Molina Clinical Policy
3D Interpretation and Reporting of Imaging Studies: Policy No. 124

Last Approval: 10/12/2023
Next Review Due By: October 2024

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Three-dimensional images (3D reconstruction or 3D rendering) are a distinct diagnostic procedure that describes a separate procedure or process that can be applied to computed tomography (CT), magnetic resonance imaging (MRI), ultrasound or other tomographic modalities. The availability of 3D images enables the provider interpreting the images to have a view of the patient's entire anatomy. The original two-dimensional (2D) images provide comparison and confirmation. An image is reconstructed by using multiple thin-section (typically axial) images. The images can then be manipulated and rotated into various views to better understand the relationship of one structure to another. In addition, it provides a view of the structure along its length as opposed to just on a single trans-axial image. The shading, coloring, and perspective of a 3D volume rendering is useful in surgical planning as well as for identifying critical areas for avoidance or targeting. Applications of this technology include visualization of central nervous system vasculature, coronary artery imaging, enhanced imaging of the thorax to include embolic disease, inflammatory and neoplastic lesions, imaging of facial malformations, complex facial fractures/trauma, aortic aneurysms, and multiple others.

The physician supervises and/or creates the 3D reconstructions and adjust the projection to optimize visualization of anatomy or pathology for the 3D reconstruction performed on an independent workstation and the physician will discuss with the technologist the need for 3D imaging and supervise the technologist in creating 3D images for studies not requiring image post-processing on an independent workstation. The 3D rendering codes are intended to address complex renderings such as shaded surface rendering, volumetric rendering, maximum intensity projections, fusion of images from other modalities, and quantitative analysis (segmental volumes and surgical planning).

COVERAGE POLICY

Three-Dimensional (3-D) Rendering of Imaging Studies, also be referred to as 3-D reconstruction or 3-D reformation, **may be considered medically necessary** under the following circumstances:

1. Cerebral Aneurysms, known or suspected (CTA) [1-6]
2. Congenital skull or facial abnormalities (CT) [7-10]
    a. Craniosynostosis
    b. Cleft palate
    c. Craniofacial microsomia
    d. Ear malformations
    e. Branchial arch abnormalities
3. Complex facial fractures (CT) [11-13]
4. Prior to volumetric, stereotactic cranial surgery (CT, MRI) [14-16]
5. Lead placement for Deep Brain stimulation (MRI, CT) [17-19]

6. MRCP (Magnetic Resonance Cholangiopancreatography) (MRI)[20-21]
7. Eagle syndrome (elongation of styloid process) (CT)[22-23]
8. Prior to surgery for chest wall deformity (e.g., severe pectus)[24-27]
9. Vascular malformations (to characterize lesion and assess feeding arterial supply and draining veins) (CTA)[28-30]
10. Atlanto-axial or Craniocervical anomalies (CT)[31-33]
11. Prior to surgical, radiation, high intensity focused ultrasound (HIFU) or IR treatment of tumors of the spine, liver, pancreas, uterus, prostate or other viscera e.g. Yttrium 90 radioembolization; HIFU for prostate cancer, uterine fibroids (CT, MRI)[34-38]
12. Trauma, to assess for vascular and visceral organ injury and hemorrhage (CTA)[39-41]
13. Complex spine fractures (CT)[42-44]
14. Complex extremity fractures (CT)[45-47]
15. Complex pelvic fractures (CT)[48-50]
16. Fetal Spinal Dysraphism/Skeletal Dysplasia
17. Scoliosis (CT, MRI)[51-53]
18. Ultrasound 3D Indications:[54-60]
    a. Abscess drainage in the pelvis and abdomen
    b. Congenital anomalies of the uterus (e.g., septate vs bicornuate uterus)
    c. Planned myomectomy-mapping or uterine artery embolization of uterine fibroids
    d. Suspected cornual (Interstitial) ectopic pregnancy
    e. Suspected Intrauterine device malposition
    f. Suspected fetal anomalies
19. Cardiac MRI[61-70]
20. Echocardiography[71-76]
21. Preprocedural evaluation for aortic endovascular/endograft intervention[77-80]

Limitations and Exclusions

The following services are excluded and **NOT covered**:

1. 3D rendering (CPT codes 76376 and 76377) is considered an inherent component, and cannot be reported with **ANY** of the following procedures:
    a. Bronchoscopy (CPT code 31627)
    b. Computed tomographic angiography (CTA) of the head, neck, chest, pelvis, upper and lower extremity, abdomen, and abdominal aorta, and bilateral ileofemoral lower extremity vessels (CPT codes 70496-70498, 71275, 72191, 73206, 73706, 74174, 74175, 75635)
    c. Magnetic resonance angiography (MRA) of the head, neck, spinal canal, and upper and lower extremities (CPT codes 70544-70549, 71555, 72159, 72198, 73225, 73725, 74185)
    d. Nuclear Radiology (CPT codes 78012-78999)
    e. Computed tomographic (CT) colonography (virtual colonoscopy) (CPT codes 74261-74263)
    f. Computed tomography (CT) heart and (CTA) heart, coronary arteries, and bypass grafts (CPT codes 70496, 70498, 71275, 72191, 73206, 73706, 74174-74175, 74261-74263, 75571-75574, 75635)
    g. Computer-aided detection (CPT codes 77048-77049)
    h. Digital breast tomosynthesis (DBT) (CPT codes 77061-77063)

2. Mapping of hippocampal atrophy in Alzheimer's disease is considered **experimental, investigational, or unproven** due to insufficient evidence in the peer reviewed medical literature.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

For peer-reviewed studies used in the development and update of this policy, please see the *Reference* section.

National and Specialty Organizations

In 2022, the **American College of Radiology (ACR)** in collaboration with the **Association of Physicists in Medicine (AAPM), Society for Imaging Informatics in Medicine (SIIM),** and **Society for Pediatric Radiology (SPR)** published the *ACR–AAPM–SIIM–SPR Practice Parameter for Digital Radiography.* The document offers guidance on the clinical use of digital radiography (DR) equipment (excluding mammography) to provide necessary image quality at a suitable radiation dose as well as provide excellent safety and care for patients undergoing digital radiography examinations.[81]

The ACR also published the *ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI).* Guidance is provided on indications and contraindications for MRI, provider qualifications to perform MRI, specifications of the examination, proper documentation, equipment specifications, and safety guidelines. A section regarding quality control and improvement is also included with information on safety, infection control, and patient education. [82]

Currently no *ACR Appropriateness Criteria* is available specific to 3D interpretation and reporting of imaging studies.

The ACR published a bulletin titled *Seeing in 3D* which discusses the joint ACR and **Radiological Society of North America (RSNA)** 3DP Registry. The registry was developed to track clinical 3DP performed at the point of care. By collecting anonymized 3DP case information, patient care is improved and allows a view of how resources are utilized including the tracking of clinical outcomes, facilitate quality improvement, and examine 3DP reimbursement. This allows users to compare their workflow processes with others who have joined the 3DP Registry. The registry will aid providers with quality improvement and support reimbursement. Currently four Category III reimbursement codes exist for 3DP. By collecting data and literature, the goal is to support the creation of Category I codes related to reimbursement from third-party payers (including CMS).[83-85]

In February 2022, the ACR submitted comments to the **United States Food and Drug Administration (FDA)** with respect to the discussion paper *3D Printing Medical Devices at the Point of Care*. An announcement is pending from the FDA. The ACR recommendations include: [86-88]

- Designation of anatomic models created by end-user health care facilities (HCFs) as very low risk.
- Exercise enforcement discretion with respect to very low-risk devices created by end-user HCFs.
- Discontinue use of the term “point of care” for describing 3D printing within HCFs.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

CPT	Description
76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; 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 with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/12/2023	Policy reviewed. Coverage criteria revised to include cerebral aneurysms, lead placement for Deep Brain stimulation, MRCP, Eagle syndrome, prior to surgery for chest wall deformity, trauma, to assess for vascular and visceral organ injury and hemorrhage, ultrasound 3D indications, and aortic endovascular/endograft intervention. Indications removed spinal canal or osseous spinal tumor radiotherapy planning and High Intensity Focused Ultrasound ablation of tumors of prostate, liver, pancreas, and uterine fibroids. Removed chest/abdomen/pelvis MRA, planning aortic endograft, and cardiac MRI from exclusions. IRO peer review by a practicing physician board certified in Radiology, October 2023.
02/08/2023	Policy reviewed, included additional indications in the Coverage Policy section – brain tumors, congenital cardiac/cardiovascular anomalies; complex fractures (especially those extending intra-articularly) ; endovascular intervention for aneurysms; hepatic tumors for targeted radiotherapy or radioembolization; High Intensity Focused Ultrasound ablation of tumors of prostate, liver, pancreas and uterine fibroids; maxillofacial tumors or congenital anomalies; spinal canal or osseous spinal tumor radiotherapy planning; temporal bone procedures involving semicirular canals or cochlear; tumors for planned radiofrequency, microwave, or other thermal ablation; and vascular stents and grafts.
12/14/2022	Policy reviewed, no changes to coverage criteria; updated overview and references; added Summary of Medical Evidence.
12/08/2021	Policy reviewed, no changes to coverage criteria, updated references.
12/09/2020	Policy reviewed, no changes to coverage criteria, updated references.
12/10/2019	Policy reviewed, no changes to coverage criteria, updated references.
12/13/2018	Policy reviewed, no changes to coverage criteria, updated references.
11/06/2018	Policy reviewed, updated references. Changes to coverage criteria,
09/19/2017	Policy reviewed, no changes to coverage criteria, updated references.
08/09/2016	Policy reviewed, updated references. Changes to coverage criteria.
12/16/2015	Policy reviewed, no changes to coverage criteria, updated references.
02/12/2015	Policy reviewed, updated references. Changes to coverage criteria,
12/12/2012	New policy.

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*