

Surgery of the Foot

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[➔ Instructions for Use](#)

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Community Plan Policy
• Surgery of the Foot

Application

UnitedHealthcare Commercial

This Medical Policy applies to all UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans in all states except for Colorado.

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)
- 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 the following criteria are met:

- Diagnosis of hallux limitus or hallux rigidus to include the following:
 - 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 and/or shoe inserts
 - Medical therapy (NSAIDs, analgesics or intra-articular injections)
 - Activity modification
 - Debridement of hyperkeratotic lesions if present

Due to insufficient evidence of efficacy, 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).

Hallux Limitus or 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 the following criteria are met:

- Diagnosis of hallux limitus or 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 and/or shoe inserts; and
 - Medical therapy (NSAIDs, analgesics or intra-articular injections); and
 - Activity modification; and
 - Debridement of hyperkeratotic lesions if present

Documentation Requirements

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 documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT Codes*	Required Clinical Information
Surgery of the Foot	
28285 28289 28291 28292 28296 28297 28298 28299 29893	<p>Medical notes documenting the following, when applicable:</p> <ul style="list-style-type: none"> • Upon request, we may require the specific diagnostic image(s) that show the abnormality for which surgery is being requested, which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be of benefit to select the optimal images <ul style="list-style-type: none"> ○ Note: When requested, diagnostic image(s) must be labeled with: <ul style="list-style-type: none"> ▪ The date taken ▪ Applicable case number obtained at time of notification, or member's name and ID number on the image(s) ○ Upon request, diagnostic image(s) must be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted • Reports of recent imaging studies and applicable diagnostic tests, including confirmation of joint pathology using a standard scale, such as the Coughlin and Shurnas or Hattrup Johnson Classification • Condition requiring procedure • Severity of pain, skin breakdown, and details of functional impairment, including impact on activities of daily living (ADL) • Pertinent physical examination of the relevant joint • Co-morbid medical condition(s) • Prior therapies/treatments (e.g., padding, orthotic, footwear, physical therapy, activity modification, medications, etc.) tried, failed, or contraindicated; include the dates, duration, and reason for discontinuation • History of previous foot surgery(ies), if applicable • Physician's treatment plan including pre-op discussion

CPT Codes*	Required Clinical Information
Surgery of the Foot	
	<ul style="list-style-type: none"> For revision surgery, also include: <ul style="list-style-type: none"> Details of complication Complete (staged) surgical plan If the location is being requested as an inpatient stay, provide documentation to support site of care

*For code descriptions, refer to the [Applicable Codes](#) section.

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
Arthrodesis or Arthroplasty, Interphalangeal Joint, Second-Fifth Toes	
28285	Correction, hammertoe (e.g., interphalangeal fusion, partial or total phalangectomy)
Exostectomy, First Metatarsophalangeal (MTP) Joint (Bunionectomy)	
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 (bunionectomy), with sesamoidectomy, when performed; with resection of proximal phalanx base, when performed, any method
Osteotomy, Proximal, First Metatarsal (MT) (Bunionectomy)	
28295	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal metatarsal osteotomy, any method
28297	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method
28298	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal phalanx osteotomy, any method
28299	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with double osteotomy, any method
Osteotomy, Distal Transpositional, First Metatarsal (MT) (Bunionectomy)	
28296	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with distal metatarsal osteotomy, any method
28299	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with double osteotomy, any method
Plantar Fascial Release	
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 metatarsophalangeal joint 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 metatarsophalangeal joint 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

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.

Rajan et al. (2021) supplied an in-depth biomechanical analysis to examine the effects of the first metatarsophalangeal joint (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 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 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 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 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. He concluded that more long-term prospective RCT studies 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. There is very little evidence for the non-operative management of hallux rigidus. The results of this review included 11 studies that were then assigned to 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 this 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 after the non-operative. 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 Level I randomized controlled trials with validated outcome measures to allow for stronger recommendations to be made. 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.

Deland and Williams (2012) reviewed the surgical management of Hallux rigidus. Hallux rigidus is the most common degenerative joint pathology of the foot. If left untreated, it may result in notable limitations in gait, activity level, and daily function. Positive outcomes can be achieved with nonsurgical management; surgery is recommended for the symptomatic individual when nonsurgical measures have failed to control symptoms adequately. Surgery is carefully chosen based on the grade of involvement. Early to mid-stage hallux rigidus is best treated with cheilectomy or cheilectomy and proximal phalanx osteotomy. Cheilectomy, whether alone or in combination with phalangeal osteotomy, has resulted in high satisfaction rates in persons with grade 1 or 2 hallux rigidus and without pain during the midrange of motion. Studies have often grouped grades 1 through 3 together, and there needs to be more studies that specifically evaluate individuals with grade 3 hallux rigidus. Arthrodesis and arthroplasty are reserved for late-stage hallux rigidus.

Maffulli et al. (2011) systematically reviewed the surgical management of hallux rigidus. This included cheilectomy, Keller resection arthroplasty, arthrodesis, Silastic implantation, phalangeal or metatarsal osteotomy, capsular arthroplasty, partial or total joint replacement, and interposition arthroplasty. A total of 70 studies were included in the results. Results indicated that the success rate was 74% after cheilectomy, 69% after osteotomy, 73.2% after arthrodesis, 70.2% after arthroplasty, and 73.4% after interpositional arthroplasty. The surgical criteria are based on the deformity grading classified by a grading scale. Hattrup and Johnson's and Coughlin and Shurnas' classifications are the most used scales. The indications for surgical management are somewhat unclear. Regardless of the classification, cheilectomy and osteotomy should be performed in the early stages of hallux rigidus (stages I-II), arthrodesis or arthroplasty are indicated to manage more severe cases (stages III-IV). No study

reported on the clinical and functional status and the return to a preoperative level. (Hatrup 2013 and Coughlin 2003 are included in this review.) Various scales have been used to grade the severity of hallux rigidus, although the scales proposed by Hatrup and Johnson and Coughlin and Shurnas are the most common. Either scale can be used to determine whether hallux rigidus is mild, moderate, or severe.

Radiographic	Clinical	Qualitative	Hatrup 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

Roukis et al. (2010) in a systematic review, studied the safety and efficacy of cheilectomy with phalangeal dorsiflexory for treating all grades of hallux rigidus. Studies were considered only if they involved consecutively enrolled participants undergoing cheilectomy with phalangeal dorsiflexory osteotomy. Eleven studies involving a total of 374 procedures were identified that met the inclusion criteria. Pain was relieved or improved in 149/167 (89.2%) procedures, and 139/217 (77%) participants related to being satisfied or very satisfied with their outcomes. A total of 18 (4.8%) procedures underwent surgical revision. Six studies involving 177 procedures specified the grade of hallux rigidus as follows: grade I, 10.2%; grade II, 72.3%; and grade III, 17.5%. The results of this systematic review validate the general improvement in objective and subjective data as well as the low incidence of revision surgery required after cheilectomy with phalangeal dorsiflexory osteotomy for hallux rigidus. Consequently, cheilectomy with phalangeal dorsiflexory osteotomy should be considered a first-line surgical treatment for hallux rigidus. Nevertheless, there is still a need for methodologically sound prospective cohort studies that concentrate on using this procedure for specific grades of hallux rigidus and compare the subjective and objective outcomes and the need for surgical revision with other procedures.

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.

In 2005, NICE published interventional procedures guidance for MTPJ replacement of the hallux. The guidance reads as follows:

- Existing data on the safety and efficacy of MTPJ replacement of the hallux seems sufficient to support this procedure, given that the standard agreements are in place for consent, audit, and clinical governance.
- Clinicians ought to confirm that individuals comprehend the ambiguities about the place of this procedure relative to alternate treatment possibilities. Individuals should be supplied with clear written information, and, in addition, the use of the Institute's information for the public is suggested.
- Patient selection is critical and should consider the probable strength and length of use of the joint based on the individual's activities and ambitions.
- More research will be beneficial in determining the long-term results of various types of prostheses.

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 and ankle are procedures and, therefore, not regulated by the FDA. However, devices and instruments used during the surgery may require FDA approval. Refer to the following website using product codes HWC or LZJ for additional information: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed February 18, 2023)

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Policy History/Revision Information

Date	Summary of Changes
10/01/2023	<p>Application</p> <p>Individual Exchange Plans</p> <ul style="list-style-type: none">Removed language indicating this Medical Policy does not apply to Individual Exchange benefit plans in the states of Massachusetts, Nevada, and New York <p>Supporting Information</p> <ul style="list-style-type: none">Archived previous policy version 2023T0624G

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.