Articular cartilage damage, either from a focal lesion or diffuse osteoarthritis, can result in disabling pain. Cartilage is a hydrogel, comprised mostly of water with collagen and glycosaminoglycans, that does not typically heal on its own. There is a need for improved treatment options. In 2016, a synthetic polyvinyl alcohol hydrogel disc received marketing approval by the U.S. Food and Drug Administration for the treatment of degenerative or posttraumatic arthritis in the first metatarsophalangeal (MTP) joint. If proven successful for the treatment of the MTP joint, off-label use is likely.

**OBJECTIVE**

The objective of this evidence review is to evaluate whether a commercially available synthetic cartilage implant improves health outcomes in individuals with joint pain due to articular cartilage damage.

**POLICY STATEMENT**

Synthetic cartilage implants are considered not medically necessary for the treatment of articular cartilage damage.
BENEFIT APPLICATION

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

FDA REGULATORY STATUS

The Cartiva PVA implant was approved by the U.S. Food and Drug Administration in 2016 for the treatment of arthritis of the MTP joint. It has been distributed commercially since 2002 with approval in Europe, Canada, and Brazil. The Cartiva Synthetic Cartilage Implant (Cartiva, Alpharetta, GA) was approved by the Food and Drug Administration through the premarket approval process (P150017) for painful degenerative or posttraumatic arthritis in the first MTP joint along with hallux valgus or hallux limitus and hallux rigidus. Lesions greater than 10 mm in size and insufficient quality or quantity of bone are contraindications. Continued approval depends on a study evaluating long-term safety and effectiveness. The post-approval study will follow the subjects treated with Cartiva Synthetic Cartilage Implant for five years. Food and Drug Administration product code: PNW.

RATIONALE

Summary of Evidence

For individuals who have early-stage first MTP joint osteoarthritis (OA) who receive a synthetic cartilage implant, the evidence is lacking. The relevant outcomes are symptoms, functional outcomes, quality of life (QOL), and treatment-related morbidity. The pivotal study was performed in patients with Coughlin stage 2, 3, or 4 hallux rigidus. No evidence was identified in patients with stage 0 to early-stage 2 hallux rigidus. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have advanced first MTP joint OA who receive a synthetic cartilage implant, the evidence includes a pivotal non-inferiority trial. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Arthrodesis is the established treatment for advanced arthritis of the great toe, although the lack of mobility can negatively impact sports and choice of footwear, and is not a preferred option of patients. Implants have the potential to reduce pain and maintain mobility in the first MTP joint but have in the past been compromised by fragmentation, dislocation, particle wear, osteolysis, and loosening. A polyvinyl alcohol hydrogel implant has shown properties similar to articular cartilage in vitro and was approved by the Food and Drug administration in 2016 for the treatment of painful degenerative or posttraumatic arthritis in the MTP joint. Results at 2 years from the pivotal non-inferiority trial showed pain scores that were slightly worse compared to patients treated with arthrodesis and similar outcomes between the groups for activity of daily living (ADL) and sports. In a non-inferiority trial, some benefit should be observed to justify the non-inferiority margin. However, the benefit of Cartiva with respect to increased range of motion does not appear to translate to improved activities of daily living, sports activities, or patient report of well-being compared to arthrodesis. In addition, the Cartiva group showed a higher rate of adverse outcomes (Moderate Difficulty, Extreme Difficulty, and Unable to Do) compared to the arthrodesis group for walking for 15 min (16% vs 0%), Up Stairs (6% vs 0%) and Squats (19% vs 8%). Some bias in favor of the novel motion preserving implant was also possible, as suggested by the high dropout rate in the arthrodesis group after randomization. Five-year follow-up of both the randomized and run-in patients who received an implant was reported in 2018 for 135 of 152 patients. At this time point, 15% of implants had been removed with conversion to arthrodesis. Comparison to arthrodesis at long-term follow-up is needed to determine whether the implant improves function. Corroboration of long-term results in an independent study is also needed to determine the benefits and risks of the implant. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have articular cartilage damage in joints other than the great toe who receive a synthetic cartilage implant, the evidence includes observational studies. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. No RCTs were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

No guidelines or statements were identified.

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.
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


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# FEP 7.01.160 Synthetic Cartilage Implants for Joint Pain

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## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>March 2018</td>
<td>New policy</td>
<td>Policy created with literature review through October 16, 2018. Considered not medically necessary for all indications.</td>
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<tr>
<td>June 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through January 8, 2019; no references added. Policy statement unchanged.</td>
</tr>
<tr>
<td>September 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 1, 2019; no references added. Policy statement unchanged.</td>
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