DRAFT

BlueCross BlueShield of Alabama

Name of Policy:
Three-Dimensional Printed Orthopedic Implants

Policy #: 717
Category: Surgical
Latest Review Date: July 2018
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

This evidence review 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 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.

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

For patient specific cutting guides, see medical policy #716- *Patient Specific instrumentation for Joint Arthroplasty*.

Policy:

Custom 3D printed implants for patients with bone or joint deformity **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage **when the devices are produced at a central manufacturing facility and meet FDA custom device exemption requirements.**

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 **do not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational**.

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 **do not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational**.

Three-dimensional printed orthopedic implants produced outside of FDA-regulated manufacturing facilities **do not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational**.

Blue Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate 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.

Key Points:

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of

life, and ability to function- including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Standard-Sized 3-Dimensional Printed Orthopedic Implants

There is limited data on the performance of orthopedic implants produced by additive manufacturing. Porosity can be increased with 3-dimensional (3D) printing, and basic research has suggested an increase in osteointegration with more porous surfaces. Although a number of spinal interbody spacers are currently manufactured with 3D printing, it is not clear at this time whether the titanium implants lead to improved health outcomes compared with standard polyetheretherketone (PEEK) cages. Recent evidence, described below, has suggested an increase in subsidence (sinking or settling into the adjacent bone) with titanium compared with PEEK cages. The movement of an implant into the adjacent vertebra can result in a loss of disc height.

One RCT found that use of solid titanium interbody cages for anterior cervical discectomy and fusion resulted in worse clinical and radiologic outcomes compared with PEEK interbody cages at a mean at 7-year follow-up. In this trial, 80 patients with cervical spondylotic myelopathy were randomized to multilevel anterior cervical discectomy and fusion with titanium or PEEK interbody cages. The group who received anterior cervical discectomy and fusion with solid titanium implants had greater loss of Cobb angle and a greater proportion of patients showing loss of intervertebral height over 3 mm (34.5%), indicating cage subsidence, compared with the PEEK group (5.4%, $p<0.05$). Clinical outcome measures (Japanese Orthopaedic Association and Neck Disability Index) were significantly worse in the group with titanium cages.

A meta-analysis by Seaman et al (2017), which identified 6 studies (3 level IV evidence and 2 level III [all retrospective], and the level II prospective RCT described above), found no statistically significant difference between solid titanium and PEEK implants for spinal fusion rates, but there was a statistically significant increase in the rate of subsidence with titanium implants (odds ratio, 3.59; 95%, confidence interval, 1.28 to 10.07; $p=0.015$). Most studies used solid titanium implants and evaluated interbody devices of different designs. Comparison of porous 3D-printed titanium implants with PEEK implants has not been reported. The only RCT

identified found significant differences in favor of the PEEK group for the patient-reported outcome measures.

The effect of titanium on bone resorption is unclear. The literature on femoral stems for hip arthroplasty indicated that osteolysis and long-term failure might increase with titanium compared with cobalt-chromium stems, which some authors have suggested is due to the increased flexibility of titanium compared with cobalt-chromium. Other investigators suggested that fully porous 3D printed titanium femoral stems may reduce bone resorption and loosening from stress-shielding. In addition to the choice of metal, the process of additive manufacturing may also result in more flexibility of the orthopedic implant than traditional manufacturing.

Section Summary: Standard-Sized 3-Dimensional Printed Orthopedic Implants
There is limited data on the performance of orthopedic implants produced by additive manufacturing. Three-dimensional 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. The effect on adjacent bone of porous titanium implants produced by 3D-printing is unknown. Due to these uncertainties, clinical trials are needed to evaluate how 3D-printed implants perform over the long-term compared with devices manufactured traditionally.

Patient-matched 3D Printed Orthopedic Implants
No published RCTs have been identified on patient-matched knee implants. Results from an RCT (NCT02494544) comparing the ConforMIS iTotal CR Knee Replacement System with off-the-shelf implants are expected in 2025. It is notable that a number of RCTs have been performed with implants produced using traditional manufacturing and designed specifically for women. These studies with sex-specific implants have not shown improvements in clinical outcomes. Similarly, trials on patient-specific cutting guides have not shown improved clinical outcomes compared with standard cutting guides (see medical policy #716- *Patient Specific instrumentation for Joint Arthroplasty*.)

Section Summary: Patient-Matched 3D Printed Orthopedic Implants
Patient-matched implants refer to the production of orthopedic implants that are modified based on 3D images. No studies have been identified to evaluate whether matching orthopedic implants to individual patient anatomy improves the net health outcome.

Custom 3D Printed Orthopedic Implants
Examples of custom implants are summarized in Table 1 and include implants for revision arthroplasty with severely compromised acetabulum, reconstruction following bone resection in orthopedic oncology, and complex spinal pathology. Most cases address severe acetabular defects with revision total hip arthroplasty that cannot be reconstructed using commercially available cages. In the report by Citak et al (2017), patients had undergone as many as 8 prior revision hip arthroplasties. The custom 3D printed implants are typically designed with flanges to attach the acetabular cup to the pelvis. Postoperative evaluations have shown 30- to 40-point improvements in the Harris Hip Score and up to 91% implant survival at 72 months.

The second most commonly reported indication for custom implants is pelvic or long bone reconstruction after tumor resection. Case series include up to 35 patients with a follow-up of approximately 2 years. Postoperative scores have ranged from 19 out of 30 on the Musculoskeletal Tumor Society Score (MSTS) for a tibial bone block to 25.8 on the International Society of Limb Salvage score for custom plate fixation or total joint (see Table 2). Liang et al (2017) have reported outcomes with the MSTS following pelvic tumor resection and reconstruction. The custom devices were designed with a hook, crest, and either flange or braids to attach the device to the adjacent bone. Mean MSTS scores at 20.5 months were 22.7 for an iliac prosthesis, 19.8 for a hemipelvic prosthesis, and 17.7 for a screw-rod connected prosthesis.

Three-dimensional printed spinal implants have also been used to treat complex spinal pathology. One case involved tumor resection and vertebral reconstruction, and another used a custom-designed titanium fusion cage for an unusual congenital deformity. The authors reported that the custom implants were easily placed in position, which reduced the surgical time and eliminated the need to harvest autograft bone to intraoperatively fit the defect.

Table 1. Key Case Series Characteristics of Custom Orthopedic Implants

Study	Country	Participants	Treatment Delivery	Follow-Up, mo
Acetabulum				
Mao et al (2015)	China	22 patients with revision THA and severe acetabular defects	Customized acetabular cages	82
Li et al (2016)	China	24 patients with revision THA and severe acetabular defects	Rapid prototyping with custom acetabular cages	67
Citak et al (2017)	Germany	9 patients with an average of 5 THA revisions and severe acetabular defects	Customized acetabular cages	29
Pelvis				
Liang et al (2017)	China	35 patients with pelvic tumor resection	3D printed modular iliac or hemipelvic prostheses	20.5
Distal femur or proximal tibia				
Ding et al (2013)	China	12 patients with osteosarcoma in the distal femur or proximal tibia	Plate fixation or full knee reconstruction	26.5 (range, 5-74)
Luo et al (2017)	China	4 patients with tumors of the proximal tibia	En-block resection with customized tibial bone block	5-8
Spine				
Mobbs et al (2017)	Australia	1 patient with craniocervical chordoma and 1 patient with a congenital spine deformity	Vertebral reconstruction with customized spinal cages	9 and 12

THA: total hip arthroplasty.

Table 2. Key Case Series Results of Custom Orthopedic Implants

Study	Treatment	Outcome	Outcome	Outcome
Acetabulum				
Mao et al (2015)	Revision THA with custom acetabular cages	HHS 39.6 preoperatively to 80.9 at follow-up ($p<0.01$)	Implant survival of 91.2% (95% CI, 58.10% to 73.95%)	
Li et al (2016)	Revision THA with custom acetabular cages	HHS 36 preoperatively to 82 at follow-up ($p<0.001$)	75% of patients could walk unaided and 21% used a cane	

Citak et al (2017)	Revision THA with custom acetabular cages	HHS 22.1 preoperatively to 58.7 at follow-up	89% implant survival	
Pelvis				
Liang et al (2017)	Modular titanium iliac or hemipelvic prostheses	MSTS of 22.7 for iliac prosthesis	MSTS of 19.8 for standard hemipelvic prosthesis	MSTS of 17.7 for screw-rod connected prosthesis
Distal femur or proximal tibia				
Ding et al (2013)	Custom endoprosthesis	ISLS score of 25.8 (range, 18- 27)		
Luo et al (2017)	Custom titanium tibial bone block with standard knee prosthesis	MSTS score, 19		
Spine				
Mobbs et al (2017)	Spinal fusion with custom implants	Case 1: successful tumor resection and fusion	Case 2: Improvement in back and leg pain	Case 2: ODI improved from 68% to 0%

HHS: Harris Hip Score; ISLS: International Society of Limb Salvage; MSTS; Musculoskeletal Tumor Society Score; ODI: Oswestry Disability Index; THA: total hip arthroplasty.

Section Summary: Custom 3D Printed Orthopedic Implants

The most effective use of 3D printing in orthopedics may be for custom implants, defined by FDA as devices 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. Potential benefits of 3D printed custom devices are flexibility in design, reduced cost, and faster production time in comparison with conventionally manufactured custom implants. Consistent with the limited number of implants that are considered custom, the literature consists of case reports and case series. The largest series with the longest follow-up are from China and the largest number of cases is for revision hip arthroplasty in patients with severe acetabular defects. Another reported use is for bone reconstruction following tumor resection. These cases require a custom process for design and manufacturing. The design and manufacturing of a single implant with 3D printing is an advantage of this technology.

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 (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.

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

Approved by Governing Bodies:

In 2017, UFDA 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."

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.

FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

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

L8699 Prosthetic implant, not otherwise specified.

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