Three-Dimensional Printed Orthopedic Implants

Description

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 a bone or joint deformity.

OBJECTIVE

The objective of this evidence review is to determine whether 3-dimensional printed orthopedic implants have a similar net health outcome compared with traditionally manufactured orthopedic implants.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
POLICY STATEMENT

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 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 are considered investigational.

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.

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

POLICY GUIDELINES

This policy does not address custom mandible or maxillofacial implants.

There are no specific codes for 3-dimensional printed orthopedic implants.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

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)."

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
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 (PEEK) 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).

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

- iFuse 3D (SI Bone).

Custom knee implants, which have received marketing clearance by the FDA through the 510(k) process, 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).

**Rationale**

**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 clinical trial (RCT) and systematic review. The relevant outcomes include symptoms, functional outcomes, and quality of life (QOL). 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 QOL. 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 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.

SUPPLEMENTAL INFORMATION

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.

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.

REFERENCES


The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

7. Castagnini, FF, Bordini, BB, Stea, SS. Highly porous titanium cup in cementless total hip arthroplasty: registry results at eight years. Int Orthop, 2018 Aug 25. PMID 30141142

8. Cohen, RR, Sherman, NN, James, SS. Early Clinical Outcomes of a New Cementless Total Knee Arthroplasty Design. Orthopedics, 2018 Sep 1;41(6). PMID 30168838


The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.