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MEDICAL POLICY – 7.01.599

Total Ankle Arthroplasty in Adults

Effective Date:	**Nov. 7, 2025**	RELATED MEDICAL POLICIES:
Last Revised:	Jul. 8, 2025	7.01.550 Knee Arthroplasty in Adults
Replaces:	N/A	7.01.573 Hip Arthroplasty in Adults

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RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Total ankle arthroplasty, also called ankle replacement, is a surgery that replaces a worn-out or damaged ankle joint with artificial parts. It is most often used for adults with severe joint disease of the ankle, such as osteoarthritis, rheumatoid arthritis, or post-traumatic arthritis who have pain and trouble walking. This procedure is intended to maintain movement in the ankle while reducing pain which may allow improvement in daily activities and support a more active lifestyle. This policy describes when total ankle arthroplasty may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Note: This policy only applies to individuals aged 19 and older

Procedure	Medical Necessity

Total ankle arthroplasty	**Total ankle arthroplasty may be considered medically necessary for joint disease when All of the following are met:**
	• There is a documented diagnosis of one of the following:
	  ○ Osteoarthritis
	  ○ Rheumatoid arthritis
	  ○ Post-traumatic arthritis
	AND
	• Treatment is needed because of the following:
	  ○ Disabling pain for at least 3 months duration, and
	  ○ Functional disability of the ankle joint, which interferes with the ability to carry out activities of daily living
	AND
	• Imaging findings are consistent with advanced or end-stage arthritis of the tibiotalar joint in the 12 months prior to surgery with the presence of one or more of the following:
	• Joint space narrowing
	• Osteophytes
	• Subchondral sclerosis
	• Subchondral cysts
	• Deformity and bone remodeling
	AND
	• Documentation of three months of failed non-operative conservative management as demonstrated by a trial of one or more of the following medications:
	  ○ Non-steroidal anti-inflammatory drugs
	  ○ Acetaminophen
	  ○ Antirheumatic drugs (DMARDs*), if appropriate
	AND
	• And a trial of one or more of the following physical measures
	  ○ Ankle-foot orthosis used greater than or equal to 12 weeks
	  ○ Physical therapy, which may include home exercises greater than or equal to 12 weeks
	
	Notes: DMARDs-Disease-Modifying Anti-Rheumatic Drugs (e.g. methotrexate, hydroxychloroquine, adalimumab ,infliximab, tofacitinib)

Procedure	Medical Necessity
Not medically necessary	**Total ankle arthroplasty is considered NOT medically necessary when ANY of the following conditions are present:** • Absence of the medial or lateral malleolus or both • Active infection in the ankle joint or adjacent bones • Avascular necrosis of the talus • Charcot joint of the affected ankle • Hindfoot, forefoot, or knee malalignment • Insufficient bone stock (lack of enough bone to support an implant) • Insufficient ligament support (ligaments are not providing the required level of stability) • Loss of musculature support in the affected limb • Peripheral neuropathy of the affected ankle • Peripheral vascular disease affecting the lower extremity targeted for surgery • Poor skin conditions resulting from surgical scars or trauma • Severe ankle deformity precluding proper alignment • Severe osteoporosis or osteopenia which may affect bony fixation • Skeletal maturity not reached
Revision of total ankle arthroplasty	**Revision of previous total ankle arthroplasty may be considered medically necessary if there is evidence of any of the following:** • Implant loosening • Implant malposition • Periprosthetic fracture • Periprosthetic infection

Procedure	Investigational
Total talar prosthesis (TTP)	**Total talar prosthesis used in total ankle arthroplasty or revision of a total ankle arthroplasty, or total ankle arthroplasty combined with total talar prosthesis is considered investigational (e.g., Patient Specific Talus Spacer 3D-printed talus implant, Restor3d Talus Replacement, 4WEB Medical Talar Replacement Device)**

Documentation Requirements

The patient's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- For severe osteoarthritis, severe rheumatoid arthritis, post-traumatic arthritis with ALL of the following:
  - Needs treatment because of 3 months of disabling pain and limited ankle function that interferes with activities of daily living (ADLs)

  AND
  - Imaging findings are consistent with advanced or end-stage arthritis of the tibiotalar joint in the 12 months prior to surgery with the presence of one or more of the following: joint space narrowing, osteophytes, subchondral sclerosis, subchondral cysts, or deformity and bone remodeling.

  AND
  - History of trial and failure of three-months of non-operative conservative management with one or more of the following medications: non-steroidal anti-inflammatory drugs, acetaminophen, or antirheumatic drugs (DMARDs), if appropriate and a 12-week trial of one or more of the following physical measures: ankle-foot orthosis or physical therapy, which may include home exercises
- For revision of previous total ankle arthroplasty there is evidence of one of the following:
  - Implant loosening
  - Implant malposition
  - Periprosthetic fracture
  - Periprosthetic infection

Coding

Code	Description
CPT	
27700	Arthroplasty, ankle;
27702	Arthroplasty ankle, with implant, total ankle
27703	Arthroplasty, ankle, revision total ankle

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

Description

Total ankle arthroplasty (TAA), also known as total ankle replacement (TAR), is a surgical procedure that removes diseased bone and replaces it with artificial prosthetic components typically made from metal and polyethylene (a type of plastic) The procedure has generally been used as an alternative to ankle arthrodesis (fusion) in individuals with disabling pain and loss of ankle function that is refractory to medical management due to severe osteoarthritis, severe rheumatoid arthritis, or post-traumatic arthritis. Total ankle arthroplasty aids in preserving the motion at the joint, whereas an ankle arthrodesis fuses the tibia bone to the talus bone, preventing flexion and extension of the foot and thus limiting the ankle's range of motion. An ankle fusion may also accelerate degeneration of adjacent joints and may lead to alterations in gait.

Background

The ankle joint is a complex joint that allows your foot to rotate and pivot in relation to your leg. The ankle joint consists of three separate bones: the tibia (the large leg bone), the fibula (the smaller bone on the outside of the leg), and the talus (the connecting bone from your leg to your foot). These bones are stabilized by tendons and ligaments. When cartilage covering the end of these bones becomes damaged or wears down due to injury or disease (osteoarthritis) the bone surfaces are worn away causing pain and stiffness in the joint. A total ankle arthroplasty removes these worn surfaces of the tibia and talus and replaces them with metal and plastic prostheses (implants). This helps to alleviate the pain and preserves the motion and flexibility in the joint.

After a total ankle arthroplasty, the individual must be non-weight bearing for a time after the surgery and their foot must be initially elevated most of the time while wearing a splint or a cast. Physical rehabilitation usually begins four weeks after the surgery once the individual is able to

bear weight onto the leg using a protective boot. Ankle implants are generally expected to last approximately 10 years.

Total ankle arthroplasty (TAA) began being used in the 1970s but quickly fell out of favor due to high failure rates. Since then, there has been an evolvement with substantial improvement in the design of implants as we are now seeing the third, fourth, and fifth generation of implants in use, some of which have fixed or mobile bearings with most having gone to a cementless fixation and advancements in the biomaterials used in the making of the implants has increased the fixation, wear, and longevity of the implants.

Summary of Evidence

Ankle arthrodesis (AA) was previously considered the gold standard treatment option. Yet no randomized controlled trials exist comparing the two options of ankle arthrodesis and ankle arthroplasty so there is a reliance on high quality systematic reviews to compare outcomes between the two treatment options. Gougoulias et al (2010) reported a 10% failure rate at 5 years with residual pain in 23%-60% of cases of ankle arthroplasties[3]. Daniels et al (2014) reviewed 388 ankles (281 in the ankle replacement group and 107 in the arthrodesis group) in the Canadian Orthopaedic Foot and Ankle Society (COFAS) Prospective Ankle Reconstruction Database and found seven (7%) of the arthrodeses and forty-eight (17%) of the ankle replacements underwent revision. The major complications rate was 7% for arthrodesis and 19% for ankle replacement[9]. Thus, rates of reoperation and major complications were higher after ankle replacement. Lawton et al in 2020, found in their systematic review and meta-analysis of 4312 third generation TAAs and 1118 AA individuals with mean follow-up of 4.9 years in the TAA cohort and 4.0 years in the AA cohort, the most common complication in TAA was wound complication (9.3%) followed by intra-operative or post-operative fracture (6.9%). Non-union was the most common complication for those who underwent AA (7.4%) followed by wound complication (6.5%).[23] Concluding, there was no significant difference in overall complication or failure rate between the two procedures as well as revision or re-operation rates between TAA and AA. Nor were there differences in rates of revision to amputation between the two. Thus, stating, "The current literature does not strongly favor either procedure for the treatment of end-stage tibiotalar arthritis in the general population". Jordan et al (2014) concluded from their systematic review the following: "Insufficient evidence is available to decide whether total ankle replacement or ankle arthrodesis improves functional outcomes and further research in the form of robust RCTs is indicated[10]." Thus, the current literature indicates that over the last few decades, improved surgical techniques in AA and advancements in TAA prosthesis design have led to improved outcomes with both procedures.

Total ankle arthroplasty with implantation of a total talar prosthesis has been proposed for those with avascular necrosis of the ankle or trauma related issues to regain motion and reduce pain. The FDA notes that other conventional procedures used in these scenarios are amputation or total joint fusion. Total joint fusion is difficult in restoring leg length in this situation because of the missing talus bone and surgeons must rebuild the individual's ankle using allograft, which half of the time leads to non-union and may then lead to amputation[35]. Anastasio et al (2024) concludes from their systematic review "although this is a promising treatment modality for improving short-term functional outcomes, standardized reporting, longer-term follow-ups, and further research to establish the procedure's efficacy and safety, particularly in comparison to other treatment modalities is needed[31]."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01620541	Comparing Ankle Arthrodesis to Ankle Arthroplasty	516 (Actual)	May 2027
NCT02128555	A Randomised, Multi-centre, Non-blinded, Prospective, Parallel Group Trial of Total Ankle Replacement (TAR) Versus Ankle Arthrodesis in Patients With End Stage Ankle Osteoarthritis, Comparing Clinical Outcomes and Cost-effectiveness.	303 (Actual)	Feb 2029

NCT: National clinical trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

American College of Foot and Ankle Surgeons

Approved in 2023, the ACFAS Position Statement[32] states, "…total ankle replacement surgery is currently a safe and effective treatment option for appropriate patients with end stage ankle arthritis. Total ankle replacement surgery improves patient function, reduces pain, reduces energy expenditure in gait, and promotes improved quality of life.

In 2020, the ACFAS developed a Consensus Statement on the Diagnosis and Treatment of Ankle Arthritis[22] which stated the following are viable options for treatment of ankle arthritis: total ankle arthroplasty and open and arthroscopic arthrodesis.

American Orthopaedic Foot and Ankle Society

Approved in 2022, the AOFAS Position Statement[33] states, "The American Orthopaedic Foot & Ankle Society (AOFAS) endorses the use of total ankle replacement surgery as an option for treatment of arthritic conditions of the ankle in select patients with this condition who have failed nonoperative treatment. We do not consider this procedure to be experimental."

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Total ankle arthroplasty is a surgical procedure and therefore is not regulated by the FDA. However, devices used during the surgery require FDA approval or clearance. Several devices have received FDA approval or clearance. Product codes for these devices are: HSN and NTG.

In February 2021, the FDA granted the humanitarian device exemption (HDE), (H200001) for the Patient Specific Talus Spacer 3D-printed talus implant (Additive Orthopaedics, LLC.). This implant was the first 3-D implant to replace the talus bone in patients with avascular necrosis of the ankle joint. In 2023, Restor3d Talus Replacement (Restor3d, Inc.) received an HDE (H23003) and in 2024, the 4WEB Medical Talar Replacement Device (Stryker) also received an HDE (H240001). FDA Product code: QNN.

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History

Date	Comments
08/01/25	New policy, approved July 8, 2025, effective for dates of service on or after November 7, 2025, following 90-day provider notification. Add to Surgery section. Total ankle arthroplasty may be considered medically necessary when criteria are met.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.