BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

First-Trimester Detection of Down Syndrome Using Fetal Ultrasound Markers Combined with Maternal Serum Assessment

Policy #: 233
Category: Obstetrics

Latest Review Date: December 2020
Policy Grade:
Effective December 13, 2016: Active Policy but no longer scheduled for regular literature reviews and updates.

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat first-trimester screening for detection of Down syndrome, which consists of a calculation of risk based on maternal age, maternal serum markers such as human chorionic gonadotropin and pregnancy-associated plasma protein A, and ultrasonic measurement of fetal nuchal translucency as a a **covered benefit** for women who are adequately counseled and desire information on the risk of having a child with Down syndrome. .

Blue Advantage will treat first-trimester screening for detection of Down syndrome using measurement of nuchal translucency alone as a **non-covered benefit.**

Blue Advantage will treat first-trimester screening for detection of Down syndrome incorporating fetal nasal bone assessment translucency as a **non-covered benefit** and as investigational.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Ultrasound markers can potentially increase the sensitivity of biochemical measures for first trimester detection of Down syndrome. Nuchal translucency (NT) refers to the ultrasound detection of subcutaneous edema in the fetal neck between weeks 10 and 13 of gestation. Fetal nasal bone examination involves ultrasound assessment at 11-14 weeks' gestation to identify the presence or absence of the nasal bone.

Definitive diagnosis of Down syndrome and other chromosomal abnormalities requires amniocentesis or chorionic villus sampling (CVS), both of which are invasive procedures that carry a risk of miscarriage estimated at 0.5% to 1%. Because of this risk, before biochemical screening existed, diagnosis was generally only offered to women 35 years or older, for whom the risk of the procedure approximated the risk of Down syndrome. However, the majority of babies with Down syndrome are born from mothers younger than 35 years, even though the mothers are at lower individual risk. This situation created interest in developing less-invasive screening programs based on assessment of serum markers that have shown associations with Down syndrome. In the late 1980s, biochemical screening at 16 weeks' gestation was developed and began to be offered to all pregnant women. Biochemical screening consists of maternal serum measurements of alpha-fetoprotein, human chorionic gonadotropin, and unconjugated estriol (i.e., triple screen). More recently, there has been the option of a fourth marker, inhibin-A (quadruple screen). The triple screen identifies approximately 69% of Down syndrome

pregnancies and the quadruple screen 81%, both at a 5% false-positive rate. This false-positive rate refers to the proportion of all tests administered that are falsely positive at the cutoff point that produces that particular value of sensitivity. Among women who test positive, only about 2% actually have a fetus with Down syndrome.

There has also been interest in ultrasound markers to improve the accuracy of biochemical screening. One potential marker is fetal 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, but also trisomy 18 and 13. NT could be done alone as a first-trimester screen, or in combination with the 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.

Note: This policy only addresses the ultrasound markers, nuchal translucency, and fetal nasal bone assessment.

KEY POINTS:

The literature was reviewed through December 3, 2020.

Summary of Evidence

For individuals who are pregnant and in the first trimester who receive first-trimester Down syndrome screening of maternal serum markers and nuchal translucency, the evidence includes observational screening studies. Relevant outcomes are test accuracy and validity and resource utilization. There is sufficient evidence from 2 large multicenter prospective studies- the Serum, Urine, and Ultrasound Screening Study (SURUSS) and the First and Second Trimester

Evaluation of Risk (FASTER) trial- as well as several smaller studies, that first-trimester screening for Down syndrome with measurement of fetal NT and maternal serum markers is at least as accurate as alternative tests and may allow earlier confirmation or exclusion of Down syndrome. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who are pregnant and in the first trimester who receive first-trimester Down syndrome screening of nuchal translucency alone, the evidence includes observational screening studies. Relevant outcomes are test accuracy and validity and resource utilization. The large multicenter prospective studies SURUSS and FASTER found, overall, that first-trimester screening with NT alone is inferior to first- or second-trimester combined screening. Additional testing may not be necessary in those few cases when NT is at least 4.0 mm due to the high likelihood of Down syndrome, but this would affect only a very small number of cases (0.09%-0.3%). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are pregnant and in the first trimester who receive first-trimester Down syndrome screening of fetal nasal bone, the evidence includes several observational studies. Relevant outcomes are test accuracy and validity and resource utilization. The accuracy of testing in the published literature is variable, with some studies reporting relatively low sensitivity rates. The variability in accuracy reported may reflect the difficulty in performing and interpreting this test, and test results are likely prone to differences in operator characteristics. Limited evidence has suggested that there may be modest incremental benefit when the test is used in combination with NT measurement and serum markers, but the degree of benefit is unclear. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

American College of Obstetricians and Gynecologists (ACOG)

In December 2016, ACOG issued practice bulletin 175 for ultrasound in preganancy. The following recommendations and conclusions in the bulletin are relevant to this evidence review:

Level A recommendation (based on good and consistent scientific evidence:
"Measurement of nuchal translucency alone is less effective for first-trimester screening of the singleton pregnancy than is combined testing (nuchal translucency measurement and biochemical markers)."

There is no specific recommendation regarding nasal bone assessment, but they state the following:
"Other first trimester screening ultrasonographic markers such as nonvisualization of the nasal bone, tricuspid regurgitation, and abnormal ductus venosus waveforms have been associated with trisomy 21, but their clinical usefulness in the general population remains uncertain."

In May 2016 (reaffirmed 2018), the American College of Obstetricians and Gynecologists issued practice bulletin 163 on screening for fetal aneuploidy, replacing practice bulletin 77. The following recommendations and conclusions in the bulletin are relevant to this evidence review:

Level A recommendations (based on good and consistent scientific evidence:
"Women who have a negative screening test result should not be offered additional screening tests for aneuploidy because this will increase their potential for a false-positive test result."

"If an enlarged nuchal translucency, an obvious anomaly, or a cystic hygroma is identified on ultrasonography, the patient should be offered genetic counseling and diagnostic testing for aneuploidy as well as follow-up ultrasonography for fetal structural abnormalities."

"Patients with an enlarged nuchal translucency or cystic hygroma and normal fetal karyotype should be offered an anatomic evaluation in the second trimester, fetal cardiac ultrasonography, and further counseling regarding the potential for genetic syndromes not detected by aneuploidy screening."

"Women with a positive screening test result for fetal aneuploidy should be offered further detailed counseling and testing."

Level C (based primarily on consensus and expert opinion):
"Aneuploidy screening or diagnostic testing should be discussed and offered to all women early in pregnancy, ideally at the first prenatal visit."

"All women should be offered the option of aneuploidy screening or diagnostic testing for fetal genetic disorders, regardless of maternal age."

"If an isolated ultrasonographic marker for aneuploidy is detected, the patient should be offered aneuploidy screening if it was not offered previously."
"Some women who receive a positive test result from traditional screening may prefer to have cell-free DNA screening rather than undergo definitive testing. This approach may delay definitive diagnosis and management and may fail to identify some fetuses with aneuploidy."

"Parallel or simultaneous testing with multiple screening methodologies for aneuploidy is not cost effective and should not be performed."

U.S. Preventive Services Task Force Recommendations
Not applicable

KEY WORDS:
First trimester screening, nuchal translucency, NT, pregnancy-associated plasma protein, PAPP-A, serum estriol, Down syndrome, free beta-hCG, fetal nasal bone assessment, Maternal fetal screen, T1 SM, T1+Y Chromosome SM, free beta SM, Eurofins

APPROVED BY GOVERNING BODIES:
Fetal ultrasound uses available instrumentation and as a surgical procedure is not subject to regulation by the U.S. Food and Drug Administration.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT codes:
The following codes should be used for ultrasound measurement of nuchal translucency:

76813	Ultrasound, pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; single or first gestation
76814	Ultrasound, pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; each additional gestation (list separately in addition to code for primary procedure)

There is no specific CPT code for ultrasound assessment of fetal nasal bone translucency. It should be reported using CPT code 76815- Ultrasound, pregnant uterus, real time with image documentation, limited (e.g., fetal heartbeat, placental location, fetal position and/or qualitative amniotic fluid volume), one or more fetuses.

The following codes should be used to report combination testing:

81508	Fetal congenital abnormalities, biochemical assays of two proteins (PAPP-A, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score (Do not report 81508 in conjunction with 84163, 84702)
81509	Fetal congenital abnormalities, biochemical assays of three proteins (PAPP-A, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score (Do not report 81509 in conjunction with 84163, 84702, 86336)
81510	Fetal congenital abnormalities, biochemical assays of three proteins (AFP, uE3, hCG [any form], utilizing maternal serum, algorithm reported as a risk score (may include additional results from previous biochemical testing)
81511	Fetal congenital abnormalities, biochemical assays of four analytes (AFP, uE3, hCG [any form], DIA) utilizing maternal serum, algorithm reported as a risk score (may include additional results from previous biochemical testing) (Do not report 81511 in conjunction with 82105, 82677, 84702, 86336)
81512	Fetal congenital abnormalities, biochemical assays of five analytes (AFP, uE3, total hCG,

	hyperglycosylated hCG, DIA) utilizing maternal serum, algorithm reported as a risk score (Do not report 814XX5 in conjunction with 82105, 82677, 84702, 86336)

Previous Coding:

0124U	Fetal congenital abnormalities, biochemical assays of three analytes (free beta-hCG, PAPP-A, AFP), time-resolved fluorescence immunoassay, maternal dried blood spot, algorithm reported as risk scores for fetal trisomies 13/18 and 21 (Effective 10/01/19- Deleted 07/01/2020)
0125U	Fetal congenital abnormalities and perinatal complications, biochemical assays of 5 analytes (free beta-hCG, PAPP-A, AFP, placental growth factor and inhibin-A), time-resolved fluorescence immunoassay, maternal serum, algorithm reported as risk scores for fetal trisomies 13/18, 21, and preeclampsia (Effective 10/1/19 - Deleted 07/01/2020)
0126U	Fetal congenital abnormalities and perinatal complications, biochemical assays of 5 analytes (free beta-hCG, PAPP-A, AFP, placental growth factor and inhibin-A), time-resolved fluorescence immunoassay, includes qualitative assessment of Y chromosome in cell-free fetal DNA, maternal serum and plasma, predictive algorithm reported as a risk scores for fetal trisomies 13/18, 21, and preeclampsia (Effective 10/1/19 - Deleted 07/01/2020)

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