Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First	**Submission Date**: 1/2/2025
Policy Number: ccp.1389	**Effective Date:** 10/2018 **Revision Date:** November 1, 2024
Policy Name: Three-dimensional imaging and interpretation	

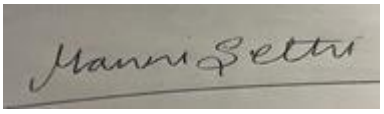
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☒ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Statewide PDL**

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

See tracked changes below.

Name of Authorized Individual (Please type or print):	**Signature of Authorized Individual:**
Manni Sethi, MD, MBA, CHCQM	

Three-dimensional imaging and interpretation

Clinical Policy ID: CCP.1389

Recent review date: 11/2024

Next review date: 3/2026

Policy contains: Endoscopy; three-dimensional rendering or reconstruction; tomography; ultrasonography.

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP'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 Keystone First- CHIP, on a case by case basis, 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. Keystone First- CHIP'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. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

Three-dimensional imaging (also called three-dimensional reconstruction or rendering), interpretation, and reporting are clinically proven and, therefore, medically necessary when all of the following criteria are met (American Association of Endodontists/American Academy of Oral and Maxillofacial Radiology, 2015; Centers for Medicare & Medicaid Services, 2019a, 2019b; National Imaging Associates, 2021; Plana, 2014; Simpson, 2017; Virani, 2016):

- 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.

Limitations

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 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, 2021).

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 multi-detector computed tomographic imaging capture large volumes of information in digital form, which, in turn, allows data to be manipulated 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.

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). 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.

Findings

We included eight systematic reviews and meta-analyses (An, 2017; Bastawrous, 2018; Bohner, 2018; Fergo, 2017; Kosy, 2018; Nieuwenhuis, 2017; Xu, 2017) and five evidence-based guidelines (American Academy of Oral and Maxillofacial Radiology, 2013; National Imaging Associates, 2018; Plana, 2014; Simpson, 2017; U.S. Preventive Services Task Force, 2016) 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 (Plana, 2014; Simpson, 2017; Virani, 2016). 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).

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.

In 2019, we updated the National Imaging Associates guidelines (2019). We replaced an American Academy of Oral and Maxillofacial Radiology (2013) position statement on cone beam computed tomography in endodontics with a joint statement on the topic by the American Association of Endodontists/American Academy of Oral and Maxillofacial Radiology (2015). The citation for Bohner (2018) was finalized and changed to Boehner (2019).

We added several systematic reviews and meta-analyses examining a range of clinical uses for three-dimensional imaging methods: assessment and treatment planning in dentistry and oral surgery (Awarun, 2019; Hartman, 2019; Thierens, 2018; Wismeijer, 2018); breast cancer detection (specifically ultrasonography) (Bin, 2019); facilitation of laparoscopic and thoracoscopic surgeries (Liang, 2018; Vettoretto, 2018); detection of soft tissue defects of the knee (Shakoor, 2018) and rotator cuff (Teng, 2018); and tubal sterilization microinsert positioning (Carretti, 2019).

These new results confirm previous findings in this policy that some three-dimensional imaging modalities offer at least comparable diagnostic performance to current two-dimensional modalities or other three-dimensional modalities considered standard of care, but the intended clinical application will determine the degree of accuracy and precision required, along with the desire to reduce radiation exposure. The incremental value of three-dimensional imaging over current imaging standards for many indications has not been determined, and justification for the additional information would be needed. No policy changes are warranted at this time.

In 2020, we updated the reference list. No policy changes are warranted.

In 2021, we updated the National Imaging Associates (2021) guideline. We added three systematic reviews and meta-analyses comparing three-dimensional imaging to two-dimensional imaging in orthognathic surgical planning (Chen, 2021, n = five randomized controlled trials with 199 patients), guiding brachytherapy for cervical cancer (Kim, 2020, n = six studies), and performing urological laparoscopy (Sánchez-Margallo, 2021, n = 25 studies). The results of these studies are consistent with previous findings and no policy changes are warranted.

In 2022, we updated the reference list. No policy changes are warranted.

In 2023, we identified no newly published, relevant literature to add to the policy.

In 2024, we identified two relevant systematic reviews and meta-analysis. No policy changes were warranted. A systematic review and meta-analysis of five studies published between 2012 and 2019 (n=450) compared the diagnostic test accuracy of three-dimensional transvaginal ultrasound and magnetic resonance imaging for preoperative staging of deep myometrial invasion and cervical invasion in endometrial cancer. The pooled sensitivity for detecting deep myometrial invasion using three-dimensional transvaginal ultrasound was 77% (95% confidence interval, 66–85%) with a positive likelihood ratio of 4.57 and a negative likelihood ratio of 0.31; for magnetic resonance imaging, the pooled sensitivity was 80% (95% confidence interval, 73–86%) with a positive likelihood ratio of 4.22 and a negative likelihood ratio of 0.24. For cervical invasion, the pooled logarithm of the diagnostic odds ratio was 3.11 (95% confidence interval, 2.09–4.14) for three-dimensional transvaginal ultrasound and 2.36 (95% confidence interval, 0.90–3.83) for magnetic resonance imaging, indicating comparable diagnostic performance between the two imaging modalities. Overall, the findings suggest that

three-dimensional transvaginal ultrasound is as effective as magnetic resonance imaging for preoperative staging in endometrial cancer (Spagnol, 2022).

A systematic review and meta-analysis of 12 studies (n=595) assessed the impact of three-dimensional technology on preoperative evaluation for rhinoplasty. The findings indicated that surgeons reported higher satisfaction with three-dimensional approaches based on precision and postoperative results, with a mean difference of –0.13 (95% confidence interval, –0.20 to –0.06; p=0.0002). Patients also expressed greater satisfaction due to better understanding of the procedure and enhanced communication with surgeons. Although three-dimensional technology provided higher precision compared to two-dimensional approaches, it was more expensive and not cost-efficient. There were no significant differences in reoperation rates (odds ratio 0.16, 95% confidence interval, 0.02–1.36; p=0.09) or surgical time between three-dimensional and two-dimensional methods. Overall, the study suggests that three-dimensional technology offers higher surgeon satisfaction and increased precision but at a higher cost. (Werathammo, 2024)

References

On October 11, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Imaging, Three-Dimensional” (MeSH), “three-dimensional imaging,” “three-dimensional rendering,” and “three-dimensional reconstruction.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

6/2018: initial review date and clinical policy effective date: 10/2018

10/2019: Policy references updated.

10/2020: Policy references updated.

10/2021: Policy references updated.

11/2022: Policy references updated.

11/2023: Policy references updated.

11/2024: Policy references updated.