INLAND EMPIRE HEALTH PLAN

IEHP UM Subcommittee Approved Authorization Guidelines

Full Integrated & Serum Integrated Screening for All Pregnant Women

Policy:

IEHP should not be billed for charges relating to the Serum portion of the Full integrated Screen (including PAPP-A, unconjugated estriol, maternal serum AFP, hCG or dimeric inhibin A) and the cell-free DNA (cfDNA or Fetal Free DNA test) as the charges for these services are carved out to Fee for Service and are billed directly to Medi-Cal by the Genetic Disease Screening Program. The only fee billable to IEHP is for the blood draw and providers who collect blood specimens as part of the procedure may bill this part of the service using CPT-4 code 99000.Prenatal screening, including maternal serum quadruple marker screening including alpha-fetoprotein [AFP], estriol, human chorionic gonadotropin [hCG] and inhibin A, and pregnancy-associated plasma protein A (PAPP-A) is reimbursable only once for women in the first and/or second trimester of pregnancy and can include any combination of the five analytes. Women with positive screen results also should receive follow-up services and diagnostic tests **as authorized through GDSP. 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. Thus IEHP will not reimburse providers for services listed above (see Medi-Cal's Provider Manual: Genetic Counseling and Screening (2009) section) that result from a screen positive test.

IEHP does not cover comparative genomic hybridization (CGH) Microarray, Chromosomal Microarray, or SNP Microarray for the prenatal screening. **HCPCS Code S3870** Comparative genomic hybrization (CGH) microarray is not a covered benefit through Medi-Cal.

IEHP will reimburse once in a given pregnancy for a NT ultrasound performed between 11 weeks 2 days -14 weeks 2 days of gestational age.

Appropriate CPT codes for NT ultrasound are 76813 (for singleton or first fetus) and 76814 (for additional fetus) with a capped maximum of 4 fetuses.
No consult code will be reimbursed for this service and no other additional ultrasound codes will be allowed. Please note that 76813 includes an evaluation of fetal viability along with crown-rump length determination.

American College of Obstetricians and Gynecologists (ACOG) Committee Opinion No 545 (2012):

A new opinion from the American College of Obstetrics and Gynecology (ACOG) and the Society of Maternal and Fetal Medicine (SMFM) supports the use of a new non-invasive method of prenatal testing that uses cell-free fetal DNA for detecting fetal chromosomal abnormalities (16). This uses maternal plasma to detect abnormal fetal cells, thus avoiding the risk of miscarriage that is seen in traditional methods of detection, including chorionic villus sampling and amniocentesis. Approximately 10% of circulating cell-free DNA in maternal plasma is of fetal origin by the end of the first trimester (17). These cells are extracted using a technology known as massively parallel genomic sequencing, which uses a highly sensitive assay and is able to accurately detect Trisomy 13, 18, and 21 as early as the 10^{th} week of pregnancy (18-20). Several studies have shown detection rates for these chromosomal abnormalities with greater than 98% accuracy and a false positive rate of less than 0.5% (19-26). The indications for the use of cell-free fetal DNA is for pregnant women with a **single** gestation who meet any of the following criteria:

1. Women age 35 or older at time of delivery;
2. Fetal ultrasound findings that suggest increased risk of fetal aneuploidy
3. History of a prior pregnancy with an aneuploidy;
4. Positive screening test for an aneuploidy, including first trimester, sequential, or integrated screen, or second trimester screen;
5. Parental (mother or father) balanced Robertsonian translocation with increased risk of fetal trisomy 13 or trisomy 21.

The American College of Obstetrics and Gynecologists recommends that the test be offered as an informed patient choice after pretest counseling. Patients should understand that it only tests Trisomy 13, 18, and 21, and does not replace the accuracy of diagnostic tests (chorionic villus sampling and amniocentesis). (16)

ACOG recommends that cfDNA should not be part of routine screening. Furthermore, it should not be offered to low-risk women or women with multiple gestations since it has not been evaluated sufficiently in these groups. (16)

The National Society of Genetic Counselors supports Noninvasive Prenatal Testing (NIPT) and recommends that genetic counseling should be given if NIPT results are abnormal, and patients should be given the option of standard confirmatory diagnostic testing (27).

California Expanded AFP Program Prenatal Care Provider Handbook:

Expanded AFP Screening Program is $162. The fee covers the blood test **as well as follow up services** when the result is *screen positive*. This fee may change over time.

Follow-up services authorized by the California Expanded AFP Screening Program are only provided at State-approved Prenatal Diagnosis Centers (PDCs). *See Appendix B.*

When follow-up services are **authorized by the Program**, the clinician is notified by an Expanded AFP coordinator. The **clinician should contact the patient and offer a referral to a State-approved Prenatal Diagnosis Center for authorized services at no additional cost**. Authorized **services include genetic counseling, ultrasound and amniocentesis** if indicated. The referral should be made as soon as possible in order to allow the patient access to all available follow-up services and options. *No follow-up services are authorized after 24 weeks gestation.*

- Blood drawing and handling fees are not covered by the Expanded AFP Screening Program and will be charged to the patient or her insurance by the blood collection facility.

Medi-Cal or Medi-Cal Managed Care:

The Expanded AFP Program will bill Medi-Cal directly if, on the Expanded AFP form, there is a patient birthdate **and** a Medi-Cal ID number or a Presumptive Eligibility number. If a patient receives a billing form from the Expanded AFP Program, she should return the bill with her current Medi-Cal number written on it.

Medi-Cal's Provider Manual: Genetic Counseling and Screening (2009):

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 or after October 1, 2015 ICD-10 236) 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.

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 HCPCS code S3626 (maternal serum quadruple marker screening including alpha-fetoprotein [AFP], estriol, human chorionic gonadotropin [hCG] and inhibin A), pregnancy-associated plasma protein A (PAPP-A), and cell free fetal DNA is 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)/*Reserved for Local Use* 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 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	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
81749	(unlisted molecular pathology procedure). A Treatment Authorization Request (TAR) is required. This requires that criteria for testing (as listed above) are met.

Medi-Cal Provider Bulletin (May 2009):

New Ultrasound Test Benefits: Effective for dates of service on or after March 30, 2009, CPT-4 codes 76813 and 76814 are new benefits for Medi-Cal and Presumptive Eligibility recipients.

CPT-4 Code	Benefit Description
76813	Ultrasound, pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; single or first gestation.
76814	Each additional gestation. This test is restricted to four per day, when billing for a quantity greater than one. Providers must document the number of fetuses in the *Remarks* field (Box 80) of the claim.

Updated ICD-9 Diagnosis

- 796.5 Abnormal finding on antenatal screening
- V23.81 Supervision of elderly primigravida
- V23.82 Supervision of elderly multigravida
- V28.89 Other specified antenatal screening (genomic)
- V82.79 Other genetic screening

ICD-10 Diagnosis (effective 10/01/2014):

- O09.511-O09.529 Supervision of elderly primigravida and multigravida
- O28.0-O28.9 Abnormal findings on antenatal screening of mother
- Z36 Encounter for antenatal screening of mother
- Z31.438 Encounter for other genetic testing of female for procreative management

Note: Providers should not bill another obstetric ultrasound for the purpose of dating. An additional ultrasound may only be performed if another medical indication exists.

Providers must bill for codes 76813 and 76814 in conjunction with ICD-9-CM diagnosis code V28.89 or after October 01, 2015 Z36. In addition, these codes require documentation in the *Remarks* field (Box 80) that the ultrasound was performed by a sonographer certified by either the National Translucency Quality Review program or the Fetal Medicine Foundation.

Medical Provider Manual Pregnancy and Early Care (2009):

Ultrasound During Pregnancy: Ultrasound performed for routine screening during pregnancy is considered an integral part of patient care during pregnancy and its reimbursement is included in the obstetrical fee. Ultrasound during pregnancy is reimbursable only when used for the diagnosis or treatment of specific medical conditions.

Background:

Fetal nuchal translucency (NT) refers to the ultrasound detection of a hypoechoic sonolucent region in the posterior fetal neck (1). The measurement is gestational-age dependent; on average, it increases 15 to 20 percent per week (2). The optimal time to perform Nuchal translucency ultrasounds is between 11 weeks 2 days and 14 weeks 2 days of gestational age (14). NT testing alone provides a detection rate of approximately 70 – 71% for Down syndrome, with a 3.5 to 5 percent false-positive rate (3, 4). A nuchal translucency of > 3.5 mm is associated with major congenital heart defects, defects of the great vessels, fetal malformations, dysplasias, deformations, disruptions, and genetic syndromes (5, 6, 7). Abnormal NT may lead to an earlier diagnosis of congenital heart defects. In a combined screening approach (like full integrated Screen) NT testing is performed together with serum PAPP-A and hCG in a first trimester improving Trisomy 21 detection rates (8, 9, 10). Low levels of both serum markers are associated with poor outcomes. For women < 35 years of age this combined screen is equivalent to a quadruple screen. This testing allows for early detection and the performance of confirmatory tests, so that early termination can be offered. Detection rates for integrated serum screening (PAPP-A in 1st trimester + quadruple screen in the 2nd trimester) yields detection rates of 85-88%, and full integrated screen (PAPPA+ nuchal trasnlucency testing in 1st trimester followed by quadruple screen in 2nd trimester) provides detection rates of 94-96% (14). As of April 2009 the California Expanded AFP program added the serum markers for the serum integrated screen and quad marker screen to their Genetic Disease Screening Program (GDSP).

This program is carved out to fee-for- service Medi-Cal for managed Medi-Cal recipients as detailed in California Expanded AFP Program Prenatal Care Provider Handbook (11).

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Bibliography:

1. Shipp TD, Benacerraf BR. Second trimester ultrasound screening for chromosomal abnormalities. *Prenat Diagn*. 2002;22(4):296-307
2. Snijders RJ, Thom EA, Zachary JM, et al. First-trimester trisomy screening: nuchal translucency measurement training and quality assurance to correct and unify technique. *Ultrasound Obstet Gynecol*. 2002;19(4):353-359.
3. Comstock C, Malone FD, Ball RH, et al., for the FASTER Research Consortium. Is there a nuchal translucency millimeter measurement above which there is no added benefit from first trimester screening? *Am J Obstet Gynecol*. 2006;195(3):843-847.
4. Saltvedt S, Almström H, Kublickas M, et al. Screening for Down syndrome based on maternal age or fetal nuchal translucency: a randomized controlled trial in 39,572 pregnancies. *Ultrasound Obstet Gynecol*. 2005;25(6):537-545.
5. Bahado-Singh RO, Wapner R, Thom E, et al., for the First Trimester Maternal Serum Biochemistry and Fetal Nuchal Translucency Screening Study Group. Elevated first-trimester nuchal translucency increases the risk of congenital heart defects. *Am J Obstet Gynecol*. 2005;192(5):1357-1361.
6. Hyett J, Perdu M, Charland G, Snijders R, Nicolaides KH. Using fetal nuchal translucency to screen for major congenital cardiac defects at 10-14 weeks of gestation: population based cohort study. *BMJ*. 1999;318(7176):81-85.
7. Souka AP, Von Kaisenberg C, Hyett JA, Sonek JD, Nicolaides KH. Increased nuchal translucency with normal karyotype. *Am J Obstet Gyneco l.* 2005;192(4):1005-1021.
8. Wapner R, Thom E, Simpson JL, et al., for the First Trimester Maternal Serum Biochemistry and Fetal Nuchal Translucency Screening (BUN) Study Group. First-trimester screening for trisomies 21 and 18. *N Engl J Med*. 2003;349(15):1405-1413.
9. Nicolaides KH. Nuchal translucency and other first-trimester sonographic markers of chromosomal abnormalities. *Am J Obstet Gynecol*. 2004;191(1):45-67.
10. Malone FD, Berkowitz RL, Canick JA, D'Alton ME. First-trimester screening for aneuploidy: research or standard of care? *Am J Obstet Gynecol*. 2000;182(3):490-496.
11. California Expanded AFP Program Prenatal Care Provider Handbook accessed on April 2, 2009 at www.cdph.ca.gov/programs/pns/Documents/ProviderHndbkv08.pdf.
12. Medi-Cal Provider Manual Genetic Counseling and Screening April 2009. Accessed on May 14, 2009 at http://files.medi-cal.ca.gov/pubsdoco/Manuals_menu.asp.
13. Medi-Cal Provider Bulletin. Billing and Policy May 2009 • Bulletin 416. Acessed at http://files.medi-cal.ca.gov/pubsdoco/publications/bulletins/cBull/ips20090501.doc. on 5/20/09.
14. ACOG Practice Bulleting Clinical Management Guideline. Screening for Fetal Chromosomal Abnormalities. Number 77, Jan 2007.
15. Medi-Cal Provider Manual Pregnancy and Early Care and Diagnostic Services April 2009. Accessed on May 14, 2009 at http://files.medi-al.ca.gov/pubsdoco/Manuals_menu.asp.
16. American College of Obstetricians and Gynecologists (ACOG). Committee opinion no 545: noninvasive prenatal testing for fetal aneuploidy. Obstet Gynecol. 2012; 120 (6): 1532-1534

17. Handley D, Peters DG. Noninvasive prenatal chromosomal aneuploidy detection using plasma cell-free nucleic acid. Expert Rev Obstet Gynecol. 2010; 5(5) 581-590.
18. Fan HC, Blumenfeld YJ, Chitkara U, Hudgins L, Quake SR. Noninvasive diagnosis of fetal aneuploidy by shotgun sequencing DNA from maternal blood. Proc Natl Acad Sci U S A 2008;105:16266–71.
19. Chiu RW, Akolekar R, Zheng YW, Leung TY, Sun H, Chan KC, et al. Non-invasive prenatal assessment of trisomy 21 by multiplexed maternal plasma DNA sequencing: large scale validity study. BMJ 2011;342:c7401.
20. Ehrich M, Deciu C, Zwiefelhofer T, Tynan JA, Cagasan L, Tim R, et al. Noninvasive detection of fetal trisomy 21 by sequencing of DNA in maternal blood: a study in a clinical setting. Am J Obstet Gynecol 2011;204:205.e1–11.
21. Sparks AB, Wang ET, Struble CA, Barrett W, Stokowski R, McBride C, et al. Selective analysis of cell-free DNA in maternal blood for evaluation of fetal trisomy. Prenat Diagn 2012;32:3–9.
22. Palomaki GE, Kloza EM, Lambert-Messerlian GM, Haddow JE, Neveux LM, Ehrich M, et al. DNA sequencing of maternal plasma to detect Down syndrome: an international clinical validation study. Genet Med 2011;13:913–20.
23. Palomaki GE, Deciu C, Kloza EM , Lambert-Messerlian GM, Haddow JE, Neveux LM, et al. DNA sequencing of maternal plasma reliably identifies trisomy 18 and trisomy 13 as well as Down syndrome: an international collaborative study. Genet Med 2012;14:296–305.
24. Chen EZ, Chiu RW, Sun H, Akolekar R, Chan KC, Leung TY, et al. Noninvasive prenatal diagnosis of fetal trisomy 18 and trisomy 13 by maternal plasma DNA sequencing. PLoS ONE 2011;6:e21791.
25. Bianchi DW, Platt LD, Goldberg JD, Abuhamad AZ, Sehnert AJ, Rava RP. Genome-wide fetal aneuploidy detection by maternal plasma DNA sequencing. MatErnal Blood IS Source to Accurately diagnose fetal aneuploidy (MELISSA) Study Group. Obstet Gynecol 2012;119:890–901.
26. Norton ME, Brar H, Weiss J, Karimi a, Laurent LC, Caughey AB, et al. Non-Invasive Chromosomal Evaluation (NICE) study: results of a multicenter, prospective, cohort study for detection of fetal trisomy 18. Am J Obstet Gynecol 2012; doi:10.1016/j.ajog.2012.05.021.
27. National Society of Genetic Counselors (NSGC). Noninvasive prenatal testing/noninvasive prenatal diagnosis: the position of the National Society of Genetic Counselors. Available at http://www.nsgc.org/Portals/0/Advocacy/NSGC%20NIPT%20White%20Paper.pdf. Accessed on August 29, 2013

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