

Corporate Medical Policy

Maternal and Fetal Diagnostics

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Description of Procedure or Service

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).

The following topics are addressed in this policy:

Ultrasound in Maternity Care. Ultrasound performed during pregnancy is a diagnostic test used to visualize the uterus and fetus. A hand held device is passed over the abdominal surface, recording echoes 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. Although 3-D or 4-D fetal ultrasound can produce more “realistic” and recognizable images than conventional 2-D ultrasound, the clinical significance of this remains unclear. 2-D imaging remains the principal diagnostic modality.

Fetal Echocardiography. 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.

Prenatal Genetic and Chromosomal Metabolic Testing. 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) 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 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

Maternal and Fetal Diagnostics

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.

There has been interest in ultrasound markers to improve the accuracy of biochemical screening. One potential marker is fetal nuchal translucency (NT). This refers to the ultrasound detection of subcutaneous edema in the fetal neck and is measured as the maximal thickness of the sonolucent zone between the inner aspect of the fetal skin and the outer aspect of the soft tissue overlying the cervical spine or the occipital bone. In the early 1990s, screening studies of pregnant women reported an association between increased NT in the first trimester of pregnancy (10–13 weeks of gestation) and chromosomal defects, most commonly Down syndrome (trisomy 21), but also trisomy 18 and 13. Nuchal translucency could be done alone as a first-trimester screen or in combination with maternal serum markers, free beta subunit of human chorionic gonadotropin (B-hCG) and pregnancy-associated plasma protein-A (PAPP-A). These are different serum markers than those used in the second-trimester triple or quadruple screen.

Another potential ultrasound marker is fetal nasal bone examination. The technique for assessing the nasal bone using ultrasound involves viewing the fetal face longitudinally and exactly in the midline. The nasal bone synostosis resembles a thin echogenic line within the bridge of the nose. The nasal bones are considered to be present if this line is more echogenic than the overlying skin and absent if the echogenicity is the same or less than the skin, or if it is not visible. The absence of fetal nasal bone is considered to be a positive test result, indicating an increased risk of Down syndrome. In some cases, the sonographer will not be able to visualize the nasal area of the fetus's face and thus cannot make a determination of the presence or absence of nasal bone. The inability to visualize the nasal bone is regarded as an unsuccessful examination, rather than a positive test result. Fetal nasal bone examination can be done from 11 weeks to just before 14 weeks' gestation. It is sometimes recommended that, if the nasal bone is absent on ultrasound done between 11 and 12 weeks' gestation, a second examination be done 2 weeks later. Fetal nasal bone assessment can be done along with NT, or in the second step of a 2-stage screen for cases that are borderline using other first-trimester markers.

Related Policies:

Noninvasive Prenatal Testing for Fetal Aneuploidies Using Cell-Free Fetal DNA Carrier Testing

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for the Ultrasound, Fetal Echocardiography, and Prenatal Genetic and Chromosomal Metabolic Testing when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

***Please see appropriate section for policy guidelines.**

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Maternal and Fetal Diagnostics

Coverage Guidelines for Ultrasound in Maternity Care

Ultrasound is not medically necessary in every routine pregnancy, however, it may be medically necessary 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 medically necessary if the study will be used to alter or confirm a treatment plan.

Ultrasound codes 76801 and 76802 are reported when the maternal and fetal ultrasound evaluation is performed during the first trimester. CPT codes 76813 and 76814 are to be used between 10 and 14 weeks' gestation for the evaluation of the nuchal translucency as part of the first trimester screening process. The only indication for performing the 76813 examination is to measure the fetal nuchal translucency as one component of screening for fetal aneuploidy. Codes 76801/76802 should not be billed routinely in combination with the codes 76813/76814 unless there is either a maternal and/or fetal indication to do so.

Ultrasound in pregnancy is not medically necessary when it fails to meet the policy guidelines listed above.

It is not medically necessary as a screening test or in the absence of medical indications or predisposing factors.

It is not medically necessary 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.

Maternal and Fetal Diagnostics

3-D or 4-D fetal ultrasound is considered not medically necessary.

Coverage Guidelines for Fetal Echocardiography

Fetal echocardiography may be medically necessary 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;
 - Suspicion of twin-twin transfusion syndromes;
 - 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);
 - Teratogenic exposure (e.g., alcohol, amphetamines, anticonvulsives, lithium paroxetine);
 - Maternal metabolic disorders (e.g., diabetes mellitus, collagen vascular disease, phenylketonuria);
 - Maternal autoimmune disorders (e.g., collagen vascular disease, systemic lupus erythremia, Sjogren's);
 - Maternal infection (e.g., Rubella);
 - Maternal seizure disorder and not currently taking anti-seizure medication
 - Familial syndromes (Ellisvan, Creveld, Marfan, Noonan's, etc).

Fetal echocardiography is not medically necessary 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.

Coverage Guidelines for Amniocentesis or Chorionic Villus Sampling (CVS)

- 1.) Amniocentesis may be medically necessary 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;

Maternal and Fetal Diagnostics

- 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 reasons other than genetic testing. It may be medically necessary for:

- Rh incompatibility sensitization
- Fetal lung maturity when early delivery is anticipated
- Increased risk for neural tube defect (e.g., a family history or elevated maternal serum alpha-fetoprotein level)

Amniocentesis and CVS are not medically necessary 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

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.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes for Ultrasound in Maternity Care: 76801, 76802, 76805, 76810, 76811, 76812, 76815, 76816, 76817, 76818, 76819

Applicable codes for fetal echocardiography: 76825, 76826, 76827, 76828, 93325

Applicable codes for prenatal genetic and chromosomal metabolic testing : 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).

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and /or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Maternal and Fetal Diagnostics

Scientific Background and Reference Sources

Policy entitled: Ultrasounds in Maternity Care

National Association - 3/96

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

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.14, 12/8/11.

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.14, 8/8/13.

Specialty Matched Consultant Advisory Panel – 9/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.14, 4/10/14

Specialty Matched Consultant Advisory Panel – 9/2014

Maternal and Fetal Diagnostics

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.14, 4/23/15

Specialty Matched Consultant Advisory Panel – 9/2015

Society for Maternal-Fetal Medicine (SMFM), White paper on billing combination of 76801 and 76813. 2010.

Salomon LJ, Alfirevic Z, Bilardo CM, Chalouhi GE, Ghi T, Kagan KO, Lau TK, Papageorgiou AT, Raine-Fenning NJ, Stirnemann J, Suresh S, Tabor A, Timor-Tritsch IE, Toi A, Yeo G. ISUOG Practice Guidelines: performance of first-trimester fetal ultrasound scan. *Ultrasound Obstet Gynecol* 2013; 41: 102–113.

Screening for fetal chromosomal abnormalities. ACOG Practice Bulletin No. 77. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2007;109:217-27. Reaffirmed 2013.

Specialty Matched Consultant Advisory Panel – 3/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.14, 10/13/16

American College of Obstetricians and Gynecologists (ACOG). Practice Bulletin #101.

Ultrasonography in pregnancy. *Obstet Gynecol*. 2009; 113(2 Pt 1):451-461. Reaffirmed 2014

Policy Implementation/Update Information

Policy entitled: Ultrasounds in Maternity Care

10/79	Original policy
6/83	Reaffirmed
6/84	Reaffirmed
3/88	Revised and reaffirmed
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
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Maternal and Fetal Diagnostics

- 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.
- 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)
- 1/1/13 Policy changed to Active status and will undergo routine literature review. Added information regarding fetal nasal bone assessment to Section IV. Added statement that "First-trimester screening for detection of Down syndrome incorporating fetal nasal bone assessment is not recommended" to Not recommended section in Section IV. References updated. Added CPT codes 81508, 81509, 81510, 81511, and 81512 to Section IV Billing/Coding. (sk)
- 4/29/14 Reference added. Specialty Matched Consultant Advisory Panel review 9/18/13. No change to Guideline statement. (sk)
- 10/14/14 Related policy added. Specialty Matched Consultant Advisory Panel review 9/30/14. Guideline recommendation statement reworded. No change to Guideline intent. (sk)

Maternal and Fetal Diagnostics

- 9/1/15 Evidence based guideline converted to corporate medical policy. Medical director review. Reference added. Notification given 9/1/15 for policy effective date 10/30/15. (sk)
- 10/30/15 Specialty Matched Consultant Advisory Panel review 9/2015. (sk)
- 4/1/16 Policy reformatted. The following information added to the Guidelines for Ultrasound in Maternity Care: Ultrasound codes 76801 and 76802 are reported when the maternal and fetal ultrasound evaluation is performed during the first trimester. CPT codes 76813 and 76814 are to be used between 10 and 14 weeks' gestation for the evaluation of the nuchal translucency as part of the first trimester screening process. The only indication for performing the 76813 examination is to measure the fetal nuchal translucency as one component of screening for fetal aneuploidy. Codes 76801/76802 should not be billed routinely in combination with the codes 76813/76814 unless there is either a maternal and/or fetal indication to do so. Specialty Matched Consultant Advisory Group review 3/30/2016. **Notification given 4/1/16 for effective date 5/31/16.** (an)
- 11/22/16 All policy information related to First-Trimester Detection of Down Syndrome Using Fetal Ultrasound Markers Combined With Maternal Serum Assessment have been removed from this policy. (an)
- 4/28/17 Added information regarding 3-D and 4-D fetal ultrasound to Description section. Added fetal and maternal risk factors to the list in the Fetal Echocardiography section. Added an indication for amniocentesis to the section on Amniocentesis and Chorionic Villus Sampling. Reference added. Specialty Matched Consultant Advisory Panel review 3/29/2017. (an)
- 4/27/18 Specialty Matched Consultant Advisory Panel review 3/28/2018. No change to policy statement. (an)

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