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: AmeriHealth Caritas Pennsylvania Community Health Choices	**Submission Date**: 8/1/2024
Policy Number: ccp.1488	**Effective Date:** 8/2021 **Revision Date:** July 1, 2024
Policy Name: **Medical three-dimensional printing**	

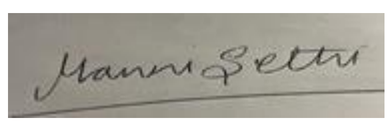
Type of Submission – Check all that apply:

- [ ] **New Policy**
- [x] **Revised Policy***
- [ ] **Annual Review – No Revisions**
- [ ] **Statewide PDL**

***All revisions to the policy <u>must</u> 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): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Medical three-dimensional printing

Clinical Policy ID: CCP.1488

Recent review date: 7/2024

Next review date: 11/2025

Policy contains: Additive manufacturing; craniofacial surgery; customized implant; knee surgery; maxillofacial surgery; spinal surgery; three-dimensional printing.

Coverage policy

Three-dimensional printing (i.e., additive manufacturing) of anatomic structures for surgical planning, implant templating, procedural guidance, or customized implants is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

No alternative covered services were identified during the writing of this policy.

Background

Medical three-dimensional printing, also called additive manufacturing, produces a three-dimensional object from a digital file of high-quality data collected from multiplanar medical imaging (Ballard, 2018). Most systems involve separating a digital design file into two-dimensional layers, building a three-dimensional object from raw material one layer at a time, and joining them to the layer directly below. Three-dimensional printing adds material only where it is needed (i.e., additive), unlike conventional manufacturing, which cuts and shapes an object from a solid block of material (i.e., subtraction).

A range of methods and materials can be used to produce three-dimensional devices with potential application in patient education and medical education and training. Clinical applications that have the potential to improve patient outcomes and increase economic feasibility include surgical planning, intraoperative guidance, and individualized implants (Kim, 2016). In addition, three-dimensional printing with cells (bioprinting) may allow for regenerative scaffolds and cell-specific replacement tissue and organs.

In general, three-dimensional devices are classified as implantable or nonimplantable, and patient-matched (or patient-specific) or non-patient-matched (Di Prima, 2016). The term “patient-matched” is often used interchangeably with the term “custom,” but, for regulatory purposes, they are not synonymous (U.S. Food and Drug Administration, 2017). Custom devices may be exempt from premarket approval requirements and review if they meet all of the following criteria:

- Are created or modified to comply with the order of an individual physician or dentist.
- Do not exceed five units per year.
- Are reported by the manufacturer to the U.S. Food and Drug Administration for devices manufactured and distributed under section 520(b) of the Food, Drug, and Cosmetic Act.

Patient-matched devices do not automatically meet all of these requirements. Patient-matched devices are typically based on an existing, standardized template model that is matched to a patient with normal bone or joint anatomy using medical imaging (U.S. Food and Drug Administration, 2017).

Findings

Guidelines

The Radiological Society of North America 3D Printing Special Interest Group guidelines recommend the use of three-dimensional printing for several specific clinical scenarios. For congenital heart disease, three-dimensional printing is highly recommended, with a rating of 7 to 9, for preoperative planning, particularly in complex cases such as septal defects and transposition of the great arteries, as it can significantly reduce operation and cardiopulmonary bypass time (Chepelev, 2018). In craniomaxillofacial pathologies, three-dimensional printing is advised for both trauma and congenital malformations, aiding in both functional and aesthetic restoration, with differentiation between simple and complex cases (Chepelev, 2018).

For musculoskeletal pathologies, three-dimensional printing is recommended for fractures, chronic osseous abnormalities, and preoperative planning, enabling the creation of custom implants and surgical guides to improve surgical outcomes and reduce operating time (Chepelev, 2018). Vascular pathologies, especially complex aortic aneurysms and dissections, benefit from three-dimensional printing for preoperative planning and simulation, aiding in device selection and understanding complex anatomy. In genitourinary pathologies, three-dimensional printing is useful for complex kidney tumors and other urological conditions, enhancing anatomical comprehension and surgical planning to improve patient outcomes (Chepelev, 2018). Lastly, for breast pathologies, three-dimensional printing aids in depicting the extent of disease and planning oncologic and reconstructive surgeries, potentially reducing operating time and improving patient outcomes (Chepelev, 2018).

Systematic reviews and meta-analyses

For this policy, we included evidence from several systematic reviews and meta-analyses, which are discussed below. The clinical applications of three-dimensional printing fall into two general categories: procedural uses and material uses. We considered the role of three-dimensional printing in surgical planning, implant templating, procedural guidance, and customized implants. The most common clinical applications represented in the literature are craniomaxillofacial reconstruction, orthopedic repair and replacement, and spinal surgery, which are discussed below. Other emerging specialty areas include surgery for congenital heart defects (Lau, 2019), colorectal surgery (Emile, 2019), and nephrectomy (Jiang, 2020b; Sun, 2018).

While the evidence from systematic reviews and meta-analyses confirms the expanding interest and role in three-dimensional printing across multiple disciplines, it also confirms the paucity of high-quality research supporting the medical necessity of three-dimensional printed materials and procedural uses at this time. Pre-surgical three-dimensional models and anatomic guides may improve intraoperative metrics and surgical outcomes by making the procedure safer and more predictable. Compared to off-the-shelf products, customized three-dimensional printed materials may offer improved fit and functional outcomes and the ability to address unique and complex anatomy.

However, the research has failed to clearly delineate a clinical advantage of three-dimensional printing relative to conventional procedures and materials, which would require higher quality comparative trials. Limitations to the research include the diversity of workflows and applications involving different materials, printers, and testing methods. In addition, the custom-made nature of implants prevents meaningful comparison of three-dimensional printed interventions to conventional interventions and off-the-shelf products.

Three-dimensional printing provides an opportunity to customize upper limb prostheses, but the evidence consists of case studies and small case series that lack external validity and avoidance of bias. The evidence fails to demonstrate statistically significant improvements in comfort, functionality, durability, and long-term effects on patient quality of life compared to conventional prostheses (Diment, 2020).

A systematic review (Francoisse, 2020) examined pediatric applications of three-dimensional printing from 139 low-quality observational studies (n = 508 total pediatric patients). Six of the studies compared three-dimensional printing to conventional methods for procedural outcomes. Three-dimensional printed contour models, guides, splints, and implants were at least equivalent to conventional methods, with shorter operating time and fluoroscopy exposure, more accurate hardware placement, and fewer complications. The results highlighted the potential of three-dimensional printing to address challenges unique to the pediatric population, such as compact anatomy, unique congenital variants, greater procedural risk, and growth over time.

<u>Craniomaxillofacial surgery</u>

In oral and craniomaxillofacial surgery, three-dimensional printed bone models were mainly used as training or simulation models for tumor removal, bone reconstruction, or complex deformity (Meglioli, 2020). In mandibular reconstruction, a systematic review and meta-analysis (Serrano, 2019) of 14 studies of mixed quality and high risk of bias examined three-dimensional printing applications for surgical guides and templates, anatomical models, and implants. The most frequently reported clinical outcomes were operating time (n = five studies; 35.7%) and the final aesthetic result (n = four studies; 28.6%). Three-dimensional printing led to a significant reduction in operating times (overall estimated effect of 21.2%, 95% confidence interval 10% to 33%, $P < .001$).

For nasal prostheses, evidence from three systematic reviews (Crafts, 2017; Martelli, 2016; Tack, 2016) consist of animal modeling studies, technical feasibility reports, and a low-quality retrospective case series and case reports. Currently, most otolaryngologic applications for three-dimensional printing are at preliminary stages of development, as manufacturing processes continue to be refined. Three-dimensional printing can produce accurate, patient-specific nasal prostheses, which may be particularly helpful to patients with unique anatomies, but their superiority to conventionally manufactured prostheses has not been demonstrated. Reducing malalignment does not automatically result in improved clinical outcomes (e.g., better fit, comfort, or satisfaction), and long-term revision rates (i.e., prosthesis survival) have not been reported. Mismatched skin tone is a major limitation of three-dimensionally printed facial prostheses. Whether the additional upfront costs of three-dimensional printing result in lower overall costs of care is unclear.

Orthopedics

Three-dimensional printing clinical applications in orthopedics include surgical planning, implant templating, and anatomical assessment of pathologies. Custom-made metal three-dimensional printed, patient-specific implants and instruments are increasingly being studied for pelvic oncologic resection (reconstruction of resected defects) and revision hip arthroplasties (Goodson, 2019). Results of several systematic reviews and meta-analyses suggest that, compared to conventional planning, three-dimensional printing-assisted preoperative planning improves intraoperative metrics (i.e., reduced operative time, intraoperative blood loss, and exposure to fluoroscopy to confirm positioning), but its effects on clinical outcomes are not well-defined (Jiang, 2020a; Morgan, 2020). In terms of fracture healing time, postoperative joint function, or postoperative complications, the variability in results was likely due to the location and complexity of the fracture, among other factors (González-Alonso, 2020; Wang, 2020; Xie, 2018). All analyses call for large-sample randomized controlled trials to confirm the superiority of three-dimensional printing-assisted orthopedic surgery.

A health technology assessment (DEFACTUM, 2019) of six randomized controlled trials and two systematic reviews found very low-quality to low-quality evidence supporting the superiority of three-dimensional printed guides or implants over standard instrumentation with respect to malalignment and deviation in adults undergoing total knee arthroplasty for osteoarthritis or rheumatoid arthritis. The limitations of the evidence were a high risk of bias and imprecision of the estimates in the included studies. The authors called for higher quality evidence to validate these findings.

Spinal surgery

Spinal implants fall into two categories: fusion (cages, plates with screws, rods with hooks, and pedicle screws) and non-fusion (artificial discs and expandable rods). Medical-grade titanium and poly-ether-ketone-ketone are widely used for conventional off-the-shelf implants. Three-dimensional printed implants can be designed for complex tumor pathology and atypical bone defects that are considered difficult to treat or that have additional features, such as preplanned screw trajectories or conformities. In an appropriately selected patient, three-dimensional printed patient-specific spinal implants may improve outcomes in terms of surgical efficiency, stability, and potential osseointegration. Randomized controlled trials are needed to confirm these findings.

Two systematic reviews compared the safety and efficacy of three-dimensional printed patient-specific and off-the-shelf devices (Burnard, 2020; Wallace, 2020). The evidence consists of case reports and case series focused on patient-specific titanium implants for anatomically complex cases. Three-dimensional printed products appear safe with positive subjective feedback from surgeons and patients. However, the clinical and radiographic outcomes, particularly long-term data, are still uncertain.

Another systematic review of adults with spinal deformity (Lopez, 2020) compared the effects of using a three-dimensional printed drill guide template with not using such a template. The use of the template was associated with higher screw placement accuracy (96% versus 81.5%, $P < .001$, n = 22 studies), lower operative duration (272 versus 258 minutes, $P < .05$), and similar perioperative blood loss (924.6 mL versus 935.6 mL, $P = .058$). A three-dimensional printed drill guide template had a favorable deformity correction rate (n = 245 patients, 72.5%). Influential variables were the types, materials, and manufacturing costs and times of three-dimensional printed technology.

In 2022, we added a systematic review of 16 studies determined that additive manufacturing implant-supported fixed prostheses demonstrate similar accuracy as conventional and computer-aided design and computer-aided manufacturing techniques in vitro (Rutkunas, 2022).

In addition, we added systematic reviews on three-dimensional printing and changes in patient outcomes:

- Twenty (20) studies of patients with treated for tibial plateau fractures (n = 1,074) found 3D-assisted (compared with conventional) surgery reduced operation time, blood loss, and frequency of fluoroscopy (P < 0.01 for each), with no differences in functional outcomes (Assink, 2021).
- Thirteen (13) studies (four randomized) of patients treated for acetabular fractures determined 3D printing-assisted surgery decreased operation time (-38.8 minutes), intraoperative blood loss (-259.7 ml), and instrumentation time (-34.1 minutes). Traditional surgery was 47% less likely to achieve good/excellent function of hip and 19% more likely to have complications (Cao, 2021).

In 2023, we added several large reviews:

- Five studies (meta-analysis) of foot and ankle fracture surgery found three dimensional-assisted pre-operative plaFranning reduced average time (- 23.52 minutes, *P* = .003), intraoperative blood loss (-30.59 mL, *P* = .0001), and number of fluoroscopies used (- 3.20 times, *P* < .0001) (Wood, 2022).
- 58 studies of 906 patients (systematic review/meta-analysis) found that after orbital reconstruction, 3D-printed orbit models and preoperative plate contouring groups were less likely to have diplopia (*P* < .001) and enophthalmos (*P* < .001). However, authors state the contribution of 3D printing alone to these improvements remains unclear due to a lack of controlled studies (Murray-Douglas, 2022).

In 2024, we added the Radiological Society of North America guideline (Chepelev, 2018). We also found a systematic narrative review on in-hospital three-dimensional printing in hip surgery that analyzed 62 studies (n = 1,065) participants across various clinical applications. These studies ranged from case reports to retrospective and prospective comparative studies, as well as randomized trials. Specific applications included proximal femoral osteotomies, periacetabular osteotomies, primary and revision total hip arthroplasties, and osteosynthesis of femur fractures, among others. The review highlighted the potential benefits of three-dimensional printing in terms of surgical precision, reduced operation time, and minimized radiation exposure, although it emphasized the need for further high-quality, randomized studies to establish these advantages conclusively (Aguado-Maestro, 2024).

References

On June 4, 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 “three dimensional," “printing,” “additive manufacturing,” and “printing, three dimensional” (MeSH). 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.

Aguado-Maestro I, Simón-Pérez C, García-Alonso M, Ailagas-De Las Heras JJ, Paredes-Herrero E. Clinical applications of "in-hospital" 3D printing in hip surgery: a systematic narrative review. *J Clin Med*. 2024;13(2):599. Doi:10.3390/jcm13020599.

Assink N, Reininga IHF, Duis KT. Does 3D-assisted surgery of tibial plateau fractures improve surgical and patient outcomes? A systematic review of 1074 patients. *Eur J Trauma Emerg Surg*. 2021 Aug 31. Doi: 10.1007/s00068-021-01773-2.

Ballard DH, Trace AP, Ali S, et al. Clinical applications of 3d printing: Primer for radiologists. *Acad Radiol*. 2018;25(1):52-65. Doi: 10.1016/j.acra.2017.08.004.

Burnard JL, Parr WCH, Choy WJ, Walsh WR, Mobbs RJ. 3d-printed spine surgery implants: A systematic review of the efficacy and clinical safety profile of patient-specific and off-the-shelf devices. *Eur Spine J.* 2020;29(6):1248-1260. Doi: 10.1007/s00586-019-06236-2.

Cao J, Zhu H, Gao C. A systematic review and meta-analysis of 3D printing technology for the treatment of acetabular fractures. *Biomed Res Int*. 2021:5018791. Doi: 10.1155/2021/5018791.

Chepelev L, Wake N, Ryan J, et al. Radiological Society of North America (RSNA) 3D printing Special Interest Group (SIG): guidelines for medical 3D printing and appropriateness for clinical scenarios. *3D Print Med*. 2018;4(1):11. Doi:10.1186/s41205-018-0030-y.

Crafts TD, Ellsperman SE, Wannemuehler TJ, et al. Three-dimensional printing and its applications in otorhinolaryngology-head and neck surgery. *Otolaryngol Head Neck Surg*. 2017;156(6):999-1010. Doi: 10.1177/0194599816678372.

DEFACTUM, Osteba. Custom-made or customisable 3D printed implants and cutting guides versus non-3D printed standard implants and cutting guides for improving outcome in patients undergoing knee, maxillofacial, or cranial surgery. EUnetHTA Project ID: OTCA11. https://www.eunethta.eu/wp-content/uploads/2019/04/OTCA11_Final_.pdf. Published April 2019.

Di Prima M, Coburn J, Hwang D, et al. Additively manufactured medical products - the FDA perspective. *3D Print Med*. 2016;2:1. Doi: 10.1186/s41205-016-0005-9.

Diment LE, Thompson MS, Bergmann JH. Three-dimensional printed upper-limb prostheses lack randomised controlled trials: A systematic review. *Prosthet Orthot Int.* 2018;42(1):7-13. Doi: 10.1177/0309364617704803.

Emile SH, Wexner SD. Systematic review of the applications of three-dimensional printing in colorectal surgery. *Colorectal Dis.* 2019;21(3):261-269. Doi: 10.1111/codi.14480.

Francoisse CA, Sescleifer AM, King WT, Lin AY. Three-dimensional printing in medicine: A systematic review of pediatric applications. *Pediatr Res.* 2021. 89(3):415-425. Doi: 10.1038/s41390-020-0991-6.

González-Alonso M, Hermida-Sánchez M, Martínez-Seijas P, Ruano-Ravina A. Application of 3d printing in the treatment of appendicular skeleton fractures: Systematic review and meta-analysis. *J Orthop Res.* 2021. 39(10):2083-2092. Doi: 10.1002/jor.24939.

Goodson AM, Kittur MA, Evans PL, Williams EM. Patient-specific, printed titanium implants for reconstruction of mandibular continuity defects: A systematic review of the evidence. *J Craniomaxillofac Surg.* 2019;47(6):968-976. Doi: 10.1016/j.jcms.2019.02.010.

Jiang M, Chen G, Coles-Black J, Chuen J, Hardidge A. Three-dimensional printing in orthopaedic preoperative planning improves intraoperative metrics: A systematic review. *ANZ J Surg.* 2020;90(3):243-250. Doi: 10.1111/ans.15549.(a)

Jiang Y, Zeng H, Zhu Z, Chen J, Chen H. Three-dimensional printing assisted laparoscopic partial nephrectomy vs. conventional nephrectomy in patients with complex renal tumor: A systematic review and meta-analysis. *Front Oncol.* 2020;10:551985. Doi: 10.3389/fonc.2020.551985.(b)

Kim GB, Lee S, Kim H, et al. Three-dimensional printing: Basic principles and applications in medicine and radiology. *Korean J Radiol.* 2016;17(2):182-197. Doi: 10.3348/kjr.2016.17.2.182.

Lau IWW, Sun Z. Dimensional accuracy and clinical value of 3d printed models in congenital heart disease: A systematic review and meta-analysis. *J Clin Med*. 2019;8(9). Doi: 10.3390/jcm8091483.

Lopez CD, Boddapati V, Lee NJ, et al. Three-dimensional printing for preoperative planning and pedicle screw placement in adult spinal deformity: A systematic review. *Global Spine J.* 2020:2192568220944170. Doi: 10.1177/2192568220944170.

Martelli N, Serrano C, van den Brink H, et al. Advantages and disadvantages of 3-dimensional printing in surgery: A systematic review. *Surgery*. 2016;159(6):1485-1500. Doi: 10.1016/j.surg.2015.12.017.

Meglioli M, Naveau A, Macaluso GM, Catros S. 3d printed bone models in oral and cranio-maxillofacial surgery: A systematic review. *3D Print Med.* 2020;6(1):30. Doi: 10.1186/s41205-020-00082-5.

Morgan C, Khatri C, Hanna SA, Ashrafian H, Sarraf KM. Use of three-dimensional printing in preoperative planning in orthopaedic trauma surgery: A systematic review and meta-analysis. *World J Orthop.* 2020;11(1):57-67. Doi: 10.5312/wjo.v11.i1.57.

Murray-Douglass A, Snoswell C, Winter C, Harris R. Three-dimensional (3D) printing for post-traumatic orbital reconstruction, a systematic review and meta-analysis. *Br J Oral Maxillofac Surg*. 2022;60(9):1176-1183. Doi: 10.1016/j.bjoms.2022.07.001.

Rutkunas V, Gedrimiene A, Auskalnis L, Admakin O, Mangano F. Accuracy of fixed implant-supported dental prostheses additively manufactured by metal, ceramic, or polymer: A systematic review. *J Prosthodont*. 2022;31(S1):70-87. Doi: 10.1111/jopr.13449.

Serrano C, van den Brink H, Pineau J, Prognon P, Martelli N. Benefits of 3d printing applications in jaw reconstruction: A systematic review and meta-analysis. *J Craniomaxillofac Surg.* 2019;47(9):1387-1397. Doi: 10.1016/j.jcms.2019.06.008.

Sun Z, Liu D. A systematic review of clinical value of three-dimensional printing in renal disease. *Quant Imaging Med Surg.* 2018;8(3):311-325. Doi: 10.21037/qims.2018.03.09.

Tack P, Victor J, Gemmel P, Annemans L. 3d-printing techniques in a medical setting: A systematic literature review. *Biomed Eng Online*. 2016;15(1):115. Doi: 10.1186/s12938-016-0236-4.

U.S. Food and Drug Administration. Medical applications of 3D printing. https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/3DPrintingofMedicalDevices/ucm500539.htm. Last updated December 4, 2017.

Wallace N, Schaffer NE, Aleem IS, Patel R. 3d-printed patient-specific spine implants: A systematic review. *Clin Spine Surg.* 2020;33(10):400-407. Doi: 10.1097/bsd.0000000000001026.

Wang J, Wang X, Wang B, et al. Comparison of the feasibility of 3d printing technology in the treatment of pelvic fractures: A systematic review and meta-analysis of randomized controlled trials and prospective comparative studies. *Eur J Trauma Emerg Surg.* 2020. Doi: 10.1007/s00068-020-01532-9.

Wood L, Ahmed Z. Does using 3D printed models for pre-operative planning improve surgical outcomes of foot and ankle fracture fixation? A systematic review and meta-analysis. *Eur J Trauma Emerg Surg*. 2022 Nov 24. Doi: 10.1007/s00068-022-02176-7.

Xie L, Chen C, Zhang Y, et al. Three-dimensional printing assisted ORIF versus conventional ORIF for tibial plateau fractures: A systematic review and meta-analysis. *Int J Surg.* 2018;57:35-44. Doi: 10.1016/j.ijsu.2018.07.012.

Policy updates

7/2021: initial review date and clinical policy effective date: 8/2021

7/2022: Policy references updated.

7/2023: Policy references updated.

7/2024: Policy references updated.