BlueCross BlueShield of North Carolina

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# Corporate Medical Policy

# Synthetic Cartilage Implants for Joint Pain

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| **File Name:** | synthetic_cartilage_implants_for_joint_pain |
| **Origination:** | 1/2018 |
| **Last CAP Review:** | 2/2021 |
| **Next CAP Review:** | 2/2022 |
| **Last Review:** | 2/2021 |

## Description of Procedure or Service

**ARTICULAR CARTILAGE DAMAGE**

Articular cartilage damage may present as focal lesions or as more diffuse osteoarthritis (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 metatarsophalangeal (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. 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.

**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, shoulder, 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 patients with advanced OA of the MTP joint may be treated surgically. Cheliectomy (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 patients 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.

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. 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.

**REGULATORY STATUS**

In July 2016, Cartiva® Synthetic Cartilage Implant (Cartiva, Alpharetta, GA) 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. 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 5 years.

**Related Policies**

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

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

## Policy

**Synthetic cartilage implants are considered investigational for the treatment of articular cartilage damage. BCBSNC does not provide coverage for investigational services or procedures.**

## Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Synthetic Cartilage Implants for Joint Pain are covered

Not applicable.

## When Synthetic Cartilage Implants for Joint Pain are not covered

Synthetic cartilage implants are considered investigational for the treatment of articular cartilage damage.

## Policy Guidelines

For individuals who have early-stage first MTP joint osteoarthritis 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 the effects of the technology on health outcomes.

For individuals who have advanced first MTP joint osteoarthritis 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 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 patients treated with arthrodesis and similar outcomes between the groups for 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, 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 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. 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 the effects of the technology on health outcomes.

## Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

# Synthetic Cartilage Implants for Joint Pain

*Applicable codes*: *28291, L8641, L8642, L8699*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources


BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.160, 12/14/2017

Specialty Matched Consultant Advisory Panel 2/2018

Specialty Matched Consultant Advisory Panel 2/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.160, 2/14/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.160, 7/11/2019

Specialty Matched Consultant Advisory Panel 2/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.160, 7/16/2020

Specialty Matched Consultant Advisory Panel 2/2021


## Policy Implementation/Update Information

1/26/18 New policy developed. Synthetic cartilage implants are considered investigational for the treatment of articular cartilage damage. (sk)

2/23/18 Correction to Billing/Coding section. Code L8646 deleted. Code L8642 added. (sk)

5/11/18 Specialty Matched Consultant Advisory Panel review. (sk)

3/12/19 Specialty Matched Consultant Advisory Panel review 2/20/2019. (sk)

4/16/19 Reference added. Policy Guidelines updated. (sk)

10/15/19 Reference added. Policy Guidelines updated. (sk)

3/10/20 Specialty Matched Consultant Advisory Panel review 2/19/2020. (sk)

3/9/21 Reference added. Specialty Matched Consultant Advisory Panel review 2/17/2021. (sk)