Clinical Policy Title: Three-dimensional imaging and interpretation

Clinical Policy Number: CCP.1389

Effective Date: October 1, 2018
Initial Review Date: June 5, 2018
Most Recent Review Date: August 30, 2018
Next Review Date: September 2019

Related policies:

CCP.1023 Orthognathic surgery
CCP.1047 Proton beam therapy
CCP.1053 Robotic assisted surgery
CCP.1116 Transvaginal and transabdominal ultrasound
CCP.1170 Stereotactic radiosurgery and stereotactic body radiotherapy
CCP.1191 Prenatal obstetrical ultrasound
CCP.1327 Antepartum fetal surveillance
CCP.1361 Radiofrequency ablation of tumors

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of three-dimensional imaging (also called three-dimensional reconstruction or rendering), interpretation, and reporting to be clinically proven and, therefore, medically necessary when all of the following criteria are met (National Imaging Associates, 2018; Simpson, 2017; Virani, 2016; American College of Obstetricians and Gynecologists, 2015; Plana, 2014; American Academy of Oral and Maxillofacial Radiology, 2013):

- The additional imaging detail will impact the diagnosis or clinical course of the member.
• The service is consistent with accepted standards of medical practice.
• Sufficient clinical expertise is available to perform the procedure and interpret the results.
• A written order or referral documents the medical necessity for the additional three-dimensional imaging.
• The interpreting physician’s report addresses the medical necessity identified by the ordering or referring health care provider.

Please refer to the following policies for specific medical necessity criteria for:
• CCP.1204  Breast cancer screening in women.
• CCP.1207  Echocardiographic assessment of myocardial strain for cancer patients.

Limitations:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

The interpreting physician shall maintain a copy of the test results and interpretation along with a copy of the ordering or referring health care provider’s order for the study.

The use of three-dimensional imaging, interpretation, and reporting is not medically necessary when any of the following conditions are present:
• Equivalent information obtained from the test has already been provided by another procedure (such as ultrasound, magnetic resonance imaging, or angiography).
• Equivalent information obtained from the test could be provided by a standard (two-dimensional) imaging study without reconstruction.
• The procedure is performed routinely based on the internal protocols of the testing facility.
• The procedure is not consistent with accepted standards of medical practice.
• Documentation of the medical necessity is lacking.

Three-dimensional imaging considered an essential component of a medically necessary procedure (e.g., conformal radiation therapy and stereotactic procedures), in accordance with current practice standards, is not separately reimbursable (National Imaging Associates, 2018).

Three-dimensional printing for surgical planning is not medically necessary, as its effectiveness has not been established (Bastawrous, 2018; Kiraly, 2018).

Alternative covered services:

Standard of care patient evaluation and management by a network health care provider.
**Background**

The majority of medical imaging is presented as two-dimensional information. Advances in multidetector computed tomographic imaging capture large volumes of information in digital form, which, in turn, allows for manipulation of the data into other planes that were not acquired directly during the acquisition (Fenster, 2011). Multidetector tomographic modalities (e.g., computed tomography, magnetic resonance tomography, and positron-emission tomography) and ultrasonography can create three-dimensional depictions of morphologic and physiologic attributes characteristic of health and disease (Fishman, 2006).

Rendering techniques are computer algorithms used to transform two-dimensional imaging data into three-dimensional images. Many techniques may be used to produce three-dimensional imaging and improve the understanding of a pathologic process. Among the most common is volume rendering (Fenster, 2011; Fishman, 2006). Volume rendering has broader clinical application for its superior ability to display the vascular anatomy and define soft tissue, muscle, and bone, in color. Others, such as maximum-intensity projection, may serve as useful adjuncts to volume rendering.

**Searches**

Prestige Health Choice searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on August 6, 2018. Search terms were: “Imaging, Three-Dimensional” (MeSH) and free text terms “three-dimensional imaging,” “three-dimensional rendering,” and “three-dimensional reconstruction.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.
We included nine systematic reviews and meta-analyses (Bastawrous, 2018; Bohner, 2018; Kiraly, 2018; Kosy, 2018; An, 2017; Fergo, 2017; Nieuwenhuis, 2017; Xu, 2017) and six evidence-based guidelines (National Imaging Associates, 2018; Simpson, 2017; U.S. Preventive Services Task Force, 2016; American College of Obstetricians and Gynecologists, 2015; Plana, 2014; American Academy of Oral and Maxillofacial Radiology, 2013) for this policy. Three-dimensional rendering and reconstruction represent important technological advancements that capture more anatomically accurate data sets and, in turn, provide additional detail and a dimension of depth of anatomy and pathology not found with standard two-dimensional modalities.

Low- to moderate-quality evidence demonstrates comparable to superior aspects of diagnostic accuracy of three-dimensional imaging versus two-dimensional imaging for many clinical applications. However, the impact of these technological advancements on diagnostic certainty, treatment planning, and clinical outcomes has not been quantified, and the clinical or cost effectiveness compared to less expensive and more readily available alternatives has not been established, lending ambiguity to the optimal choice of imaging.

Nonetheless, a number of guidelines support three-dimensional imaging when the additional information will impact diagnosis or treatment planning and when sufficient expertise is available to perform the procedure and interpret the results (Simpson, 2017; Virani, 2016; Plana, 2014). The National Imaging Associates (2018) does not provide guidance for three-dimensional rendering, other than for the conventional evaluation of suspicious known masses or for further evaluation of indeterminate or questionable findings found only by physical exam or imaging study (such as ultrasonography).

Three-dimensional imaging is considered an essential component of conformal radiation therapy and should not be regarded as a separate procedure (National Imaging Associates, 2018). Likewise, three-dimensional imaging is an essential component of robotic surgery and should not be considered separately (American College of Obstetricians and Gynecologists, 2015).

Three-dimensional imaging can be justified on an individual basis based on clinical presentation taking into account specific use, optimization protocols, radiation dose, risk-assessment strategies, and current standards of practice.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
<th>Key points:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bohner (2018)</td>
<td>Accuracy of digital technologies for the scanning of facial, skeletal, and intraoral tissues</td>
<td>Systematic review of 34 studies assessing the diagnostic accuracy of three-dimensional imaging and factors influencing diagnostic accuracy. Dimensional accuracy was described by means of deviation/discrepancy values. Overall quality: high with a low risk of bias.</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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| **Kosy (2018)**          | - Scanner technology, object shape, scanning strategies, and scanned tissue influenced diagnostic accuracy.  
                          | - Current digital technologies have acceptable diagnostic accuracy; the intended clinical use will define whether high or low accuracy is required (e.g., treatment planning, prototyping, or bone dimension measurements).  
                          | - Further studies correlating deviation values to clinical outcomes are needed.                                                                                                                                                      |
| **Key points:**          | - A systematic review to identify radiological methods used to assess anterior cruciate ligament reconstruction tunnel position in relation to either native anatomy or clinical results.  
                          | - Three-dimensional imaging with computed tomography and magnetic resonance tomography is only required in revision surgery or research studies.                                                                                 |
| **An (2017)**            | - Systematic review and meta-analysis of two randomized controlled trials, four prospective comparative studies, and one retrospective comparative study of preoperative cutting guides derived from three-dimensional reconstruction of either magnetic resonance imaging (153 knees) or computed tomography (150 knees) in total knee arthroplasty.  
                          | - Overall quality: heterogeneous reporting of alignment angles.                                                                                           
                          | - Magnetic resonance imaging produced a lower proportion of outliers in the overall coronal alignment of the limb ($P = .01$) but comparable results in terms of femoral sagittal ($P = .08$), femoral coronal ($P = .33$), and tibial coronal ($P = .18$) planes, and axial rotation of the femoral component ($P = .76$).  
                          | - Unclear impact on patient outcomes and of confounding factors (e.g., surgical expertise and interobserver differences).                                                                                                                  |
| **Fergo (2017)**         | - Systematic review included 13 randomized controlled trials, of which two were clinical trials and 11 were simulation studies.                                                                                                         
                          | - Research suggests three-dimensional laparoscopy significantly reduces performance time and error, and is at least equal or superior to two-dimensional laparoscopy.                                                                 |
                          | - Impact on clinical outcomes is unclear.                                                                                                                                                                                             |
| **Nieuwenhuis (2017)**   | - Systematic review of 13 diagnostic test accuracy studies, randomized controlled trials, and prospective cohort studies ($n = 1,053$); 11 studies ($n = 846$) were suitable for meta-analysis, and eight reported accuracy according to the type of focal abnormality.  
                          | - Overall quality: low with high or unclear risk of bias.                                                                                                          |
                          | - Meta-analysis revealed no statistically significant differences in accuracy between the two modalities.                                                                                                                                 |
                          | - Consider both modalities as alternatives to diagnostic hysteroscopy when intracavitary errors are expected.                                                                                                                       |
Citation | Content, Methods, Recommendations
---|---
diagnosis of focal intracavitary lesions | pathology is suspected in subfertile women and in those with abnormal uterine bleeding.

**Simpson (2017) for the European Association of Cardiovascular Imaging and the American Society of Echocardiography**

Three-dimensional echocardiography in congenital heart disease

**Key points:**
- Clinically useful in presurgical planning, guidance of catheter-based intervention, and functional assessment of the heart:
  - Assessing valvar lesions, septal defects, and complex abnormalities of the cardiac connections, as a complement to two-dimensional assessment.
  - Assisting catheter-guided closure of selected atrial and ventricular septal defects, particularly multiple, irregularly shaped, or residual defects.
  - Assessing of ventricular volume and function.

**Xu (2017)**

Three-dimensional versus two-dimensional video-assisted thoracic surgery for thoracic disease

**Key points:**
- Systematic review and meta-analysis of three randomized controlled trials and four observational studies (n = 525 for three-dimensional; n = 555 for two-dimensional).
- Overall quality: high risk of detection bias (no blinding of outcome), but low risk of other biases.
- Three-dimensional imaging had shorter operation times (standard mean difference = -0.66, 95% confidence interval -0.98 to -0.34; P < .001).
- Benefits of less blood loss and shorter postoperative drainage times in observational studies were not confirmed in randomized studies.
- No differences in postoperative hospital stay, total postoperative drainage volume, postoperative drainage volume in 24 hours, number of lymph nodes dissected, or postoperative complications.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


Kosy JD, Mandalia VI. Plain radiographs can be used for routine assessment of ACL reconstruction tunnel position with three-dimensional imaging reserved for research and revision surgery. *Knee Surg Sports Traumatol Arthrosc.* 2018; 26(2): 534 – 549. DOI: 10.1007/s00167-017-4462-5.


**Centers for Medicare and Medicaid Services National Coverage Determinations:**

No National Coverage Determinations identified as of the writing of this policy.

**Local Coverage Determinations:**

A53268 3D interpretations and reporting of imaging studies.

L33416 3D interpretation and reporting of imaging studies.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
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<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>
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<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>
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<td>ICD-10 Code</td>
<td>Description</td>
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<tr>
<td>M41-M41.9</td>
<td>Scoliosis</td>
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<tr>
<td>Q75.0</td>
<td>Craniosynostosis</td>
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<tr>
<td>S02.2-S02.42</td>
<td>Fracture of facial bones</td>
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<tr>
<td>S02.6-S02.69</td>
<td>Fracture of mandible</td>
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<tr>
<td>S12-S12.9</td>
<td>Fracture of cervical vertebra</td>
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<tr>
<td>S22.0-S22.089</td>
<td>Fracture of thoracic vertebra</td>
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<tr>
<td>S32.0-S32.059</td>
<td>Fracture of Lumbar vertebra</td>
<td></td>
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<tr>
<td>S32.3-S32.9</td>
<td>Fracture of pelvis</td>
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<thead>
<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
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