Medical three-dimensional printing

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

This policy is a Sandhills Center Clinical Coverage Policy adopted from AmeriHealth Caritas of North Carolina. These clinical policies are used to assist with making coverage determinations. Sandhills Center'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 Sandhills Center 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. Sandhills Center 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. Sandhills Center's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Sandhills Center will update its clinical policies as necessary. Sandhills Center clinical policies are not guarantees of payment.

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

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.

Craniomaxillofacial surgery

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) and one case series (Ethunandan, 2010) consists 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 nonfusion (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.

References

On February 17, 2021, 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.

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Policy updates

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