



Medical Coverage Policy

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Metatarsophalangeal Joint Replacement

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Related Coverage Resources

[Orthotic Devices and Shoes](#)

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Overview

This Coverage Policy addresses a partial or total replacement of the first metatarsophalangeal (MTP) joint for persistent severe disabling symptoms from hallux valgus or hallux rigidus due to degenerative joint disease of the first MTP joint.

Coverage Policy

Partial or total replacement of the first metatarsophalangeal (MTP) joint is considered medically necessary as an alternative to arthrodesis when BOTH of the following criteria have been met:

- Persistent severe disabling symptoms from hallux valgus or hallux rigidus due to degenerative joint disease of the first MTP joint
- Failure of conservative medical management

Partial or total replacement of the first MTP joint or any other foot joint using ANY of the following is considered experimental, investigational or unproven:

- ceramic implant (e.g., Moje prosthesis [Orthosonics, Ltd., Devon UK])
- synthetic cartilage implant (e.g., Cartiva Synthetic Cartilage Implant)

Each of the following procedures is considered experimental, investigational or unproven:

- MTP joint replacement for joints other than the first MTP joint
- Replacement of any other toe joint (e.g., interphalangeal joints)
- Replacement of tarsal metatarsal (TMT) joint

General Background

Hallux valgus is defined as a deviation of the great toe (hallux) toward the midline of the foot and is frequently accompanied by deformity and symptoms in the lesser toes. Medial soft tissue enlargement of the first metatarsal head may also be present. The condition may be associated with osteoarthritis or rheumatoid arthritis, biomechanical instability, connective tissue disorders, neuromuscular disease, or trauma. Hallux valgus may lead to painful joint motion and difficulty with footwear. Hallux rigidus, also referred to as hallux limitus, is a progressive disorder of the first MTP joint, characterized by restriction or loss of range of motion of this joint. The alignment usually remains normal, with dorsal changes noted, including dorsal bunion. Individuals typically report pain on motion.

Conservative treatments for hallux valgus and hallux rigidus include adaptive footwear, exercises, orthoses, physical therapy, nonsteroidal anti-inflammatory drugs, and steroid injections into the joint. Surgical treatment may be considered for patients with hallux valgus or hallux rigidus with severe symptoms when conservative treatment is not effective. Choice of the procedure is based on the condition of the joint, the patient's goals and expectations of surgical outcome, and motivation. The goal of surgery is to relieve pain, improve function, maintain stability of the first MTP joint and improve quality of life (Lam, et al., 2017).

The simplest surgical procedure consists of shaving off the bony prominence interfering with joint movement (i.e., cheilectomy). When conservative medical management and less invasive procedures have failed, procedures involving joint destruction may be considered. Joint destructive procedures include resection arthroplasty (i.e., removal of the medial eminence on the metatarsal head and removal of part of the proximal phalanx, leaving a flexible joint [e.g., Keller's arthroplasty]), arthrodesis (i.e. excision of the metatarsal head along with part of the proximal phalanx, and fusion of the joint), and implant arthroplasty (i.e., partial or total joint replacement with an artificial implant).

Numerous hallux MTP joint replacement implant devices have been developed since the 1970s, spurred in part by successful joint replacements of the hip and knee. Metals and acrylics were the first materials researched. Early failures of these devices led to the development of single-stem and double-stem hinged silastic implants. Many complications with silastic implants emerged in the 1980s, including reactive synovitis, late failures due to wear, osteolysis, foreign body immune response, fracture and displacement of components. Bone liners and titanium grommets were developed to protect implants from sharp edges and excessive shearing forces seen in the hallux MTP joint. Implants are also fabricated of metal-on-polyethylene and metal alloys, such as cobalt-chrome and titanium.

The Moje ceramic implant has been evaluated in several case series in the United Kingdom. The ceramic coating is intended to allow the implant to achieve early osteointegration and consolidate the implant with the surrounding bone to decrease the likelihood of loosening (Arbuthnot, et al., 2008). This implant has not received FDA approval.

The Cartiva Synthetic Cartilage Implant (Cartiva, Inc., Alpharetta, GA) device is a molded, cylindrical implant created from a biocompatible hydrogel made of polyvinyl alcohol and saline. Cartiva SCI has elastic and compressive mechanical properties similar to articular cartilage and maintains range of motion in the joint. The device is intended to replace focal areas of painful damaged cartilage in the first MTP joint.

MTP implants have been proposed as treatment for disorders effecting joints other than the first MTP joint, for other toe joints (e.g. Interphalangeal joints), and for the tarsal metatarsal (TMT) joint. The use of implants for these indications has not been studied in the published medical literature.

U.S. Food and Drug Administration (FDA)

Numerous prostheses fabricated from various components including metal (e.g., Titanium), acrylic, silastic, and metal alloys, have received FDA approval as Class II devices through the 510(k) process.

The Moje ceramic implant (Orthosonics, Ltd., Devon UK) is a two-component first MTP endoprosthesis made of zirconium oxide coated with the machinable, bioreactive glass ceramic Bioverit. The Moje implant has not received FDA approval.

In 2016 the Cartiva Synthetic Cartilage (Cartiva, Inc., Alpharetta, GA) Implant received premarket approval (PMA) approval from the FDA and 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. Nine supplemental approvals have been issued for this device since the original PMA but the indications for use have not changed with the reasons for the supplemental approvals included manufacturing process changes, approval for a postapproval study protocol, modification of the Surgical Implantation Technique Guide, and the addition of a new manufacturing site.

Literature Review

Stevens et al. (2017) conducted a systematic review of surgery for hallux rigidus including total joint replacement and arthrodesis of the first metatarsophalangeal joint. Thirty-three studies with 741 arthrodeses and 555 total joint replacements were included in the qualitative analysis. Six different prostheses were used for total joint replacement, and various fixation techniques were used for arthrodesis. The results of 6 arthrodesis studies and 7 total joint replacement studies were pooled in the quantitative analysis. Pooled results showed superiority of arthrodesis compared with total joint replacement for improving clinical outcome (by 43.8 versus 37.7 points on the AOFAS-HMI score) and reducing pain (a decrease of 6.56 versus 4.65 points on the VAS pain score). It was found that fewer intervention-related complications (23.1% versus 26.3%) and revisions (3.9% versus 11%) were reported after arthrodesis as compared with total joint replacement, with pain and nonunion and prosthetic loosening being the most commonly reported complications after arthrodesis and total joint replacement, respectively. The authors concluded that the systematic review indicates that arthrodesis is superior for improving clinical outcome and reducing pain, and is less often accompanied by intervention-related complications and revisions, compared with total joint replacement in patients with symptomatic hallux rigidus; however, prospective, randomized controlled trials are needed to verify this conclusion.

Maffulli et al. (2011) conducted a systematic review of the published literature on the surgical management of hallux rigidus. A total of 70 studies (10 prospective, 58 retrospective, one prospective/retrospective, and one randomized trial) published from 1957 to 2010 reported postoperative outcome related data of patients undergoing surgery for management of hallux rigidus. The heterogeneity in terms of study design, length of follow-up, classification, grading systems, radiological and clinical findings did not allow comparison of extracted data. The variety of scales assessing clinical status limited the statistical power of the study, and, in addition, non-validated scoring systems assessing outcomes were used in many reports. The authors stated that there is a need to perform appropriately powered randomized clinical trials using standard diagnostic assessment, and common and validated scoring systems comparing reported outcomes and duration of follow up greater than two years.

A Cochrane Systematic Review was conducted to identify controlled trials evaluating interventions for osteoarthritis of the big toe and to determine the optimum intervention(s) (Zammit et al., 2010). Only one trial met the inclusion criteria. This trial evaluated the effectiveness of two physical therapy programs in 20 individuals with osteoarthritis of the big toe joint. The authors concluded that although differences in outcomes between treatment and control groups were reported, the risk of bias was high. The trial did not employ appropriate randomization or adequate allocation concealment, and included a relatively small sample size and short follow-up. Conclusions that could be drawn from the presented data were therefore limited. The inclusion of only one trial indicated the need for more robust randomized controlled trials that determine the efficacy of interventions for this condition.

Brewster (2010) conducted a systematic review to compare the functional outcomes of arthrodesis and joint replacement, based on the hypothesis that total joint replacement would yield higher functional outcome scores because of the ability to provide a mobile joint, compared to the solid arthrodesis. Of ten articles eligible for inclusion, five focused on total joint arthroplasty and five on arthrodesis. One inclusion criterion was the use of the Orthopaedic Foot and Ankle Society Hallux Metatarsophalangeal Interphalangeal (AOFAS-HMI) scoring system. Although numerous other scoring systems were encountered, the AOFAS-HMI system was the only method used frequently enough to compare across studies. There was significant and similar improvement in scores for both procedures. The median postoperative score for joint replacement was 83/100 (range 74–95) and 82/100 (range 78–89) for arthrodesis. The median revision rate was 7% for joint replacement, compared to 0% for arthrodesis. The AOFAS-HMI scores points lost by lack of mobility in an arthrodesis were lost at a similar rate by the supposedly mobile joint replacement. The authors stated that it is not clear whether this loss is attributable to pain, malalignment, or other reasons, and questioned whether, with both options yielding similar results, the extra expense, complication rates, and long-term revision potential tips the balance in favor or arthrodesis.

A case series conducted by Brewster et al. (2010) evaluated the functional outcomes of first MTP joint replacement with the Moje ceramic implant. A total of 29 consecutive patients (32 joints) were followed for a mean duration of 34 (range 6–74) months. Hallux rigidus was the primary diagnosis in 28 patients. The mean AOFAS-HMI score at final follow-up was 74/100 (range 9–100), with 13 joints rated good to excellent. Preoperative AOFAS-HMI scores were not reported, however. One joint was revised to arthrodesis at 41 months and another at 63 months following arthroplasty. Postoperative complications occurred in six patients (18.75%).

Cook et al. (2009) conducted a meta-analysis to evaluate the MTP arthroplasty in terms of patient satisfaction. The analysis included 47 studies/3049 procedures with a mean follow-up of 61.48 months. The mean patient age was 54.98 ± 4.82 years. The primary outcome measure was the proportion of patients who were satisfied with the surgical procedure. Because of the variability in the way satisfaction was reported, results were divided into two categories. In studies with four categories of satisfaction the two highest categories and the two lower categories were merged. In studies with three categories, the two highest categories were merged. The analysis does not detail the specific patient satisfaction factors considered. Overall patient satisfaction was 85.7%. The authors stated that the results should be carefully considered given the high degree of heterogeneity among the studies, and that adoption of standardized outcome measures for future studies would improve the accuracy of pooled data.

In a retrospective case series, Raikin et al. (2006) compared the long-term outcomes of metallic hemiarthroplasty to outcomes of arthrodesis for treatment of severe arthritis of the first MTP joint. A series of patients were treated with a metallic (Biopro) hemiarthroplasty (n=21 feet; 20 patients) or an arthrodesis (n=27 feet; 26 patients) between 1999 and 2005. Patients were assessed clinically, radiographically, and with a questionnaire, by an independent observer. Postoperative satisfaction and function were graded using the American Orthopaedic Foot and Ankle Society Hallux Metatarsophalangeal Interphalangeal (AOFAS-HMI) scoring system. Of the 20 patients (21 feet) treated with hemiarthroplasty, 17 (18 feet) were available for evaluation at a mean follow-up of 79.2 months (range 68–85.7 months). Five (24%) of the 21 joints required subsequent surgical treatment at an average of 13 months because of failure of the hemiarthroplasty. One of these patients was treated with revision hemiarthroplasty, and four were treated with arthrodesis. Eight of the feet in which the hemiprosthesis survived had evidence of plantar cutout of the prosthetic stem on the final follow-up radiograph. The satisfaction ratings in the hemiarthroplasty group at final follow-up were: good or excellent, 12 feet; fair, 2 feet; and poor or a failure, 7 feet. All 27 arthrodesis patients achieved fusion, and no revisions were required. Two patients required hardware removal, which was performed as an office procedure. At a mean final follow-up of 30 months, the satisfaction ratings in the arthrodesis group were: good or excellent, 22 feet; fair, 4 feet; and poor, one foot. The mean pain score was significantly better in the arthrodesis group (0.7 of 10), than in the hemiarthroplasty group (2.4 of 10) ($p=0.021$). The mean AOFAS-HMI score was also significantly higher at final follow-up in the arthrodesis group, increasing from 36.1 of 100 points preoperatively, to 83.8 at final follow-up, compared to an increase from 35.6 of 100 points preoperatively, to 71.8, for the 16 feet (15 patients) with a surviving hemiprosthesis ($p=0.006$).

Pulavarti et al. (2005) reviewed the functional results at a minimum follow-up of 36 months in 32 patients (36 implants) who received the Bio-Action great toe implant for symptomatic advanced degenerative changes in the

first MTP joint. The MTP scoring system developed by Kitaoka et al. was used to evaluate outcomes. The authors reported significant improvement in the hallux MTP scale and range of motion achieved after the procedure and stated that 77% of patients considered the results to be good or excellent. The authors stated that the main problems associated with implant arthroplasty of the MTP joint are a lack of standard outcome measures, incremental design changes and limited reports on long-term follow-up. The authors further stated that there are many centers in Europe and North America using some form of total joint replacement system, using different outcome measures. They emphasized the need for a universal scoring system and a large, multicenter prospective trial to further prove the usefulness of a total hallux MTP joint system.

Gibson and Thompson (2005) conducted a randomized controlled trial to evaluate clinical outcomes after first MTP joint arthrodesis and replacement arthroplasty. Between 1998 and 2001, a total of 63 patients with unilateral or bilateral MTP joint arthritis were randomized to MTP arthrodesis (22 patients/38 toes) or arthroplasty (27 patients/39 toes). A single surgeon performed all procedures. The primary outcome measure, a decrease in pain as measured on a Visual Analog Scale (VAS), was assessed at six months, one year and two years. At 24 months, pain improved in both groups, but there were significantly greater improvements and fewer complications after arthrodesis. The mean dorsiflexion angle in the arthrodesis group was 26 degrees. In the arthroplasty group, six of 29 implants had to be removed because of phalangeal component loosening. The range of motion in the remaining patients was poor, and the patients tended to bear weight on the outer borders of the foot. The authors concluded that outcomes after arthrodesis were better than those after arthroplasty, and that even when data from the implant failures was removed, arthrodesis was clearly preferred by most patients.

Stone et al. (2017) published 15-year follow-up to the above randomized, controlled trial (Gibson and Thompson, 2005). At 15 years, patients with an arthrodesis experienced less pain and were more satisfied compared to those with an arthroplasty. No functional differences were seen between these two groups. There were more revisions in the arthroplasty group. The authors concluded that even though there was hope of better function, less pain, and greater satisfaction from MTP joint replacement, this was not found in this group. The long-term results of the study indicated that arthrodesis outperformed arthroplasty.

Harrison and Loughhead (2003) attempted to trace 82 patients who had received MTP arthroplasties with implants at the authors' hospital between 1972 and 1983, in order to evaluate long-term outcomes. Approximately 25% of the patients were located; a total of 22 patients attended for clinical review. The diagnosis in all patients except one was hallux valgus or hallux rigidus; one patient with a diagnosis of rheumatoid arthritis was excluded from review. The author therefore reviewed 21 single-stemmed silastic MTP arthroplasties in 18 patients. The mean follow-up was 18 years, nine months. Two patients with hallux rigidus had their implants removed at between two and three years, one due to swelling from silicone synovitis or infection. The reason for the second removal was uncertain. Assessment involved clinical scoring using the hallux MTP-interphalangeal (MTP-IP) scale of Kitaoka. In this scale 40 points were assigned to pain, 45 to function and 15 to alignment. The mean score was 79 (range 62–95). Patients were asked to self-assign to one of the following groups: A (much improved, all that was expected; B (improved, but not all that was expected; C (satisfactory, unchanged), or D (worse). Radiographs were evaluated using a system devised by the authors to assess lucency around the implant, cysts in the proximal phalanx, cysts in the metatarsal head, and obvious fracture. A score of 0 on the scale represented no change, while a score of IV represented very marked radiographic change. Radiographic score was: grade zero, one patient (5%); grade I, five patients (24%); grade II, six patients (28%); grade III, 5 patients (24%); grade IV, four patients (19%). The authors stated that there was no correlation between radiographic grading and preoperative diagnosis, clinical score of duration of implantation, and that the erosive bone changes and subsequent loss of bone stock did not appear to cause clinical detriment. The authors stated that single-stemmed silastic MTP arthroplasties have been abandoned in many centers because of short-term complications, and have been superseded by hinged implants.

Roukis et al. (2003) compared the BIOPRO resurfacing endoprosthesis to periarticular osteotomy in 44 patients (47 feet) with hallux rigidus. Twenty patients (20 feet) underwent a periarticular osteotomy and seven patients (nine feet) were treated with a BIOPRO resurfacing endoprosthesis. Short-term follow-up at one year demonstrated that both procedures provided subjective patient improvement and satisfaction, and minimal increase in first MTP joint range of motion, but there was a progression of radiographic abnormalities in the osteotomy group. The authors suggested that the need to perform a periarticular osteotomy for hallux rigidus should be questioned, although a correlation between these changes and any actual effect on the dynamic

function of the first MTP joint has not been proven and requires further investigation before any solid conclusions can be stated. It is difficult to generalize these findings because of the small number of patients, short-term follow-up, lack of a control group and lack of standardized assessment criteria.

Literature review—Cartiva synthetic cartilage implant

Hayes conducted a health technology brief for Cartiva synthetic cartilage implant (SCI) for Treatment of First Metatarsophalangeal Joint Arthritis (2019; 2020). Findings of this report note that a noninferiority analysis from one fair-quality RCT suggests that the Cartiva SCI is noninferior to arthrodesis for treatment of degenerative or posttraumatic arthritis of the first MTP joint for up to 12 months postoperatively, based on a composite clinical success score that included pain, function, and safety. However, individual outcome measures are inconsistent and some suggest better outcomes with arthrodesis. Patients treated with Cartiva reported statistically significantly worse pain scores (i.e., more pain) when compared with the arthrodesis group from 6 weeks to 2 years postprocedure. In addition, analyses of the Foot and Ankle Ability Measure (FAAM) sports score suggest that by six and 12 months, patients treated with arthrodesis reported statistically significantly better scores; however, no statistically significant difference was noted at 24 months. The clinical success rate was maintained for up to a mean of 5.8 years after implantation of Cartiva. Regarding the quality of evidence it is noted that a very-low-quality body of evidence consisting of 1 fair-quality study is insufficient to draw conclusions regarding the efficacy or safety of Cartiva SCI for treatment of degenerative or posttraumatic arthritis of the first MTP joint. The body of evidence is limited by the publication of one study within which results were conflicting and did not demonstrate a clear benefit of the Cartiva SCI over the standard, arthrodesis. Limitations of the study include the inability of the study to achieve the prespecified power threshold, a greater number of patients withdrawing prior to treatment from the arthrodesis arm than from the Cartiva arm, and lack of data beyond 2 years for the arthrodesis arm. The Hayes report concluded that very-low-quality body of evidence is insufficient to draw conclusions regarding the effectiveness and safety of Cartiva SCI for treatment of first MTP joint arthritis. Substantial uncertainty exists due to a single identified trial, inconsistencies within the individual study results, and lack of long-term comparative effectiveness data. Large studies assessing the comparative effectiveness and safety of Cartiva SCI are needed.

Brandao et al. (2020) conducted a prospective cohort study of 55 patients (14male, 41female; 37R, 18L) at a single center with symptomatic hallux rigidus who underwent Cartiva implant interpositional arthroplasty. First metatarsophalangeal joint arthritis was radiographically graded according to the Hattrup and Johnson (HJ) classification. Pre-operative and post-operative patient-reported outcomes (PROMs) were evaluated using the Foot and Ankle Ability Measure (FAAM) activities of daily living subscale and the Manchester-Oxford Foot Questionnaire (MOXFQ). The patients were followed up for an average of 21 months (min=12, max=38). Fourteen patients suffered from HJ2/moderate arthritis and 41 patients with grade HJ3/severe arthritis. Post-operative mean FAAM scores showed statistically significant improvement ($p < 0.0001$). Patients reported a 40% increase in functionality during activities of daily living. All 3 MOXFQ Domain scores improved significantly ($p < 0.02$). The Index score improved by 34 points ($p < 0.0001$). There was no correlation between length of follow up or age and PROMs ($r = 0.129$). No statistical difference was demonstrated between sexes. Clinically, however, males and older patients exhibited better outcomes. Durability and survivability of the implant will continue to be studied in this cohort. Limitations of the study include lack of randomization, lack of comparator and small number of subjects.

Eble et al. (2020) conducted retrospective study to review patient-reported outcome scores and clinical outcomes for patients treated for hallux rigidus with PVA hydrogel implant. The study included 103 patients who underwent first MTP hemiarthroplasty with PVA hydrogel implant. Baseline Patient-Reported Outcomes Measurement Information System (PROMIS) scores for the Physical Function, Pain Interference, Pain Intensity, Global Physical Health, Global Mental Health, and Depression domains were collected prospectively and compared with PROMIS scores collected at a minimum of one year postoperatively (average, 13.9 months). Seventy-three patients had both preoperative and postoperative scores. Ten of these patients had undergone a prior procedure of the first MTP, and 52 underwent concurrent Moberg osteotomy at the time of PVA hydrogel implantation. For patients with baseline and postoperative PROMIS scores, significant pre- to postoperative improvement was detected for the Physical Function, Pain Interference, Pain Intensity, and Global Physical Health domains ($P < .05$). Patients who had undergone a prior procedure of the first MTP had significantly higher postoperative Pain Intensity scores compared with those who did not undergo a prior procedure. Patients undergoing concurrent Moberg osteotomy had significantly lower postoperative Pain Interference and Pain

Intensity scores compared with those who did not undergo a Moberg. Two patients underwent revision procedures in the first 2 years postoperatively, one with revision hemiarthroplasty and one with conversion to arthrodesis. The study was limited by the retrospective nature of study, lack of randomization and control group and the length of follow-up.

Baumhauer et al. (2016) reported on a prospective, randomized non-inferiority study to compare the efficacy and safety of a synthetic cartilage implant to the gold standard of a great toe arthrodesis for advanced-stage hallux rigidus. The study included 152 implant and 50 arthrodesis patients randomized (2:1) to a synthetic cartilage implant or first metatarsophalangeal (MTP) joint arthrodesis. VAS pain scale, validated outcome measures (Foot and Ankle Ability Measure [FAAM] sport scale), great toe active dorsiflexion motion, secondary procedures, radiographic assessment, and safety parameters were evaluated. Analysis was performed using intent-to-treat (ITT) and modified ITT (mITT) methodology. The primary endpoint for the study consisted of a single composite endpoint using the 3 primary study outcomes (pain, function, and safety). The individual subject's outcome was considered a success if all of the following criteria were met: improvement (decrease) from baseline in VAS pain of $\geq 30\%$ at 12 months; maintenance of function from baseline in FAAM sports subscore at 12 months; and absence of major safety events at 2 years. The proportion of successes in each group was determined and 1-sided 95% confidence interval for the difference between treatment groups was calculated. Noninferiority of the implant to arthrodesis was considered statistically significant if the 1-sided 95% lower confidence interval was greater than the equivalence limit ($<15\%$). The VAS pain scores decreased in both the implant and arthrodesis groups from baseline at 12 and 24 months. Similarly, the FAAM sports and activity of daily living subscores improved at 12 and 24 months in both groups. First MTP active dorsiflexion motion improvement was 6.2 degrees (27.3%) after implant placement and was maintained at 24 months. Subsequent secondary surgeries occurred in 17 (11.2%) implant patients (17 procedures) and 6 (12.0%) arthrodesis patients (7 procedures). Fourteen (9.2%) implants were removed and converted to arthrodesis, and 6 (12.0%) arthrodesis patients (7 procedures [14%]) had isolated screws or plate and screw removal. There were no cases of implant fragmentation, wear, or bone loss. When analyzing the ITT and mITT population for the primary composite outcome of VAS pain, function (FAAM sports), and safety, there was statistical equivalence between the implant and arthrodesis groups.

Additional studies were published as follow-up to the above Baumhauer study (Goldberg, et al., 2017; Baumhauer, et al., 2017; Glazebrook, et al., 2019).

Goldberg et al. (2017) retrospectively evaluated data from the above clinical trial (Baumhauer, et al., 2016) of first metatarsophalangeal joint (MTPJ1) implant hemiarthroplasty and arthrodesis to determine the association between patient factors and clinical outcomes. The patient demographics and baseline outcome measures were similar. Success rates between implant MTPJ1 hemiarthroplasty and arthrodesis were similar ($P > .05$) when stratified by hallux rigidus grade, gender, age, BMI, symptom duration, prior MTPJ1 surgery status, and preoperative VAS pain, hallux valgus, and ROM. There was a loss of 15 patients who initially consented to randomization and treatment and subsequently withdrew from the original trial following randomization to arthrodesis.

Baumhauer et al. (2017) retrospectively evaluated the above study (Baumhauer, et al., 2016). Patients underwent preoperative clinical examination, radiographic assessment, hallux rigidus grade assignment, and intraoperative assessment of cartilage loss. Visual analog scale (VAS) score for pain was obtained preoperatively and at 24 months. Correlation was made between active peak dorsiflexion, VAS pain, cartilage loss, and hallux rigidus grade. Fisher's exact test was used to assess grade impact on clinical success ($P < .05$). The analysis noted in 202 patients, 59 (29%), 110 (55%), and 33 (16%) were classified as Coughlin grades 2, 3, and 4, respectively, that there was no correlation between grade and active peak dorsiflexion (-0.069 , $P = .327$) or VAS pain (-0.078 , $P = .271$). Rank correlations between grade and cartilage loss were significant, but correlations were small. When stratified by grade, composite success rates between the 2 treatments were nearly identical.

Glazebrook et al. (2019) prospectively assessed safety and efficacy outcomes for synthetic cartilage implant hemiarthroplasty at a minimum of 5 years of the above clinical trial (Baumhauer, et al., 2016). Of 135 eligible patients from the original trial, 112 (83.0%) were enrolled females. Pain visual analog scale (VAS), Foot and Ankle Ability Measure (FAAM) Activities of Daily Living (ADL), and FAAM Sports subscales were completed preoperatively and 2 and 5 years postoperatively. Great toe active dorsiflexion, weightbearing radiographs,

secondary procedures, and safety parameters were also evaluated. At 24 months, 14/152 (9.2%) patients had undergone implant removal and conversion to arthrodesis. In years two to five, 9/119 (7.6%) patients underwent implant removal and conversion to arthrodesis. 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, from 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%) patients, respectively. Patient-reported outcomes at 24 months were maintained at 5.8 years in patients who were not revised. Active MTP joint peak dorsiflexion was maintained.

Professional Societies/Organizations

A clinical practice guideline in the form of an algorithm on diagnosis and management of first metatarsophalangeal joint disorders was published by the First Metatarsophalangeal Joint Disorders Panel of the American College of Foot and Ankle Surgeons in 2003. The guideline states that interpositional arthroplasty with double-stem silicone hinged implants is still a useful procedure for the end-state arthrosis of hallux, and that titanium grommets are recommended to minimize ectopic bone formation and protect the implant from the adjacent bone. The guideline states that patients should be informed of the alternatives to implant arthroplasty and their potential complications. In addressing total joint systems, the guideline states that numerous implant systems have been developed during the years and several are still used clinically, although long-term clinical usefulness has yet to be established. Judicious use and strict criteria are recommended to avoid complications and problematic revisions (Vanore, et al., 2003).

Use Outside of the U.S.

NICE published Interventional Procedure Guidance in 2005 based on analysis of seven case series: Hanyu et al. (2001); Sharnkar, et al., (1991); Cracchiolo et al., (1992); Granberry et al., (1991); Bommireddy et al., (2003); Ibrihim et al., (2004); and Malviya et al., (2004). The main outcome measures reported were pain relief and patient satisfaction. Three studies reported that 73% (8/11), 79% (46/58) and 100% (7/7) of joints with implants were pain free after mean follow-ups of 17 months, 12 years, and 35 months, respectively. Another study including 86 implants reported significant improvement in pain scores after the procedure and two studies reported pain relief in 66% (59/90) of implants and 94% (30/32) of patients, with a mean follow-up of three years and eight years, respectively. The NICE guidance concluded that current evidence on the safety and efficacy of MTP joint replacement of the hallux appears adequate to support the use of this procedure. The guidance also states, however, that there is little evidence on the durability of newer implants, and that complications may necessitate removal of the joint. These complications include persistent pain, infection, implant loosening, implant fracture, osteolysis, bone over-production, cyst formation, silastic granulomas and transfer metatarsalgia.

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

- Note:** 1) This list of codes may not be all-inclusive.
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
28291†	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant

HCPCS Codes	Description
L8641†	Metatarsal joint implant
L8642†	Hallux implant

†Note: Experimental/Investigational/Unproven/Not Covered when used to report joint replacement using ceramic implant.

Experimental/Investigational/Unproven/Not Covered when used to report partial replacement of the first MTP joint using synthetic Cartilage implant (e.g. Cartiva Synthetic Cartilage Implant), replacement of joints other than the first MTP joint, replacement of any other toe joint (e.g., interphalangeal joints) or replacement of the tarsal metatarsal (TMT) joint:

CPT®* Codes	Description
28899	Unlisted procedure, foot or toes

HCPCS Codes	Description
L8699	Prosthetic implant, not otherwise specified

*Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.

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