Anthem

Medical Policy

Subject: Synthetic Cartilage Implant for Metatarsophalangeal Joint Disorders
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Description/Scope

This document addresses the use of a metatarsophalangeal synthetic cartilage implant. These implants may be used as a treatment for hallux limitus or hallux rigidus in the first metatarsophalangeal joint with or without the presence of mild hallux valgus, or for other metatarsophalangeal joint disorders.

Position Statement

Investigational and Not Medically Necessary:

Use of a metatarsophalangeal synthetic cartilage implant (consisting of biocompatible, molded cylindrical hydrogel) is considered **investigational and not medically necessary** as a treatment for metatarsophalangeal joint disorders including but not limited to hallux limitus or hallux rigidus.

Rationale

The metatarsophalangeal synthetic cartilage implant (Cartiva Synthetic Cartilage Implant [Cartiva, Inc., Alpharetta, GA]) is an 8 or 10 mm biocompatible, molded cylindrical hydrogel implant for use in the metatarsophalangeal joint. Prior to implantation, dorsal, medial, and lateral osteophytes are removed while preserving the cortical rim of the metatarsal head. During implantation, the device is placed using a specialized delivery tube and seated to allow for 1 to 2 mm of the implant to extend beyond the native cartilage of the metatarsal head in the first metatarsophalangeal (MTP) joint. The synthetic cartilage implant has been proposed as motion preserving treatment for hallux limitus and hallux rigidus in the first metatarsophalangeal joint.

Baumhauer and colleagues (2016) report the results of an industry sponsored study and pivotal trial; the MOTION study (#NCT00969969). The prospective, unblinded study included a total of 236 subjects from centers in Canada and the United Kingdom and evaluated the safety and effectiveness of the Cartiva synthetic cartilage implant in the treatment of first metatarsophalangeal joint osteoarthritis. Participants were randomly assigned in a 2:1 ratio to undergo either implantation of the Cartiva device or first MTP joint arthrodesis. The primary endpoint was based on a single composite for pain, function, and safety. Safety was evaluated through 24 months and effectiveness at 12 months. During the 24-month period, at least one adverse event was reported in 69.1% of participants in the Cartiva group and 72% of participants in the arthrodesis group. The incidence rate of serious device-related adverse events was 7.2% in the Cartiva arm and 4.0% in the arthrodesis arm. Reported adverse events included procedural pain, device pain and joint pain. In the Cartiva cohort, a total of 14 (9.2%) subjects underwent subsequent removal of the implant, whereas 4 (8%) subjects in the arthrodesis group underwent subsequent removal of screws implanted during the procedure. With regards to effectiveness, based on the visual analog scale, both treatment groups experienced clinically meaningful reductions in pain during the study. Both treatment arms also had clinically meaningful improvements based on the Foot and Ankle Mobility Activities of Daily Living (FAAM ADL) subscale and the mean Foot and Ankle Mobility Ability Measure (FAAM sports) subscale scores. Analysis of the primary composite outcome of VAS pain, function (FAAM sports) and safety showed statistical equivalence between the implant and arthrodesis groups. One limitation of this study was the loss of 23% (15) of the arthrodesis subjects who initially consented to randomization but withdrew from the study prior to fusion. Inclusion of these 15 participants in the intention-to-treat analysis created the potential for bias of the results favoring implant. A separate, modified intention-to-treat analysis of only those who completed surgery was also performed. This separate analysis also showed statistical equivalence between the implanted and fused cohorts. Another limitation of the study is the limited follow-up to judge the durable benefit and safety of the implant. The authors acknowledge the lack of data beyond 24 months is a limitation and report plans to follow each cohort out to 5 years.

Daniels and colleagues (2017) prospectively determined 5-year outcomes of first MTP hemiarthroplasty with the PVA hydrogel implant (Cartiva) as part of the MOTION trial (Baumhauer, 2016). At the time of this study, a total of 29 participants had reached the 5-year follow-up time point and were therefore eligible for this midterm follow-up study. Two participants were lost to follow-up, leaving 27 subjects with a mean follow-up of 5.4 (range, 4.9-6.4) years. All participants underwent physical examination and radiographic evaluation and completed a pain VAS, as well as the Short-Form-36 (SF-36), the activities of daily living (ADL) subscale and the Foot and Ankle Ability Measure (FAAM) sports subscale. Postoperative peak MTP dorsiflexion and active MTP natural joint dorsiflexion were 29.7 (range, 10.0-45.0) degrees and a mean 18.2 (range, 10.0-30.0), respectively. The pain VAS, SF-36, FAAM ADL, and FAAM sports scores showed clinically and statistically significant improvements. Based on radiographic evaluation, no participant demonstrated changes in implant position, implant loosening or subsidence, or implant wear. One individual had the implant removed followed by fusion due to persistent pain at 2 years.

Glazebrook and colleagues (2017) used the data from the 2016 Baumhauer trial to retrospectively evaluate operative time and recovery period for implant hemiarthroplasty (n=152) and MTPJ1 arthrodesis (n=50). Perioperative data were evaluated for operative and anaesthesia times. Recovery and return to function were prospectively evaluated with the FAAM Sports and ADL subscales and SF-36 subscore. The mean operative time for hemiarthroplasty was 35 ± 12.3 min and 58 ± 21.5 min for arthrodesis ($p<0.001$). Anaesthesia time was 28 min shorter with hemiarthroplasty ($p<0.001$). At postoperative weeks 2 and 6, the individuals who underwent hemiarthroplasty demonstrated clinically and statistically significantly higher FAAM Sport, FAAM ADL, and SF-36 PF subscores versus arthrodesis subjects. The authors concluded that first MTP hemiarthroplasty with the Cartiva implant required less operative time and resulted in faster recovery than arthrodesis.

In another study, Goldberg colleagues (2017) used the 2016 Baumhauer trial data to determine the association between patient factors and clinical outcomes. Study participants included individuals ≥ 18 years with hallux rigidus grade 2, 3, or 4 who were treated with synthetic cartilage implant MTPJ1 hemiarthroplasty or arthrodesis. Pain visual analog scale (VAS), Foot and Ankle Ability Measure (FAAM) sports and activities of daily living (ADL) scores, and Short Form-36 Physical Function (SF-36 PF) subscore were evaluated preoperatively, and at 2, 6, 12, 24, 52, and 104 weeks postoperatively. Final outcome data, great toe active dorsiflexion motion, secondary procedures, radiographs, and safety parameters were assessed for 129 implant hemiarthroplasties and 47 arthrodeses. The composite primary endpoint criteria for clinical success consisted of VAS pain reduction ≥ 30%, maintenance/improvement in function, no radiographic complications, and no secondary surgical intervention at 24 months. Predictor

variables were comprised of hallux rigidus grade; gender; age; body mass index (BMI); symptom duration; prior MTPJ1 surgery; preoperative hallux valgus angle, range of motion (ROM), and pain. Two-sided Fisher exact test was utilized ($p<0.05$). Patient demographics and baseline outcome measures were similar for both groups. Success rates between implant MTPJ1 hemiarthroplasty and arthrodesis were similar ($p>0.05$) when classified by hallux rigidus grade, gender, age, BMI, symptom duration, prior MTPJ1 surgery status, and preoperative VAS pain, hallux valgus, and ROM.

In 2019, Glazebrook and colleagues reported the safety and efficacy outcomes for synthetic cartilage implant hemiarthroplasty at a minimum of 5 years. Of the 152 subjects in the original trial (#NCT00969969), at 24 months, 14/152 (9.2%) subjects had undergone implant removal and 3 subjects withdrew from the study. However, implant removal status was known for all 152 participants. Therefore, 135 participants (that is, 152 – 14 – 3 = 135, 88.8%) who underwent first MTP joint hemiarthroplasty with the synthetic cartilage implant were eligible for inclusion in this 5-year follow-up study. By the 5th year of follow-up, 17 of 135 (12.6%) subjects were unable to be contacted or did not respond, but implant status was known for 7 of these participants: the implant was removed in 3 subjects and for 4 participants with the implant present, the surgeon failed to obtain consent for the follow-up study and the data could not be utilized. A total of 5 of 135 (3.7%) participants declined to participate in the follow-up study, and 1/135 individual (0.7%) expired prior to reaching 5 years' follow-up. Therefore, a total of 112/135 (that is, 135 – 17 – 5 – 1 = 112, 83.0%) subjects were included in the 5-year follow-up study.

The study's primary outcome was implant survival at a minimum of 5 years. Primary endpoint analyses included the 112 participants in the analysis set plus the 7 participants not enrolled in the follow-up study but for whom device status was known (which included 3 implant removals), for a total n=119/135 (88.1%). The study's secondary outcomes included safety data (n=112/135, 83.0%) and patient-reported clinical outcome measures (VAS pain, FAAM ADL, and FAAM Sports [n=106/135, 78.5%]). At 5.8 years, implant survivorship was 84.9%. The implant status at a mean of 5.8 years' follow-up was known for 119 of the 138 remaining participants; 9/119 (7.6%) were known to have undergone implant removal and conversion to arthrodesis in years 2 to 5. No cases of implant loosening were reported in the current study. At mean 5.8 ± 0.7 (range, 4.4-8.0) years' follow-up, pain VAS, FAAM ADL, and FAAM Sports scores improved by 57.9 ± 18.6 points, 33.0 ± 17.6 points, and 47.9 ± 27.1 points, respectively, compared to baseline. Clinically significant changes in VAS pain, FAAM ADL, and FAAM Sports were reported by 103/106 (97.2%), 95/105 (90.5%), and 97/104 (93.3%) participants, respectively. Patient-reported outcomes at 24 months were maintained at 5.8 years in subjects who were not revised. Active MTP joint peak dorsiflexion was also maintained.

Joo and colleagues (2021) reported the results of a retrospective analysis of 181 individuals who underwent arthrodesis (n=122) or Cartiva implant (n=59) at their institution. The objective of this study was to investigate pre- and postoperative physical function (PF) and pain interference (PI) levels of participants undergoing synthetic cartilage implant hemiarthroplasty vs arthrodesis for treatment of hallux rigidus using the Patient-Reported Outcomes Measurement Information System (PROMIS). Of the 181 participants called for final follow-up, 101 (41 synthetic cartilage implant subjects and 61 arthrodesis) recipeints responded to phone survey and were included for secondary postoperative analysis. One AD participant completed the PI survey only and not the PF survey, so they were included in the PI analysis and removed from the PF analysis as a missing case. At baseline, the participants that received the synthetic cartilage implant had higher physical function scores (47.1) than participants undergoing arthrodesis (43.9: $p<0.01$), and this dissimilarity remained significant at the mean final follow up of 33 months (51.4 vs. 45.9; $p<0.01$). Pain interference scores were similar between both the two groups at baseline (57.4 vs. 55.6; $p=0.07$) and remained similar at final follow up (46.9 vs. 48.2; $p=0.49$). Significant pain was reported by 4 subjects (10%) in the synthetic cartilage implant group and 5 subjects (8%) in the arthrodesis group at final follow-up ($p=0.76$). Complications occurred in 2 (3%) participants in the synthetic cartilage implant cohort ($p=0.72$) and 3 (2.4%) participants in the arthrodesis arm. Complications amongst the synthetic cartilage implant recipients included the removal of the implant and conversion to arthrodesis in two individuals, while complications in the arthrodesis group included 2 hardware failures with revision following the initial surgery and 1 hardware removal due to pain 22 months post surgery). The authors concluded that subjects who underwent synthetic cartilage implantation for hallux rigidus reported slightly better improvement in PF t scores at all followup time points compared to the arthrodesis group. Complications and reported PI were similar between the groups. A limitation of this study includes significant preoperative differences in the PROMIS PF t scores between the 2 cohorts, making a direct comparison of function difficult to measure. This may illustrate a selection bias inasmuch as patient preferences, patient characteristics, and surgeon preference all factor into operative planning and decision making when selecting between the 2 treatment modalities.

With the exception of the trial discussed above (Baumhauer, 2016), a search of the peer-reviewed medical literature did not identify any other randomized controlled studies addressing this technology. Due to the limited published data on this device, the short- and long-term benefits and hazards are not yet fully understood; additional data from prospective, randomized controlled studies with medium- to long-term follow-up are needed to better understand the benefits and hazards related to use of the synthetic cartilage implant for MTP joint disorders. Uncontrolled studies suggest that surgical treatment of hallux rigidus with cheilectomy or arthrodesis provides long-term relief of pain and improved function (Coughlin, 2003).

Background/Overview

Osteoarthritis of the forefoot most frequently affects the MTP joint and may be the result of repetitive trauma (including microtrauma), severe bunion deformities (hallux valgus), hallux limitus, hallux rigidus or recurrent hallux deformity following surgery. Individuals with hallux rigidus have joint pain and restricted motion at the first MTP joint. The first MTP plays a functional role during gait (Baumhauer, 2016; Jacob, 2001).

Hallux valgus is a condition in which the great toe (hallux) is bent outward (toward the midline of the foot) so that it overlaps the second toe. Hallux valgus may or may not be accompanied by a bunion. Conservative treatment options for hallux valgus include changing to footwear that fits properly and does not compress the toes, padding to provide a "bunion-shield", the use of orthotics to take pressure off of the bunion, icing to reduce inflammation and medications to treat pain and inflammation. In more severe cases, surgical removal of the bunion and arthrodesis may be considered. Arthrodesis results in the permanent loss of joint motion.

Hallux limitus is a term used to describe loss of motion in the MTP joint. Hallux rigidus, a state in which the ability to move the MPT is lost or severely restricted, is considered by many to be the end (severe) stage of hallux limitus. Hallux rigidus usually involves erosion of the MTP joint cartilage and the development of osteoarthritis. Bone spurs may develop with hallux rigidus and act as a mechanical block to motion and cause pain. Conservative treatment options for hallux limitus and rigidus may include methods to reduce inflammation and relieve pain, including anti-inflammatory medications and icing. Cheilectomy may be considered as a treatment option to reduce pain and improve range of motion in individuals with mild to moderate hallux rigidus who failed to benefit from conservative treatment. Cheilectomy offers the advantages of being joint sparing, preserving joint motion and maintaining joint stability. Advanced stages of hallux rigidus with severe joint damage, are often treated by arthrodesis (joint fusion). With arthrodesis, the damaged cartilage is removed and the two bones are fixed together with screws and/or plates which allow the bones to fuse together. Arthrodesis offers the advantage of being a permanent correction with elimination of the arthritis and pain. However, the trade-off is that the procedure results in the permanent restriction of movement of the MTP joint.

A number of great toe implants have been studied over the years in an attempt to maintain toe motion. These often fail as a result of

loosening, dislocation, implant fragmentation and bone loss. After implant failure, salvage therapy with arthrodesis (fusion) often results in a poorer functional outcome than primary fusion. Because of this, primary first MTP arthrodesis has been considered the most reliable surgical option for advanced osteoarthritis of the great toe (Bamhauer 2016). However, the loss of joint motion with fusion can interfere with activities requiring great toe motion including running and jumping. The synthetic cartilage implant has been proposed as an alternative to fusion for hallux limitus or hallux rigidus in the first MTP joint to reduce pain, improve function and maintain joint motion, but allow for the option of fusion if needed.

The Cartiva Synthetic Cartilage Implant (SCI) received U.S. Food and Drug Administration (FDA) premarket approval in July 2016. This device has been commercially distributed since 2002 in Europe, Canada, and Brazil. According to the FDA premarket approval letter (P150017), the device “is indicated for use in the treatment of patients with painful degenerative or post-traumatic arthritis (hallux limitus or hallux rigidus) in the first metatarsophalangeal joint with or without the presence of mild hallux valgus”. The FDA approval is based on the MOTION study (Baumhauer 2016) which compared the efficacy and safety of the Cartiva SCI to the gold standard of MTP arthrodesis for advanced-stage hallux rigidus. The PMA is contingent upon the ODE Lead MOTION Extension Study, a 5-year post-approval study to evaluate long-term safety and effectiveness.

Definitions

Arthrodesis: Surgical immobilization of a joint which is accomplished by fusion of the adjacent bones.

Cheilectomy: A surgical procedure which involves the removal on bone spurs.

Hallux limitus: A condition involving the loss of motion in MTP joint of the great (big) toe when the foot is in a weightbearing or simulated weightbearing position.

Hallux rigidus: A condition involving stiffness of the great (big) toe; the end (more severe) stage of hallux limitus. This condition is often caused by degenerative arthritis or bone spurs affecting the MTP joint.

Hallux valgus deformity (bunion): A medial deviation of the first metatarsal and lateral deviation and/or rotation of the hallux, with or without medial soft-tissue enlargement of the first metatarsal head. This condition can lead to painful motion of the joint or difficulty with footwear.

Metatarsophalangeal joint: The joint on the foot located where the metatarsal meets the phalanges of the toes.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
28899	Unlisted procedure, foot or toes [when specified as implantation of a synthetic cartilage implant (SCI) into the metatarsophalangeal joint]
HCPCS	
L8699	Prosthetic implant, not otherwise specified [when specified as a synthetic cartilage implant (SCI) for use in the metatarsophalangeal joint (Cartiva SCI)]
ICD-10 Diagnosis	
	All diagnoses, including but not limited to the following:
M19.071-M19.079	Primary osteoarthritis ankle and foot
M19.171-M19.179	Post-traumatic osteoarthritis, ankle and foot
M19.271-M19.279	Secondary osteoarthritis, ankle and foot
M20.10-M20.12	Hallux valgus (acquired)
M20.20-M20.22	Hallux rigidus
M20.5X1-M20.5X9	Other deformities of toe(s) (acquired) [hallux limitus]

References

Peer Reviewed Publications:

1. 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. 2017; 38(11):1175-1182.
2. 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. 2016; 37(5):457-469.
3. Coughlin MJ, Shurnas PS. Hallux rigidus. Grading and long-term results of operative treatment. J Bone Joint Surg Am. 2003; 85-A(11):2072-2088.
4. Daniels TR, Younger AS, Penner MJ, et al. Midterm outcomes of polyvinyl alcohol hydrogel hemiarthroplasty of the first metatarsophalangeal joint in advanced hallux rigidus. Foot Ankle Int. 2017; 38(3):243-247.
5. 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. 2019; 40(4):374-383.
6. 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. 2018; 24(5):440-447.
7. 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. 2017; 38(11):1199-1206.
8. Guyton GP. Philosophies of surgical care are embedded in outcome studies: An illustrative reanalysis of the Cartiva MOTION trial. Foot Ankle Int. 2022; 43(10):1364-1369.

9. Jacob HA. Forces acting in the forefoot during normal gait—an estimate. Clin Biomech. 2001:16(9):783-792.
10. 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. 2021; 42(10):1277-1286.

Government Agency, Medical Society, and Other Authoritative Publications:

1. U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health. New device approval letter. July 1, 2016. Cartiva Synthetic Cartilage Implant. P150017. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf15/P150017A.pdf. Accessed on March 25, 2023.
2. U.S. Food and Drug Administration. Post-Approval Studies (PAS) Database. ODE Lead MOTION Extend Study. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?c_id=4019&t_id=570803. Accessed on March 25, 2023.
3. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data (SEED). Cartiva® Synthetic Cartilage Implant. April 20, 2016. Available at: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/UCM496457.pdf. Accessed on March 25, 2023.

Websites for Additional Information

1. American Academy of Orthopaedic Surgeons (AAOS). Ortho Info.
   - Bunions. Last reviewed March 2022. Available at:http://orthoinfo.aaos.org/topic.cfm?topic=a00155. Accessed on March 25, 2023.
   - Stiff Big Toe (Hallux Rigidus). Last reviewed October 2017. Available at:http://orthoinfo.aaos.org/topic.cfm?topic=a00168. Accessed on March 25, 2023.

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References, Websites for Additional Information and History sections of the document.
Reviewed	05/12/2022	MPTAC review. Updated Rationale, References, Websites for Additional Information and History sections of the document.
Reviewed	05/13/2021	MPTAC review. Updated References, Websites for Additional Information and History sections of the document.
Reviewed	05/14/2020	MPTAC review. Updated References, Websites for Additional Information and History sections of the document.
Reviewed	06/06/2019	MPTAC review. Updated Rationale, References, Websites for Additional Information and History sections of the document.
Reviewed	05/03/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale, References, Websites for Additional Information and History sections of the document.
Reviewed	05/04/2017	MPTAC review. Updated Rationale, References and History sections of the document.
New	02/02/2017	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.