CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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INSTRUCTIONS FOR USE
Coverage Policies are intended to provide guidance in interpreting certain standard CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant’s particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant’s benefit plan document always supercedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

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

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. The first metal-on-polyethylene implant was introduced in 1990. Numerous prostheses have received U.S. Food and Drug Administration (FDA) approval as Class II devices through the 510(k) process (Esway et al., 2005).

**Literature Review**

Moekel et al. (1992) conducted a retrospective review of 45 patients (67 feet) with RA who were treated between 1980 and 1985 with resection of the MTP head and insertion of a double-stemmed silicone-rubber implant. Patients were evaluated clinically and radiographically using a foot-scoring system developed for this study. Results were assessed for relief of pain, ability to walk, presence of calluses or deformity and radiographic findings. The average preoperative foot score was 47 points (range 20-65) and improved to 87 points (range 55-100) at follow-up (p< 0.001). Nine feet had a score of less than 80 points at the latest follow-up, with results classified as fair or poor. The preoperative MTP angle averaged 41 degrees, compared to 21 degrees at follow-up. There were seven feet in which recurrent dorsal subluxation of the lesser MTP joints was visible on the latest radiographs, and overgrowth of bone was evident at the distal ends of the metatarsals in three feet. Fracture of the implant was visible in two feet, resulting in dislocation and subsequent implant removal in one foot. In five feet, fragmentation of the implant was visible on radiographs, but the clinical status had not deteriorated. Six feet had evidence of erosion of bone around the implant. Seven feet subsequently required a revision procedure.

Ashford at al. (2000) conducted a retrospective review of 23 arthroplasties performed between 1994 and 1998 for pathology of the first MTP joint. One patient who did not fit the inclusion criteria was excluded from analysis. A total of 22 implants in 20 patients were evaluated by questionnaire and clinical evaluation at an average follow-up of 33 months (range 9-59 months). Sixteen patients responded to the Foot Surgery Questionnaire, providing the following subjective ratings of the results of implant surgery: 10 (5%), very satisfied; 4 (25%); good; and 2 (12.5%), fairly satisfied. The overall rating of success was 85.27 (range 18-100). One patient required implant removal; the reason for removal was not stated. Of the 16 patients who were interviewed, five (31%) reported pain within the joint and nine (56.25%) reported pain elsewhere. Patients were asked to estimate their preoperative pain level and provide a corresponding postoperative value. Median preoperative pain was 83 mm (range 11-100 mm) and postoperative pain was 13.5 mm (range 1-93 mm) (p< 0.005). Clinical exam included joint dorsiflexion (average 21 degrees, range 6–46) and hallux purchase. Hallux purchase was compared to the normal population and was significantly reduced. Physiologic function of the first MTP joint was not completely restored, with an average hallux dorsiflexion of 21° (range 6°–46°).

A retrospective review conducted by Hanyu et al. (2001) evaluated arthroplasty using a flexible hinge toe implant in 97 feet (55 patients) with RA between 1983 and 1990. At an average of 12 years postoperatively (range 9-15 years) 39 of the 55 patients completed a questionnaire, and radiographs were taken of 58 feet. Preoperatively, all 97 feet had caused mild to severe pain. At follow-up, 46 of 58 (79%) feet were pain free; eight (14%) had occasional pain; and four (7%) had moderate pain. Radiological evaluation demonstrated a change in the hallux valgus angle from 39° ± 13° preoperatively, to 18° ± 11° postoperatively. The first-second intermetatarsal angle changed from 14° ± 4° preoperatively to 11° ± 3° postoperatively. A hallux valgus angle of more than 30° was considered a recurrence. At the most recent follow-up there was recurrence in 11 feet (19%). The authors stated that the radiographic evidence did not mirror the encouraging results of the subjective and physical examination. In 41 feet (71%), osteophytes had formed around the midsection of the implant, and in six feet (10%), the proximal and distal osteophytes touched or overlapped. At the most recent follow-up, sinking of the implant had occurred in 34 joints (59%). Radiographically, there was no deformation or suspected fragmentation in 17 feet (29%), there was deformation or suspected fragmentation in 32 feet (55%), and visible
fracture of the stem or hinge in nine feet (16%). Radiographic evidence of silicone synovitis was present in 12 joints (21%). Late infection occurred in two joints, resulting in implant removal. In two of four patients with hallux valgus with recurrence of painful calluses, the implant was removed 7.4 and 10 years after arthroplasty. Radiographs revealed progressive osteolysis around the implant in both patients.

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 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.

Bomireddy et al. (2003) conducted a retrospective review of 32 patients (42 feet) who were treated with double-stem silastic joint replacement of the first MTP between 1981 and 1986. A total of 44 patients received the procedure during this period, but the study did not include four patients who were treated for rheumatoid arthritis, and eight patients who died or were lost to follow-up. Patients were assessed for pain relief; alignment; length of hallux; transfer metatarsalgia and other gait disorders; and radiographs were taken. The mean follow-up was eight years (range, 4–19 years). A total of 24 patients were completely satisfied, four were somewhat satisfied, and four were dissatisfied. One patient had a prosthetic fracture of the hinge. Radiological evidence of silicone synovitis was seen in 40% of implants, a finding that did not correlate with the subjective results.

Roukis et al. (2003) compared the BIOPRO resurfacing endoprosthesis to periaricular osteotomy in 44 patients (47 feet) with hallux rigidus. Twenty patients (20 feet) underwent a periaricular 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 periaricular 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.

Taranow et al. (2005) conducted a case review of subjective and objective outcomes of patients with severe hallux rigidus treated with metallic proximal phalangeal hemiarthroplasty. A total of 37 patients were treated by the author between 1995 and 2004. Twenty-eight patients (32 hemiarthroplasties) completed preoperative and postoperative modified Mean Foot Function Index (FFI) and patient satisfaction questionnaires, and 23 of these patients (25 hemiarthroplasties) returned for a final clinical evaluation. The average follow-up was 33.14 months (range 3–112 months). FFI scores improved from 76.14 (range 28.4–100) preoperatively, to 18.80 (range 0–79.0) postoperatively. Twenty-three of 28 patients were completely satisfied, three were satisfied with reservations, and two were dissatisfied. Radiographs demonstrated acceptable alignment of the implant and the MTP joint in 31 patients. Four patients had implants inserted in a dorsiflexed position (i.e., the stem in contact or protruding through the plantar cortex of the proximal phalanx). Three joints in two of these patients showed evidence of subsidence and loosening. Patient satisfaction did not correlate with the radiographic findings.

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 hemiarthroplasty (n=21 feet; 20 patients) or an arthrodesis (n=27 feet; 26 patients) between 1999 and 2005. All hemiarthroplasties were performed by a single surgeon, and involved a cheilectomy of the metatarsal head, removal of a small portion from the base of the proximal phalanx, including the articular cartilage, and implantation of a BioPro implant. All arthrodeses were performed by another surgeon, and included resection of the articular cartilage from both sides of the joint to achieve flat surfaces of exposed cancellous bone, followed by placement of two screws to achieve rigid internal fixation. 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 hemiprostheses 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 hemiprostheses (p=0.006).

Konkel at al. (2008) conducted a retrospective review to evaluate mid-term results of the Future hemi-great toe implant in 11 patients (13 toes) with hallux rigidus. At an average follow-up of 87 months, pain was absent in 7 toes, mild and occasional in five, and moderate and daily in one. Range of motion averaged 17 degrees of plantar flexion (range 10-30), 47 degrees of dorsiflexion (range 30-100), and total range of motion averaged 64 degrees (range 30-100). Six patients had some recurrence of the dorsal osteophyte, and three of the six recurrent dorsal bunion were associated with limited dorsiflexion and recurrent mild aching. Mild lucency was seen at the base of the implant in 10 of 11 patients, but the lucency did not extend down the stem of the implant.
Sorbie and Saunders (2008) evaluated outcomes of 19 patients (23 implants) with hallux rigidus treated with hemiarthroplasty using Trihedron cobalt chrome implants between June 2000 and Oct 2001. At an average follow-up of 68 months, the average AOFAS score was 88 (range 75-100) compared to a preoperative average score of 57 (range 39-80). Mild occasional discomfort remained in 5 patients. One patient later required hallux valgus correction. Eighteen of 19 patients experienced increased ROM, although a normal range may not have been achieved.

Kissel et al. (2008) conducted a prospective case series to evaluate outcomes of hemiarthroplasty using the Biopro cobalt chromium hemi-implant in 30 consecutive patients with hallux rigidus resistant to conservative treatment. Of 30 patients, 23 completed the 12-month follow-up. Average ACFAS Universal Foot and Ankle Score was 80.4, compared to a preoperative score of 41.2 ± 1.6 ((p=0.003). Statistically significant increases in average dorsiflexion (p=0.009) and plantarflexion (p<0.0001) were observed postoperatively compared to preoperative measurements. The authors noted that this was a pilot study to evaluate the role of hemi-implant arthroplasty in addressing various amounts of double-side joint disease of the first MTP.

Cook et al. (in-press, 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.

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); Iibrihim 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.

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.

Textbooks
Several textbooks that address treatment of hallux valgus and hallux rigidus include MTP joint replacement in the discussion of past and present surgical options. McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery states in a chapter on implants: The general indications for implant arthroplasty have changed little over the past three decades, but patient selection has become more stringent. Whether it is an interpositional or a joint replacement implant arthroplasty procedure, the joint is destroyed. As such, it is recommended that each patient be assessed for alternatives to implant arthroplasty with efforts directed toward joint preservation, whenever possible, particularly in younger, more active patients.” The implant chapter conclusions state:

“During work on solutions for painful hallux rigidus, the use of joint preservation techniques and alternatives to implant arthroplasty became better defined. Techniques of osteotomy, cheilectomy and chondroplasty allowed for salvage of joints with degenerative arthritis that not much earlier would have
been destined for implant arthroplasty. These joint-preservation techniques have become important in the younger patient population in whom more functional and durable alternatives are required. As joint implants are designed to achieve or preserve a more normal range of motion at the first MTP joint, it has been hoped that they will be more successful in younger patients with greater functional demands. This is yet to be achieved."

“The choice of joint implant is not straightforward because no perfect implant exists. There is no perfect biomaterial. Much work in the area of analysis of what we are doing as clinicians is necessary. A renewed interest in hemireplacement of the phalangeal base has been seen with metallic implants. Some good results have been reported, but well-conducted clinical studies documenting patient outcomes are still lacking.”

“What are our current recommendations in light of all that has transpired? Conservatism is the best rule. One should assess each patient for alternative procedures. Total joint replacement and interpositional arthroplasty have their place in surgical treatment. They should be applied with caution and used in patients who meet specific criteria. The patients should be those in whom other alternatives are less likely to yield a successful reconstruction.

Frontera: Essentials of Physical Medicine and Rehabilitation (2008) states, “A number of manufacturers have tried to produce artificial great toe joints, made of silastic, metal, and polyethylene or ceramic, but the long-term results of these have not lived up to expectations.”

Firestein: Kelley’s Textbook of Rheumatology (2008) in a discussion of surgical treatment of foot and ankle pain, states:

“In the forefoot, fusion surgery is indicated only for the first MTP joint. This procedure is used for arthrosis and advanced hallux valgus (bunion) deformities.”

“Fusion surgery generally provides reliable pain relief and a stable, plantigrade foot. Nevertheless, the loss of motion of the fused joint can lead to increased motion and altered biomechanics at adjacent joints. This alteration ultimately may lead to arthritic changes in these joints. Fusion surgery may lead to subtle, albeit real changes in gait. Finally, the minimal ramifications of fusing just one joint may become much greater in the setting of a subsequent fusion in either the ipsilateral or the contralateral limb. Such concerns drive many researchers to work toward improving joint replacement surgery (arthroplasty) in the foot and ankle.”

“In the foot, arthroplasty is performed by some surgeons for the first MTP joint. The relevant literature is still conflicted, however. Although there were some encouraging early results with arthroplasty, other studies have shown high rates of implant failure and loosening secondary to synovitis from Silastic particle wear. Advanced deformity, often present in patients with rheumatoid arthritis and inflammatory arthritis, is considered to be a relative contraindication to first MTP joint arthroplasty. Nevertheless, new implant designs may hold increased promise. Generally, these implants are lower profile and resect less bone, which also makes it easier to perform a subsequent fusion, if necessary.”

Canale and Beaty: Campbell’s Operative Orthopedics (2007) states:

Silicone-rubber, single-stem replacement arthroplasty components gave satisfactory results in 86% of patients reported by Wenger and Whalley. The concern with this technique is for the occurrence of silicone-rubber synovitis. Hemiarthroplasty of the proximal phalanx with a metallic resurfacing component also has been described, with high success rates reported, but large, controlled studies with long-term follow-up are unavailable for evaluation of this procedure.”

“The results of replacement arthroplasty of the first metatarsophalangeal joint for correction of recurrent hallux valgus have varied. Cracchiola recommended replacement arthroplasty of the first metatarsophalangeal joint in patients with rheumatoid arthritis and severe destruction of the metatarsophalangeal joints, but in most patients resection of the base of the proximal phalanx, lateral displacement of the first metatarsal, temporary internal fixation after fibular sesamoid excision, and
medial capsular repair provide just as good results as replacement arthroplasty with less expense and fewer complications.

“Koopman: Arthritis and Allied Conditions (2005) notes, “Advanced hallux valgus deformity in RA is most effectively treated with an arthrodesis of the metatarsophalangeal joint. The benefits of this procedure include stable alignment of the toe, pain relief, and improved stability of the medial side of the foot. The failure rate of implant arthroplasty of the first metatarsophalangeal joint makes this a less desirable choice in all but the most low-demand patients, or perhaps, in patients with a fused first interphalangeal joint.”

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.

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.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

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<th>CPT* Codes</th>
<th>Description</th>
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<td>Correction, hallux valgus (bunion), with or without sesamoidectomy; resection of joint with implant</td>
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<td>28899†</td>
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<td>Metatarsal joint implant</td>
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<td>L8642†</td>
<td>Hallux implant</td>
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†Note: Covered when medically necessary when used to report metatarsophalangeal joint replacement of the hallux.
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<td>735.2</td>
<td>Hallux rigidus</td>
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References

1. Ashford RL, Vogiatzoglou F, Tollafield DR, Casella JP. Retrospective analysis of Sanson Silastic double-stemmed great toe implants with titanium grommets following podiatric surgery for arthritic joint disease. The Foot; 2000 (10); 69-74.


Policy History

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<td>0445</td>
<td>Metatarsophalangeal Joint Replacement of the Hallux</td>
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