MEDICAL POLICY – 7.01.161

Three-Dimensional Printed Orthopedic Implants

BCBSA Ref. Policy: 7.01.161
Effective Date: Aug. 1, 2018
Last Revised: July 10, 2018
Replaces: N/A

RELATED MEDICAL POLICIES:
7.01.144 Patient-Specific Cutting Guides and Custom Knee Implants

Select a hyperlink below to be directed to that section.

POLICY CRITERIA  |  DOCUMENTATION REQUIREMENTS  |  CODING
RELATED INFORMATION  |  EVIDENCE REVIEW  |  REFERENCES  |  HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

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.

Policy Coverage Criteria
### 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 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 | 3D 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>HCPCS</td>
<td></td>
</tr>
<tr>
<td>L8699</td>
<td>Prosthetic implant, not otherwise specified.</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

**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 1 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 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. Relevant outcomes include symptoms, functional outcomes, and quality of life. Three-dimensional printed implants are often manufactured with titanium and allow greater porosity than can be achieved with traditional manufacturing techniques. Greater porosity is believed to facilitate bony in-growth and theoretically improve the stability of the implant. However, the effect of these devices on the adjacent bone, particularly subsidence and resorption, is unknown. Studies are needed that compare these newer devices with the established alternatives. 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 (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. 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>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>NCT02494544(^a) A Prospective, Randomized, Multicenter Study to Evaluate the ConforMIS iTotal® (CR) Knee Replacement System Versus Off-the-Shelf Replacement</td>
<td>800</td>
<td>Aug 2025</td>
</tr>
</tbody>
</table>

NCT: national clinical trial
\(^a\) 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.\(^{15}\) 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. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Regulatory Status

In 2017, the FDA 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 of the criteria of section 520(b). FDA has 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.”
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).

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<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>
</tr>
</tbody>
</table>

**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 and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  • Qualified sign language interpreters
  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  • Qualified interpreters
  • Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentinquines@Premera.com

You can 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 through 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 S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Amharic):
لم يكن هناك ترجمات مهمة للعربية بخصوص طلب أو طلب هذه المعدات. قد يكون هناك ترجمات محدودة في معدات Premera Blue Cross كجزء من برامج مكافحة القيادة. لا يوجد نموذج ويجب أن تتم محاسبة المعدات بالكامل.

طة 800-722-1471 (TTY: 800-842-5357)

Français (French):

Kreyòl ayisyen (Creole):
Avi sila a gen enfòmasyon enpòtan ladan. Avi sila a kapab genyen enfòmasyon enpòtan konsénan aplikasyon w lan oswa konsènan kouvèt ou. Avi sila a kapab genyen enfòmasyon enpòtan lan qila avez. Avi sila a gen Enfòmasyon Enpòtan la bien. Avi sila a gen Enfòmasyon Enpòtan enpòtan lan qila avez.

Deutsche (German):

Oromo (Cushite):

Italiano (Italian):
Premera Blue Cross is required to provide you information and assistance about your insurance or a claim you may have.

This Aviso contains important information.

To prevent you from losing your health coverage or aid in a certain time frame, you may need to complete the form or request your information and support regarding your coverage or claim.

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

ไทย (Thai):
ประกาศนี้มีข้อมูลที่สำคัญเกี่ยวกับการขอรับการช่วยเหลือหรือการสนับสนุนของคุณผ่าน Premera Blue Cross และมีการกำหนดเวลาในการต้องการข้อมูลและเพื่อให้คุณรู้ว่าคุณมีสิทธิ์ที่จะได้รับข้อมูลและความช่วยเหลือในภาษาที่คุณต้องการไม่ว่าจะใช้ภาษาใด โปรดติดต่อ 800-722-1471 (TTY: 800-842-5357).

Український (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує можливість того, що Вам треба буде здійснити певні кроки у конкретній ситуації для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):
Thông báo này cung cấp thông tin quan trọng. Thông báo này có đồng tin quan trọng về đơn xin tham gia hoặc đóng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện những thông báo của chúng tôi hàng ngày để đảm bảo rằng chúng tôi có thể cung cấp cho quý vị những thông tin về quyền của quý vị. Quý vị có quyền được biết thông tin này mà chúng tôi có thể cung cấp trong ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).