



## Evidence Based Guideline

### Maternal and Fetal Diagnostics

**File Name:** maternal\_and\_fetal\_diagnostics  
**Origination:** 1/2000  
**Last Review:** 12/2004

**Active guideline, no longer scheduled for routine literature review**

#### Description of Procedure or Service

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**General:**

Fetal diagnostic tests are sometimes necessary to ensure that the fetus is developing normally and is healthy while inside the uterus. Diagnosis of maternal or fetal conditions allows early treatment and/or special preparations to care for either mother or infant during pregnancy, delivery, and post-partum (after birth).

This document combines 4 evidence based guidelines as follows:

- ◆ Section I - Ultrasound in Maternity Care
- ◆ Section II - Fetal Echocardiography
- ◆ Section III - Prenatal Genetic and Chromosomal Metabolic Testing
- ◆ Section IV - First-Trimester Detection of [Down Syndrome](#)

#### Evidence Based Guideline

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**BCBSNC will provide coverage for the Ultrasound, Fetal Echocardiography, Prenatal Genetic and Chromosomal Metabolic Testing and First-Trimester Detection of Down Syndrome when the test is appropriate and the evidence based guidelines shown below are met.**

**\*Please see appropriate section for evidence based guidelines.**

#### Benefits Application

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Please refer to certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

### Section I - Ultrasound in Maternity Care

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Ultrasound performed during pregnancy is a diagnostic test used to visualize the uterus and fetus. A hand

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held device is passed over the abdominal surface, recording echos of high-frequency sound waves as they are transmitted through tissues with varying density. The sound waves are then transmitted to a television monitor, where a picture of the uterine cavity and embryo or fetus can be seen. Ultrasound may be used to diagnose abnormal pregnancy or other conditions affecting the fetus and future delivery.

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### Evidence Based Guideline for Ultrasound in Maternity Care

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Ultrasound is not medically necessary in every routine pregnancy, however, it may be appropriate to diagnose any one of the following conditions:

1. Abnormality in pregnancy
  - ◆ Suspected ectopic pregnancy- (fertilized egg implants in fallopian tube/ tubal pregnancy)
  - ◆ Suspected hydatidiform mole - (abnormal pregnancy with a diseased ovum; results in miscarriage)
  - ◆ Threatened or missed abortion - (threat of not carrying pregnancy to term)
  - ◆ [Congenital](#) malformations, fetal or maternal - (birth defects)
  - ◆ Polyhydramnios/oligohydramnios - (too much or too little amniotic fluid in sac surrounding fetus)
  - ◆ Placenta previa - (placenta develops in lower uterus and blocks the uterine opening)
  - ◆ Abrupto placenta - (premature detachment of the placenta from the uterine wall)
  - ◆ Vaginal bleeding
2. A medical condition threatening the fetus and/or delivery
  - ◆ Suspected abnormal presentation - (abnormal fetal position for delivery, i.e., feet or buttocks first)
  - ◆ Suspected multiple gestation - (more than one fetus)
  - ◆ Significant difference between the size of the uterus and the time the fetus has been in the womb
  - ◆ Elevated maternal serum alpha-fetoprotein - (a protein substance that is normally produced by liver cells - can be a marker in the amniotic fluid obtained by amniocentesis for the prenatal diagnosis of anencephaly (absence of the brain and cranial vault))
  - ◆ Suspected fetal death
  - ◆ Suspected [anatomical](#) abnormality of the uterus
  - ◆ Maternal risk factors such as family history of [congenital anomalies](#), chronic systemic disease (hypertension, diabetes, sickle cell disease), or substance abuse
  - ◆ Suspected fetal growth abnormality, either growth retardation (failure of fetus to develop or grow in the uterus) or macrosomia - (fetus is abnormally large)
3. Confirmation of EDC when clinical history and exam are uncertain. In general, a single ultrasound performed between 14 and 24 weeks is sufficient for this purpose.
4. Follow up ultrasounds may be appropriate if the study will be used to alter or confirm a treatment plan.

## Medical Evidence regarding Ultrasound in Maternity Care indicates it is not recommended in the following situations:

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- ◆ Ultrasound in pregnancy is not recommended when it fails to meet the evidence based guidelines listed above.
- ◆ It is not recommended as a screening test or in the absence of medical indications or predisposing factors.
- ◆ It is not recommended when the study is used solely to determine the sex of the neonate (unless sex linked genetic defects are suspected), or to provide the mother with a picture of the baby.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 76801, 76802, 76805, 76810, 76811, 76812, 76815, 76816, 76817, 76818, 76819*

## Section II - Fetal Echocardiography

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Fetal echocardiography is a diagnostic fetal ultrasound test that checks the baby's heart while the baby is still in the uterus. It can diagnose heart defects and check for heart rhythm problems. Fetal echocardiography is performed using a two-dimensional (2-D) high resolution ultrasound system. Generally the standard 2-D echocardiogram is performed if a structural abnormality is found. Doppler flow mapping may be used to identify the area affected with an altered blood flow. The doppler then measures the speed of the flow, direction of the flow, pressure differences and cardiac output. M-mode echocardiography may also be used.

## Evidence Based Guideline for Fetal Echocardiography

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- A. Fetal echocardiography may be appropriate to diagnose patients at high-risk for [congenital](#) heart disease.
1. Fetal risk factors include any of the following:
    - ◆ Extracardiac abnormality;
    - ◆ Chromosomal abnormality;
    - ◆ Fetal cardiac [arrhythmia](#);
    - ◆ Non-immune hydrops;
    - ◆ Question of cardiac anomaly on prior sonogram;
    - ◆ Intrauterine growth retardation;
    - ◆ Family history of [Congenital](#) Heart Disease (parent or sibling).
  2. Maternal risk factors that place a neonate at risk for [congenital](#) heart disease include any of the following:
    - ◆ Family history of [Congenital](#) Heart Disease (parent or sibling);

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- ◆ [Teratogenic](#) exposure (e.g., alcohol, amphetamines, anticonvulsives, lithium);
- ◆ Maternal disorders (e.g., diabetes mellitus, collagen vascular disease, phenylketonuria);
- ◆ Maternal infection (e.g., Rubella);
- ◆ Familial syndromes (inherited).

### Medical Evidence regarding Fetal Echocardiography indicates it is not recommended in the following situations:

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Fetal echocardiography is not recommended for routine screening for [congenital](#) heart disease in the absence of risk factors noted above.

Because of the limited additive value and concern for ultrasound intensity, it is recommended that [color doppler](#) and pulsed doppler be limited to abnormal 2-D echocardiograms where additional structural and/or functional information is needed:

- ◆ when 2-D echocardiography is questionable or ambiguous;
- ◆ when the diagnosis depends on hemodynamic evaluation of intracardiac circulation, which can be obtained only with doppler;
- ◆ when the diagnosis depends on measuring fetal cardiac output; and
- ◆ to more precisely define a complicated diagnosis.

### Billing/Coding/Physician Documentation Information

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*Applicable Codes: 76825, 76826, 76827, 76828, 93325*

## Section III - Prenatal Genetic and Chromosomal Metabolic Testing

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Prenatal genetic and chromosomal metabolic tests are used to diagnose various prenatal genetic defects. What is commonly looked for is evidence of [trisomy](#), which is 3 copies of a chromosome instead of the expected 2. Trisomes indicating Edward's Syndrome ([Trisomy 18 syndrome](#)) and [Down Syndrome \(Trisomy 21\)](#) are the most common genetic defects found in the performance of these tests. Test results can be used to direct the timing of a cesarean section, fetal transfusion or in counseling the parents concerning a genetic disorder.

There are 2 common tests performed: **amniocentesis** and **chorionic villus sampling**.

- ◆ **Amniocentesis** is generally performed at between 14 and 18 weeks gestation for genetic testing. It is performed by withdrawing a sample of amniotic fluid from the mother through a needle inserted into the amniotic sac. An ultrasound is usually performed simultaneously to guide the insertion of the needle. The fluid is then used to diagnose fetal genetic abnormalities, assess fetal lung maturity

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and establish the severity of hemolytic disease in blood group isoimmunization.

- ◆ **Chorionic Villus Sampling** is also used to determine genetic defects. It is generally performed at 10-11 weeks and involves taking samples of villi (minute finger-like projections on the fetal membrane surface of tissues attached to the placenta). It involves inserting a needle or catheter into the placenta (staying outside the amniotic sac) and withdrawing a small amount of tissue. The tissue is grown in a culture and then examined for abnormalities. The approach can be through the cervix or through the abdomen. Ultrasound guidance is always used to pass the catheter within the chorion frondosum site.

### Evidence Based Guideline for Amniocentesis or Chorionic Villus Sampling (CVS)

1. Amniocentesis may be appropriate to diagnose or determine the severity of the following conditions:
  - ◆ neural tube defect (e.g., family history or elevated maternal serum alpha-fetoprotein level).
2. Amniocentesis or Chorionic Villus Sampling may be appropriate for the following clinical indications:
  - ◆ in pregnancies where the mother will be 35 years of age or older at the expected time of delivery;
  - ◆ when a previous pregnancy resulted in the birth of a child with chromosomal (e.g., [Down Syndrome](#)) or genetic abnormality, or major malformations;
  - ◆ when a chromosomal or genetic abnormality is known to exist in either parent;
  - ◆ when a history of chromosomal or genetic abnormality is present in a blood relative;
  - ◆ when there is history of multiple (3 or more) spontaneous abortions in this marriage or in a previous mating of either spouse;
  - ◆ when the fetus is at increased risk for a hereditary error of metabolism, detectable in vitro (observable in a test tube or artificial environment).
3. A relatively infrequent indication for amniocentesis and/or chorionic villus sampling is for fetal sex determination in pregnancies at risk for an X-linked hereditary disorder. In these conditions, only the male child manifests the genetic abnormality and inherits the trait from the mother who is a carrier but usually free of overt symptoms. Amniocentesis and/or chorionic villus sampling may be appropriate in the following conditions:
  - ◆ Hemophilia (inherited blood disorder)
  - ◆ X-linked mental retardation (chromosomal defect that leads to mental retardation)
  - ◆ X-linked hydrocephalus (chromosomal defect that leads to a condition marked by an accumulation of cerebrospinal fluid within the skull, an enlarged head, prominent forehead, brain atrophy, and mental retardation.
  - ◆ Duchenne Muscular Dystrophy - (form of inherited muscular dystrophy).

Amniocentesis may be performed for other reasons other than genetic testing It may be appropriate for

- ◆ Rh incompatibility sensitization
- ◆ fetal lung maturity when early delivery is anticipated.

### Medical Evidence regarding Amniocentesis or Chorionic Villus Sampling (CVS)

**indicates it is not recommended in the following situations:**

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Amniocentesis and CVS are not recommended when they are performed for sex determination in the absence of a documented increased risk of an X-linked disorder, or for routine screening in the absence of risk factors noted above.

**Billing/Coding/Physician Documentation Information**

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*Applicable codes: 59000, 59015, 76945, 76946*

*When it is an appropriate service, the analysis of fetal cells and amniotic fluid should be reported under the appropriate pathology codes as shown in the following list: 82143, 83661, 83662, 83663, 83664, 84081, 88235, 88267, 88269*

*In cases of analysis for a specific defect, the applicable code is that for the disease itself (i.e., in analyzing for glucosidase-beta deficiency, appropriate code is 82963, the code for this specific enzyme defect).*

## **Section IV - First-Trimester Detection of Down Syndrome Using Fetal Ultrasound Assessment of Nuchal Translucency Combined with Maternal Serum Assessment**

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Over the years many types of biologic markers have been investigated for use in detecting [Down syndrome](#) fetuses. Fetal nuchal translucency refers to the ultrasound detection of subcutaneous edema in the fetal neck. In the early 1990s, screening studies of pregnant women reported an association between increased nuchal translucency in the first trimester of pregnancy (10–13 weeks of gestation) and chromosomal defects, most commonly [Down syndrome](#), but also [Trisomy 18 syndrome](#) and [Trisomy 13 syndrome](#).

Ultrasonographic measurements of fetal nuchal translucency, in conjunction with maternal serum (blood) markers (human chorionic gonadotropin ( $\beta$ -hCG) and pregnancy-associated plasma protein A (PAPP-A) has been proposed as a technique for first trimester screening for [Down syndrome](#). First-trimester screening, if accurate, can provide important information to the mother several weeks before it would be available with traditional second-trimester screening. When the results are positive, such screening allows the patient to take advantage of first-trimester prenatal diagnosis by chorionic villus sampling or second-trimester amniocentesis.

Alternatives to first trimester noninvasive prenatal screening would include, but may not be limited to prenatal screening performed in the second trimester. The current gold standard of prenatal noninvasive screening for chromosomal abnormalities such as [Down syndrome](#) is commonly known as the quadruple marker screen. It consists of four laboratory tests that are performed on a sample of blood that is taken from the mother: alpha-fetoprotein (AFP), beta hCG, unconjugated estriol (uE3) and inhibin-A. AFP is a product of the fetal liver; uE3, hCG, and inhibin-A are hormones that are made by the placenta.

## Evidence Based Guideline for First-Trimester Detection of Down Syndrome using Fetal Ultrasound Assessment of Nuchal Translucency Combined with Maternal Serum Assessment

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First-trimester screening for detection of [Down syndrome](#), which consists of a calculation of risk based on maternal age, human chorionic gonadotropin ( $\beta$ -hCG), pregnancy-associated plasma protein A (PAPP-A), and ultrasonic measurement of fetal nuchal translucency, may be appropriate for women who are adequately counseled and desire information on the risk of having a child with [Down syndrome](#).

Note: It should be noted that in published studies of first trimester screening, the laboratory and imaging components of screening (i.e., fetal nuchal translucency and measurement of maternal serum factors) are performed in a coordinated fashion.

## Medical Evidence regarding First-Trimester Detection of Down Syndrome using Fetal Ultrasound Assessment of Nuchal Translucency Combined with Maternal Serum Assessment indicates it is not recommended in the following situations:

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First-trimester screening for detection of [Down syndrome](#) using measurement of nuchal translucency alone is not recommended.

Although first-trimester screening for [Down syndrome](#) and [trisomy 18](#) is an option, it is recommended that it be offered only if the following criteria can be met:

1. Appropriate ultrasound training and ongoing quality monitoring programs are in place.
2. Sufficient information and resources are available to provide comprehensive counseling to women regarding the different screening options and limitations of these tests.
3. Access to an appropriate diagnostic test is available when screening test results are positive.

(ACOG Committee Opinion No. 296, July 2004)

## Billing/Coding/Physician Documentation Information

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*Applicable codes: 76813, 76814, 84163, 84702, 84704*

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## Medical Term Definitions

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### **Anatomic**

pertaining to anatomy or the structure of an organism.

### **Arrhythmia**

abnormal rhythm of the heart; any variation from the normal rhythm of the heart beat.

### **Color doppler**

a way to see the flow in color, to determine how fast the blood is flowing.

### **Congenital**

existing at, and usually before birth; referring to conditions that are present at birth, regardless of their causation.

### **Congenital anomalies**

marked deviation from the normal standard, especially as a result of congenital defects.

### **Doppler echo**

checks for blood flow through the heart and blood vessels.

### **Down syndrome**

a chromosome disorder characterized by a small, anteroposteriorly flattened skull, short, flat-bridge nose, epicanthal fold, short phalanges, widened spaces between the first and second digits of hands and feet, and moderate to severe mental retardation, with Alzheimer's disease developing in the fourth or fifth decade. The chromosomal aberration is trisomy of chromosome 21 associated with late maternal age. Called also trisomy 21.

### **Teratogenic**

tending to produce abnormalities in the formative or developmental stage.

### **Trisomy**

the state of an individual or cell with an extra chromosome instead of the normal pair of homologous chromosomes; in humans, the state of a cell containing 47 normal chromosomes.

### **Trisomy 13 syndrome**

a chromosome aberration in which an extra chromosome 13 causes central nervous system defects and mental retardation, together with cleft palate and lip, polydactyly, dermal pattern anomalies, and abnormalities of the heart, viscera, and genitalia. Called also Patau's s.

### **Trisomy 18 syndrome**

a condition characterized by mental retardation, scaphocephaly or other skull abnormality, micrognathia, blepharoptosis, low-set ears, corneal opacities, deafness, webbed neck, short digits, ventricular septal defects, Meckel's diverticulum, and other deformities. It is due to the presence of an extra chromosome 18. Called also Edwards' s. and trisomy E s.

## Scientific Background and Reference Sources

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### **Policy entitled: Ultrasounds in Maternity Care**

National Association - 3/96

## Policy: Maternal and Fetal Diagnostics

Consultant Review - 4/93

MPAG Review - 3/99

### **Policy entitled: Fetal Echocardiography**

National Association - 3/96

Medical Policy Advisory Group Review - 3/99

### **Policy entitled: Prenatal Genetic and Chromosomal Metabolic Testing**

Plan Consultant - 4/93

Blue Cross Blue Shield Association, policy 74.01.02, issued 12/1/96

Medical Policy Advisory Group - 1/99

### **Policy entitled: Fetal Non-Stress Test**

Independent Review by Senior Director of Medical Affairs, 11/94

Consultant Review - 11/94

Medical Policy Advisory Group Review - 3/99

### **Policy entitled: Maternal and Fetal Diagnostics**

Ultrasound in Maternity Care, Fetal Echocardiography, Prenatal Genetic and Chromosomal Metabolic Testing, and Fetal Non-stress Test combined to form Maternal and Fetal Diagnostics. 9/99

Creasy, R.K. and Resnik, R. (194). Maternal Fetal Medicine (3rd ed.) Philadelphia: W.B. Saunders Company

BCBSA Medical Policy Reference Manual, 10/8/02; 4.01.07

BCBSA Medical Policy Reference Manual, 12/18/02; 4.01.02

BCBSA Medical Policy Reference Manual, 7/17/03; 4.01.01

Specialty Matched Consultant Advisory Panel - 8/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.07, 2/25/04.

ECRI Hotline Response - First Trimester Screening for Chromosomal Abnormalities: 10/29/04 from [http://www.ta.ecri.org/Hotline/Prod/summary/detail.aspx?doc\\_id+7377&q=nuchal+translucency&anm](http://www.ta.ecri.org/Hotline/Prod/summary/detail.aspx?doc_id+7377&q=nuchal+translucency&anm)

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.14, 7/15/04.

ACOG Committee Opinion. First trimester screening for fetal aneuploidy. No. 296, July 2004

Specialty Matched Consultant Advisory Panel - 12/2004

## **Policy Implementation/Update Information**

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### **Policy entitled: Ultrasounds in Maternity Care**

10/79 Original policy

6/83 Reaffirmed

6/84 Reaffirmed

3/88 Revised and reaffirmed

## **Policy: Maternal and Fetal Diagnostics**

- 8/96 Revised: National Association review 3/96. Combined National and Local policies. Added: IC review if reported more than once per month and ultrasound is allowed separately when performed in conjunction with amniocentesis
- 3/99 Reaffirmed

### **Fetal Echocardiography**

- 11/87 Evaluated: Doppler echocardiography investigational for cardiac abnormalities
- 8/92 Evaluated: Eligible for coverage for high risk cases
- 8/96 Reaffirmed: National Association reviewed 3/96. No changes.
- 3/99 Reviewed by MPAG. Reaffirm

### **Prenatal Genetics and Chromosomal Metabolic Testing**

- 1/79 Original policy - Generally accepted medical practice
- 6/83 Reaffirmed
- 8/88 Reviewed: assessment of fetal lung maturity and hemolytic disease of the newborn added
- 7/96 Revised: National Asso. reviewed 12/95. No changes. Combined previous separate policies amniocentesis and CVS policies into one. Combined local and National policies for ultrasound guidance during amniocentesis or CVS.
- 1/99 Reaffirmed

### **Policy entitled: Fetal Non-stress Test**

- 11/94 Original policy
- 11/96 Reaffirmed policy
- 3/99 Reviewed by MPAG, reaffirmed

### **New policy created entitled: Maternal and Fetal Diagnostics**

- 5/99 Reformatted, Medical Term Definitions added. Combined with Prenatal Genetic and Chromosomal Metabolic Testing, Fetal Echocardiography, and Fetal Non-stress test under new policy entitled "Maternal and Fetal Diagnostics". Descriptions changed.
- 9/00 System coding changes.
- 12/00 2001 CPT codes 83663 and 83664 added to policy. System coding changes.
- 9/01 Specialty Matched Consultant Advisory Group review.
- 10/01 Coding format changes.
- 12/01 Removed statement from Billing and Coding Guidelines for Fetal Non-stress Test section indicating that the test is not indicated prior to gestation age of 33 weeks.
- 12/03 Specialty Matched Consultant Advisory Panel review 8/2003. Benefits Applications and Billing/Coding sections revised. Under "When Fetal Echocardiography is Covered" #2-added "Rubella" as an example of Maternal infection. Typos corrected.
- 1/20/05 Specialty Matched Consultant Advisory Panel review - 12/9/04. Individual CPT codes listed for CPT code ranges 76801-76818 under Billing/Coding section for Section I - Ultrasound in Maternity Care. Added Section V - First-Trimester Detection of Down Syndrome. CPT codes 76819, 83662, 84081, 84163, 84702, 84703, 93325 added under appropriate sections. Medical term definitions and reference sources added.
- 11/3/05 HCPCS code S3626 (effective October 1, 2005) added to Section V- Billing/Coding and Billing/Coding section for entire policy.

## Policy: Maternal and Fetal Diagnostics

- 1/3/07 Medical Policy changed to Evidence Based Guideline. Fetal Non-stress Test section has been archived. CPT codes 76813 and 76814 effective 1/1/07 added to Section IV Billing/Coding section. CPT codes 84703 and S3626 removed from Section IV Billing/Coding section. CPT code 84703 is for qualitative hCG (is it present?); the most appropriate code is 84702-quantitative hCG (how much?). HCPCS code S3626 is for maternal serum quadruple marker screen which is usually performed in the second trimester; Section IV is regarding testing in the first trimester. (pmo)
- 8/13/07 Added HCPCS code S3618 to Section IV Billing/Coding. (pmo)
- 12/31/07 Under Section IV Billing/Coding, removed deleted HCPCS code S3618 and added new CPT code 84704 effective 1/1/08 that replaced it. (pmo)
- 6/22/10 Policy Guideline Number(s) removed (amw)

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