



# Louisiana

## Synthetic Cartilage Implants for Joint Pain

Policy # 00149

Original Effective Date: 06/01/2018

Current Effective Date: 04/12/2021

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions is addressed separately in medical policy 00006.*

*Note: Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions is addressed separately in medical policy 00091.*

## Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers synthetic cartilage implants for the treatment of articular cartilage damage to be **investigational**.\*

## Background/Overview

### **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.

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### **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.

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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.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

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<sup>®‡</sup> 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/Source**

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.

For individuals who have early-stage first MTP joint osteoarthritis 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.

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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 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, 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.

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### **Supplemental Information**

#### **Practice Guidelines and Position Statements**

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.

#### **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**

<b>NCT No.</b>	<b>Trial Name</b>	<b>Planned Enrollment</b>	<b>Completion Date</b>
<i>Ongoing</i>			
NCT03935880	Treatment of Hallux Rigidus With Synthetic Hemiarthroplasty Versus Cheilectomy: A Randomized Controlled Trial	120	Apr 2022
NCT03247439 <sup>a</sup>	A Prospective Study to Evaluate the Safety and Effectiveness of the Cartiva <sup>®‡</sup> Synthetic Cartilage Implant for CMC in the Treatment of First Carpometacarpal Joint Osteoarthritis as Compared to LRTI Comparator (GRIP2)	47	Jan 2024
<i>Unpublished</i>			
NCT02391506 <sup>a</sup>	A Prospective Study to Evaluate the Safety and Effectiveness of the Cartiva <sup>®‡</sup> Synthetic	50	Mar 2019

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NCT No.	Trial Name	Planned Enrollment	Completion Date
	Cartilage Implant for CMC in the Treatment of First Carpometacarpal Joint Osteoarthritis		

NCT: national clinical trial.

<sup>a</sup>Denotes industry-sponsored or cosponsored trial.

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## Policy History

Original Effective Date: 06/01/2018

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03/01/2018 Medical Policy Committee review

03/21/2018 Medical Policy Implementation Committee approval. New policy.

03/07/2019 Medical Policy Committee review

03/20/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

03/05/2020 Medical Policy Committee review

03/11/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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03/04/2021 Medical Policy Committee review

03/10/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2022

### **Coding**

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	28291
HCPCS	L8641, L8642, L8699

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ICD-10 Diagnosis	All related diagnoses
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\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

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**NOTICE:** If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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