APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.
BACKGROUND

First-trimester prenatal screening involves determination of maternal serum free β-human chorionic gonadotropin (hCG) and pregnancy-associated plasma protein A (PAPP-A) levels combined with ultrasonographic measurement of nuchal translucency. The results of these tests, in conjunction with maternal age, are used to calculate patient-specific risk for fetal chromosomal disorders. The goal of first-trimester prenatal screening is to provide risk information early in pregnancy, thereby allowing for additional diagnostic testing and optimal pregnancy management or early termination.1

Birth defects are the leading cause of infant mortality in the United States, accounting for more than 20% of all infant deaths. Although the causes of approximately 70% of all birth defects are unknown, many birth defects can be attributed to chromosomal abnormalities. Pregnant women who have a high risk of fetal chromosomal disorders, such as those 35 years of age or older, are generally offered chorionic villus sampling or amniocentesis, which allows the karyotype of the fetus to be determined. However, these tests are invasive and can cause miscarriage, and are not indicated as screening tests for women at average risk. Therefore, a number of noninvasive prenatal tests have been developed to screen for fetal abnormalities and to determine the need for additional diagnostic testing. Pregnant women typically undergo prenatal screening during the second trimester with tests that evaluate specific hormone levels in the serum and/or ultrasonographic examination of the fetus. Serum concentrations of human chorionic gonadotropin (hCG), a-fetoprotein, and unconjugated estradiol can be measured, allowing calculation of the risk of fetal abnormalities and determination of the need for further diagnostic testing, such as amniocentesis. These biochemical tests, known as the “triple screen,” are typically performed during the 15th to 18th weeks of gestation. Ultrasonography can also be used as either a screening or diagnostic test to detect certain fetal abnormalities. However, second-trimester screening fails to detect every case of fetal abnormality and falsely identifies many healthy pregnancies as being at significant risk for abnormalities. In addition, second-trimester screening limits the time for the patient to receive information that may influence choice of treatments, such as termination of pregnancy. Pregnancy termination is safer and more widely available in the first trimester and in the first half of the second trimester.1

To address the shortcomings of second-trimester screening, a protocol for first-trimester screening has been developed. This approach requires determination of maternal serum free b-hCG and pregnancy-associated plasma protein A (PAPP-A) levels, in combination with ultrasonographic measurement of nuchal translucency, the thickness of the space between the back of fetal neck and the overlying skin. Once the risk of fetal genetic abnormality has been calculated based on maternal age, nuchal translucency measurement, and free b-hCG and PAPP-A levels, the patient is advised of her treatment options. Amniocentesis or chorionic villus sampling is recommended if the risk of chromosomal abnormality exceeds the risk of miscarriage due to the sampling procedure. The fetal karyotype obtained from the collected cells then allows definitive diagnosis of chromosomal aberrations. First-trimester screening is only intended to estimate the risk of chromosomal disorders, and does not detect open neural tube defects.1

American College of Obstetricians and Gynecologists (ACOG) Position Statement 2

ACOG notes the following Level A recommendations, based on scientific evidence and support the use of screening:

Clinical Coverage Guideline

• First-trimester screening using both nuchal translucency measurement and biochemical markers is effective in testing for Down syndrome in the general population.
• Nuchal translucency measurement alone is less effective in first-trimester screening than the combined test (measurement and biochemical markers).
• Women with an increased risk of aneuploidy with first-trimester screening should be referred for genetic counseling, as well as the option of CVS or second-trimester amniocentesis.
• Neural defect screening should be offered in the second trimester to women who elect only first-trimester screening for aneuploidy.

Level B recommendations include:
• Screening and invasive diagnostic testing should be available to women presenting for prenatal care before 20 weeks, regardless of maternal age. Differences in screening and invasive diagnostic testing should be discussed.
• Integrated first- and second-trimester screening is more sensitive with lower false-positive rates than first-trimester screening alone.
• Serum integrated screening is a useful option in pregnancies where nuchal translucency measurement is not available or cannot be obtained.
• An abnormal finding on second-trimester ultrasound examination identifying a major congenital anomaly significantly increases the risk of aneuploidy and warrants further counseling and the offer of a diagnostic procedure.
• Patients who have a fetal nuchal translucency measurement of 3.5 mm or higher in the first trimester, despite a negative aneuploidy screen, or normal fetal chromosomes, should be offered a targeted ultrasound examination, fetal echocardiogram, or both.
• Down syndrome risk assessment in multiple gestation using first- or second-trimester serum analytes is less accurate than in singleton pregnancies.
• First-trimester nuchal translucency screening for Down syndrome is feasible in twin or triplet gestation but has a lower sensitivity than first-trimester screening in singleton pregnancies.

POSITION STATEMENT

Applicable To:
✓ Medicaid – Florida, Georgia, Hawaii, Kentucky

For markets noted below, please refer to Care Core National Radiology / Imaging criteria available at www.wellcare.com/provider/CCGs.

✓ Medicaid – Illinois, Missouri, New Jersey, New York, South Carolina

Fetal ultrasound assessment of nuchal translucency (NT) is considered medically necessary if ALL of the following criteria are met:

1) Documented evidence of appropriate ultrasound training and ongoing quality monitoring programs are in place through an approved credentialing process for NT measurements (MFMF/NTQR/ and FMFUS); AND,

2) Documented evidence that measurement of NT is being performed in combination with maternal serum assessment which must include the following:
• Serum human chorionic gonadotropin (free β-hCG or total hCG); AND,
• Serum pregnancy-associated plasma protein A (PAPP-A)

AND,
3) Documented evidence that NT assessment will be performed between 10 weeks/4 to 7 days and 13 weeks/6 to 7 day.

AND,

4) Member has received adequate counseling regarding possible positive screening outcome.

**CODING**

**Covered CPT® Codes**

- 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

**HCPCS Codes** - No applicable code.

**ICD-9-CM Procedure Codes** - No applicable code.

**Draft ICD-10-PCS codes** - No applicable code.

**Covered ICD-9-CM Diagnosis Codes**

- V23.81 Elderly primigravida, First Pregnancy in a woman who will be 35 years of age or older at delivery
- V23.82 Elderly multigravida, Second or more pregnancy in a woman who will be 34 years of age or older at delivery
- V26.31 Genetic counseling and testing
- V28.89 Nuchal Translucency Testing

**Covered Draft ICD-10-CM Diagnosis Codes**

- O09.511 - O09.513 Supervision of elderly primigravida
- O09.521 - O09.523 Supervision of elderly multigravida
- O09.891 - O09.893 Supervision of other high risk pregnancies
- Z31.430 Encounter of female for testing for genetic disease carrier status for procreative management
- Z36 Encounter for antenatal screening of mother, i.e., nuchal translucency testing


**REFERENCES**


**MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS**

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<td>7/11/2015</td>
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<tr>
<td>8/7/2014</td>
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<td>8/9/2013</td>
<td>Reinstated for markets where CareCore is not a vendor.</td>
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<td>6/7/2012</td>
<td>Retired by MPC due to coverage by CareCore criteria.</td>
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