

### UnitedHealthcare® Commercial and Individual Exchange *Medical Policy*

# **Surgery of the Foot**

Policy Number: 2025T0624N Effective Date: August 1, 2025

Instructions for Use

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### Related Commercial/Individual Exchange Policy

- Extracorporeal Shock Wave Therapy (ESWT) for <u>Musculoskeletal Conditions and Soft Tissue</u> Wounds
- Outpatient Surgical Procedures Site of Service

#### **Community Plan Policy**

Surgery of the Foot

### **Application**

#### **UnitedHealthcare Commercial**

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

### UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

# 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
- 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 Limitus or Rigidus (Correction Without Implant)**

Correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release without implant is proven and medically necessary when all of the following criteria are met:

- Diagnosis of hallux limitus or hallux rigidus to include the following:
  - o Radiographic imaging to confirm a mild to moderate 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
  - o Medical therapy (NSAIDs, analgesics, or intra-articular injections)
  - Activity modification
  - Debridement of hyperkeratotic lesions, if present

Surgery of the Foot UnitedHealthcare Commercial and Individual Exchange Medical Policy Correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release without implant is unproven and not medically necessary for severe hallux rigidus (e.g., a grading scale such as the Coughlin and Shurnas or Hattrup Johnson Classification may be used) due to insufficient evidence of efficacy.

#### **Hallux Rigidus (Correction With Implant)**

Correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release with implant (<u>Hemi-Implant</u> or <u>Total Implant Arthroplasty</u>) 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 <u>grading scale such as the Coughlin and</u> 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
  - o Medical therapy (NSAIDs, analgesics, or intra-articular injections)
  - Activity modification
  - o Debridement of hyperkeratotic lesions, if present

### Osteochondral Allograft or Autograft Transplantation

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

### **Medical Records Documentation Used for Reviews**

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the protocol titled Medical Records Documentation Used for Reviews.

### **Definitions**

**Hemi-Implant Arthroplasty**: A surgical procedure to replace one side of a joint with a prosthetic implant. Also known as partial joint replacement. This does not include <u>Interposition Arthroplasty</u> [American Orthopaedic Foot & Ankle Society (AOFAS), 2025].

**Interposition Arthroplasty**: A surgical procedure to remove some of the damaged bone and place a spacer (e.g., soft tissue graft) between two bones to minimize contact on either side of the joint. Also known as joint resurfacing (AOFAS, 2025).

**Total Implant Arthroplasty**: A surgical procedure to replace both sides of a joint with prosthetic implants. Also known as total joint replacement. This does not include <u>Interposition Arthroplasty</u> (AOFAS, 2025).

# **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 the member specific benefit plan document 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

CPT Code	Description
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.

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.

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

Radiographic	Clinical	Qualitative	Hattrup and Johnson	Coughlin and Shurnas
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. Most available studies are small, retrospective case series or cohort studies with limited long-term follow-up. There is heterogeneity in techniques and outcome measures. 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)

Guidance from NICE (2022) on synthetic cartilage implant insertion for first MTPJ OA (hallux rigidus) provides 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:
  - o Notify the clinical governance leaders in their healthcare organization.
  - Offer individuals (and their relatives and caregivers as applicable) explicit printed material to support <u>shared</u> 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 <u>British Orthopaedic Foot & Ankle Society (BOFAS) Registry</u> and evaluate local clinical results.
  - o 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 longterm 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: <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm</a>. (Accessed March 25, 2025)

### References

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Diniz P, Pacheco J, Flora M, Quintero D, Stufkens S, Kerkhoffs G, Batista J, Karlsson J, Pereira H. Clinical applications of allografts in foot and ankle surgery. Knee Surg Sports Traumatol Arthrosc. 2019 Jun;27(6):1847-1872.

Hattrup SJ, Johnson KA. Subjective results of hallux rigidus following treatment with cheilectomy. Clin Orthop Relat Res. 1988 Jan;(226):182-91.

Maffulli N, Papalia R, Palumbo A, et al. Quantitative review of operative management of hallux rigidus. Br Med Bull. 2011; 98:75-98.

McNeil DS, Baumhauer JF, Glazebrook MA. Evidence-based analysis of the efficacy for operative treatment of hallux rigidus. Foot Ankle Int. 2013 Jan;34(1):15-32.

National Institute for Health and Care Excellence (NICE) Interventional procedures guidance (IPG727). Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus). June 2022.

Park YH, Jung JH, Kang SH, Choi GW, Kim HJ. Implant Arthroplasty versus Arthrodesis for the Treatment of Advanced Hallux Rigidus: A Meta-analysis of Comparative Studies. J Foot Ankle Surg. 2019 Jan;58(1):137-143.

Rajan RA, Kerr M, Evans H, Outram T. A prospective clinical and biomechanical analysis of feet following first metatarsophalangeal joint replacement. Gait Posture. 2021 Sep; 89:211-216.

### Policy History/Revision Information

Date	Summary of Changes
<b>Date</b> 08/01/2025	Related Policies  Added reference link to the Medical Policy titled Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds  Coverage Rationale Hallux Rigidus (Correction With Implant)  Replaced language indicating "correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release with implant is proven and medically necessary when all of the [listed] criteria are met" with "correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release with implant (Hemi-Implant or Total Implant Arthroplasty) is proven and medically necessary when all of the [listed] criteria are met"  Definition
	<ul> <li>Added definition of:</li> <li>Hemi-Implant Arthroplasty</li> <li>Interposition Arthroplasty</li> <li>Total Implant Arthroplasty</li> </ul>

Date	Summary of Changes
	Supporting Information
	Updated Clinical Evidence and References sections to reflect the most current information
	Archived previous policy version 2025T0624M

### **Instructions for Use**

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.