



# Cigna Medical Coverage Policy

**Subject Metatarsophalangeal Joint Replacement**

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## Coverage Policy

**Cigna covers partial or total replacement of the first metatarsophalangeal (MTP) joint as 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

**Cigna does not cover partial or total replacement of the first MTP joint or any other foot joint using a ceramic implant (e.g., Moje prosthesis [Orthosonics, Ltd., Devon UK]) because it is considered experimental, investigational or unproven.**

**Cigna does not cover ANY of the following because each is considered experimental, investigational or unproven (this list may not be all inclusive):**

- 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 is a localized painful arthritic condition of the first metatarsophalangeal (MTP) joint characterized by limitation of motion and periarticular bone formation. 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 involving bony and/or soft tissue correction may be considered for patients with severe symptoms when conservative treatment is not effective. The simplest surgical procedure consists of shaving off the bony prominence interfering with joint movement (i.e., exostectomy or cheilectomy). More complex procedures include 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); excision of the metatarsal head along with part of the proximal phalanx and fusing the joint (i.e., arthrodesis); or joint replacement (i.e., arthroplasty) with an artificial implant (Ferrari, et al., 2005; National Institute for Health and Clinical Excellence [NICE], 2005).

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 (Aruthnot et al., 2008)

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, acrylic, silastic, and metal alloys, have received U.S. Food and Drug Administration (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 U.S. FDA approval.

#### **Literature Review**

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.

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.

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 ( $p=0.006$ ).

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  $54.98 \pm 4.82$  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.

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.

Arbuthnot et al. (2008) conducted a prospective observational study of 40 patients (42 toes) treated for hallux rigidus with MTP joint replacement arthroplasty using a Moje ceramic implant (Orthosonics, Ltd., Devon UK). The mean AOFAS score increased from  $36 \pm 10.79$  preoperatively to  $82.20 \pm 9.54$  at three months ( $p < .001$ );  $87.00 \pm 10.62$  at 12 months, and  $84.20 \pm 10.69$  at 24 months. There was no statistically significant change in scores after three months. The first MTP range of motion preoperatively was  $4.9^\circ \pm 5.52^\circ$ , and increased to  $70.80^\circ \pm 15.97^\circ$  in the operating room, but decreased to  $45.60^\circ \pm 12.28^\circ$  at three months,  $40.00^\circ \pm 12.72^\circ$  at 12 months and  $33.30^\circ \pm 17.19^\circ$  at 24 months.

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%).

McGraw and Jameson reported mid-term results of MTP joint replacement with the Moje prosthesis performed between 2002 and 2007 in 48 consecutive patients (63 components). The AOFAS HMI scores improved from a preoperative median of 56 to a median score of 72 at a mean follow-up of 44 months ( $p = 0.009$ ). Five implants were removed (8%); four due to pain associated with implant loosening and subsidence, and one because of deep infection. A total of 57% of metatarsal and 56% of phalangeal components had subsided, and radiographic evidence of loosening was found in 58% of x-rays analyzed at the latest follow-up. The authors stated that, due to the widespread loosening and subsidence encountered, the long-term outcome following this procedure is uncertain.

A Cochrane Systematic Review of interventions for treating hallux valgus (Ferrari et al., 2005) does not address MTP replacement, and stated that in the one included trial that compared osteotomy to arthroplasty (Gibson and Thompson, described above) there was limited evidence to suggest that the osteotomy gave the better outcomes. The review cited the poor methodological quality and small size of included trials.

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.

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.

### **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.

### **Use Outside 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); Ibrhim 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.

### **Summary**

Surgical treatment may be considered for patients with hallux valgus or hallux rigidus with severe symptoms when conservative treatment is not effective. 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).

Although there is not consistent scientific evidence available that demonstrates the clinical effectiveness of partial or total replacement of the first metatarsophalangeal (MTP) joint, limited data from several studies, as

well as longstanding acceptance and limited use of this procedure by certain specialists in the practicing community, suggest that MTP joint replacement may be a reasonable option for a carefully selected subset of patients. There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of ceramic implants; MTP joint replacement for joints other than the first MTP joint; replacement of other toe joints; and replacement of tarsal metatarsal (TMT) joints.

## 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

**Covered when medically necessary:**

CPT* Codes	Description
28293 <sup>†</sup>	Correction, hallux valgus (bunion), with or without sesamoidectomy; resection of joint with implant

HCPCS Codes	Description
L8641 <sup>†</sup>	Metatarsal joint implant
L8642 <sup>†</sup>	Hallux implant

<sup>†</sup>Experimental/Investigational/Unproven/Not Covered when used to report joint replacement using ceramic implant.

**Experimental/Investigational/Unproven/Not Covered when used to report 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<sup>®</sup>) © 2013 American Medical Association: Chicago, IL.

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