



Medical Coverage Policy

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Total Ankle Arthroplasty/Replacement

Table of Contents

Overview	1
Coverage Policy.....	1
General Background.....	2
Medicare Coverage Determinations	6
Coding/Billing Information.....	6
References	7

Related Coverage Resources

- [Hip Replacement/Arthroplasty \(CMM 313\)](#)
- [Knee Replacement/Arthroplasty \(CMM 311\)](#)
- [Physical Therapy - \(CPG 135\)](#)
- [Subtalar Arthroereisis](#)

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Overview

This Coverage Policy addresses total ankle arthroplasty/replacement.

Coverage Policy

Total ankle arthroplasty/replacement for a skeletally mature individual with a FDA-approved device is considered medically necessary for the treatment of severe inflammatory arthritis (e.g., rheumatoid arthritis), severe osteoarthritis, or post-traumatic arthritis of the ankle, as an alternative to ankle arthrodesis, when ALL of the following criteria have been met:

- moderate to severe ankle pain that:
 - is function-limiting at short distances (e.g., walking less than ¼ mile, limiting activity to two city blocks, the equivalent to walking the length of a shopping mall) for at least three (3) months duration
 - interferes with the ability to carry out age appropriate activities of daily living and/or demands of employment

- failure of at least six months of conservative therapy (i.e., anti-inflammatory medications, orthotic devices, activity modification, physical therapy)
- any **ONE** of the following:
 - arthritis in adjacent joints of the involved extremity (i.e., subtalar, midfoot)
 - severe arthritis of the contralateral ankle
 - previous arthrodesis of the contralateral ankle
- absence of **ALL** the following:
 - active infection
 - insufficient bone/osteonecrosis
 - loss of musculature in the affected limb/insufficient ligament support
 - vascular insufficiency in the affected limb
 - Charcot's or other peripheral neuropathy
 - neurological impairment
 - severe ankle deformity precluding proper alignment
 - malalignment or severe deformity of involved or adjacent anatomic structures (e.g. hindfoot, forefoot, knee)
 - absence of medial or lateral malleolus, or both
 - poor skin conditions secondary to surgical scars or trauma

Revision total ankle arthroplasty is considered medically necessary for moderate to severe ankle pain secondary to failure of an implanted device (e.g., implant loosening, malpositioning, periprosthetic infection, periprosthetic fracture).

Total ankle arthroplasty/replacement for any other indication including combined with total talar prosthesis is considered experimental, investigational or unproven.

General Background

Total ankle arthroplasty (TAA) also known as total ankle replacement (TAR) is the process of replacing a diseased ankle with a prosthetic ankle. The procedure has been proposed as an alternative to ankle arthrodesis (i.e., ankle fusion) for non-inflammatory arthritic conditions such as severe osteoarthritis (OA) or post-traumatic arthritis, or inflammatory arthritic conditions, such as rheumatoid arthritis (RA) of the ankle. Arthritic ankle joints frequently result in decreased range of motion, swelling, joint stiffness, pain with weight-bearing activity, instability secondary to pain, and, in some cases, visible joint deformity. Conservative management typically consists of medications for pain control, limiting activity, the use of ankle braces to stabilize the joint, shoe modifications, heat, and physical therapy to control the pain associated with ankle arthrosis.

When conservative management fails, ankle arthrodesis (AA) has been the standard surgical treatment of choice to control the pain of severe ankle arthritis. During an ankle arthrodesis, the joint is fused together, limiting up-and-down movement. While pain may be relieved with ankle arthrodesis, the main drawback is the later development of arthrosis in the adjacent joints, particularly fusion of the subtalar joint.

Total ankle replacement (TAR) has reemerged as a viable and often preferable option to ankle arthrodesis for patients with end-stage ankle disease. The decision between ankle arthroplasty and arthrodesis should be made on a case-by-case basis. There are no consensus guidelines. A review article (Adukia, et al., 2020) states that mobile-bearing prostheses are most commonly used in Europe, while the majority of implants used in the United States of America (USA) are fixed-bearing cemented designs. Adukia et al. (2020) suggests that the ideal patient for an ankle replacement is one who is fifty years of age or older, has a body mass index (BMI) of less than 30, undertakes low demand physical activity, and who has a manageable deformity. Pre-existing ipsilateral hindfoot, hip or knee arthritis, may make total ankle arthroplasty more desirable than ankle fusion in certain patient groups. Patient contraindications to total ankle arthroplasty include relative youth, heavy manual workers, heavy smokers, diabetics (especially those with peripheral neuropathy), vascular insufficiency, severe ankle instability, significant bone loss and active local/systemic infection.

U.S. Food and Drug Administration (FDA)

First generation TARs (in the 1970s and 1980s) were constrained and cemented in design, and had a very high rate of aseptic loosening. Second-generation TARs employed bone conserving surgery without cementation and with less constraint between components. They have demonstrated upwards of 89% survival at 10 years, were developed to more closely mimic physiologic movement and stability, and avoid the osteolytic issues of the early designs. Newer, third generation implants feature a metallic baseplate fixed to the tibia and a domed component resurfacing the talus, with ultra-high molecular weight polyethylene (UHMWPE) bearings to avoid the stability issues of previous implants due to increased polyethylene wear. There have been several recall notices for various implants / implant components.

Mobile-bearing total ankle replacement (Class III devices, Product code NTG)

- Scandinavian Total Ankle Replacement (STAR[®]) system (Small Bone Innovations Inc., Morrisville, PA) Received FDA premarket approval on May 27, 2009, for use as a non-cemented implant to replace a painful arthritic ankle joint due to osteoarthritis, posttraumatic arthritis, or rheumatoid arthritis (P050050). As a condition of FDA approval, the company will evaluate the safety and effectiveness of the device during the next 8 years. There are several supplements.
- Hintermann Series H3[™] mobile-bearing Total Ankle Replacement prosthesis received FDA PMA approval June 2019 (P160036). The Hintermann Series H3[™] Total Ankle Replacement System (formerly known as HINTEGRA TAR prosthesis) (DT MedTech LLC., Towson MD) is a three-piece, mobile-bearing implant indicated for use as a non-cemented implant to replace a painful arthritic ankle joint due to primary osteoarthritis, posttraumatic osteoarthritis or arthritis secondary to inflammatory disease. The device system is for prescription use.

Fixed-component total ankle replacement (Class II devices, product code HSN)

Examples include but are not limited to:

- Agility[™] LP Total Ankle (Alvine Ankle) (DePuy Orthopaedics Inc., Jacksonville, FL)
- Cadence Total Ankle System (Integra Lifesciences Corporation, Ascension Orthopedics, Inc., Austin, Texas)
- Eclipse Total Ankle Implant (Kinetikos Medical Inc.; Integra Lifesciences Corporation, Plainsboro, NJ)
- Hintermann Series H2[™] Total Ankle System (DT MedTech LLC.)
- Inbone[™] Total Ankle (including I and II) (Wright Medical Technology Inc., Memphis, TN)
- Infinity[™] Total Ankle System (Wright Medical Technology Inc.)
- Integra[®] Cadence[™] Total Ankle Replacement System (Ascension Orthopedics) (Integra Lifesciences Corp.)
- Invision[™] Total Ankle Revision System (Wright Medical Technology Inc.)
- Kinos Axiom Total Ankle System (Kinos Medical, Wayne, Pennsylvania)
- Salto XT, Salto Talaris[®] (Tornier SAS, France; Integra Lifesciences Corp.)
- Topez Total Ankle Replacement (Topez Orthopedics Inc.)
- Vantage[®] Total Ankle System (Exactech Inc. Gainesville, FL)

FDA-approved indications vary depending on device type: fixed-bearing or mobile-bearing. In general these devices are intended for adult patients with reduced activity levels, who have severe rheumatoid arthritis, post-traumatic arthritis or osteoarthritis of the ankle. Contraindications also vary depending on device type, but may include the following:

- active infection
- insufficient bone/osteonecrosis
- loss of musculature in the affected limb/insufficient ligament support
- vascular insufficiency in the affected limb
- Charcot's or other peripheral neuropathy
- neurological impairment
- severe ankle deformity precluding proper alignment

- malalignment or severe deformity of involved or adjacent anatomic structures (e.g. hindfoot, forefoot, knee)
- absence of medial or lateral malleolus, or both
- poor skin conditions secondary to surgical scars or trauma
- patient age, weight or activity levels that introduces unnecessary risk of failure
- skeletal immaturity.

Revision surgery

Revision surgery may be necessary in the presence of failed arthroplasty. Failed arthroplasty is typically suspected when pain occurs progressively over time and is persistent, indicating implant loosening and subsidence. Periprosthetic infection should be ruled out early. Bone scans or computerized tomography (CT) scans may be performed to evaluate the implant with some individuals requiring surgical evaluation. Surgical management of failed TAR may include ankle arthrodesis, revision arthroplasty, or amputation. Contraindications to revision TAR are similar to those for initial procedure and include deep infection, neuropathic joint, insufficient bone stock, soft-tissue breakdown, absence of the distal part of the femur, instability resulting from incompetent ligaments, severe malalignment, peripheral vascular disease, significant bone loss, and morbid obesity (Murphy, 2017).

Total Talar Prosthesis

Combined TAR with implantation of a three-dimensional (3D) printed total talar prosthesis (TTP) has been proposed for degenerative joint disease of the ankle, avascular osteonecrosis, and osteomyelitis. See Literature Review section below.

Literature Review

A review of the current published peer-reviewed literature includes prospective and retrospective studies that compare TAR to ankle arthrodesis (Norvell, et al., 2019; Merrill, et al., 2019; Veljkovic, et al., 2019; Wasik, et al., 2019; Veljkovic, et al., 2019; Segal, et al., 2018; Mehdi, et al., 2018), compare TAR devices (Nunley, et al., 2019; King, et al., 2019), compare patient subpopulations undergoing TAR (e.g., degree of deformity, age of patient, etiology of osteoarthritis) (Lee, et al., 2019; Usuelli, et al., 2019; Demetracopoulos, et al., 2019), compare primary TAR versus revision TAR (Lai, et al., 2019) and evaluate survivorship of the TAR implant (Palanca, et al., 2018, 15.7 years; Lee, et al., 2019, 6.2 years; Koo et al., 2018, 5 years; Marks, et al., 2019, 4.9 years).

Hayes, Inc. published a Comparative Effectiveness Review on Total Ankle Replacement (TAR) (December 28, 2017) noting that low-quality evidence suggests the effectiveness of TAR is at least comparable with AA for the treatment of adult patients with end-stage ankle arthritis.

Lawton et al. (2017) conducted a systematic literature review to assess outcomes and complications following AA and TAR treatment of symptomatic tibiotalar arthritis. A total of six studies reporting on outcomes following TAR and five studies reporting on outcomes following AA met inclusion criteria and were included for pooled data analysis.

- TAR studies: Only studies including modern third-generation TAR implants approved for use in the USA (HINTEGRA, STAR, Salto, INBONE) were included. Five of the studies were prospective and one was retrospective. The studies report on a total of 2239 ankles operated on from 1993 to 2013. INBONE was used in 682 ankles, STAR in 455 ankles, Salto in 380 ankles, and HINTEGRA in 722 ankles. The adjusted mean follow-up was 4.8 years.
- AA studies: All studies were retrospective in nature. The studies report on a total of 635 ankles operated on from 1993 to 2013. Arthrodesis was preformed through an open approach in 577 ankles and through an arthroscopic approach in 58 ankles. Three of the studies reported mean follow-up with an adjusted mean follow-up of 4.3 years.

The adjusted overall complication rate was higher for AA (26.9%) compared to TAR (19.7%), with similar findings in the non-revision reoperation rate (12.9% for AA compared to 9.5% for TAR). The adjusted revision reoperation rate for TAR (7.9%) was higher than AA (5.4%). Analysis of results from ten studies directly comparing TAR to AA suggests a more symmetric gait and less impairment on uneven surfaces after TAR. The authors stated that pooled data analysis demonstrated a higher overall complication rate after AA, but a higher reoperation rate for

revision after TAR. Based on the existing literature, the decision to proceed with TAR or AA for end-stage ankle arthritis should be made on an individual patient basis.

Undén et al. (2020) conducted an analysis of the Swedish Ankle Registry including reviewing prosthetic survival, using exchange or permanent extraction of components as endpoint for 1,226 prostheses with mean follow-up of 7 years (0–24). Differences between current (Hintergra, Mobility, CCI, Rebalance, and TM Ankle) and early prosthetic designs (STAR, BP, and AES) were examined. The authors found an overall prosthetic survival rate at 5 years of 0.85, at 10 years 0.74, at 15 years 0.63, and at 20 years 0.58. For early prosthetic designs the 5- and 10-year survival rates were 0.81 and 0.69 respectively, while the corresponding rates for current designs were 0.88 and 0.84. Current prosthetic designs had better survival (log rank test $p < 0.001$).

Li et al. (2020) conducted a meta-analysis, including studies that compared TAR with ankle arthrodesis (AAD). A total of 1280 patients were included in the 7 studies selected, of which 927 were treated with TAR and 353 with AAD. The follow-up cycles were provided in all 7 studies, with the shortest one being 12.0 months and the longest being 77.0 months. This meta-analysis showed no statistically significant difference between TAR and AAD in clinical outcome, patient satisfaction, complications, and survival.

Kim et al. (2017) conducted a meta-analysis including comparative studies that assessed TAR versus AA for the treatment of end-stage ankle arthritis. The primary outcomes were clinical scores and patient satisfaction and secondary outcomes were the prevalence of complications and the re-operation rate. Ten comparative studies were included (four prospective and six retrospective studies). There were no significant differences between the two procedures in the American Orthopaedic Foot and Ankle Society ankle-hindfoot score, Short Form-36 physical component summary and mental component summary scores, visual analogue scale for pain, and patient satisfaction rate. The risk of re-operation and major surgical complications were significantly increased in the TAR group. A limitation of this meta-analysis is the majority of included studies were retrospective design. The authors stated that further studies of high methodological quality with long-term follow-up are needed.

van der Plaat, et al. (2017) conducted a literature review and concluded:

- The optimal patient for TAR is said to be physically low-demanding, nonobese, older, with end-stage non-traumatic primary ankle arthrosis or multiple joint arthritis with minimal deformity, good bone stock, no neurovascular leg impairment and excellent/more than two-thirds of normal range of motion.
- Unfortunately, the majority of our patients do not meet these requirements, and scientific evidence for these recommendations is unavailable.
- Unfortunately, the characteristics of patients with failed TARs are rarely specified (except incidentally etiology of arthritis), which makes it difficult to determine the risk factors for failure.
- Many factors historically considered to be contraindications for TAR should no longer be considered contraindications based on scientific evidence. Some of these factors are probably interconnected (for instance, BMI, activity level, diabetes and vascular disease). Instead of considering each of these factors in isolation, the surgeon should try to judge the patient as a whole when choosing between TAR and AA.

Maffulli et al. (2017) performed a systematic literature review, including 21 prospective and retrospective studies, reporting a total of 32,422 procedures for the management of end stage ankle arthritis. A total of 26,175 (80.7%) AA and 6247 (19.3%) TAR procedures were performed. Seven studies, reporting 647 TAR procedures, also reported the type of prosthesis of choice. TAR was performed using two- or three-component designs. These were also classified as fixed or mobile-bearing. Average follow-up was 73.1 months (76.2 months for AA group, and 61.3 months for the TAR group). The authors noted that there is some evidence to support TAR to conserve ankle motion and offer improved function and decreased pain with high satisfaction rates. Revision rates for TAR are significantly higher than revision rates for AA. They concluded proper patient selection should be better addressed in future studies for successful treatment of end-stage ankle OA.

Literature Review (Total Talar Prosthesis): Combined TAR with implantation of a total talar prosthesis (TTP) has been proposed for some patients including younger patients, patients with stage 3 and 4 osteonecrosis, and patients with talar collapse. An artificial talar prostheses is proposed to prevent leg length discrepancy, preserve the joint function, and allow early weight bearing. There is a lack of large, well-designed prospective trials evaluating the long term outcomes of total talar prosthesis (West, et al., 2020; Kanzaki, et al., 2019; Kurokawa, et al., 2019; Shnol, et al., 2018; Taniguchi, et al., 2015).

Professional Societies/Organizations

American College of Foot and Ankle Surgeons (ACFAS): The ACFAS Position Statement on Total Ankle Replacement Surgery (February 2020) notes that not every patient with end-stage arthritis of the ankle is a sound candidate for ankle replacement. A surgeon experienced in total ankle surgery can make this determination through careful history and physical evaluation. As with any total joint replacement, patients who are candidates for this procedure should be made aware of alternative treatments and expected outcomes. Furthermore, adjunctive procedures are often necessary as part of the surgical plan to ensure proper device function.

In the United States, total ankle replacement surgery is currently a safe and effective treatment option for select patients with end stage ankle arthritis. Studies have shown total ankle replacement surgery improves patient function, reduces pain, and promotes improved quality of life.

American Orthopaedic Foot & Ankle Society (AOFAS): The AOFAS Position Statement on The Use of Total Ankle Replacement for the Treatment of Arthritic Conditions of the Ankle (approved April 2018) concludes “Ankle arthritis is a condition that can result in substantial pain and dysfunction. The American Orthopaedic Foot & Ankle Society supports the use of total ankle replacement as an option for the treatment of ankle arthritis that has failed conservative management in select patients due to its demonstrated improved outcomes in multiple peer reviewed publications.”

The American Board of Internal Medicine’s (ABIM) Foundation Choosing Wisely® Initiative

No relevant information.

Use Outside of the US

No relevant information.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
27702†	Arthroplasty, ankle; with implant (total ankle)
27703†	Arthroplasty, ankle; revision, total ankle
27704	Removal of ankle implant

HCPCS Codes	Description
C1776†	Joint device (implantable)
L8699	Prosthetic implant, not otherwise specified

†Note: Experimental/investigational/unproven when used to report total ankle arthroplasty/replacement when combined with total talar prosthesis

***Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.**

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