LifeWise
Health Plan of Washington

MEDICAL POLICY – 7.01.160

Synthetic Cartilage Implants for Joint Pain

BCBSA Ref. Policy:	7.01.160
Effective Date:	Oct. 1, 2024
Last Revised:	Sept. 9, 2024
Replaces:	N/A

RELATED MEDICAL POLICIES:

7.01.48	Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions
7.01.570	Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

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Introduction

Cartilage is a connective tissue in the body. There are different types of cartilage, including a specific form of cartilage that covers the ends of bones at joints. This is known as articular cartilage. Articular cartilage is smooth, cushions the bones, and makes them glide when the joint bends. Wear-and-tear arthritis (osteoarthritis) damages joint cartilage. This can result in pain and a decreased range of motion. There are several well-proven methods to successfully treat the symptoms of osteoarthritis. A new technique calls for a synthetic cartilage, made of plastics and other materials, to be placed between the bones of a painful joint. Synthetic cartilage implants are investigational. More studies are needed to find out if these implants are safe and effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Synthetic cartilage implants	**Synthetic cartilage implants (e.g., Cartiva) are considered investigational for the treatment of articular cartilage damage.**

Note: the codes listed below are not specific to synthetic cartilage implants. The scope of this policy is review only of synthetic cartilage implants (e.g., Cartiva), if any other type of implant is requested this policy does not apply.

Coding

Code	Description
CPT	
28291	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant
HCPCS	
L8641	Metatarsal joint implant
L8642	Hallux implant
L8699	Prosthetic Implant, not otherwise specified

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

Description

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 United States (US) Food and Drug Administration (FDA) for the treatment of degenerative or posttraumatic arthritis in the first metatarsophalangeal (MTP) joint. If proven successful for treatment of the MTP joint, off-label use is likely.

Background

Articular Cartilage Damage

Articular cartilage damage may present as focal lesions or as more diffuse OA. Cartilage is a biological hydrogel that is comprised mostly of water with collagen and glycosaminoglycans and does not typically heal on its own. OA or focal articular cartilage lesions can be associated with substantial pain, loss of function, and disability. OA is most frequently observed in the knees, hips, interphalangeal joints, first carpometacarpal joints, first MTP joint, and apophyseal (facet) joints of the lower cervical and lower lumbar spine. OA less commonly affects the elbow, wrist, shoulder, and ankle. Knee OA is the most common cause of lower-limb disability in adults over age 50, however, OA of the MTP joint with loss of motion (hallux rigidus) can also be severely disabling due to pain in the "toe-off" position of gait. An epidemiologic study found that OA of the first MTP joint may be present in as many as 1 in 40 people over the age of 50.[1]

Treatment

Treatment may include débridement, abrasion techniques, osteochondral autografting, and autologous chondrocyte implantation. Débridement involves the removal of the synovial membrane, osteophytes, loose articular debris, and diseased cartilage and is capable of producing symptomatic relief. Subchondral abrasion techniques attempt to restore the articular surface by inducing the growth of fibrocartilage into the chondral defect. Diffuse OA of the knee, hip, or ankle may be treated with joint replacement.

Early-stage OA of the first MTP joint is typically treated with conservative management, including pain medication and change in footwear. Failure of conservative management in individuals with advanced OA of the MTP joint may be treated surgically. Cheilectomy (removal

of bone osteophytes) and interpositional spacers with autograft or allograft have been used as temporary measures to relieve pain.

Although partial or total joint replacement have been explored for MTP OA, complications from bone loss, loosening, wear debris, implant fragmentation, and transfer metatarsalgia are not uncommon. Also, since the conversion of a failed joint replacement to arthrodesis has greater complications and worse functional results than a primary arthrodesis (joint fusion), MTP arthrodesis is considered the most reliable and primary surgical option. Arthrodesis can lead to a pain-free foot, but the loss of mobility in the MTP joint alters gait, may restrict participation in running and other sports, and limits footwear options, leading to patient dissatisfaction. Transfer of stress and arthritis in an adjacent joint may also develop over time.

Because of the limitations of MTP arthrodesis, alternative treatments that preserve joint motion are being explored. Synthetic cartilage implants have been investigated as a means to reduce pain and improve function in individuals with hallux rigidus. Some materials such as silastic were found to fragment with use. Other causes of poor performance are the same as those observed with metal and ceramic joint replacement materials and include dislocation, particle wear, osteolysis, and loosening.

Synthetic polyvinyl alcohol (PVA) hydrogels have water content, and biomechanical properties similar to cartilage and they are biocompatible. PVA hydrogels have been used in a variety of medical products including soft contact lens, artificial tears, hydrophilic nerve guides, and tissue adhesion barriers. This material is being evaluated for cartilage replacement due to the rubber elastic properties and, depending on the manufacturing process, high tensile strength and compressibility.[2]

The Cartiva implant is an 8- to 10-mm PVA disc that is implanted with a slight (1- to 1.5-mm) protrusion to act as a spacer for the first MTP joint. It comes with dedicated reusable instrumentation, which includes a drill bit, introducer, and placer.

Summary of Evidence

For individuals who have early-stage first MTP joint OA who receive a synthetic cartilage implant, the evidence is lacking. The relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The pivotal study was performed in individuals with Coughlin stage 2, 3, or 4 hallux rigidus. No evidence was identified in individuals 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. The 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 PVA hydrogel implant has shown properties similar to articular cartilage in vitro and was approved by the FDA in 2016 for the treatment of painful degenerative or posttraumatic arthritis in the MTP joint. Results at two years from the pivotal non-inferiority trial showed pain scores that were slightly worse compared to individuals 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 individuals. 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. The 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT03247439[a]	A Prospective Study to Evaluate the Safety and Effectiveness of the Cartiva Synthetic Cartilage Implant for CMC in the Treatment of First Carpometacarpal Joint Osteoarthritis as Compared to LRTI Comparator (GRIP2)	74	Mar 2024 (last update Dec 2020)
NCT02391506[a]	A Prospective Study to Evaluate the Safety and Effectiveness of the Cartiva Synthetic Cartilage Implant for CMC in the Treatment of First Carpometacarpal Joint Osteoarthritis	50	Mar 2019
NCT03935880	Treatment of Hallux Rigidus With Synthetic Hemiarthroplasty Versus Cheilectomy: A Randomized Controlled Trial	20 (actual)	Sept 2021 (terminated due to difficulty meeting recruitment goals)

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion 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. 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.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

The Cartiva PVA Implant was approved by the 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.

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Appendix

Appendix Table 1. Coughlin Clinical-Radiographic System for Grading Hallux Rigidus

Grade	Dorsiflexion	Radiographic Findings	Clinical Findings
0	40°-60° and/or 10%-20% loss vs normal side	Normal	No pain; only stiffness and loss of motion
1	30°-40° and/or 20%-50% loss vs normal side	Minimal changes	Mild or occasional pain and stiffness
2	10°-30° and/or 50%-75% loss vs normal side	Osteophytes, mild-to-moderate joint-space narrowing	Moderate-to-severe pain and stiffness that may be constant; pain occurs at maximum flexion
3	≤10° and/or 75%-100% loss vs normal side	Osteophytes, substantial joint space narrowing	Nearly constant pain and substantial stiffness at extremes ROM, not at mid-range
4	Same as grade 3	Same as grade 3	Same as grade 3 but definite pain at mid-ROM

ROM: range of motion.

History

Date	Comments
05/01/19	New policy, approved April 9, 2019, effective August 2, 2019. Policy created with literature review through January 2019. Synthetic cartilage implants are considered investigational for the treatment of articular cartilage damage. Added codes L8641 and L8642.
10/01/19	Interim Review, approved September 5, 2019. Policy updated with literature review through July 2019; no references added. Policy statement unchanged.
10/01/20	Annual Review, approved September 1, 2020. Policy updated with literature review through June 2020; references added. Policy statement unchanged.
10/01/21	Annual Review, approved September 2, 2021. Policy updated with literature review through June 2, 2021; references added. Policy statement unchanged.
09/01/22	Annual Review, approved August 22, 2022. Policy updated with literature review through April 18, 2022; no references added. Policy statement unchanged.
08/01/23	Minor update to Related Policies. Removed 7.01.569 and replaced with 7.01.48 Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions.
12/01/23	Annual Review, approved November 6, 2023. Policy updated with literature review through August 3, 2023; no references added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.

Date	Comments
10/01/24	Annual Review, approved September 9, 2024. Policy updated with literature review through June 5, 2024; one reference added. Policy statement unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.