Introduction

An orthopedic implant is a device that fixes a bone or joint problem. The implant can replace a joint or reinforce or support a damaged bone. There are a wide variety of implants that come in many shapes and sizes. Typically, medical imaging is used to look at the damaged area to determine the shape and size of the implant. Standard implants can often be used to address a patient’s particular problem. In some cases, however, a standard implant can’t be made to fit the area due to unusual anatomy or bone shape. In these cases, a 3-dimensional (3D) custom implant may be created. The implants rely on a technique known as 3D printing, which adds material one very thin layer at a time. These custom implants are truly custom. The shape can’t be made over and over again and marketed to other patients who need similar implants. This policy describes when a 3D custom implant may be covered.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
### Implant | Medical Necessity
--- | ---
**Custom Three-dimensional (3D) printed implants** | 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 (eg, not at the point-of-care)
  **AND**
- The devices meet FDA custom device exemption requirements (see **Regulatory Status**)

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

**Patient-matched 3D printed implants** | 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.

**3D printed orthopedic implants, non-FDA** | Three-dimensional printed orthopedic implants produced outside of FDA-regulated manufacturing facilities are investigational.

**Note:** This policy does not address custom mandible or maxillofacial implants.

### Documentation Requirements

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:
- For Custom 3D printed implants for patients with bone or joint deformity:
  - Documentation that the devices are produced at a central manufacturing facility (eg, not at the point-of-care)
  - Documentation that the device meets FDA custom device exemption requirements
### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8699</td>
<td>Prosthetic implant, not otherwise specified.</td>
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</table>

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### Related Information

N/A

### Evidence Review

### Description

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.

### Background

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.\(^1\) 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 in-growth, 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 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.
Summary of Evidence

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 an RCT and systematic review. The 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 PEEK 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. The 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 (eg, 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. The 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.
Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td>Ongoing</td>
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<td></td>
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<tr>
<td>NCT04062630*</td>
<td>Sacroiliac Joint Stabilization in Long Fusion to the Pelvis: Randomized Controlled Trial</td>
<td>220</td>
<td>May 2022</td>
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<tr>
<td>NCT03649490*</td>
<td>A Prospective Multicenter Study Evaluating the Effect of Implant Material and/or Surface Structure on Progression of Fusion in XLIF® Surgery</td>
<td>300</td>
<td>Aug 2022</td>
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<tr>
<td>NCT04086784</td>
<td>3D-printed Porous Titanium Alloy Cages Versus PEEK Cages: Pedicle Screw Loosening Rate and Fusion Rate in Patients With Osteoporosis (3DCOP)</td>
<td>90</td>
<td>Dec 2022</td>
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<tr>
<td>NCT03647501*</td>
<td>Lumbar Fusion With 3D-Printed Porous Titanium Interbody Cages - A Single-Blinded Randomized Controlled Trial Evaluating Nexxt Matrixx(TM) Versus PEEK Cages</td>
<td>70</td>
<td>Sep 2024</td>
</tr>
<tr>
<td>NCT02494544*</td>
<td>A Prospective, Randomized, Multicenter Study to Evaluate the ConforMIS iTotal® (CR) Knee Replacement System Versus Off-the-Shelf Replacement</td>
<td>187</td>
<td>Aug 2029</td>
</tr>
</tbody>
</table>

NCT: national clinical trial
* Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

American Society for Testing and Material

The American Society for Testing and Material has drafted standards for additive manufacturing. The specification on Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion covers additively manufactured titanium-6aluminum-4vanadium components using full-melt powder bed fusion such as electron beam melting and laser melting. The Society states that “the components produced by these processes are used typically in applications that require mechanical properties similar to machined forgings and wrought products. Components
manufactured to this specification are often, but not necessarily, post processed via machining, grinding, electrical discharge machining, polishing, and so forth to achieve desired surface finish and critical dimensions.”

**Medicare National Coverage**

There is no national coverage determination.

**Regulatory Status**

The FDA (2017) published guidance for industry and technical considerations for 3D printed medical devices.¹ 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 the criteria of section 520(b). FDA has published guidance for industry and on the custom device exemption act in 2014.² Custom devices are those created or modified to comply with the order of an individual physician or dentist, do not exceed five 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.

The 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. The 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.”

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)
- CONDUIT (DePuy Synthes)
- EIT (Emerging Implant Technologies)Fortilink IBF system (RTI Surgical)
- Foundation 3D (CoreLink)
- IB3D (Medicrea)
- Modulus XLIF (NuVasive)
- NanoHive interbodies (HD Lifesciences)
- Spira-C (Camber)
- Tirbolox (Captiva Spine)
- Tritanium (Stryker)

A porous 3D printed titanium implants for minimally invasive sacroiliac joint fusion have received 510(k) clearances:
iFuse 3D (Si Bone)

Patient matched 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).

References


### History

<table>
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<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
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<tr>
<td>08/01/18</td>
<td>New policy, approved July 10, 2018. Add to Surgery section. Policy created with literature review through March 2018. 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.</td>
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**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review
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  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
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  - Qualified interpreters
  - Information written in other languages

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Email AppealsDepartmentInquiries@Premera.com

You can also file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically; on the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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