Ankle Arthroplasty - Single Service

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: July 16, 2024

Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Diseases & Disorders of the Musculoskeletal System (M00-M99)
Guideline Name: Ankle Arthroplasty (Single Service)

Literature review current through: 7/16/2024
Document last updated: 7/16/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Ankle Arthroplasty

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** Repeat ankle arthroplasty may be indicated if previous surgery has failed due to implant failure, infection, incorrect positioning, or periprosthetic fracture.
- **Recommended Clinical Approach:** Ankle arthroplasty is a treatment for end-stage arthritis of the ankle using an FDA-approved artificial implant to replace a damaged ankle joint due to severe arthritis, arthrodesis of the contralateral ankle, or trauma. Physical therapy increases expected outcomes post-surgery, including reduced pain and improved mobility, quality of life, and function.[1-2]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Ankle arthroplasty** is considered medically necessary when **ALL** of the following are **TRUE**[1-20]:

- ◆ No nicotine product use for 6 weeks with a negative lab test; **AND**
- ◆ **ANY** of the following is **TRUE**:
  - The procedure is an initial ankle arthroplasty and **ALL** of the following are **TRUE**:
    - Degenerative joint disease is present with **ALL** of the following:
      - ◆ The patient requires treatment to improve **ONE** of the following:
        - Disabling pain; **OR**
        - Functional disability; **AND**
      - ◆ Imaging findings are consistent with arthritis of the ankle; **AND**
      - ◆ Failure of conservative management for greater than 6 months, including **ALL** of the following:
        - Oral steroids, anti-inflammatory medications, or analgesics; **AND**
        - Physical therapy; **AND**

- Orthotic devices; **AND**
- **ANY** of the following:
  - Corticosteroid injection if medically appropriate; **OR**
  - Corticosteroid injection is contraindicated; **AND**

◆ The patient is not a candidate for joint preserving procedures; **AND**

- The patient is experiencing **ANY** of the following:
  - ◆ Moderate or severe pain that limits activities of daily living appropriate for the patient's age for a minimum of three months; **OR**
  - ◆ Reduction of mobility; **OR**
  - ◆ Affected ankle has a loss of function; **AND**
- The procedure involves **ONE** of the following FDA-approved devices:
  - ◆ Depuy Agility LP Total Ankle; **OR**
  - ◆ Paragon 28 Apex 3D Total Ankle Replacement System; **OR**
  - ◆ Integra Cadence Total Ankle System; **OR**
  - ◆ Kinetikos Eclipse Total Ankle Implant; **OR**
  - ◆ Wright INBONE Total Ankle System; **OR**
  - ◆ Wright INFINITY Total Ankle System; **OR**
  - ◆ Smith + Nephew Salto Talaris Total Ankle Prosthesis; **OR**
  - ◆ Wright INVISION Total Ankle Revision System; **OR**
  - ◆ Kinos Axiom Total Ankle Replacement System; **OR**
  - ◆ In2Bones Quantum Total Ankle; **OR**
  - ◆ Stryker Scandinavian Total Ankle Replacement (STAR) System; **OR**
  - ◆ Exactech Vantage Total Ankle System; **OR**
  - ◆ Zimmer Biomet Trabecular Metal Total Ankle; **AND**
- The provider educated the patient regarding other available treatments and their respective outcomes (e.g., joint debridement, distraction arthroplasty, osteotomy, arthrodesis); **OR**

- Revision ankle arthroplasty is considered medically necessary when previous surgery has failed due to **ANY** of the following:
  - Implant failure; **OR**
  - Infection; **OR**

- Incorrect positioning; **OR**
- Periprosthetic fracture; **OR**
- Aseptic loosening.

Non-Indications

- **Ankle arthroplasty** is not considered appropriate for patients with **ANY** of the following[16,21-23]:
  - Absence of the distal part of the fibula; **OR**
  - Acute or chronic infection (with or without osteomyelitis or osteitis); **OR**
  - Allergic reaction to metal; **OR**
  - Circulatory disorders; **OR**
  - Instability due to incompetent ligaments; **OR**
  - Neuropathy (e.g., Charcot foot); **OR**
  - Neuromuscular diseases; **OR**
  - Osteonecrosis; **OR**
  - Peripheral vascular disease; **OR**
  - Poor bone quality (e.g., due to steroid treatment); **OR**
  - Poor skin integrity due to scarring or trauma; **OR**
  - Severe malalignment; **OR**
  - Severe osteoporosis; **OR**
  - Significant bone loss.
- **Ankle arthroplasty** may not be considered appropriate for patients with **ANY** of the following:
  - Class III obesity defined as a body mass index [BMI] of 40 or higher or a BMI of 35 or higher for patients with obesity-related health conditions); **OR**
  - Diabetes mellitus; **OR**
  - Diabetic neuropathy; **OR**
  - Ankle deformity (e.g., hindfoot, forefoot, knee); **OR**
  - Ankle instability or lack of ligament support.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Codes	Code Description
C1776*	Joint device (implantable)

27700	Arthroplasty, ankle
27702*	Arthroplasty, ankle; with implant (total ankle)
27703*	Arthroplasty, ankle; revision, total ankle
27704	Removal of ankle implant
27870	Arthrodesis, ankle, open

* Experimental/investigational/unproven when used to report total ankle arthroplasty when combined with total talar prosthesis

Medical Evidence

Norvell et al. (2019) discuss a multisite prospective cohort on treatment methods 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 at 24 month follow-up among patients who underwent total ankle arthroplasty as compared to patients who underwent ankle arthrodesis. The authors conclude that both procedures are effective however, arthroplasty yields greater improved outcomes.[16]

National and Professional Organizations

The **American College of Foot and Ankle Surgeons (ACFAS)** published a position statement titled *Total Ankle Replacement Surgery*. Ankle fusion has been the long-standing treatment for end-stage ankle arthritis. The restriction of range of motion can put additional stress on adjacent joints thus the joints may also become arthritic. Ankle replacement techniques are more refined 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 a secondary surgical procedure. Compared to ankle arthrodesis, ankle arthroplasty shows “marked improvement in quality of life, paint, 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]

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Clinical Guideline Revision History/Information

Original Date: September 7, 2023		
Review History		
Version 2	7/16/2024	Updated language regarding conservative treatment and nicotine use.