



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

WellCare Health Plans of New Jersey, Inc.

WellCare of Florida, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

WellCare of Kentucky, Inc.

WellCare of Louisiana, Inc.

WellCare of New York, Inc.

WellCare of Ohio, Inc.

WellCare of Texas, Inc.

WellCare Prescription Insurance, Inc.

3D and 4D Ultrasound

Policy Number: HS-109

Original Effective Date: 6/15/2009

Revised Date(s): 6/25/2010; 8/2/2011;
5/3/2012 RETIRED

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. 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.

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

Three-dimensional (3D) ultrasound (US) is used to create both a surface image of the fetus in utero and cross-sectional images from any angle; images of extrafetal and maternal structures can be created in a similar manner. In constructing the 3D US image, the software automatically records and stores the image as part of the process. The stored virtual 3D US image can be rotated for different surface views and cross sections from angles not available with two-dimensional (2D) US. This has potential use in detecting and diagnosing abnormalities in maternal and extrafetal structures as well as in the developing fetus. Four-dimensional (4D) US, or real-time 3D US, can create many images per second, so that fetal motion can be observed in three dimensions. While use of 3D US and 4D US has been commercialized to create nondiagnostic “keepsake” images, the value of these detailed images for informing parental decision making and pregnancy and postpartum management is currently under investigation.

Three-dimensional (3D) ultrasound (US) is achieved by stacking together multiple 2D US images or cross sections in the manner of tomography. Computer software converts these multiple 2D US images into a virtual 3D US volume.

The pixels of the 2D US image (the smallest piece of digital information) are transformed into voxels of the 3D US image.

The 2D US images can be acquired by moving the probe or scanner perpendicular to the 2D US planes or in a fanlike pattern, methods typically used for transabdominal (TA) images, or by rotation, used for transvaginal (TV) images.

The appropriate scanner motion can be motorized, or can be done freehand, with a positional marker that synchronizes the 2D US planes. Entirely freehand acquisition can also be done, but this method is not precise enough for carrying out measurements. A single scan of the complete volume can take a few seconds for highest spatial resolution, but the latest instruments can carry out 20 or more scans per second for 4D US motion studies. A cine-loop capability allows repeated viewing of real-time motion.

The virtual volume is recorded and stored in a computer. The information can be transferred to hard disks or transported electronically to distant locations. Although the volume is acquired in a matter of seconds, it is available for manipulation and study at length (Hayes, 2006).

The American College of Obstetricians and Gynecologists (ACOG) issued a committee opinion (2004) endorsing the “prudent use” of ultrasonography and discouraging its non-medical use (see references below).

POSITION STATEMENT

Use of three-dimensional and four-dimensional ultrasound techniques **are considered NOT medically necessary** for all indications.

CODING**Non-Covered CPT* Codes**

- 76376** 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.
- 76377** 3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound or other tomographic modality; requiring image postprocessing on an independent workstation.

ICD-9-CM Procedure Code - No applicable code

HCPCS Codes - No applicable codes

ICD-9-CM Diagnosis Codes - Not covered for all conditions.

*Current Procedural Terminology (CPT) 2010 American Medical Association: Chicago, IL.®©

REFERENCES

Peer Reviewed

1. Hayes Directory. Three-Dimensional and Four-Dimensional Ultrasound for High-Risk Pregnancies and Routine Screening. November 9, 2005.
2. Hayes Directory. Three-Dimensional and Four-Dimensional Ultrasound for Fetal Head Abnormalities. November 24, 2005.
3. Hayes Directory. Three-Dimensional and Four-Dimensional Ultrasound for Fetal Limbs and Skeletal Structures. December 5, 2005.
4. Hayes Directory. Three-Dimensional and Four-Dimensional Ultrasound for Fetal Growth and Volume Measurements. December 20, 2005.
5. Hayes Directory. Three-Dimensional and Four-Dimensional Ultrasound for Fetal Cardiovascular Diagnosis. February 9, 2006.
6. Hayes Directory. Three-Dimensional and Four-Dimensional Ultrasound for Extrafetal and Maternal Structures in Pregnancy. July 18, 2006.

Government Agencies, Professional and Medical Organizations

1. American College of Obstetricians and Gynecologists (ACOG) Committee on Ethics. Committee Opinion, Number 297. Nonmedical Use of Obstetric Ultrasonography. August, 2004.
2. Centers for Medicare and Medicaid Services. National Coverage Determination for Ultrasound Diagnostic Procedures (220.5). Effective Date: May 22, 2007.

HISTORY AND REVISIONS

Date	Action
5/3/2012	<ul style="list-style-type: none">• Retried by MPC; covered by CareCore criteria.
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
8/2/2011	<ul style="list-style-type: none">• Approved by MPC. No changes.