PHP_7.01.160	Synthetic Cartilage Implants for Joint Pain		
Original Policy Date:	December 1, 2025	**Effective Date:**	December 1, 2025
Section:	7.0 Surgery	**Page:**	Page 1 of 16

State Guidelines

As of the publication of this policy, there are no applicable Medi-Cal guidelines (Provider Manual or All Plan Letter). Please refer to the Policy Statement section below.

Policy Statement

In the absence of any State Guidelines, please refer to the criteria below.

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

Policy Guidelines

Coding

See the Codes table for details.

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 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.

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 (Cartiva) has shown properties similar to articular cartilage in vitro and was approved by the 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.

Additional Information
Not applicable

Related Policies

- N/A

Benefit Application

Blue Shield of California Promise Health Plan is contracted with L.A. Care Health Plan for Los Angeles County and the Department of Health Care Services for San Diego County to provide Medi-Cal health benefits to its Medi-Cal recipients. In order to provide the best health care services and practices, Blue Shield of California Promise Health Plan has an extensive network of Medi-Cal primary care providers and specialists. Recognizing the rich diversity of its membership, our providers are given training and educational materials to assist in understanding the health needs of their patients as it could be affected by a member's cultural heritage.

The benefit designs associated with the Blue Shield of California Promise Medi-Cal plans are described in the Member Handbook (also called Evidence of Coverage).

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 metatarsophalangeal (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.

Health Equity Statement

Blue Shield of California Promise Health Plan's mission is to transform its health care delivery system into one that is worthy of families and friends. Blue Shield of California Promise Health Plan seeks to advance health equity in support of achieving Blue Shield of California Promise Health Plan's mission.

Blue Shield of California Promise Health Plan ensures all Covered Services are available and accessible to all members regardless of sex, race, color, religion, ancestry, national origin, ethnic group identification, age, mental disability, physical disability, medical condition, genetic information, marital status, gender, gender identity, or sexual orientation, or identification with any other persons or groups defined in Penal Code section 422.56, and that all Covered Services are provided in a culturally and linguistically appropriate manner.

Rationale

Background

Articular Cartilage Damage

Articular cartilage damage may present as focal lesions or as more diffuse osteoarthritis. Cartilage is a biological hydrogel that is comprised mostly of water with collagen and glycosaminoglycans and does not typically heal on its own. Osteoarthritis or focal articular cartilage lesions can be associated with substantial pain, loss of function, and disability. Osteoarthritis 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. Osteoarthritis less commonly affects the elbow, wrist, shoulder, and ankle. Knee osteoarthritis is the most common cause of lower-limb disability in adults over age 50, however, osteoarthritis 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 osteoarthritis 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 debridement, abrasion techniques, osteochondral autografting, and autologous chondrocyte implantation. Debridement 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 osteoarthritis of the knee, hip, shoulder or ankle may be treated with joint replacement.

Early-stage osteoarthritis 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 osteoarthritis 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 osteoarthritis, 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. Polyvinyl alcohol 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 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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function - including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Early-Stage First Metatarsophalangeal Osteoarthritis

Clinical Context and Therapy Purpose

The purpose of a synthetic cartilage implant in individuals who have early-stage first metatarsophalangeal (MTP) joint osteoarthritis (OA) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with early-stage first MTP OA.

Interventions

The therapy being considered is the Cartiva synthetic cartilage implant.

Comparators

The following therapies are currently being used:

- Conservative nonoperative treatment which would include modification of footwear and non-steroidal anti-inflammatory drugs (NSAIDS);
- Cheilectomy.

Outcomes
The general outcomes of interest are symptoms, typically measured with a visual analog score (VAS) for pain. Functional outcomes and quality of life are measured with the Foot and Ankle Ability Measure (FAAM). The FAAM is a validated measure of sports activities and activities of daily living (ADL), with a minimal clinically important difference defined as 9 points for sports and 8 points for ADL subscales. Adverse events from the implantation procedure would be measured within 30 days, while dislocation and wear would be monitored at 5 to 10 years.

A beneficial outcome of the implant would be a reduction in pain and improvement in function.

A harmful outcome of the implant would be an increase in pain and a reduction in function.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
No studies were identified on the use of synthetic cartilage implants for early-stage first MTP OA.

Section Summary: Early-Stage First Metatarsophalangeal Osteoarthritis
The evidence is insufficient to determine the effects of the synthetic cartilage implant for early-stage first MTP OA. RCTs and long-term follow-up are needed to determine implant survival and its effect on health outcomes.

Advanced First Metatarsophalangeal Osteoarthritis
Clinical Context and Therapy Purpose
The purpose of a synthetic cartilage implant in individuals who have advanced first MTP OA is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with advanced MTP OA.

Interventions
The therapy being considered is the Cartiva synthetic cartilage implant.

Comparators
The following therapies are currently being used:

- Conservative nonoperative treatment which would include modification of footwear and NSAIDS;
- Cheilectomy;
- Arthrodesis.

Outcomes

The general outcomes of interest are symptoms, typically measured with a VAS for pain. Functional outcomes and quality of life are assessed with the FAAM. Adverse events from the implantation procedure would be measured within 30 days while harms from dislocation and wear would be measured at 5 to 10 years.

A beneficial outcome of the implant would be a reduction in pain and improvement in function.

A harmful outcome of the implant would be an increase in pain and a reduction in function.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Review

Smyth et al (2020) conducted a systematic review of PVA implants in patients with hallux rigidus. The authors identified 7 publications, 6 of which were related to the key randomized controlled trial described below, and the final publication was a case series by Cassenelli et al (2019) which is also included below.[3,4,5] The systematic review noted the lack of information independent of the original RCT as a primary limitation.[4] They concluded that a moderate recommendation can be given for use of a polyvinyl alcohol implant in the short-term, but long-term data are lacking.

A systematic review by Butler et al (2024) compared PVA implants (n=1349), cheilectomy (n=168), and arthrodesis (n=322) in patients with moderate to severe hallux rigidus.[6] A total of 9 comparative studies were identified with 3 comparing PVA to cheilectomy and 6 comparing PVA to arthrodesis. Complication rates were higher with PVA (27.9%) than with cheilectomy (11.8%) or arthrodesis (24.2%). Failure rates were also higher with PVA (14.8%) than cheilectomy (1.6%) or arthrodesis (6.5%). No meta-analysis was performed due to the lack of high-quality, head-to-head studies and the high heterogeneity of included studies. The authors concluded that the safety and efficacy of PVA implants was questionable.

Randomized Controlled Trial

The U.S. Food and Drug Administration (FDA) approval of the Cartiva synthetic cartilage implant was based on an unmasked, multicenter, noninferiority trial (Cartiva MOTION) that compared the implant with arthrodesis of the first MTP joint (see Table 1). This study was published by Baumhauer et al (2016).[7,3] The primary outcome was a composite of a 30% or greater difference in VAS scores for pain, maintenance of function on the FAAM ADL subscale, and absence of major safety events at 2 years. The primary effectiveness endpoint was achieved by 80% of patients in both groups, and the implant met the 15% noninferiority margin (p<.0075).

Table 1. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Active Intervention	Comparator Intervention
Baumhauer et al (2016);[3] MOTION	US, Canada, EU	12	2009-2012	197 patients with advanced hallux rigidus (Coughlin grade 2, 3, or 4 [see Appendix Table 1]) with VAS ≥40/100. Patients were	132 patients received the Cartiva	65 patients underwent arthrodesis

Study; Trial	Countries	Sites	Dates	Participants	Active Intervention	Comparator Intervention
				excluded if they had lesions >10 mm in size, hallux varus to any degree, or hallux valgus >20	cartilage implant	

RCT: Randomized controlled trial; VAS: visual analog score

VAS pain scores decreased significantly in both groups but were consistently lower in the arthrodesis group from 6 weeks through 2 years (see Table 2). Nearly all patients (97%) who underwent fusion had 30% or greater relief in pain compared with 89% of patients who received the implant. Maintenance of function, as measured by the FAAM ADL subscale, was observed in 98.3% of patients who received the implant and in 97.6% of patients who underwent fusion. Fourteen (9.2%) implants were removed and converted to arthrodesis, while in the arthrodesis group 6 (12%) patients had removal of screws or screws and plates. As expected, dorsiflexion was significantly better in the implant group (29) than in the fusion group (15; p<.001). Radiographic measurements showed 4 (8%) occurrences of mal-union or non-union in the fusion group and no device displacement, fragmentation, or avascular necrosis with the implant. Some instances of radiolucency, bony reactions, and heterotopic ossification were observed, but these events did not correlate with individual patient success.

Glazebrook et al (2018) reported a reduction in operative and recovery time with the implant compared to arthrodesis.[8] Additional analysis of data (2017) from the pivotal trial did not identify any factors (e.g., hallux rigidus grade, preoperative pain, duration of symptoms, body mass index) that affected the success of the procedure.[9] The analysis raised questions whether Coughlin grade (symptoms, radiographic measures, range of motion), is the most appropriate method to identify patients for the procedure, leading the investigators to recommend using only clinical signs and symptoms to guide treatment.[10]

Table 2. Outcome Scores for Synthetic Cartilage Implant and Arthrodesis

Outcomes	Baseline	6 Weeks	3 Months	6 Months	1 Year	2 Years
VAS pain						
Implant	68 (13.9)	33.3 (24.7)	29.4 (23.2)	28.9 (27.75)	17.8 (23.0)	14.5 (22.1)
Arthrodesis	69.3 (14.3)	17.2 (17.6)	15.5 (13.1)	11.7 (18.3)	5.7 (8.5)	5.9 (12.1)
p-value	.571	<.001	<.001	<.001	.001	.002
FAAM ADL						
Implant	59.4 (16.9)	69.0 (19.0)	77.3 (17.70)	82.7 (17.5)	88.6 (14.4)	90.4 (15.0)
Arthrodesis	56.0 (16.8)	59.6 (24.8)	82.5 (14.9)	89.9 (12.4)	94.1 (6.8)	94.6 (7.1)
p-value	.222	.008	.079	.014	.018	.082
FAAM sports						
Implant	36.9 (20.9)	39.5 (26.3)	55.1 (26.5)	66.6 (26.3)	75.8 (24.8)	79.5 (24.6)
Arthrodesis	35.6 (20.5)	22.4 (22.5)	53.9 (29.5)	78.6 (23.8)	84.1 (16.9)	82.7 (20.5)
p-value	.694	<.001	.804	.010	.043	.461

Values are mean (standard deviation).
ADL: activities of daily living; FAAM: Foot and Ankle Ability Measure; VAS: visual analog score.

A selection of results from the FAAM ADL questionnaire, which is made up of 21 related questions, were reported on the FDA's Summary of Safety and Effectiveness (see Table 3).[7] Only the "Up on Toes" was superior in the Cartiva group. Of concern is the greater difficulty of the Cartiva group (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%).

Table 3. Foot and Ankle Ability Measure (FAAM) Activities of Daily Living Questionnaire Excerpt

Outcomes	Group	No Difficulty	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to Do
Daily Activities	Arthrodesis	94%	6%	0%	0%	0%
	Cartiva	88%	10%	0%	2%	0%

Outcomes	Group	No Difficulty	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to Do
Walk 15 Min	Arthrodesis	85%	13%	0%	0%	0%
	Cartiva	67%	17%	9%	5%	2%
Upstairs	Arthrodesis	87%	13%	0%	0%	0%
	Cartiva	83%	10%	4%	2%	0%
Up on Toes	Arthrodesis	36%	28%	17%	9%	11%
	Cartiva	37%	33%	15%	7%	9%
Squat	Arthrodesis	70%	21%	6%	2%	0%
	Cartiva	57%	18%	11%	6%	2%

Limitations in relevance and design and conduct are shown in Tables 4 and 5.

Table 4. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Baumhauer et al (2016);[3] MOTION				2. Range of motion is an intermediate measure.	1,2. Follow-up in this publication was for 2 years, but the Cartiva group will be followed for 5 years.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 5. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Baumhauer et al (2016);[3] MOTION				1. Withdrawals after randomization were higher in the control group (15/65 vs. 2/132), suggesting possible bias in expectations and subjective outcome assessments in favor of the novel joint preserving procedure. A modified intention-to-treat analysis was requested by the U.S. Food and Drug Administration to adjust for the difference in study withdrawals. The modified intention-to-treat analysis included 130 patients in the Cartiva group and 50 patients in the fusion group.		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

An FDA regulated safety and efficacy follow-up study was required through 5 years.[11,12] The patients in the follow-up study included the randomized and nonrandomized run-in group who received the implant for a total of 152 patients (see Table 6) but did not include the arthrodesis group. By year 5, 15.1% of the implant group had undergone removal and conversion to arthrodesis (see Table 7). The overall Kaplan-Meier synthetic cartilage implant survivorship at 5.8 years of follow-up was 84.9%. Of the patients who retained the implant, 97.2% reported a clinically significant improvement in pain, 90.5% reported a clinically significant improvement in FAAM ADL, and 93.3% reported a clinically significant improvement in FAAM sports. Independent radiographic review found no evidence of avascular necrosis, device migration, or fragmentation. Because there was no follow-up of the arthrodesis arm from the randomized trial, conclusions about the comparative effectiveness of the 2 treatment options are limited.

Comparative Observational Study

Budde et al (2024) conducted a retrospective matched case-control study comparing patients with moderate to severe hallux rigidus.[13] Eighteen patients who underwent Cartiva implant (mean follow-up: 17.7 months) were compared to propensity score matched 18 patients with metatarsophalangeal joint arthrodesis (mean follow-up: 20 months). While both groups experienced significant pain reduction, the arthrodesis group (mean VAS: 11.8 [SD: 14.6]) reported significantly lower exertion pain than the Cartiva implant group (mean VAS: 35.4 [SD: 25.7]) (p=0.004). There was no significant difference in mean postoperative FAAM between Cartilage transplant group (83.4 [SD: 15.5]) and arthrodesis group (82.3 [SD: 21.6]) (p=0.58).

Joo et al (2021) conducted a retrospective review of 181 patients who underwent arthrodesis (n=122) or Cartiva implant (n=59) at their institution.[14] At baseline, patients receiving Cartiva had higher physical function scores (47.1) than those undergoing arthrodesis (43.9: p<.01), and this difference remained significant at the mean final follow up of 33 months (51.4 vs. 45.9; p<.01). Pain interference scores were similar between groups at baseline (57.4 vs. 55.6; p=.07) and remained similar at final follow up (46.9 vs. 48.2; p=.49). Significant pain was reported by 4 patients (10%) in the Cartiva group and 5 patients (8%) in the arthrodesis group at final follow-up (p=.76). Complications occurred in 3 (2.4%) patients in the arthrodesis group and 2 (3%) in the Cartiva group (p=.72).

Case Series

Cassinelli et al (2019) conducted a retrospective review of early outcomes and complications from the Cartiva implant for the treatment of hallux rigidus at their institution.[5] Sixty consecutive patients treated between August 2016 and April 2018 with a mean of 15 months of follow-up (range, 2 to 30) were included. Out of 60 patients (64 implants), 30% of patients underwent magnetic resonance imaging (MRI) due to pain, 20% had additional surgery and 38% were unsatisfied or very unsatisfied. Magnetic resonance imaging showed residual capsular inflammation, bone marrow edema, and

degenerative changes/edema of the phalanx or metatarsal. A limitation of these results is that 45% of patients underwent additional procedures at the time of implantation and 23% had prior surgery of the hallux. Therefore, these results are not representative of isolated implant procedures, but may be indicative of results outside of the investigational setting.

In a subsequent report, An et al (2019) provided further detail on the 16 of 60 (27%) treated patients from their institution who were evaluated for persistent pain following Cartiva implantation.[15] There was a reduction of joint space on plain radiographs, MRI showed a reduction in implant diameter from 10 mm to 9.7 (standard deviation [SD] 0.4) mm and bony channel widening to 11.2 (SD 0.8) mm. Peri-implant fluid suggested instability at the implant-bone interface. There was also evidence of subsidence, with the implant below the subchondral bone of the metatarsal head, and persistent edema was observed in all 16 cases. Radiographic findings from another series of 27 consecutive patients by Shi et al (2019) also suggested subsidence of the implant into the soft medullary canal.[16] An analysis of the Manufacturer and User Facility Device Experience (MAUDE) also found subsidence to be a concern with 16 voluntary reports between July 2016 and October 2019.[17] It has been noted that the implants in the reports by Cassinelli et al and An et al were initially seated 2 to 2.5 mm above the adjacent bone, rather than the 0.5 to 1.5 mm that is recommended by the manufacturer.[18,19] Further study is needed to clarify these issues.

Table 6. Summary of Key Case Series Characteristics

Study	Country/institution	Participants	Follow-Up
Glazebrook et al (2018)[12]	US, Canada, EU	152 randomized and roll-in patients treated with Cartiva cartilage implant from the pivotal trial	5 yr
Cassinelli et al (2019)[5]	US	60 patients who received the Cartiva implant between August 2016 and April 2018	

Table 7. Summary of Key Case Series Results

Study	Baseline	Follow-up	
Glazebrook et al (2018)[12]		2 Year	5 Year
n (%)	152	135 (88.8%)	112 (73.6%)
Cumulative Device Removals, n (%)		14/135 (10.4%)	23/112 (20.5%)
Number of Patients with Device Present at 5 Years and Assessed for Clinical Outcomes	106	106	106
Patients Reporting Pain VAS ≥30% decrease		100/106 (94.3%)	103/106 (97.2%)
FAAM ADL ≥8 points increase, n (%)		98/105 (93.3%)	95/105 (90.5%)
FAAM Sports ≥9 points increase		94/103 (91.3%)	97/104 (93.3%)
Cassinelli et al (2019)[5]		15 mo (range 2 - 30)	
Patients unsatisfied and very unsatisfied	64	24/64 (38%)	
Magnetic resonance imaging due to pain		19/64 (30%)	
Reoperation Rate		13/64 (20%)	

ADL: activities of daily living; FAAM: Foot and Ankle Ability Measure; VAS: visual analog score.

Section Summary: Advanced First Metatarsophalangeal Osteoarthritis

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 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, 15% of implants had been removed with conversion to arthrodesis. There are additional safety signals in an independent study by Cassinelli et al (2019) and An et al (2019). In that report, 30% of patients underwent magnetic resonance imaging due to pain, 20% had additional surgery and 38% were unsatisfied or very unsatisfied. A retrospective comparative observational study found few differences in either safety or efficacy between arthrodesis and Cartiva with a limited mean follow-up of 33 months. Further long-term study of potential adverse events with this novel technology is needed. In addition, 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 RCT is also needed to determine the effect of the implant on health outcomes.

Articular Cartilage Damage of Joints Other Than the Great Toe

Clinical Context and Therapy Purpose

The purpose of a synthetic cartilage implant in individuals who have advanced OA of joints other than the first MTP joint is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with OA of joints other than the MTP joint.

Interventions

The therapy being considered is the synthetic cartilage implant.

Comparators

The following therapies are currently being used:

- Conservative nonoperative treatment;
- Osteochondral autografting;
- Autologous chondrocyte implantation;
- Arthroplasty.

Outcomes

The general outcomes of interest are symptoms, typically measured with a VAS for pain. Functional outcomes and quality of life are measured with questionnaires such as the FAAM. Adverse events from the implantation procedure would be measured within 30 days while harms from dislocation and wear would be measured at 5 to 10 years.

A beneficial outcome of the implant would be a reduction in pain and improvement in function.

A harmful outcome of the implant would be an increase in pain and a reduction in function.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Use of polyvinyl alcohol hydrogel implants has been reported in a few observational studies for articular cartilage lesions of the knee and the second MTP joint. A study to evaluate the polyvinyl alcohol hydrogel implant for OA of the first carpometacarpal joint has been conducted but remains unpublished (see Table 8). No other RCTs on synthetic cartilage implants for joints other than the great toe have been identified.

Section Summary: Articular Cartilage Lesions of Joints Other Than the Great Toe
The evidence is insufficient to determine the effects of the synthetic cartilage implant for joints other than the great toe. Randomized controlled trials and long-term follow-up are needed to determine implant survival and the effect on health outcomes.

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

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 U.S. professional society, an international society with U.S. 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.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 8.

Table 8. 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 Ligament Reconstruction Tendon Interposition (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)	Sep 2021 (terminated

NCT No.	Trial Name	Planned Enrollment	Completion Date
			due to difficulty meeting recruitment goals)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

Appendix 1

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.

References

1. Gould N, Schneider W, Ashikaga T. Epidemiological survey of foot problems in the continental United States: 1978-1979. Foot Ankle. Jul 1980; 1(1): 8-10. PMID 6115797
2. Baker MI, Walsh SP, Schwartz Z, et al. A review of polyvinyl alcohol and its uses in cartilage and orthopedic applications. J Biomed Mater Res B Appl Biomater. Jul 2012; 100(5): 1451-7. PMID 22514196
3. Baumhauer JF, Singh D, Glazebrook M, et al. Prospective, Randomized, Multi-centered Clinical Trial Assessing Safety and Efficacy of a Synthetic Cartilage Implant Versus First Metatarsophalangeal Arthrodesis in Advanced Hallux Rigidus. Foot Ankle Int. May 2016; 37(5): 457-69. PMID 26922669
4. Smyth NA, Murawski CD, Hannon CP, et al. The Use of a Synthetic Cartilage Implant for Hallux Rigidus: A Systematic Review. Foot Ankle Spec. Aug 2021; 14(4): 366-371. PMID 32618201
5. Cassinelli SJ, Chen S, Charlton TP, et al. Early Outcomes and Complications of Synthetic Cartilage Implant for Treatment of Hallux Rigidus in the United States. Foot Ankle Int. Oct 2019; 40(10): 1140-1148. PMID 31195830
6. Butler JJ, Dhillon R, Wingo T, et al. Polyvinyl alcohol hydrogel implant for the treatment of hallux rigidus is associated with a high complication rate and moderate failure rate at short-term follow-up: a systematic review. Eur J Orthop Surg Traumatol. May 2024; 34(4): 1765-1778. PMID 38554163
7. U.S. Food and Drug Administration. Cartiva: Summary of Safety and Effectiveness. 2016; https://www.accessdata.fda.gov/cdrh_docs/pdf15/p150017b.pdf. Accessed June 3, 2024.
8. Glazebrook M, Younger ASE, Daniels TR, et al. Treatment of first metatarsophalangeal joint arthritis using hemiarthroplasty with a synthetic cartilage implant or arthrodesis: A comparison of operative and recovery time. Foot Ankle Surg. Oct 2018; 24(5): 440-447. PMID 29409199
9. Goldberg A, Singh D, Glazebrook M, et al. Association Between Patient Factors and Outcome of Synthetic Cartilage Implant Hemiarthroplasty vs First Metatarsophalangeal Joint

Arthrodesis in Advanced Hallux Rigidus. Foot Ankle Int. Nov 2017; 38(11): 1199-1206. PMID 28820949
10. Baumhauer JF, Singh D, Glazebrook M, et al. Correlation of Hallux Rigidus Grade With Motion, VAS Pain, Intraoperative Cartilage Loss, and Treatment Success for First MTP Joint Arthrodesis and Synthetic Cartilage Implant. Foot Ankle Int. Nov 2017; 38(11): 1175-1182. PMID 28992721
11. U.S. Food and Drug Administration. Cartiva: Post approval studies. Updated 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?c_id=4019&t_id=570803. Accessed June 4, 2024.
12. Glazebrook M, Blundell CM, O'Dowd D, et al. Midterm Outcomes of a Synthetic Cartilage Implant for the First Metatarsophalangeal Joint in Advanced Hallux Rigidus. Foot Ankle Int. Apr 2019; 40(4): 374-383. PMID 30501401
13. Budde K, Claassen L, Plaass C, et al. Synthetic cartilage implant vs. first metatarsophalangeal arthrodesis for the treatment of hallux rigidus. Arch Orthop Trauma Surg. Sep 2024; 144(9): 4343-4354. PMID 39287788
14. Joo PY, Baumhauer JF, Waldman O, et al. Physical Function and Pain Interference Levels of Hallux Rigidus Patients Before and After Synthetic Cartilage Implant vs Arthrodesis Surgery. Foot Ankle Int. Oct 2021; 42(10): 1277-1286. PMID 34024138
15. An TW, Cassinelli S, Charlton TP, et al. Radiographic and Magnetic Resonance Imaging of the Symptomatic Synthetic Cartilage Implant. Foot Ankle Int. Jan 2020; 41(1): 25-30. PMID 31538827
16. Shi E, Todd N, Rush S, et al. First Metatarsophalangeal Joint Space Area Decreases Within 1 Month After Implantation of a Polyvinyl Alcohol Hydrogel Implant: A Retrospective Radiographic Case Series. J Foot Ankle Surg. Nov 2019; 58(6): 1288-1292. PMID 31679683
17. Metikala S, Mahmoud K, O'Connor KM, et al. Adverse Events Related to Cartiva Hemiarthroplasty of First Metatarsal: An Analysis of Reports to the United States Food and Drug Administration. Foot Ankle Spec. Apr 2022; 15(2): 113-118. PMID 32723089
18. Glazebrook M, Baumhauer JF, Blundell C, et al. Letter Regarding: Early Outcomes and Complications of Synthetic Cartilage Implant for Treatment of Hallux Rigidus in the United States. Foot Ankle Int. Oct 2019; 40(10): 1149-1151. PMID 31600478
19. Thordarson DB, Cassinelli SJ, Charlton TP, et al. Response to "Letter Regarding: Early Outcomes and Complications of Synthetic Cartilage Implant for Treatment of Hallux Rigidus in the United States". Foot Ankle Int. Oct 2019; 40(10): 1152-1153. PMID 31600477

Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical findings (i.e., pertinent symptoms and duration)
  - Comorbidities
  - Activity and functional limitations
  - Family history, if applicable
  - Reason for procedure/test/device, when applicable
  - Pertinent past procedural and surgical history
  - Past and present diagnostic testing and results
  - Prior conservative treatments, duration, and response
  - Treatment plan (i.e., surgical intervention)
- Consultation and medical clearance report(s), when applicable
- Radiology report(s) and interpretation (i.e., MRI, CT, discogram)
- Laboratory results
- Other pertinent multidisciplinary notes/reports: (i.e., psychological or psychiatric evaluation, physical therapy, multidisciplinary pain management), when applicable

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	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

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
12/01/2025	New policy.

Definitions of Decision Determinations

Healthcare Services: For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

Medically Necessary or **Medical Necessity** means reasonable and necessary services to protect life, to prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, as required under W&I section 14059.5(a) and 22 CCR section 51303(a). Medically Necessary services must include services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity.

For Members less than 21 years of age, a service is Medically Necessary if it meets the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) standard of Medical Necessity set forth in 42 USC section 1396d(r)(5), as required by W&I sections 14059.5(b) and 14132(v). Without limitation, Medically Necessary services for Members less than 21 years of age include all services necessary to achieve or maintain age-appropriate growth and development, attain, regain or maintain functional capacity, or improve, support, or maintain the Member's current health condition. Contractor must determine Medical Necessity on a case-by-case basis, taking into account the individual needs of the Child.

Criteria Determining Experimental/Investigational Status
In making a determination that any procedure, treatment, therapy, drug, biological product, facility, equipment, device, or supply is "experimental or investigational" by the Plan, the Plan shall refer to evidence from the national medical community, which may include one or more of the following sources:

1. Evidence from national medical organizations, such as the National Centers of Health Service Research.
2. Peer-reviewed medical and scientific literature.
3. Publications from organizations, such as the American Medical Association (AMA).
4. Professionals, specialists, and experts.
5. Written protocols and consent forms used by the proposed treating facility or other facility administering substantially the same drug, device, or medical treatment.
6. An expert physician panel selected by one of two organizations, the Managed Care Ombudsman Program of the Medical Care Management Corporation or the Department of Managed Health Care.

Feedback

Blue Shield of California Promise Health Plan is interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at www.blueshieldca.com/en/bsp/providers.

For medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Questions regarding the applicability of this policy should be directed to the Blue Shield of California Promise Health Plan Prior Authorization Department at (800) 468-9935, or the Complex Case Management Department at (855) 699-5557 (TTY 711) for San Diego County and (800) 605-2556 (TTY 711) for Los Angeles County or visit the provider portal at www.blueshieldca.com/en/bsp/providers.

Disclaimer: Blue Shield of California Promise Health Plan may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield of California Promise Health Plan reserves the right to review and update policies as appropriate.