



FEP Medical Policy Manual

FEP 7.01.160 Synthetic Cartilage Implants for Joint Pain

Annual Effective Policy Date: January 1, 2024

Original Policy Date: March 2018

Related Policies:

7.01.48 - Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

Synthetic Cartilage Implants for Joint Pain

Description

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Articular cartilage damage, either from a focal lesion or diffuse osteoarthritis (OA), 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.

POLICY GUIDELINES

None

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 (FDA) 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 (Wright Medical, Alpharetta, GA; now Stryker) was approved by the FDA 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. FDA product code: PNW.

RATIONALE

Summary of Evidence

For individuals who have early-stage first metatarsophalangeal (MTP) joint osteoarthritis (OA) who receive a synthetic cartilage implant, the evidence is lacking. Relevant outcomes are symptoms, functional outcomes, quality of life, 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 that the technology results in an improvement in the net health outcome.

For individuals who have advanced first MTP joint OA who receive a synthetic cartilage implant, the evidence includes a pivotal non-inferiority trial. Relevant outcomes are symptoms, functional outcomes, quality of life, 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 U.S. Food and Drug Administration (U.S. FDA) in 2016 for the treatment of painful degenerative or post-traumatic 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 activities 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 ADL, 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, 21% 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 that the technology results in an improvement in the net health outcome.

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. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. No randomized controlled trials were identified. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

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.

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

Date	Action	Description
March 2018	New policy	Policy created with literature review through October 16, 2018. Considered not medically necessary for all indications.
June 2019	Replace policy	Policy updated with literature review through January 8, 2019; no references added. Policy statement unchanged.
September 2019	Replace policy	Policy updated with literature review through July 1, 2019; no references added. Policy statement unchanged.
September 2020	Replace policy	Policy updated with literature review through June 3, 2020; references added. Policy statement unchanged.
September 2021	Replace policy	Policy updated with literature review through June 2, 2021; references added. Policy statement unchanged.
September 2022	Replace policy	Policy updated with literature review through April 18, 2022; no references added. Policy statement unchanged.
December 2023	Replace policy	Policy updated with literature review through August 3, 2023; no references added. Policy statement unchanged.

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