Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for ultrasound in pregnancy when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
The member is eligible for a nuchal translucency scan at 11-14 weeks gestation and a routine obstetrical ultrasound at 20 weeks. Additional ultrasounds performed would need to meet the medically necessary criteria defined below.

The following guidelines should be utilized in determining the medical necessity for the use of 2-D ultrasound in maternity care beyond the initial routine ultrasound:

1. Ultrasound in diagnosing abnormal pregnancy, e.g.,
   - Suspected ectopic pregnancy;
   - Suspected hydatidiform mole;
   - Threatened or missed abortion;
   - Congenital malformation, fetal or maternal;
   - Polyhydramnios/oligohydramnios;
   - Placenta previa;
   - Abruptio placenta;
   - Vaginal bleeding.

2. Ultrasound for diagnosing other conditions affecting the fetus and/or delivery, e.g.:
   - Suspected abnormal presentation;
   - Suspected multiple gestation;
   - Significant discrepancy between uterine size and dates;
   - Elevated maternal serum alpha-fetoprotein;
   - Suspected fetal death;
   - Suspected anatomical uterine abnormality;
   - Maternal risk factors such as family history of congenital anomalies, chronic systemic disease (e.g., hypertension, diabetes, sickle cell disease), or substance abuse;
   - Suspected fetal growth abnormality, either growth retardation or macrosomia;
   - Determination of gestation for uncertain dates.
Serial ultrasounds, every 3-4 weeks, with evidence of maternal Zika virus infection.

**When Policy Topic is not covered**
The use of ultrasound not meeting the criteria above is **not medically necessary**.

The use of three-dimensional or four-dimensional (real time three-dimensional) ultrasound in obstetrics is considered **not medically necessary**. Although 3-D or 4-D ultrasound may be superior to 2-D ultrasound in demonstrating cleft lip or palate and for accurate identification of the level of spine involvement by a neural tube defect, the significance of this in terms of improved clinical outcomes has not been demonstrated.

**Considerations**
Follow-up scans should be given individual consideration based on abnormal findings in the initial scan.
Real-time ultrasonography should be included in the global fee for obstetrical care.

Although ultrasound is medically necessary as an adjunct to some procedures, it is an integral part of the procedure and should be included in the global fee or charge. Some examples of ultrasound as a procedure adjunct are:
- Amniocentesis;
- Cerclage placement;
- External version;
- Amnioscopy/fetoscopy;
- Chorionic villus sampling.

**Description of Procedure or Service**
The visualization of inner structures (uterus, placenta, fetus, etc.) of the body is achieved by recording the reflection of high frequency, nonelectromagnetic nonionizing sound waves directed into the tissues of the abdomen. 2D ultrasound images are made up of a series of thin image 'slices', with only one slice being visible at any one time to create a 'flat' looking picture.

Three dimensional (3-D) or volume ultrasonography acquires a volume (rather than a slice) of ultrasonographic data which is then stored. In the multiplanar display, three perpendicular planes are displayed simultaneously, and can be manipulated to obtain suitable views for potential diagnosis and geometric measurements.

The difference between 3-D and 4-D ultrasound is that in 4-D ultrasound the three-dimensional view can be seen in real time. In both, substantial post-processing rendering is required to get the image detail and benefits of the technique.
Rationale

2-D ultrasound
A search of the literature was completed through the MEDLINE database for the period of January 1990 through January 1996. The search strategy focused on references containing the following Medical Subject Headings:
- Obstetric or Prenatal
- Ultrasound

3-D and 4-D ultrasound
Although 3-D ultrasound can produce more “realistic” and recognizable images than conventional 2-D ultrasound, the clinical significance of this remains unclear. The perceived superiority of 3-D ultrasound for a number of fetal abnormalities has not been definitively established. For example, Levental and colleagues reported that compared to two-dimensional ultrasonography, non-cardiac gated three-dimensional sonography yielded inadequate reconstructive image quality of basic echocardiographic views (four-chamber view, right ventricular outflow tract, left ventricular outflow tract). (1) Additionally, false-positive or false-negative findings were observed on 3-D ultrasonograms. Although gated 3-D volume data sets result in improved imaging capabilities, according to Meyer-Wittkopf, et al, two-dimensional imaging remains the principal diagnostic modality.

Michailidis and colleagues noted that real-time 2-D ultrasound is still the best way to examine fetal anatomy in the first trimester. (2) A comparison of the diagnostic capabilities of 2-D and 3-D sonography for the study of conjoined twins revealed that 2-D sonography provided more definitive and specific information about shared organs and 2-D sonography is the primary modality for diagnosing and evaluating conjoined twins.

Although three-dimensional ultrasound may be useful in evaluating abdominal abnormalities such as bowel obstruction, gastroschisis, omphalocele, and wall defects secondary to bands, the advantages compared with two-dimensional ultrasound have not been identified. (3) Three-dimensional ultrasound may be superior to two-dimensional ultrasound in demonstrating cleft lip or palate and for accurate identification of the level of spine involvement by a neural tube defect, however, the significance of this in terms of improved clinical outcomes has not been demonstrated. Dyson and colleagues performed 3-D ultrasound imaging in 63 patients in whom a 2-D study suggested an anomaly and 3-D imaging was felt likely to provide useful information. (4) Patient management was said to “change” in 3 patients (5%) based on the additional information provided by the 3-D study; however two of these “changes” referred to the patients’ decision regarding termination of the pregnancy because of better clarification of a cleft lip and palate and in the third, where the level of a neural tube defect was better identified, there is no information as to the management decisions taken.

Several authors have noted that it is difficult to evaluate the net effect of 3-D ultrasound on obstetric practice and on outcome. They also note that no comparative studies are available to support the superiority of 3-D ultrasound
versus 2-D for evaluation of the central nervous system. (5-6) Although the uterine cervix in pregnancy has become a focus of 3-D ultrasound, insufficient good data is available to assess fully the additional clinical advantage of 3-D ultrasound in this context.

In summary, although 3-D ultrasound may provide improved imaging for certain areas of fetal anatomy and abnormalities, it has not been demonstrated in clinical studies to result in improved health outcomes when compared to conventional 2-D ultrasound imaging.

References

Billing Coding/Physician Documentation Information

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>76376</td>
<td>3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality; not requiring image postprocessing on an independent workstation</td>
</tr>
<tr>
<td>76377</td>
<td>3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality; requiring image postprocessing on an independent workstation</td>
</tr>
<tr>
<td>76801</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester, transabdominal approach; single or first gestation</td>
</tr>
<tr>
<td>76802</td>
<td>Each additional gestation</td>
</tr>
<tr>
<td>76805</td>
<td>Ultrasound, pregnant uterus, real-time with image documentation; fetal and maternal evaluation, after first trimester, transabdominal approach; single or first gestation</td>
</tr>
<tr>
<td>76810</td>
<td>Same as 76805, each additional gestation</td>
</tr>
<tr>
<td>76811</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; single or first gestation</td>
</tr>
<tr>
<td>76812</td>
<td>Same as 76811. Each additional gestation</td>
</tr>
<tr>
<td>76813</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; single or first gestation</td>
</tr>
<tr>
<td>76814</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, first...</td>
</tr>
</tbody>
</table>
trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; each additional gestation (List separately in addition to code for primary procedure)

76815 Ultrasound, pregnancy uterus, real time with image documentation, limited (fetal growth rate, heart beat, anomalies, placental location) – one or more fetuses

76816 Ultrasound, pregnancy uterus, real time with image documentation, follow-up, transabdominal approach, per fetus

76817 Ultrasound, pregnancy uterus, real time with image documentation, transvaginal

76818 Fetal biophysical profile with non-stress testing

76819 Fetal biophysical profile without non-stress testing

76825 Echocardiography, fetal cardiovascular system, real time with image documentation (2D), with or without M-Mode recording

76826 Same as 76825 – follow-up or repeat study

76827 Doppler echocardiography, fetal, cardiovascular system, pulsed wave and/or continuous wave with spectral display, complete

76828 Same as 76827 – follow up or repeat study

76999 Unlisted ultrasound procedure (eg, diagnostic, interventional)

Additional Policy Key Words
N/A

Policy Implementation/Update Information
10/1/88 New policy.
12/1/00 No policy statement changes.
12/1/01 Added post amniocentesis studies to covered indications.
4/1/02 Removed a statement from the considerations section, no changes to the policy statement.
12/1/02 Added “routine” to the policy statement for ultrasound as not medically necessary for all pregnancies.
12/1/03 No policy statement changes.
12/1/04 Added 3-D and 4-D to the policy as investigational. Clarified the policy statement that an initial routine ultrasound is included in the Maternity Global Fee Inclusions and Exclusions policy.
12/1/05 No policy statement changes.
7/1/06 Removed language regarding global maternity.
12/1/06 No policy statement changes.
12/1/07 No policy statement changes.
12/1/08 No policy statement changes.
12/1/09 No policy statement changes.
3/1/10 Policy clarified to indicate the member is eligible for one routine ultrasound during pregnancy. Ultrasounds beyond the routine ultrasound require medical necessity.
12/1/10 No policy statement changes.
12/1/11 No policy statement changes.
12/1/12 Policy statement clarified regarding coverage of nuchal translucency
<table>
<thead>
<tr>
<th>Date</th>
<th>Change Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/1/13</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>12/1/14</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>12/1/15</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>12/1/16</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>3/1/17</td>
<td>Added Serial ultrasounds, every 3-4 weeks, with evidence of maternal Zika virus infection to Medically Necessary policy statement.</td>
</tr>
<tr>
<td>12/1/17</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>12/1/18</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>12/1/19</td>
<td>No policy statement changes.</td>
</tr>
</tbody>
</table>

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.