using Tandem Mass Spectrometry (amino acid disorders such as phenylketonuria [PKU], organic acid disorders and fatty acid oxidation disorders), galactosemia, primary congenital hypothyroidism, hemoglobinopathies and classical congenital adrenal hyperplasia 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 (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. When performed on infants older than age 1, the tests included in the newborn screening test panel must be billed using CPT-4 code 82776, 83021, 83498, 83789 or 84443.

The newborn metabolic screening panel (S3620) comprises the following laboratory tests:

- Galactose-1-phosphate uridyl transferase (GALT)
- Hemoglobin fractionation and quantitation; chromatography
- Hydroxyprogesterone, 17-d (17-OHP)
- Tandem mass spectrometry; quantitative (MS/MS)
- Thyroid stimulating hormone (TSH)

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 by contacting the Genetic Disease Branch (GDB) at:

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

Providers must complete the *Newborn Screening Test Request Form* (TRF), and obtain a blood specimen from the infant's heel onto a *Newborn Screening Specimen Collection Card*, provided by the GDB. This collection form is the only form that may be used for collecting specimens for these tests and must be submitted to one of the GDB designated laboratories within the State of California.

Chorionic Villus Sampling

CPT-4 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% – 0.10% (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)/ *Reserved for Local Use* 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)/*Reserved for Local Use* 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.