

Surgery of the Foot (for Ohio Only)

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[Instructions for Use](#)

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Related Policy

- [Outpatient Surgical Procedures – Site of Service \(for Ohio Only\)](#)

Application

This Medical Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

Coverage Rationale

Surgery of the foot is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures:

- Arthrodesis or Arthroplasty, Interphalangeal Joint, Second-Fifth Toes
- Cheilectomy, First Metatarsophalangeal (MTP) Joint
- Exostectomy, First Metatarsophalangeal (MTP) Joint (Bunionectomy)
- Osteotomy, Distal Transpositional, First Metatarsal (MT) (Bunionectomy)
- Osteotomy, Proximal, First Metatarsal (MT) (Bunionectomy)
- Osteotomy, Proximal Phalanx, First Toe +/- Bunionectomy
- Plantar Fascial Release

[Click here to view the InterQual® criteria.](#)

Hallux Rigidus (Correction With Implant)

Correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release with implant is proven and medically necessary when all of the following criteria are met:

- Diagnosis of hallux rigidus to include the following:
 - Radiographic imaging to confirm a moderate to severe pathology (e.g., a [grading scale such as the Coughlin and Shurnas or Hattrup Johnson Classification](#) may be used)
- Persistent pain despite a reasonable trial of conservative treatment including one or more of the following:
 - Orthotics, shoe modification (e.g., high and wide toe box, rocker bottom sole), and/or shoe inserts
 - Medical therapy (NSAIDs, analgesics, or intra-articular injections)
 - Activity modification
 - Debridement of hyperkeratotic lesions if present

Osteochondral allograft or autograft transplantation is unproven and not medically necessary for treating cartilage defects of the foot due to insufficient evidence of efficacy.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
28285	Correction, hammertoe (e.g., interphalangeal fusion, partial or total phalangectomy)
28289	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; without implant
28291	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant
28292	Correction, hallux valgus with bunionectomy, with sesamoidectomy when performed; with resection of proximal phalanx base, when performed, any method
28295	Correction, hallux valgus with bunionectomy, with sesamoidectomy when performed; with proximal metatarsal osteotomy, any method
28296	Correction, hallux valgus with bunionectomy, with sesamoidectomy when performed; with distal metatarsal osteotomy, any method
28297	Correction, hallux valgus with bunionectomy, with sesamoidectomy when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method
28298	Correction, hallux valgus with bunionectomy, with sesamoidectomy when performed; with proximal phalanx osteotomy, any method
28299	Correction, hallux valgus with bunionectomy, with sesamoidectomy when performed; with double osteotomy, any method
28899	Unlisted procedure, foot or toes
29893	Endoscopic plantar fasciotomy

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Description of Services

Hallux rigidus also known as a stiff great toe, is a common condition in individuals with a degenerative joint disease such as osteoarthritis, rheumatoid arthritis, or gout. Symptoms involve pain and swelling resulting from friction between denuded bone surfaces of the damaged first metatarsophalangeal joint (MTPJ) and stiffness resulting from abnormal bone growths, known as osteophytes, which lock the joint in place. The condition typically worsens over time and may cause significant disability if untreated. Surgery is indicated when conservative measures fail to provide sufficient relief.

In cases of early hallux limitus and/or hallux rigidus with mild damage, removing some bone and the bone spur on the dorsum of the foot and big toe can be sufficient. This procedure is known as a cheilectomy. Osteophyte and outer epiphysis bone resection to restore range of motion. Cheilectomy is less drastic than arthrodesis and/or joint arthroplasty and can preserve motion, but symptoms are likely to return as joint degeneration progresses. This procedure can be combined with other procedures such as an osteotomy where the metatarsal diaphysis is shortened to separate the first MTPJ surfaces which relieves pressure at the top of the joint.

Advanced stages of hallux rigidus with moderate to severe joint damage can be treated with arthrodesis and/or arthroplasty.

Clinical Evidence

Hallux Limitus or Hallux Rigidus

There are several surgical approaches available for treating severe hallux rigidus if conservative measures are not effective. Cheilectomy without implant is often performed in the early stages of hallux rigidus while cheilectomy with implant is more effective for moderate to severe conditions. Additional published randomized control trials (RCTs) with long term follow-up are needed to demonstrate the efficacy of cheilectomy without implant for severe hallux rigidus.

A systematic review and meta-analysis by de Bot et al. (2022) compared arthrodesis to metallic hemiarthroplasty for the treatment of end-stage hallux rigidus. The authors evaluated clinical outcomes, pain reduction, complications, and revision rates. A total of 33 studies were included for analysis. Only six studies were eligible for the meta-analysis. Clinical outcomes, complication rates, and revisions were comparable after both interventions. The lowest pain score was observed after arthrodesis. The authors concluded that arthrodesis seems to be superior in pain reduction, while metallic hemiarthroplasty is a suitable alternative for patients performing activities that requires motion in the first MTPJ. Study limitations include a lack of RCTs comparing both interventions. Included evaluation and retrospective cohort studies were moderate to low level evidence. Additionally, the majority of studies had short- to mid-term follow-up.

Rajan et al. (2021) supplied an in-depth biomechanical analysis to examine the effects of the first MTPJ replacement for hallux rigidus on gait mechanics. Pressure plate readings, the Manchester-Oxford Foot Questionnaire (MOXFQ) and a validated outcome measure before surgery and 6 and 12 months after surgery. The study's findings showed that Kinematic data substantially increased stride length, cadence, and velocity after first MTPJ replacement for hallux rigidus. Foot kinematic data exposed reduced tibia-hindfoot abduction and pronation and diminished hindfoot-forefoot supination and adduction. There was no effect on the first MTPJ weight-bearing range of motion. Pressure plate data revealed improved peak pressure and pressure time integral towards the first metatarsal after surgery. There was a substantial improvement in the patient-reported outcome measures. The authors concluded an increase in pressure and total load of the plantar area under the first metatarsal head as the individual redistributes more weight to the medial column. The foot inter-segment kinematics also show changes that permit the above pressure reallocation. These favorable mechanical variations and advanced MOXFQ scores also improve self-confidence and permit improved gait velocity, stride length, and cadence.

Patel and colleagues (2019) systematically reviewed literature investigating the clinical outcomes and complications following interposition arthroplasty for moderate to severe hallux rigidus for individuals who prefer to maintain a range of motion in the first MTPJ and included a meta-analysis. Included in the review were 340 individuals, with an average duration of follow-up being 38.08 months. The results of the review utilizing the American Orthopedic Foot and Ankle Society (AOFAS) scores demonstrated across 14 studies (207 individuals) an improvement from the average preoperative score of 41.35 points to the average post-operative score of 83.17 points at a mean follow-up of 36.4 months. Of the studies, mean pain, function, and alignment scores improved from 14.1, 24.9, and 10.0 AOFAS points to post-operative values of 33.3, 35.8, and 14.5 in that order. The overall complications following autograft interposition arthroplasty included: metatarsalgia (13.9%), loss of ground contact (9.7%), osteonecrosis (5.4%), weakness of great toe (4.8%), diminished push-off power (4.2%), callous formation (4.2%), hypoesthesia (4.2%), stress fracture (2.4%), restricted movement (1.2%), and algodystrophy (0.6%). The complications of allograft interposition arthroplasty included: failure leading to revision surgery (2.8%), recurrence of hallux valgus (2.8%), claw toe deformity (1.4%), and weakness of the great toe (1.4%). There were no significant improvements from the preoperative to post-operative scores in both groups ($p < 0.001$), and no significant difference in the preoperative AOFAS scores ($p = 0.771$), and the post-operative scores in the autograft group were significantly higher than allograft group ($p = 0.003$), and significant improvements from pre- to post-operative scores in both groups was demonstrated ($p < 0.001$). The mean range of motion improved from 21.06 degrees to 46.43; joint space increased from 0.8 mm to 2.5mm. Limitations of the study include small sample size, quality of the studies (level IV and III evidence), lack of reporting of preoperative scores in many included studies, heterogeneity, and lack of long-term follow-up. The authors concluded that interposition arthroplasty is an effective treatment option with acceptable clinical outcomes for individuals with moderate-severe hallux rigidus who prefer to maintain a range of motion and accept the risk of further complications. Added randomized prospective trials with larger sample sizes, more uniform methods, and longer follow up are necessary to further support the applicability as a treatment option of choice before arthrodesis.

In 2019, Emmons and Carreira systematically reviewed the literature on the outcomes following interposition arthroplasty of the first MTPJ for treating hallux rigidus. Four hundred ninety-eight individuals were included in the review, with a follow-up of 4.5 years. The most frequent complication reported was transferred metatarsalgia of one or lesser toes, with the average incidence being 0.0% to 57.9%. Less common complications conveyed involved calluses below the lesser metatarsal heads (27.3%- 42.8%), stress fracture of one of the lesser toes subsequent transfer metatarsalgia (4.8%- 9.1%), sensory neuroma or hyperpigmentation at the autograft harvesting site (6.7%-14.3%), radiographic evidence of osteonecrosis of the first metatarsal head (7.7%-40.8%), numbness at the dorsum of the hallux or generalized hypoesthesia of the hallux (9.1%-15.8%), infection with or without the obligation of subsequent debridement (1.5%-6.7%), cock-up deformity (4.5%), proximal phalangeal cystic development (8.7%), claw-toe deformity (5.6%), extensor hallucis longus (EHL) tendon entrapment (3.1%), capsular ossification (4.5%), and regional pain syndrome (4.5%). In the 14 studies unequivocally relating the need for additional surgery on the ipsilateral first MTPJ, (3.8%) toes improved to a later operation. The subsequent surgeries incorporated arthrodesis (range of progression frequency, 2.3%- 9.5%), revision interposition arthroplasty (0.75%), manipulation under anesthesia to improve range of motion (4.8%), debridement of the joint with EHL tenolysis (0.75%), and debulking of a large graft and further proximal phalangeal resection (6.7%). Of the

eight studies recording pre- and postoperative scores through an unmodified American Orthopedic Foot and Ankle Society-Hallux Metatarsophalangeal Interphalangeal (AOFAS-HMI) scale, (75.0%) described mean improvement in the total score greater than 30.2 points, with the two other studies describing mean developments of 23.0 and 24.6, in that order. Of the four studies conveying pre- and post-operative scores by one of these procedures, all demonstrated the average progresses surpassing the minimal clinically important difference (MCID)s for their respective scoring systems (MCIDs: Foot and Ankle Ability Measure Activities of Daily Living Subscale (FAAM-ADL), 8; Foot and Ankle Ability Measure Sports Subscale (FAAM-Sports), 9; Pain Visual Analog Scale (VAS), 30% difference; (Foot Function Index) FFI-Total, 7). Ten (50%) studies described pre- and postoperative range of motion measurements with statistical therapy of the examined variations in the range of motion. Nine (90.0%) of these reports described statistically significant advancements in dorsiflexion from pre-operation to post-operation, while the two reports measuring variation in plantarflexion observed no advances in this measure. Limitations included the need for more prospective, multi-armed analyses employing a reliable and proven standard scoring measure averted the likelihood of meta-analyses and strong treatment suggestions. Furthermore, the generalizability and sustainability of the contained studies' outcomes are challenging to measure, provided that the treatment populations were less than 30 individuals in 75% of the incorporated analyses and 70% of the studies assessed individuals at fewer than midterm follow-up periods. The authors concluded that interposition arthroplasty is a practical possibility for treating moderate to severe hallux rigidus for individuals considering salvaging motion through the first MTPJ. Patient-reported results indicate high post-operative satisfaction and enhanced postoperative range of motion in dorsiflexion is commonly observed irrespective of interpositional material and operative method.

In a systematic review of 28 studies investigating the use of silastic implants for surgical management of end-stage osteoarthritis (OA) of the first MTPJ, Majeed (2019) concluded that silastic joint replacement could be a good alternative to arthrodesis in older and less active individuals who want to preserve movement in their first MTPJ. The studies included 2354 feet, of which 1884 received silastic replacements. Only one of the studies was prospective with the rest being retrospective in design. The average age was 53 years, and the average follow-up was 85.3 months. Four of the studies presented results with more than 10 years of average follow up, seven had an average follow-up of more than five years, and the remaining 17 had an average follow up of less than five years. The review demonstrated that 76.6% of 1804 feet documented improvement in pain with an average patient satisfaction rate of 84%. The author noted that 124 (5.3% of the 1884 feet with silastic implants experienced failure of the prostheses and that significantly more (11%) of those who had single-stemmed implants experienced failure than those who received double-stemmed implants (3.6%) although the length of time from surgery to implant failure was highly variable among different studies. Limitations noted by Majeed include the small populations with shorter follow-up times in most of the studies, the risk of bias from missing data in the retrospective studies, the lack of control groups and the potential difficulties individuals may have had recalling their pre- and post-operative symptoms due to the time period between surgery and survey. The author concluded that more long-term prospective RCTs with larger cohorts are needed to evaluate the use of current silastic implants as an alternative to the traditional arthrodesis procedure.

Park et al. (2019) completed a meta-analysis of five retrospective and two prospective comparative studies to identify whether implant arthroplasty or arthrodesis is superior for treating severe hallux rigidus. The authors concluded that there were no significant differences between the two surgical approaches in the AOFAS-HMI score, patient satisfaction rate, reoperation rate, or complication rate. They noted that, based on the three studies that contributed to the VAS analysis for pain, the VAS scores were significantly lower in the arthrodesis group than in the implant arthroplasty group. In their analysis of patient satisfaction, the authors noted that satisfaction tended to be lower in the implant arthroplasty group but was not statistically significant based on the three studies that contributed to the analysis of this measure. The reoperation rate did not differ significantly between the implant arthroplasty and arthrodesis groups based on their analysis of the rate in seven studies. The authors concluded that their meta-analysis showed that implant arthroplasty and arthrodesis of the first MTPJ led to similar clinical outcomes, patient satisfaction, reoperation rates, and complication rates, whereas pain was significantly lower in arthrodesis. Limitations that the authors identified included the small number of studies obtainable and the still smaller number of studies (small sample sizes) available for the analyses for pain, patient satisfaction, and the AOFAS-HMI scores. They also noted heterogeneity among the implants included in the studies and the post-operative physical therapy programs. The authors concluded that further RCTs are needed to strengthen the conclusions of their meta-analysis.

Kon Kam King et al. (2017) systematically reviewed the non-operative management of hallux rigidus. The review included 11 studies that were assigned a level of evidence (I-IV). Individual studies were reviewed to provide a grade of recommendation (A-C, I) according to the Wright classification in support of or against the non-operative modality. Based on the results of the evidence-based review, there is poor evidence (grade C) to support the use of intra-articular injections for pain relief for three months and fair evidence (grade B) against the use of intra-articular injections for long-term efficacy. There is poor evidence (grade C) to support manipulation and physical therapy and poor evidence (grade C) to support footwear, insoles, and orthotics modifications. There was no good evidence (grade A) recommending any

interventions. Overall, most of the interventions showed improvement. However, the evidence poorly recommends orthosis, manipulation, and intra-articular injections. One study limitation included the different grades of hallux rigidus that were reviewed. There is a need for high-quality RCTs with validated outcome measures to allow for stronger recommendations. Non-operative management should still be offered prior to surgical management.

A level III systematic review by McNeil et al. (2013) determined that there were no consistent findings among published studies to allow any definitive conclusions on which surgical approach is best for treating hallux rigidus. The authors reviewed 135 studies and assigned each study a level of evidence (I-V) to denote quality and to prove a grade recommendation (A-C) in support of or against the surgical approach. Based on the results of their review, the authors determined that there is fair evidence (grade B) in support of arthrodesis for treating hallux rigidus. Other approaches, including cheilectomy, osteotomy, implant arthroplasty, resection arthroplasty, and interpositional arthroplasty for treating hallux rigidus, had poor evidence (grade C) due to the mostly level IV and V studies for these approaches. The authors also determined that there was insufficient evidence (grade I) for cheilectomy with osteotomy for treating hallux rigidus. Limitations noted by the authors included the use of unvalidated rating scales in many of the studies and that the surgical approach was often chosen based on the severity of hallux rigidus and was, therefore, biased in operative selection and inclusion. This selection process may have distorted results as individuals with less severe hallux rigidus likely had a higher level of function post-operatively. They concluded that there were no consistent findings in comparative studies that were properly powered with validated and appropriate outcome measures to allow for definitive conclusions on which procedure may be superior. The authors stated that further studies with high-quality, Level I RCTs with validated outcome measures and longer-term follow-up were needed to make more substantial recommendations. (Maffulli et al. (2011), previously summarized in this policy, is included in the McNeil systematic review.)

Various scales have been used to grade the severity of hallux rigidus, although the scales proposed by Hattrup and Johnson (1988) and Coughlin and Shurnas (2003) are the most common. Either scale can be used to determine whether hallux rigidus is mild, moderate, or severe.

Radiographic	Clinical	Qualitative	Hattrup and Johnson	Coughlin and Shurnas
No radiographic evidence for osteoarthritis	No pain +/- mild stiffness		–	0
Mild-to-moderate osteophyte formation with no joint space involvement	Mild pain maximal with flexion, mild stiffness	Mild	I	1
Moderate osteophyte formation and joint space narrowing; subchondral sclerosis	Moderate-to-severe pain constant at the extremes of motion, moderate-to-severe stiffness	Moderate	II	2
Marked osteophyte formation and loss of the joint space, cystic changes with or without subchondral sclerosis	Nearly constant pain (3), pain throughout the range of motion (including midrange) (4)	Severe	III	3 or 4

Osteochondral Allograft or Autograft Transplantation

The evidence for osteochondral grafts in the foot consists of small case series and is insufficient to draw conclusions regarding the effect of this treatment on health outcomes. Further studies with a larger number of patients and longer follow-up are needed, including studies that compare osteochondral grafts with established treatments.

A systematic review of case reports and small case series evaluated surgical treatments for focal osteochondral lesions of the first metatarsal head. Eleven studies (n = 90) were included in the analysis. Osteochondral autograft was the most used technique. After surgery, an improvement was achieved in AOFAS, VAS, and hallux dorsiflexion but not in plantarflexion. The authors noted that while good clinical results have been achieved, the small number of patients limits the conclusions. Further high-level comparative studies are necessary to design an evidence-based treatment algorithm (Artioli et al., 2023).

Diniz et al. (2019) systematically reviewed the use of allografts in the surgical treatment of foot and ankle disorders in adult patients. Of 107 studies included in the analysis, three (n = 24) evaluated the use of allografts for the treatment of hallux rigidus. All three studies were evidence level IV. Two studies used interpositional arthroplasty procedures, and one study used bipolar fresh osteochondral allograft transplantation. Although AOFAS scores improved in all three studies,

range of motion remained severely restricted in the two studies that reported this outcome. The authors noted that this same increase in AOFAS score could be expected with other procedures, such as arthrodesis or arthroplasty.

Clinical Practice Guidelines

National Institute for Health and Care Excellence (NICE)

The 2022 Interventional procedures guidance published by NICE on the synthetic cartilage implant insertion for first MTPJ OA (hallux rigidus) provided the following recommendations:

- For individuals with advanced disease for whom arthrodesis is revealed, evidence on the safety of synthetic cartilage implant insertion for first MTPJ OA (hallux rigidus) displays no major safety concerns in the short term. Evidence on effectiveness is restricted in quantity and quality. Consequently, for this population, this procedure should only be utilized with unique clinical governance, consent, and audit or research provisions.
- For all others with hallux rigidus, evidence on the safety of synthetic cartilage implant insertion for hallux rigidus demonstrates no major safety concerns in the short term. Evidence on efficacy needs to be more in quantity and quality. Hence, for these individuals, this procedure should only be used in the research context.
- Clinicians intending to do synthetic cartilage implant insertion for hallux rigidus for individuals with advanced disease for whom arthrodesis is otherwise specified must:
 - Notify the clinical governance leaders in their healthcare organization.
 - Offer individuals (and their relatives and caregivers as applicable) explicit printed material to support shared decision-making, including NICE's information for the public.
 - Ensure that individuals (and their families and caregivers as applicable) comprehend the procedure's safety and efficacy and any ambiguities about these.
 - Register details about all individuals receiving synthetic cartilage implant insertion for first MTPJ OA (hallux rigidus) onto the British Orthopaedic Foot & Ankle Society (BOFAS) Registry and evaluate local clinical results.
 - Consider with the individual and family the procedure results during their annual assessment to reflect, learn and progress.
- Healthcare organizations ought to:
 - Guarantee systems encourage clinicians to assemble and report data on results and safety for every individual receiving this procedure.
 - Frequently evaluate data on results and safety for this procedure.
- Added research should incorporate adequately powered randomized controlled trials. These should inform details of patient selection, the stage of OA, and patient-reported outcomes such as pain, mobility and quality of life, and long-term results associated with the implant.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Surgeries of the foot are procedures and, therefore, not regulated by the FDA. However, devices and instruments used during the surgery may require FDA approval. Search the following website for additional information:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed October 20, 2024)

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Policy History/Revision Information

Date	Summary of Changes
04/01/2025	<p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised language pertaining to medical necessity clinical coverage criteria; added reference to the InterQual® CP: Procedures, Osteotomy, Proximal Phalanx, First Toe +/- Bunionectomy <p>Supporting Information</p> <ul style="list-style-type: none"> Archived previous policy version CS342OH.D

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]) or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC) or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC) or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC) or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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