Cohere Medicare Advantage Policy - Ankle Arthroplasty

Clinical Policy for Medical Necessity Review

Version: 3
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Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Other Notices:

Policy Information:

Specialty Area: Musculoskeletal Care
Policy Name: Cohere Medicare Advantage Policy - Ankle Arthroplasty
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

Table of Contents

Medical Necessity Criteria

Service: Ankle Arthroplasty

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.

- There are no applicable NCDs and/or LCDs for ankle arthroplasty

Description

Ankle arthroplasty, or total ankle replacement, is a surgical procedure wherein an FDA-approved artificial implant replaces a damaged ankle joint.[1,2] Newer generation three-component implants permit motion at two interfaces, allowing for greater flexibility and long-term stability of the implant.[3] Through a 10 cm incision, the surgeon first debrides osteophytes, inflamed synovial tissue, excessive joint capsule, and clears the medial and lateral gutters. Soft tissue, including tendons, are then retracted and bony structures are resected and shaped to permit implant placement and fixation.

Medical Necessity Criteria

Indications

Ankle arthroplasty is considered appropriate if **ALL** of the following are **TRUE**:

- **ANY** of the following:
  - Current nicotine user with no product use for 6 weeks; and **ANY** of the following[4,5]:
    - Negative urine (cotinine) lab test within 30 days[6]; **OR**
    - Surgery is urgently required due to documented reason; **OR**
  - No history of nicotine product use within the last 12 months[5]; **OR**
  - No lifetime history of nicotine product use[5]; **AND**

- The procedure is an initial ankle arthroplasty, and **ALL** of the following are **TRUE**:
  - TIbiotalar joint disease is present with **ALL** of the following[7]:
    - The patient is experiencing **ANY** of the following:
      - Moderate or severe pain that limits activities of daily living[8]; **OR**
      - Reduction of mobility in the affected ankle; **AND**
    - Imaging findings with radiographic report are consistent with moderate to severe osteoarthritis of the ankle[9]; **AND**
    - Failure of conservative management for greater than 3 months, including **ALL** of the following[8]:
      - Anti-inflammatory medications, non-opioid analgesics, or prescription medications (e.g., oral steroids, neuropathic pain medications) if not contraindicated; **AND**
      - Physical therapy, including a physician-directed home exercise program; **AND**
      - **ANY** of the following:
        - Corticosteroid injection if medically appropriate; **OR**
        - Documentation that corticosteroid injection is contraindicated; **AND**
    - The patient is not a candidate for joint-preserving procedures[10]; **OR**
- The procedure is a revision ankle arthroplasty of previous surgery that has failed due to **ANY** of the following[11,12]:
  - Implant failure; **OR**
  - Infection; **OR**
  - Incorrect positioning; **OR**
  - Periprosthetic fracture.

Non-Indications

Ankle arthroplasty is not considered appropriate if **ANY** of the following is **TRUE**:

- Absence of the distal part of the fibula[13]; **OR**
- Untreated infection at the surgical site (with or without osteomyelitis or osteitis)[3,8]; **OR**
- Instability due to incompetent ligaments[12]; **OR**
- Charcot foot[3,8]; **OR**
- Neuropathy and vascular insufficiency[4]; **OR**

- The patient has poorly controlled diabetes as indicated by laboratory tests.[14]

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
27700	Arthroplasty, ankle
27702	Arthroplasty, ankle; with implant (total ankle)
27703	Arthroplasty, ankle; revision, total ankle
27704	Removal of ankle implant
C1776	Joint device (implantable)

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS' required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for ankle arthroplasty may include:

- Adverse effects from delayed or denied treatment include continued and worsening pain, progressive damage to affected and adjacent structures, and loss of mobility. Patients with untreated ankle arthritis may experience quality of life limitations as severe and significant as those of patients with severe hip osteoarthritis, advanced kidney failure, and congestive heart failure.[15]
- Risks with surgical procedures include infection, bleeding requiring a transfusion, injury to neurovascular structures, anesthetic risk, and the need for repeat or additional procedures due to implant failure, periprosthetic fracture, and ongoing pain. Specific risks associated with ankle arthroplasty include intraoperative medial malleolar fractures, aseptic loosening, laceration of posterior ankle structures, poor wound-healing requiring skin grafts, and symptomatic fibular nonunion, with the relative risks of these complications differing between specific surgical approaches.[7] According to the American College of Foot and Ankle Surgeons (ACFAS), not every patient with ankle arthritis is a good candidate for an ankle arthroplasty, and the high revision rate of these procedures should be discussed with the patient.[1]

The clinical benefits of using these criteria for ankle arthroplasty may include:

- Improved patient selection, resulting in better long-term outcomes. Norvell et al. reported on a multisite prospective cohort study comparing

outcomes of surgical treatment for 517 patients with ankle arthritis.[16] Patients treated with total ankle arthroplasty had significantly greater improvement in activities of daily living compared to patients treated with other surgical procedures 24 months post-operation.

- Smoking is known to be a risk factor for poor outcomes after orthopedic procedures. Van der Plaat et al. reported on patient selection factors for successful total ankle arthroplasty.[4] Patients who smoked had a significantly higher likelihood of wound breakdown and delayed healing. Rozinthe et al. compared post-surgical healing in smokers confirmed to have stopped smoking for at least 6 weeks prior to foot and ankle surgery to healing in non-smokers.[5] There was no statistically significant difference between groups, with wound complications occurring in 13.1% of abstained smokers compared to 6.4% in non-smokers. They concluded that smoking cessation for elective foot and ankle surgery limits the risk of wound healing complications.
- Reduction in complications and adverse effects from unnecessary procedures. According to Yoon et al., 28.5% of total ankle arthroplasties required revision procedures, with the most common reason for revision being periprosthetic osteolysis.[17] Limiting unnecessary primary ankle arthroplasty procedures may help preserve bone mass and reduce patient morbidity.
- Maintenance of rigorous patient safety standards aligned to best available evidence. Patients lacking the distal part of the fibula or with instability due to incompetent ligaments who undergo ankle arthroplasty are at increased risk of valgus tilt, which can lead to component malalignment and eventual prosthetic failure.[8,13]
- Patients with infection at the surgical site (with or without osteomyelitis or osteitis) who undergo ankle arthroplasty are at increased risk of developing a prosthetic joint infection. This can lead to implant failure and, in severe cases, bone loss, limb amputation, or systemic complications including sepsis.[3,8]
- Patients with Charcot foot or neuropathy and vascular insufficiency who undergo ankle arthroplasty are at risk of prosthetic loosening, infection, fractures, and progressive joint destabilization.[3,4,8]

Medical Evidence

Mercurio et al. (2025) reviewed outcomes after ankle arthroplasty conducted via anterior and lateral surgical approaches.[7] While the more often used anterior approach provides superior access to the ankle joint and facilitates direct visualization of tibial and talar cuts, it also carries a greater risk of interoperative medial malleolar fracture and potential injury to neurovascular structures. The lateral approach, in contrast, enables greater lateral and posterior joint visualization and permits curved cuts that better align with ankle anatomy while requiring fibular osteotomy. The authors reviewed studies comparing complications after both approaches and reported that while the anterior approach resulted in higher infection rates and had a greater risk of reduced soft-tissue coverage, the lateral approach had a higher risk of complications requiring surgical revision. Short-, medium-, and long-term implant survivorship and functional outcomes were similar across approaches, with the authors concluding that approach selection should consider individual patient characteristics, including activity demands, comorbidities, and disease etiology.

Baumann et al. (2025) conducted a retrospective cohort study to evaluate whether patients with osteoporosis have an increased risk of fracture necessitating surgical revision after ankle arthroplasty.[18] Of the 540 patients included in the final analysis, 270 had a confirmed osteoporosis diagnosis, with the other 270 ankle arthroplasty patients being matched controls without osteoporosis. In the three years following initial surgery, patients with osteoporosis were no more likely to require surgical revision and were no more likely to experience postoperative periprosthetic fracture than patients without osteoporosis. The authors concluded that ankle arthroplasty is appropriate for patients with ankle arthritis regardless of osteoporosis diagnosis and that specific surgical techniques and implant technologies may provide protective effects to patients with osteoporosis.

Bagheri et al. (2023) conducted a meta-analysis evaluating long-term (ten years or longer) follow-up after ankle arthroplasty.[19] They reported that across 5 studies and 938 ankles, AOFAS (American Orthopaedic Foot and Ankle Society) scores increased by over 40 points postoperatively. Across 5 studies

and 866 ankles, visual analog score improved by 4.5 points. The overall revision rate was 20.5%. These results indicate that ankle arthroplasty can have meaningful and enduring positive effects for patients with end-stage ankle arthritis. However, the authors also note the high revision rate, comparing it to the relatively lower revision rates for hip arthroplasty (less than 5%) and knee arthroplasty (around 6%).

Norvell et al. (2019) discuss a multisite prospective cohort study comparing treatments for end-stage ankle arthritis. A total of 517 participants were included. Foot and Ankle Ability Measure (FAAM) activities of daily living and Short Form-36 (SF-36) scores were higher 24 months after surgery in patients who underwent total ankle arthroplasty compared to patients who underwent ankle arthrodesis. The authors concluded that while both procedures are effective, arthroplasty yields more improved outcomes.[16]

The American College of Foot and Ankle Surgeons (ACFAS) published a position statement titled *Total Ankle Replacement Surgery*. While ankle fusion has been the long-standing treatment for end-stage ankle arthritis, the consequent restricted range of motion can put additional stress on adjacent joints, leading to the development or worsening of arthritis in those joints. Ankle replacement techniques better preserve adjacent joint function and offer an additional treatment option. While both procedures have comparable safety profiles, the ACFAS recommends ankle replacement over ankle fusion due to better patient function, pain relief, and quality of life.[1]

The American Orthopaedic Foot and Ankle Society (AOFAS) published a position statement titled *The Use of Total Ankle Replacement for the Treatment of Arthritic Conditions of the Ankle*. While pain reduction is achieved with both ankle replacement and ankle arthrodesis, complication rates are higher following ankle replacement, including the need for secondary surgical procedures. Compared to ankle arthrodesis, ankle arthroplasty shows “marked improvement in quality of life, pain, and function”. Patients undergoing ankle arthroplasty report higher satisfaction with range of motion and gait when compared to ankle arthrodesis. Based on evidence in peer-reviewed literature, the AOFAS supports ankle arthroplasty

over ankle arthrodesis for the treatment of ankle arthritis when conservative management has failed.[2]

References

1. American College of Foot and Ankle Surgeons (ACFAS). Position statement: Total ankle replacement surgery. Approved February 2020. https://www.acfas.org/policy-advocacy/policy-position-statements/acfas-position-statement-total-ankle-replacement-surgery

2. American Orthopaedic Foot and Ankle Society (AOFAS). Position statement: The use of total ankle replacement for the treatment of arthritic conditions of the ankle. Approved July 29, 2022. https://www.aofas.org/research-policy/position-statements-clinical-guidelines

3. Bonasia DE, Dettoni F, Femino JE, et al. Total ankle replacement: Why, when and how? *Iowa Orthop J*. 2010;30:119. https://pmc.ncbi.nlm.nih.gov/articles/PMC2958283/

4. van der Plaat LW, Haverkamp D. Patient selection for total ankle arthroplasty. *Orthop Res Rev*. 2017;9:63-73. doi:10.2147/ORR.S115411. PMID: 30774478. PMCID: PMC6209350

5. Rozinthe A, Ode Q, Subtil F, et al. Impact of smoking cessation on healing after foot and ankle surgery. *Orthop Traumatol Surg Res*. 2022 Nov;108(7):103338. doi: 10.1016/j.otsr.2022.103338. Epub 2022 May 25. PMID: 35643365

6. Benowitz NL, Bernert JT, Foulds J, et al. Biochemical verification of tobacco use and abstinence: 2019 Update. *Nicotine Tob Res*. 2020;22(7):1086-1097. doi:10.1093/ntr/ntz132

7. Mercurio M, Cofano E, Kennedy JG, et al. Indications, functional outcomes, return to sport and complications of anterior and lateral approaches for total ankle arthroplasty: A comprehensive review. *Healthcare*, 2025, 13(841). doi:10.3390/HEALTHCARE13070841

8. Barg A, Wimmer MD, Wiewiorski M, et al. Total ankle replacement. *Dtsch Arztebl Int*. 2015;112(11):177-184. doi:10.3238/arztebl.2015.0177. PMID: 25837859. PMCID: PMC4390826

9. Ha J, Jones G, Staub J, et al. Current trends in total ankle replacement. *Radiographics*. Inc. 2024;44(1). doi:10.1148/RG.230111

10. Le V, Veljkovic A, Salat P, et al. Ankle arthritis. *Foot Ankle Orthop*. 2019;4(3):1-16. doi:10.1177/2473011419852931

11. National Joint Registry Steering Committee. 16th Annual Report 2019: National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. 2019. https://reports.njrcentre.org.uk/portals/0/pdfdownloads/njr%2016th%20annual%20report%202019.pdf

12. Bonnin M, Gaudot F, Laurent JR, et al. The Salto total ankle arthroplasty: Survivorship and analysis of failures at 7 to 11 years. In: *Clinical Orthopaedics and Related Research*. Vol 469. Springer New York LLC; 2011:225-236. doi:10.1007/s11999-010-1453-y

13. Pellegrini MJ, Schiff AP, Adams SB, et al. Conversion of tibiotalar arthrodesis to total ankle arthroplasty. *J Bone Joint Surg Am*. 2015;97:2004-2013. doi:10.2106/JBJS.O.00396

14. Humphers JM, Shibuya N, Fluhman BL, et al. The impact of glycosylated hemoglobin and diabetes mellitus on wound-healing complications and infection after foot and ankle surgery. *J Am Podiatr Med Assoc*. 2014;104(4):320-329. doi:10.7547/0003-0538-104.4.320

15. Herrera-Pérez M, Valderrabano V, Godoy-Santos AL, et al. Ankle osteoarthritis: Comprehensive review and treatment algorithm proposal. *EFORT Open Rev*. 2022 Jul 5;7(7):448-459. doi: 10.1530/EOR-21-0117. PMID: 35900210; PMCID: PMC9297055

16. Norvell DC, Ledoux WR, Shofer JB, et al. Effectiveness and safety of ankle arthrodesis versus arthroplasty: A prospective multicenter study. J *Bone Joint Surg Am*. 2019 Aug 21;101(16):1485-1494. doi: 10.2106/JBJS.18.01257. PMID: 31436657. PMCID: PMC7001770

17. Yoon YK, Park KH, Park JH, et al. Long-term clinical outcomes and implant survivorship of 151 total ankle arthroplasties using the HINTEGRA prosthesis: A minimum 10-year follow-up. *J Bone Joint Surg Am*. 2022;104(16):1483-1491. doi: 10.2106/JBJS.22.00060

18. Baumann AN, Krez AN, Trager RJ, et al. Osteoporosis is not associated with increased reoperation or fracture risk three years after total ankle arthroplasty: A retrospective cohort study. *Osteoporos Int*. 2025. doi:10.1007/s00198-025-07473-6

19. Bagheri K, Anastasio AT, Cantor N, et al. Outcomes after total ankle arthroplasty with a minimum average follow-up of 10 years: A systematic review and meta-analysis. *Foot Ankle Orthop*. 2023;8(4). doi:10.1177/2473011423s00050

Clinical Guideline Revision History/Information

Original Date: May 28, 2024		
Review History		
Version 2	06/10/2024	422.101 Disclaimer added
Version 3	06/26/2025	Annual review. Standardized nicotine cessation/abstinence language. Added nonindication for poorly controlled diabetes. Add references to indications. Updated references. Updated medical evidence section.