BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Three-Dimensional Printed Orthopedic Implants

Policy #: 717
Latest Review Date: June 2024
Category: Surgical

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **custom three-dimensional (3D) printed implants** for patients with bone or joint deformity as a **covered benefit** when the devices **are produced at a central manufacturing facility** and **meet FDA custom device exemption requirements.**

Blue Advantage will treat **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 as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat **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 as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat **3D-printed orthopedic implants** produced outside of FDA-regulated manufacturing facilities as a **non-covered benefit** and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

This evidence review addresses orthopedic implants that are constructed by additive manufacturing, commonly known as three-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 a bone or joint deformity.

Three-dimensional 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 a 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 the 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. Post-processing 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, the biocompatibility of materials, and sterility.

This policy does not address custom mandible or maxillofacial implants. This policy also does not address patient-specific cutting guides.

KEY POINTS:

The policy has been updated regularly with searches of the MEDLINE database. The most recent literature review was performed through June 2024. The following is a summary of the key literature.

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 a randomized controlled trial 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 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. 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 (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 a 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 QOL. The largest case series with the longest follow-up is from outside of the U.S. 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.

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."

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:

3-D implants, three-dimensional printed orthopedic implants, hip arthroplasty, knee arthroplasty, custom orthopedic implant, three-dimensional printed spinal implants, Cascadia, EIT, Emerging Implant Technologies, IB3D, Modulus, XLIF, NanoHive interbodies, iFuse 3D, ConforMIS, CONDUIT, Fortilink IBF system, Spira-C, Tirbolox, Tritanium, IB3D

APPROVED BY GOVERNING BODIES:

The FDA (2017) 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 the FDA's initial thinking and recommendations. The guidance does not apply to 3D printing at the point-of-care.

The 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). The 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 five units per year, and are reported by the manufacturer to the 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 the 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)
- IB3D (Medicrea)
- Modulus XLIF (NuVasive)
- NanoHive interbodies (HD Lifesciences)
- Spira-C (Camber)
- Tirbolox (Captiva Spine)
- Tritanium (Stryker)
- IB3D (Medicrea)

A porous 3D-printed titanium implant for minimally invasive sacroiliac joint fusion has received 510(k) clearance.

- 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)

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:
Effective 7/1/2019, use the following codes:

0559T	Anatomic model 3D-printed from image data set(s); first individually prepared and processed component of an anatomic structure
0560T	Anatomic model 3D-printed from image data set(s) each additional individually prepared and processed component of an anatomic structure (List separately in addition to code for primary procedure)

PREVIOUS CODING:
CPT
Prior to 7/1/2019, there were no specific codes for three-dimensional printed orthopedic implants. It is possible that providers may use the following code:
L8699 Prosthetic implant, not otherwise specified.

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POLICY HISTORY:

Medical Policy Panel, May 2018
Medical Policy Group, July 2018 **(7)**: New Policy
Medical Policy Administration Committee, July 2018
Available for comment July 6 through August 19, 2018
Medical Policy Group, July 2019
Medical Policy Group, July 2020
Medical Policy Group, July 2021
Medical Policy Group, July 2022: Reviewed by consensus. There is no new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, June 2023: Reviewed by consensus. Literature review completed. No change in policy statement.
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, June 2024: Reviewed by consensus. There is no new published peer-reviewed literature available that would alter the coverage statement in this policy.
UM Committee, June 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.