Surgery of the Ankle

Policy Number: 2025T0622J
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Related Commercial/Individual Exchange Policy

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Application

UnitedHealthcare Commercial

This Medical Policy applies to 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 ankle is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the:

- InterQual® CP: Procedures:
  - Arthrodesis, Ankle (Talotibial Joint)
  - Arthroscopy, Surgical, Ankle
  - Arthrotomy, Ankle
  - Total Joint Replacement (TJR), Ankle
- InterQual® Client Defined, CP: Procedures:
  - Arthroplasty, Ankle (Without Implant) (Custom) - UHG
  - Arthroplasty, Removal or Revision, Ankle (Custom) - UHG

Click here to view the InterQual® criteria.

Osteochondral allograft or autograft transplantation is unproven and not medically necessary for treating cartilage defects of the ankle 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.

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
Arthrotomy, Ankle	
27685	Lengthening or shortening of tendon, leg or ankle; single tendon (separate procedure)
28446	Open osteochondral autograft, talus (includes obtaining graft[s])
28899	Unlisted procedure, foot or toes
Total Joint Replacement (TJR), Ankle	
27700	Arthroplasty, ankle
27702	Arthroplasty, ankle; with implant (total ankle)
27703	Arthroplasty, ankle; revision, total ankle
27704	Removal of ankle implant
Arthroscopy, Surgical, Ankle	
29891	Arthroscopy, ankle, surgical, excision of osteochondral defect of talus and/or tibia, including drilling of the defect
29892	Arthroscopically aided repair of large osteochondritis dissecans lesion, talar dome fracture, or tibial plafond fracture, with or without internal fixation (includes arthroscopy)
29894	Arthroscopy, ankle (tibiotalar and fibulotalar joints), surgical; with removal of loose body or foreign body
29895	Arthroscopy, ankle (tibiotalar and fibulotalar joints), surgical; synovectomy, partial
29897	Arthroscopy, ankle (tibiotalar and fibulotalar joints), surgical; debridement, limited
29898	Arthroscopy, ankle (tibiotalar and fibulotalar joints), surgical; debridement, extensive
29899	Arthroscopy, ankle (tibiotalar and fibulotalar joints), surgical; with ankle arthrodesis
Arthrodesis, Ankle (Talotibilial Joint)	
29899	Arthroscopy, ankle (tibiotalar and fibulotalar joints), surgical; with ankle arthrodesis

Description of Services

Osteoarthritis is also known as degenerative arthritis and common for many people after they reach middle age, however it may occur in younger people as well. In osteoarthritis, the cartilage in the joint gradually wears away. As the cartilage wears away, it becomes frayed and rough, and the protective space between the bones decreases. This can result in bone rubbing on bone and produce painful osteophytes (bone spurs).

Posttraumatic arthritis can develop after an injury to the foot or ankle and dislocations and fractures are the most common injuries that lead to post-traumatic arthritis. Like osteoarthritis, posttraumatic arthritis causes the cartilage between the joints to wear away and can develop many years after the initial injury.

Clinical Evidence

Ankle Arthroplasty

Kunutsor et al. (2020) conducted a systematic review and meta-analysis to compare the clinical effectiveness of various treatment approaches for infected ankle prostheses. A systematic electronic search was conducted in Medline, Embase, and the Cochrane Library from inception to December 2018. The authors included longitudinal observational studies and RCTs in individuals with infected ankles that evaluated the clinical impact of any of the following six strategies: long-term suppressive antibiotic treatment without surgical intervention, debridement, and implant retention with or without polyethylene exchange, 1-stage revision surgery, 2-stage revision surgery, prostheses removal with implantation of

cement spacer, and arthrodesis. The authors found arthrodesis and debridement and implant retention (DAIR) with or without polyethylene exchange to be the most common in treating infected ankle prosthesis but associated with poor infection control. Limitations included limited data availability, which identified applied principles of infected total hip arthroplasty (THA) and total knee arthroplasty (TKA) to that of TAA, but because prosthetic joint infection (PJI) of ankles seems to originate from exogenous sources, infection is difficult to diagnose, and therefore, no consensus on the definition of PJI following TAR, thus differences on how to treat the condition.

In Hutchinson and Schweitzer (2020) the authors identify a revision of the ankle as an indication of periprosthetic infection. Following confirmation of infection, there are several options to consider, but antibiotic therapy which includes removal of the implant, and addition of an antibiotic spacer followed by reimplantation in 6 months to 12 months, is usually the first option; other options include grafting or amputation.

In an updated document on PJI, Beam and Osmon (2018) ascertain that the presence of a sinus tract on its own can be a definitive diagnosis of PJI. The most curative surgical approach for PJI involves a two-stage exchange (TSE), which starts with debridement of the infected tissue, removal of existing prosthesis and cement, culture collection, and placement of antibiotic-loaded cement spacer into the joint space to deliver high-dose local antimicrobial therapy and provide structural support.

Known complications of joint replacement continue to require revisional surgery. Steck et al. (2017) list intraoperative and postoperative complications that may require revision for TAA. Intraoperative complications include superficial/deep joint infection, fractures, implant dislocation, and aseptic loosening. Deep periprosthetic infection (DPI) is one of the most common reasons that lead to TAA failure and occurs more than 50% of the time. The authors also maintain that the following factors should be considered when assessing for joint failure: patient symptoms, pain, subsidence, alignment, infection, and implant integrity.

In the Foot and Ankle Clinic Journal, Alrashidi et al. (2017) identify key points for diagnosing and treating infection for TAA. Accurate and complete patient history is imperative to identify clues that raise suspicion for an acute or chronic infection. Physical examination should include the following: general appearance of the ankle and hindfoot, signs of swelling, joint effusion, erythema, excessive warmth, and/or wound healing issues. Range of motion (ROM) should be measured clinically using a goniometer and noted if associated with pain. Conventional radiographs should be conducted; however, CT may provide additional information regarding periprosthetic osteolysis in patients with TAA. Blood tests such as CRP and ESR are easy to perform and cost-effective screening tools and, if elevated, validate the need to perform joint aspiration and synovial fluid analysis and then send on for culture. Treatment options for infected prostheses include antimicrobial therapy, irrigation, debridement, prosthesis removal with implant replacement, or ankle arthrodesis.

Posttraumatic arthritis is common in the ankle joint. In an article titled “The Concept of Ankle Joint Preserving Surgery,” Tanaka (2012) discusses joint-preserving surgical techniques, including arthroscopic debridement, ligament reconstruction, distraction arthroplasty, and osteotomy. The author states that indications for supramalleolar osteotomy are limited but have been used to treat individuals with osteoarthritis of the ankle due to posttraumatic malunion. In addition, because a TAA is not always an indication of an ankle with severe malalignment, realignment surgery may be necessary before arthroplasty.

Osteochondral Allograft or Autograft Transplant (OAT)

There is insufficient quality evidence regarding the safety and efficacy of osteochondral allograft or autograft transplant. Future studies including RCTs with comparison groups are needed along with long-term results.

Migliorini et al. (2022) conducted a systematic review to evaluate the efficacy of surgical management techniques for osteochondral defects (OCD). Surgical management techniques included osteochondral autograft or allograft transplant (OAT), mosaicplasty, matrix-assisted autologous chondrocyte transplantation (MACT) and autologous matrix-induced chondrogenesis (AMIC). There were 13 articles included in the review with a total of 521 procedures with a median length follow-up of 47.8 months (31.7 - 66.8 months). The authors noted there was no difference between the treatment groups at baseline in terms of mean age, body mass index, patient sex, defect size, and visual analog scale (VAS) and American Orthopaedic Foot and Ankle Society (AOFAS) scores. AMIC demonstrated the lowest rates of failure (LOR, 0.94) and revision (LOR, 0.94) while OAT evidenced the highest rates of failure (LOR, 3.48) and revision (LOR, 4.60). Limitations included overall poor quality of many studies with high selection bias due to large number (10 of the 13 included studies) of retrospective comparative studies. Additionally, there were variances in the surgical approach, nature of the membrane, fixation methods, and the location of the lesion.

Lambers et al. (2017) conducted a systematic review to identify the most effective surgical treatment for talar OCD after failed primary surgery. There were 21 studies included in the review with a total of 299 patients with 301 talar OCDs. Of

those studies, 8 were retrospective case series, 12 were prospective case series, and 1 was a randomized controlled trial. Treatment strategies were divided into four groups: bone marrow stimulating (BMS), (debridement and/or drilling), osteochondral transplantation (autograft transfer, allograft transfer and mosaicplasty), cartilage implantation (MACI and ACI) and chondrogenesis-inducing techniques (AMIC). BMS success percentages were 75% (debridement alone) and 69% (debridement and microfracture) with confidence intervals of 47-91% and 42-87%. Osteochondral transplantation was the most common procedure, however, a calculated success rate for all osteochondral transplantation techniques combined was not possible since study designs varied for all studies. The authors were able to use a simplified pooling method which resulted in a mean success rate of 90% (CI 82-95%) for the osteochondral autograft transfer procedure, 65% (CI 46.2-80.6%) for mosaicplasty and 55% (CI 39.7-69.9%) for osteochondral allograft transfer procedure. There was no significant difference between MACI and ACI and the calculated success rate was 72% (CI 56-85%) and 59% (CI 39-77%). The success rates for AMIC were 67% (CI 30-90.3%) and 57% (CI 32.6-78.6%). Limitations of this study include low methodological quality of studies included and nearly half of the extracted data that were acquired through the direct approach of the authors limited the ability to collect all of the variables desired including complications, lesion size, and classification systems used. The authors noted that due to the low level of evidence and the limited number of patients, a methodologically proper meta-analysis could not be completed, and it would be inappropriate to draw firm conclusions from the collected results. Further prospective investigations in a randomized comparative clinical setting are needed.

In a 2013 (updated 2015) health technology assessment, Hayes evaluated the osteochondral allograft transplantation for articular disorders of the ankle. There were 7 small uncontrolled clinical studies that evaluated the safety and efficacy of osteochondral allografting for the treatment of osteochondral lesions of the talus or severe tibiotalar arthritis. Most of the studies were small, only one had a prospective design, and there were no randomized controlled trials identified. Four studies included patients with OLT and 2 studies included patients with ankle arthritis. Mean age range was 30-44 years and follow-up times ranges from a mean of approximately 2 years to 5 years. Most studies showed a significant improvement in the mean scores on standardized instruments for pain and function following allografting with an overall improvement rate in 52% - 89% of patients, however, a considerable number of the allografts failed, requiring repeat allografting, arthrodesis, or arthroplasty (range 11% - 48%). The authors note that the available evidence is insufficient to draw definitive conclusions regarding the safety, efficacy, and durability of osteochondral allograft transplantation for articular ankle disorders. The overall quality of the evidence is low with the existing studies having small numbers of patients and being uncontrolled with the majority being retrospective which is prone to bias. Other limitations included differences in allograft preparation, surgical protocols, inconsistent reporting of radiological outcomes, variability in outcomes measures and follow-up times. Additional studies are needed that are controlled and that compare the long-term effectiveness and safety with other methods of restoring the articular cartilage.

In a 2012 (updated 2014) health technology assessment, Hayes evaluated the osteochondral autograft transplant (OAT) or mosaicplasty for lesions of the talus. There were 10 available studies which included 1 randomized comparative trial, 1 nonrandomized prospective comparative study, 6 prospective studies, and 2 retrospective studies. The authors determined that there was insufficient evidence to support conclusions regarding the efficacy of the OAT or mosaicplasty procedure in patients with osteochondral lesions of the talus (OLT), as well as the relative effectiveness compared with standard procedures. There was an overall low quality of evidence due to poor study design, small patient population, variability in the measures used to assess outcomes, varying follow-up times, and substantial differences in surgical protocols and techniques. Additional well-designed trials with long-term follow-up are needed to evaluate the effectiveness of surgical options for OLT.

Clinical Practice Guidelines

American Academy of Orthopaedic Surgeons (AAOS)

A 2019 Evidence-Based Clinical Practice Guideline for the diagnosis and prevention of periprosthetic joint infections (PJI) recommends the following:

Blood Tests for Preoperative Diagnosis

Strong evidence supports the use of the following to aid in the preoperative diagnosis of PJI:

- Serum erythrocyte sedimentation rate (ESR)
- Serum C-reactive protein (CRP)
- Serum interleukin-6

Synovial Fluid Tests

Moderate strength evidence supports the use of the following to aid in the diagnosis of PJI:

- Synovial fluid leukocyte count and neutrophil percentage
- Synovial fluid aerobic and anaerobic bacterial cultures

- Synovial fluid leukocyte esterase
- Synovial fluid alpha-defensin (α-defensin)
- Synovial fluid C-reactive protein (CRP)
- Synovial fluid nucleic acid amplification testing [e.g., polymerase chain reaction (PCR)] for bacteria

Intraoperative Tests

Strong evidence supports the use of histopathology to aid in diagnosing PJI.
Moderate strength evidence supports the use of the following to aid in the diagnosis of PJI:

- Multiple aerobic and anaerobic bacterial periprosthetic tissue cultures
- Implant sonication fluid aerobic and anaerobic bacterial cultures
- Implant sonication fluid nucleic acid amplification testing (e.g., PCR) for bacteria

Limited strength evidence supports that periprosthetic tissue nucleic acid amplification testing for bacteria is not useful in diagnosing PJI.

Diagnostic Imaging

Limited strength evidence supports the use of the following to aid in the diagnosis of PJI:

- 18F-FDG PET/CT
- 18F-NaF PET/CT
- CT

Limited strength evidence supports the clinical utility of nuclear imaging to aid in diagnosing PJI.

Gram Stain

Moderate strength evidence supports that the practitioner avoids using intraoperative gram stain to rule out PJI.

American Orthopaedic Foot and Ankle Society (AOFAS)

In a position statement (2022a), the AOFAS supports the use of osteochondral autograft and allograft transplantation for the treatment of OLTs that have failed nonsurgical management, especially for large diameter lesions, cystic lesions, and lesions that have failed previous surgical treatment. The society considers osteochondral transplantation to be a treatment option with demonstrated improved outcomes maintained over long term follow up.

In a 2022b position statement from the AOFAS, the society endorses using TAR surgery to treat arthritic conditions of the ankle in select individuals with this condition who have failed nonoperative treatment. The AOFAS does not consider this procedure to be experimental.

In a 2020 consensus statement (Shibuya et al.), the AOFAS addressed the diagnosis and treatment of ankle arthritis. The panel was unable to reach consensus on the statement: “Resurfacing articular surfaces with biologics/scaffolds is a viable option for treatment of ankle arthritis.” Additionally, they were unable to reach consensus on the statement: “Arthroscopic debridement is a viable option for treatment of ankle arthritis.”

National Institute for Health and Care Excellence (NICE)

The 2022 NICE guideline on Osteoarthritis diagnosis and management offers the following recommendations regarding referrals for joint replacement:

- Consider referring people with hip, knee, or shoulder osteoarthritis for joint replacement if:
  - Their joint symptoms (such as pain, stiffness, reduced function or progressive joint deformity) are substantially impacting their quality of life; and
  - Non-surgical management (for example, therapeutic exercise, weight loss, pain relief) is ineffective or unsuitable
- Use clinical assessment when deciding to refer someone for joint replacement, instead of systems that numerically score severity of disease
- Do not exclude people with osteoarthritis from referral for joint replacement because of:
  - Age
  - Sex or gender
  - Smoking
  - Comorbidities
  - Overweight or obesity, based on measurements such as body mass index (BMI)
- If discussing referral for joint replacement, explain to the person with osteoarthritis that the risks of joint replacement can vary depending on the factors listed in recommendation above

In an updated osteoarthritis care and management clinical guideline, the NICE recommends a holistic approach to osteoarthritis which includes patient access to self-management strategies such as exercise, weight loss, and suitable footwear. Oral analgesics (i.e., acetaminophen), NSAIDs, and topical analgesics should be offered for pain relief; intra-articular corticosteroid injections can be considered in addition to core treatments for relieving moderate to severe pain. The guideline also suggests surgery be considered when the individual has not responded to non-surgical treatment (NICE, 2014; updated 2020).

The NICE (2015) interventional procedures guideline states that conservative treatments for ankle osteoarthritis include analgesics, corticosteroid injections to relieve pain and inflammation, in addition to PT and prescribed exercise to improve function and mobility. Surgery may be indicated when symptoms are severe, including procedures such as arthroscopic surgery, fusion, or total ankle replacement.

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 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 for additional information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed March 5, 2024)

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Policy History/Revision Information

Date	Summary of Changes
01/01/2025	**Template Update** • Created shared policy version to support application to UnitedHealthcare West plan membership **Supporting Information** • Archived previous policy versions 2024T0622I and MMG185.G

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® criteria, 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.