Medical Coverage Policy

Effective Date 9/15/2025
Next Review Date 9/15/2026
Coverage Policy Number............ 0446

Metatarsophalangeal Joint Replacement

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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)
- synthetic cartilage implant (e.g., Cartiva Synthetic Cartilage Implant)
- personalized (i.e., customized, patient-specific 3D printed) implants

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 tarsometatarsal (TMT) joint

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

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 (bunion) 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 (or "stiff big toe") is degenerative arthritis of the first metatarsophalangeal (MTP) joint, characterized by restriction or loss of range of motion of the joint. The alignment usually remains normal with possible dorsal changes, including dorsal bunion. Individuals typically report pain with movement.

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. However, a recent Cochrane meta-analysis found that shoe inserts, arch-contouring foot inserts, and hyaluronic acid injections may provide little to no benefit for pain or function (Munteanu, et al., 2024). 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.

The simplest surgical procedure consists of shaving off the bony prominence interfering with joint movement (i.e., cheilectomy). Additionally, there are several types of phalangeal and metatarsal osteotomies (i.e., reshaping or realigning the bones) that may be used to decompress the joint. 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). Arthrodesis has been considered the gold standard for the treatment of end-stage first MTP joint osteoarthritis. Studies on clinical outcomes have shown reliable improvements in function and symptoms; however, joint motion is lost. For select patients who wish to retain MTP joint mobility, implant arthroplasty may be a reasonable alternative (Galois, et al., 2020; Butterworth and Ugrinich, 2019).

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. Double-stem silastic implants are the most commonly used and studied implant for total MTP joint replacement, with reported high rates of implant survivorship and patient satisfaction. Similarly, metallic implants in hemiarthroplasty (i.e., partial joint replacement) have been in use for decades with generally positive clinical outcomes (de Bot et al., 2022; Clough and Ring, 2020).

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. Postoperative complications have included fragmentation, infection, joint pain and stiffness, radiographic loss of MTP joint space, and progression of arthritis. High surgical revision rates have been reported (Lewis, et al., 2024; Metikala, et al., 2022; An, et al., 2020; Harmer and Maher, 2020).

Three-dimensional (3D) printing, also known as rapid prototyping, is a type of additive manufacturing – a process that creates a three-dimensional object by building consecutive layers of raw material. Objects are produced from a digital file, such as a computer-aided design (CAD) drawing or a magnetic resonance image (MRI). There are numerous processes, methods, and materials used, depending on the application. 3D printing has been used for various medical applications, including orthopedic implants. Some 3D printed implants are produced from a standard design and are available in predefined distinct sizes (i.e., "off-the-shelf", not patient-specific). Other implants may be personalized for a specific patient, created from the patient's medical imaging data. Personalized, patient-specific 3D printed implants have been proposed for use in complex reconstructions, where available commercial implants are not suited or available (U.S. Food and Drug Administration [FDA], 2023; Alexander and Wake, 2022; Spencer and Watts, 2020). The manufacturing and sterilization protocols and standards, approval pathways, and regulation of personalized patient-specific 3D printed implants are not well-established.

MTP joint implants have been proposed as treatment for disorders affecting MTP joints other than the first MTP joint (i.e., of the lesser toes), for other toe joints (e.g., interphalangeal joints), and for the tarsometatarsal (TMT) joint. There is insufficient evidence in the published medical literature supporting the safety and efficacy of these implants.

U.S. Food and Drug Administration (FDA)
Since the late 1970s, numerous prostheses fabricated from various components including metal (e.g., titanium), acrylic, silastic, and metal alloys, have received FDA clearance as Class II devices through the 510(k) process. Examples include the Reference Toe System (RTS) Flexible 1st MPJ Implant (In2BonesUSA, LLC, Del Mar, CA; 2016), and the BioPro MPJ Hemi Implant (BioPro, Inc., Prior Lake, MN; 2012).

The Moje ceramic implant (Orthosonics, Ltd., Devon, UK) is a two-component first MTP joint 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 Implant (Stryker/Cartiva, Inc., Alpharetta, GA) was approved by the FDA through the Premarket Approval (PMA) process 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. Several supplemental approvals have been issued for this device since the original PMA but the indications for use have not changed. A Class II device recall for the Cartiva implant was posted by the FDA on December 4, 2024, noting that individuals "implanted with synthetic cartilage implant may experience a higher-than expected occurrence rate of the following hazards: revision, removal, implant subsidence, displacement, pain, nerve damage or fragmentation."

The FDA regulates 3D printed medical devices, including implants, via the same pathways as traditional medical devices; the standards for safety and effectiveness are equivalent. Unless a 3D printed device presents new concerns surrounding safety or effectiveness, the device would be classified into the same regulatory class as other devices of that type, regardless of the manufacturing method (Di Prima, et al., 2016).

In May 2022, the FDA granted 510(k) clearance for the restor3d MTP Implant (Restor3d, Inc., Durham, NC), as a Class II device. The approved indication is for use as a hemiarthroplasty implant for the first MTP joint in the treatment of degenerative and post-traumatic arthritis, hallux valgus, hallux rigidus, and an unstable or painful metatarsophalangeal (MTP) joint. The implant is comprised of a single laser powder bed fusion (LPBF) printed cobalt-chromium alloy.

Literature Review

First Metatarsophalangeal (MTP) Joint Replacement: 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 six arthrodesis studies and seven 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 American Orthopaedic Foot and Ankle Society-Hallux Metatarsophalangeal Interphalangeal [AOFAS-HMI] score) and reducing pain (a decrease of 6.56 versus 4.65 points on the Visual Analogue Scale [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, nonunion, and prosthetic loosening being the most commonly reported complications after arthrodesis and total joint replacement, respectively. The authors concluded 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, and 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 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 with follow-up greater than two years.

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 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 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 points lost by lack of mobility in an arthrodesis were lost at a similar rate by the mobile joint replacement. The authors stated that it is not clear whether this loss was 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 of 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 months (range 6–74). 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 MTP joint 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. (2007) 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 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). 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, two feet; and poor or a failure, seven 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, four 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 Thomson (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 postoperatively. 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 this randomized controlled trial (Gibson and Thomson, 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 Loughead (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 authors 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 et al. 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, five patients (24%); and 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 and Townley (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. The ability to generalize findings may be limited due to the small number of patients, short-term follow-up, lack of a control group, and lack of standardized assessment criteria.

Cartiva Synthetic Cartilage Implant: The evidence in the published peer-reviewed literature evaluating the use of the Cartiva synthetic cartilage implant (SCI) in the treatment of first metatarsophalangeal joint arthritis is limited. Evidence consists primarily of retrospective studies, small prospective cohort studies, and small case series; long-term data are lacking. Studies have also raised concerns of high implant failure rates necessitating removal and/or revision, as well as fragmentation, displacement, pain, infection, and nerve damage (Sanii, et al., 2025; Budde, et al., 2024; Fletcher, et al., 2024; Lewis, et al., 2024; Mahmood, et al., 2024; Radcliffe and Roukis, 2024; Metikala, et al., 2022; Akoh, et al., 2021; An, et al., 2020; Chrea, et al., 2020; Harmer, et al., 2020; Cassinelli, et al., 2019). At present, there is insufficient evidence in the medical literature to demonstrate the long-term safety and efficacy of the Cartiva implant for any indication.

Hayes conducted a health technology brief for Cartiva Synthetic Cartilage Implant (SCI) for the treatment of first MTP joint arthritis (2020). Findings of this report noted that a noninferiority analysis from one fair-quality RCT suggested 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 were inconsistent and some suggested better outcomes with arthrodesis. Patients treated with Cartiva SCI reported statistically significantly worse pain scores (i.e., more pain) when compared with the arthrodesis group from six weeks to two years postprocedure. In addition, analyses of the Foot and Ankle Ability Measure (FAAM) sports score suggested 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 was noted that a very-low-quality body of evidence consisting of one fair-quality study was insufficient to draw conclusions regarding the efficacy or safety of Cartiva SCI for the treatment of degenerative or posttraumatic arthritis of the first MTP joint. The body of evidence was 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 two 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 single-center prospective cohort study of 55 patients (14 male, 41 female) 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. Preoperative and postoperative patient-reported outcomes (PROMs) were evaluated using the FAAM Activities of Daily Living (ADL) subscale and the Manchester-Oxford Foot Questionnaire (MOXFQ). The patients were followed up for an average of 21 months (range 12—38). Fourteen patients suffered from HJ2/moderate arthritis and 41 patients with grade HJ3/severe arthritis. Postoperative mean FAAM scores showed statistically significant improvement ($p<0.0001$). Patients reported a 40% increase in functionality during activities of daily living. All three 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 a retrospective study to review patient-reported outcome scores and clinical outcomes for patients treated for hallux rigidus with polyvinyl alcohol (PVA) hydrogel implant. The study included 103 patients who underwent first MTP hemiarthroplasty with the 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 ($p<0.05$). 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 who underwent concurrent Moberg osteotomy had significantly lower postoperative Pain Interference and Pain Intensity scores compared with those who did not undergo the procedure. Two patients underwent revision procedures in the first two years postoperatively, one with revision hemiarthroplasty and one with conversion to arthrodesis. The study was limited by the retrospective nature of the study, lack of randomization and control group and short length of follow-up.

Baumhauer et al. (2016) reported on a prospective, randomized non-inferiority study to compare the efficacy and safety of the Cartiva 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 (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 three 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 ≥ 30% at 12 months; maintenance of function from baseline in FAAM sports subscore at 12 months; and absence of major safety events at two 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 six (12.0%) arthrodesis patients (seven procedures). Fourteen (9.2%) implants were removed and converted to arthrodesis, and six (12.0%) arthrodesis patients (seven 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. Per the authors, 15 arthrodesis patients withdrew from the study after randomization but were included in the ITT analysis, which could bias the results in favor of the implant.

Goldberg et al. (2017) retrospectively evaluated data from the above clinical trial (Baumhauer, et al., 2016) of first MTP joint 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 hemiarthroplasty and arthrodesis were similar (p>0.05) when stratified by hallux rigidus grade, gender, age, body mass index (BMI), symptom duration, prior first MTP joint surgery status, and preoperative VAS pain, hallux valgus, and range of motion. 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<0.05). The analysis noted of 202 patients, 59 (29%), 110 (55%), and 33 (16%) were classified as Coughlin grades 2, 3, and 4, respectively, and that there was no correlation between grade and active peak dorsiflexion (r=−0.069, p=0.327) or VAS pain (r=−0.078, p=0.271). Rank correlations between grade and cartilage loss were significant, but correlations were small. When stratified by grade, composite success rates between the two treatments were nearly identical.

Glazebrook et al. (2019) prospectively assessed safety and efficacy outcomes of the above clinical trial (Baumhauer, et al., 2016) at a minimum of five years post-surgery. Of 135 eligible patients from the original trial, 83% were female. Pain VAS, FAAM ADL, and FAAM Sports subscales were completed preoperatively and two and five 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.

Personalized 3D MTP Joint Implants: Evidence in the published, peer-reviewed scientific literature evaluating the use of personalized 3D (i.e., patient-specific) joint implants in foot surgery is limited. The literature consists primarily of small case series and case reports reporting on hindfoot procedures, with a lack of controls. Long term data regarding surgical success, implant durability, and overall performance in comparison to standard implants is lacking. Larger controlled studies with long-term follow up are needed to establish the safety and efficacy of personalized 3D metatarsophalangeal joint implants.

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 (ACFAS) 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).

In 2022, the National Institute for Health and Care Excellence (NICE) published guidance on the use of a synthetic cartilage implant for the treatment of first metatarsophalangeal joint osteoarthritis. NICE stated that, for persons with advanced joint disease for whom arthrodesis is indicated, the procedure should only be used with special arrangements for clinical governance, consent, and audit or research. For all other individuals with hallux rigidus (i.e., less advanced disease), NICE recommended the procedure only be used in a research context. The guideline noted that while evidence regarding the safety of synthetic cartilage implant insertion for first MTP joint osteoarthritis (hallux rigidus) has shown no major safety concerns in the short term, evidence on efficacy is limited in quantity and quality. Regarding patient selection, NICE noted that the procedure should not be used in people with inflammatory arthritis or diabetic peripheral neuropathy, and that evidence concerning the patients for whom the procedure is most appropriate is limited, particularly at what stage of osteoarthritis the procedure should be used.

Medicare Coverage Determinations

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

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
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

†<u>Note</u>: Considered Experimental/Investigational/Unproven when used to report joint replacement using ceramic or personalized implants.

Considered Experimental/Investigational/Unproven when used to report partial replacement of the first MTP joint using synthetic cartilage implant (e.g. Cartiva Synthetic Cartilage Implant), replacement of any other toe joint other than the first MTP joint, or replacement of the tarsometatarsal (TMT) joint:

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

HCPCS Codes	Description
L8699	Prosthetic implant, not otherwise specified

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• No clinical policy statement changes.	9/15/2025
Annual Review	• No clinical policy statement changes.	9/15/2024
Annual Review	• Updated to new template and formatting standards.	9/15/2023

Type of Revision	Summary of Changes	Date
	• Updated “tarsal metatarsal” to “tarsometatarsal”.	