# Cohere Medicare Advantage Policy - Ankle Arthroplasty

*Clinical Guidelines for Medical Necessity Review*

**Version:** 2
**Effective Date:** June 10, 2024

# 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:



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## Guideline Information:

**Specialty Area:** Disorders of the Musculoskeletal System
**Guideline Name:** Cohere Medicare Advantage Policy - Ankle Arthroplasty

**Date of last literature review**: 6/10/2024
**Document last updated:** 6/10/2024
**Type:** [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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# Medical Necessity Criteria

***Service: Ankle Arthroplasty***

## Benefit Category

Not applicable.

## 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 or post-traumatic arthritis. Physical therapy increases expected outcomes post-surgery including reduced pain and improved mobility, quality of life, and function.[1-2]

## Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of ankle arthroplasty procedures. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

**The potential clinical harms of using these criteria may include:**

- Inadequate management of severe ankle arthritis due to inappropriate denials can result in additional medical complications. According to the American College of Foot and Ankle Surgeons (ACFAS), total ankle replacement surgery is a safe and effective treatment for select patients with end-stage ankle arthritis.[1] Herrera-Perez et al performed a comprehensive review of treatment for ankle arthritis.[25] They found that patients with untreated ankle arthritis may be extremely debilitating, and can have similar repercussions on quality of life as patients with severe hip osteoarthritis. This can lead to additional medical complications such as congestive heart failure or advanced kidney failure.

- Risks with inappropriate surgical procedures include infection, bleeding requiring a transfusion, injury to neurovascular structures, anesthetic risk and need for repeat or additional procedures due to implant failure, periprosthetic fracture and ongoing pain. 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.[1] The higher rate of revision of these procedures needs to be considered and discussed with the patient.
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

**The clinical benefits of using these criteria include:**

- Improved patient outcomes by ensuring timely and appropriate access to ankle arthroplasty. Norvell et al reported on a multisite prospective cohort study comparing outcomes of surgical treatment for ankle arthritis.[16] In total 517 patients underwent surgery, and at 24 months postoperatively their improvement in activities of daily living was significantly greater in the group that had a total ankle arthroplasty as compared to other surgical treatments.
- Smoking is known to be a risk factor for orthopedic procedures. Van der Plaat et al reported on patient selection factors for successful outcomes from a total ankle arthroplasty.[22] Regarding smoking, they note that studies have shown that in patients who smoke they have a significantly higher increase of wound breakdown and delayed healing. The state “with the current knowledge of the delirious effects of smoking on bone and soft tissue healing and the benefits of (temporary) perioperative cessation, requiring patients to abstain from smoking before high-risk surgery as total ankle replacement seems reasonable". Another study by Rozinthe et al looked at the impact of smoking cessation on healing after foot and ankle surgery.[24] They compared those that stopped smoking for at least 6 weeks and confirmed with a preoperative cotinine test to non-smokers. There was no statistically significant difference between non-smokers and those who stopped smoking for at least 6 weeks with wound complications occurring at 13.1% in this group compared to 6.4% in non-smokers. They concluded that smoking cessation for elective foot and ankle surgery seems to limit the risk of wound healing complications. For an elective ankle

arthroplasty it is therefore important that the patient is not currently smoking for at least 6 weeks.
- Reduction in complications and adverse effects from unnecessary procedures. According to Yoon et al, 28.5% of total ankle arthroplasties required revision procedures.[19] The most common reason for revision is periprosthetic osteolysis. Due to a high rate of revision, preventing unnecessary primary ankle arthroplasty using these criteria is important to prevent the need for a revision surgery.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

## Medical Necessity Criteria

### Indications

➔ **Ankle arthroplasty** is considered medically necessary when **ALL** of the following are **TRUE 1-20**:
- ◆ The patient has not smoked in greater than or equal to the last 6 weeks; **AND**
- ◆ **ANY** of the following is **TRUE:**
  - Initial ankle arthroplasty is considered medically necessary when **ALL** of the following are **TRUE**:
    - Degenerative joint disease is present with **ALL** of the following:
      - ◆ The patient is experiencing **ANY** of the following:
        - Moderate or severe pain that limits activities of daily living; **OR**
        - Reduction of mobility in the affected ankle; **AND**
      - ◆ Imaging findings are consistent with osteoarthritis of the ankle; **AND**

- Failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 3 months. Documentation should include detailed evidence of the measures taken, rather than solely a physician's statement; **AND**
- The patient is not a candidate for joint preserving procedures; **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[21-23]:

- Absence of the distal part of the fibula; **OR**
- Infection at the surgical site (with or without osteomyelitis or osteitis); **OR**
- Instability due to incompetent ligaments; **OR**
- Charcot foot; **OR**
- The patient has smoked within the last 6 weeks.[24]

## Level of Care Criteria

Inpatient or Outpatient.

## Procedure Codes (HCPCS/CPT)

| HCPCS/CPT 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 |

# 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]

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

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