

Corporate Medical Policy

Three Dimensional Printed Orthopedic Implants

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Description of Procedure or Service

This policy addresses orthopedic implants that are constructed by additive manufacturing, commonly known as 3-dimensional (3D) printing. Three situations are considered: 3D printing of standard-sized implants, 3D printing of patient-matched implants for individuals who have typical bone and joint anatomy, and custom 3D printed implants for patients who have bone or joint deformity.

Three-dimensional (3D) printed implants are made by a process of additive manufacturing. Additive manufacturing uses a computer-aided process with a 3D printer to build devices one layer at a time. The most commonly used technologies in medical devices are powder bed fusion, stereolithography, fused filament fabrication, and liquid-based extrusion. Stereolithography systems use a vat of liquid that is cured by light. Fused filament fabrication melts a solid filament at the point of deposition, after which it solidifies, while liquid-based extrusion systems eject a liquid which then solidifies. Orthopedic implants are frequently made with cobalt-chromium or titanium powder bed fusion, which uses an energy source such as laser or electron beam to melt or sinter a layer of metal powder onto the layer below.

Additive manufacturing contrasts with the traditional methods of manufacturing, which include forging (shaped by hammering or bending), casting (formed by molten metal poured into a mold), and machining (removes material to create the desired geometry). Traditional manufacturing methods are frequently used with cobalt-chromium alloys for orthopedic implants. Titanium is also used for implants, including the femoral stems and acetabular cups used for total hip arthroplasty. The manufacturing of titanium and titanium alloys with traditional production methods is more difficult. Production of complex shapes is also limited with forging, casting, or machining.

Advantages of additive manufacturing include the ability to manufacture complex structures that traditional manufacturing processes cannot, and to create devices individually matched to the patient's anatomy. Additive manufacturing also allows rough or porous surface textures that promote bone ingrowth, and some have proposed that fully porous implants may reduce bone resorption around the implant. Three-dimensional printed models of a joint or spine can also be constructed to plan and practice complex surgeries. In addition to increased design flexibility and potential improvements in function, additive manufacturing wastes less raw materials and may reduce processing costs.

Additive manufacturing may, however, introduce variability into the manufacturing process. A number of factors affect the production of patient-matched orthopedic implants. One factor is whether the device is based on a standard template or custom-designed. Another is if the design could be affected by image quality, rigidity of anatomic structures, or clarity of anatomic landmarks. Some patient-matched devices are based on a standard-sized template with specific

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features modified within a defined design or performance envelope. Patient-matched devices that follow the patient anatomy more precisely are more vulnerable to design errors.

Manufacturing processes that occur after printing can also affect device performance and material properties. Postprocessing may include removal of manufacturing residues, heat treatments, and final machining and polishing when needed and where surfaces are accessible. For devices made with additive manufacturing, the U.S. Food and Drug Administration (FDA) recommends process validation, revalidation if there are any changes to the device or process, and mechanical device testing in a manner similar to testing of devices made with a traditional manufacturing method. Three-dimensional printing of orthopedic implants at a central facility permits the manufacturer to regulate quality, biocompatibility of materials, and sterility.

REGULATORY STATUS

In 2017, FDA published guidance for industry and technical considerations for 3D printed medical devices. The recommendations in this guidance are intended to supplement any device-specific recommendations and represent FDA's initial thinking and recommendations. The guidance does not apply to 3D printing at the point-of-care.

FDA expects "that AM [additive manufacturing] devices will follow the same regulatory requirements and submission expectations as the classification and/or regulation to which a non-AM device of the same type is subject." The required information, characterization, and testing will depend on a variety of factors, such as whether it is an implant or instrument, and whether it is available in standard sizes or is patient-matched.

The FDA has noted that although patient-matched devices are sometimes referred to as customized devices, they are not custom devices meeting custom device exemption requirements under the U.S. Federal Food, Drug, and Cosmetic Act unless they comply with all of the criteria of section 520(b). FDA published guidance for industry and on the custom device exemption act in 2014. Custom devices are those created or modified to comply with the order of an individual physician or dentist, do not exceed 5 units per year, and are reported by the manufacturer to FDA for devices manufactured and distributed under section 520(b) of the Food, Drug, and Cosmetic Act.

Under Section 520(b) of the Food, Drug, and Cosmetic Act, custom devices are exempt from premarket approval (PMA) requirements and conformance to mandatory performance standards.

"A device not covered by an existing marketing approval would require either a PMA or a valid exemption from the requirements to obtain PMA approval in order to be introduced into interstate commerce. Examples of potential valid exemptions or alternatives from the PMA requirement include: (1) establishing the substantial equivalence of the new device to a valid predicate device, (2) approval of an Investigational Device Exemption (IDE) or (3) meeting all custom device exemption requirements."

"Custom Devices are not exempt from any other requirements, including, but not limited to, the Quality System Regulation, including Design Controls (21 CFR Part 820); Medical Device Reporting (21 CFR Part 803); Labeling (21 CFR Part 801); Corrections and Removals (21 CFR Part 806); and Registration and Listing (21 CFR Part 807)."

A custom device may not be marketed to the general public.

FDA has also noted that most patient-matched devices will fall within the existing regulatory pathway for that device type. In addition to standard labeling, specific labeling information is recommended for AM devices that are patient-matched. FDA has stated that "modifications to a 510(k)-cleared device that maintain its original intended use and could be clinically studied do not appropriately qualify as a custom device."

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A number of titanium spinal interbody implants with increased roughness and porosity than traditional designs have received marketing clearance by FDA through the 510(k) process. They have a biomechanical stiffness similar to polyetheretherketone cages and less than solid titanium. They include:

- Cascadia™ Cervical and Cascadia™ AN Lordotic Oblique Interbody Systems (K2M)
- EIT (Emerging Implant Technologies)
- IB3D (Medicrea)
- Modulus XLIF (NuVasive)
- NanoHive interbodies (HD Lifesciences).

Porous 3D printed titanium implants for minimally invasive sacroiliac joint fusion have received 510(k) clearances.

- iFuse 3D (SI Bone)

Custom knee implants include:

- ConforMIS iTotal® Cruciate Retaining Knee Replacement System (ConforMIS)
- ConforMIS iTotal® Posterior Stabilized Knee Replacement System (ConforMIS)
- ConforMIS iUni® Unicondylar Knee Replacement System (ConforMIS)
- ConforMIS iTotal Hip system (ConforMIS).

RELATED POLICIES

Patient Specific Instrumentation (e.g., Cutting Guides) for Joint Arthroplasty
Computer Assisted Surgical Navigational Orthopedic Procedures

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Three Dimensional Printed Orthopedic Implants when they are determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Three Dimensional Printed Orthopedic Implants are covered

Custom 3D printed implants for patients with bone or joint deformity may be considered medically necessary when the devices are produced at a central manufacturing facility and meet FDA custom device exemption requirements.

When Three Dimensional Printed Orthopedic Implants are not covered

Three-dimensional (3D) printed orthopedic implants that have a design that is approved or cleared by the Food and Drug Administration (FDA) and produced in standard sizes for patients with typical bone and joint anatomy are investigational.

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Patient-matched 3D printed implants that are based on non-standard shapes and sizes for patients with typical bone and joint anatomy and do not qualify as custom devices according to FDA custom device exemption requirements are investigational.

Three-dimensional printed orthopedic implants produced outside of FDA-regulated manufacturing facilities are investigational.

Policy Guidelines

This policy does not address custom mandible or maxillofacial implants.

For individuals who have typical bone and joint anatomy and are undergoing standard orthopedic procedures who receive a standard-sized 3D printed implant, the evidence includes a randomized controlled trial and systematic review. Relevant outcomes include symptoms, functional outcomes, and quality of life. There is limited data on the performance of orthopedic implants produced by additive manufacturing. 3D-printed implants are often manufactured with titanium and permit greater porosity than traditional manufacturing techniques. The literature on solid titanium implants has suggested greater subsidence compared with polyetheretherketone interbody spacers for spinal fusion and greater bone resorption compared with cobalt-chromium femoral stems in total hip arthroplasty. Other evidence suggests that porous titanium implants produced by 3D-printing may improve osteointegration and reduce aseptic loosening. Due to these conflicting findings, clinical trials are needed to evaluate how 3D-printed implants perform over the long-term compared with conventionally manufactured devices. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have typical bone and joint anatomy and are undergoing standard orthopedic procedures who receive a patient-matched 3D printed implant, the evidence includes no comparative studies. Relevant outcomes include symptoms, functional outcomes, and quality of life. Studies are needed to determine whether patient-matched implants improve outcomes compared with conventional implants. It is noted that other methods for the customization of orthopedic procedures, specifically patient-specific cutting guides and sex-specific implants, have failed to demonstrate improvements in health outcomes. Demonstration of improvement in key outcome measures is needed to justify the greater resource utilization (e.g., time, imaging) of patient-matched 3D printed devices. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have bone or joint deformity requiring a custom orthopedic implant who receive a custom 3D printed implant, the evidence includes case series. Relevant outcomes include symptoms, functional outcomes, and quality of life. The largest case series with the longest follow-up is from outside of the United States. The most commonly reported indications are for revision total hip arthroplasty with severe acetabular defects, reconstruction following orthopedic tumor resection, and spinal abnormalities. These cases would require a custom process for design and manufacturing, even with traditional manufacturing methods. Therefore, the design and manufacturing of a single implant with 3D printing is an advantage of this technology. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

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There are no specific codes for 3-dimensional printed orthopedic implants. It is possible that providers may use the following code: L8699

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration. Technical considerations for additive manufactured medical devices: Guidance for industry and Food and Drug Administration staff. 2017; <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm499809.pdf>. Accessed June 8, 2018.

U.S. Food and Drug Administration. Custom device exemption: Guidance for industry and Food and Drug Administration Staff. 2014; <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm415799.pdf>. Accessed June 8, 2018.

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.161, 5/4/2018

Specialty Matched Consultant Advisory Panel 2/2019

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.161, 7/11/2019

Policy Implementation/Update Information

6/29/18 New policy added. Three-dimensional printed implants are considered medically necessary for custom implants for patients with bone or joint deformity and investigational for standard and patient-matched implants. (sk)

3/12/19 Specialty Matched Consultant Advisory Panel review 2/20/2019. (sk)

10/15/19 Reference added. Policy Guidelines updated. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.