Medical Coverage Policy

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Total Ankle Arthroplasty/Replacement

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health

benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses total ankle arthroplasty/replacement and revision total ankle arthroplasty.

Coverage Policy

Total ankle arthroplasty/replacement for a skeletally mature individual with a U.S. Food and Drug Administration (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 is considered not medically necessary.

Total ankle arthroplasty/replacement 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 or injured 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, and for 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. Mobile-bearing prostheses are most commonly used in Europe, while the majority of implants used in the United States are fixed-bearing cemented designs. The suggested ideal patient for an ankle replacement is a person 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 or 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 (Murphy, 2021; Adukia, et al., 2020).

A 2020 study found that, compared to white patients, Black patients who underwent TAR had an increased risk of in-hospital complications and longer length of stay, and were more likely to be discharged to an inpatient rehabilitation facility. Hispanic TAR patients were more likely than white patients to experience an in-hospital infection, and to have higher hospital charges. Overall, factors which increased healthcare utilization and/or in-hospital complications after TAR included: age over 50 years, non-white race/ethnicity, Medicaid payer status, and higher comorbidity (Singh and Cleveland, 2020).

A study by Brodeur et al. (2022) found that, in New York state, the use of arthroplasty to treat ankle osteoarthritis had increased by 757% over the course of nine years, overtaking arthrodesis as the preferred surgical management modality. Compared with ankle arthroplasty, ankle arthrodesis was found to be associated with increased rates of hospital readmission, surgical site infection, acute renal failure, cellulitis, urinary tract infection, and deep vein thrombosis. Further, African American race, federal insurance, workers compensation, presence of comorbidities, and

higher social deprivation index (SDI) score were associated with increased odds of having an ankle arthrodesis versus an ankle arthroplasty.

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 collapse. Periprosthetic infection should be ruled out early. Bone scans or computed 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. Absolute contraindications to revision TAR include deep infection, neuropathic joint, insufficient bone stock, and soft-tissue breakdown. Relative contraindications to revision TAR include absence of the distal part of the fibula, instability resulting from incompetent ligaments, severe malalignment, peripheral vascular disease, significant bone loss, and morbid obesity (Murphy, 2021).

U.S. Food and Drug Administration (FDA)
First generation TARs (developed 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. The choice of implant depends on the clinical scenario and the surgeon's training and experience.

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

- Scandinavian Total Ankle Replacement (STAR®) system (DJO Global, Austin, TX) 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. As a condition of FDA approval, the company evaluated the safety and effectiveness of the device during the next eight years. The final FDA post-approval study data reported 82 device-related adverse events over the 8-year study period. These included polyethylene fracture requiring revision, cyst formation requiring surgical treatment, and other device-related secondary procedures for revision or removal. The overall implant survivorship was 75.5%, which was found to be not worse than the predefined arthrodesis control.
- Hintermann Series H3™ mobile-bearing Total Ankle Replacement prosthesis received FDA premarket approval June 25, 2019. 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.

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

Examples of devices approved by the FDA 510(k) process include but are not limited to:

- Cadence® Total Ankle System (Integra Lifesciences Corporation, Ascension Orthopedics, Inc., Austin, Texas)
- Hintermann Series H2™ Total Ankle System (DT MedTech LLC., Towson, MD)
- Inbone™ Total Ankle (Wright Medical Technology Inc., Memphis, TN)

- Infinity™ Total Ankle System (Wright Medical Technology Inc., Memphis, TN)
- Invision™ Total Ankle Revision System (Wright Medical Technology Inc., Memphis, TN)
- Kinos Axiom Total Ankle System (Restor3d, Durham, NC)
- Salto XT, Salto Talaris® (Tornier SAS, France; Integra Lifesciences Corp.)
- Vantage® Total Ankle System (Exactech Inc., Gainesville, FL)

FDA-approved indications vary depending on device type: fixed-bearing or mobile-bearing. Generally, 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

Literature Review
The available published peer-reviewed literature on total ankle arthroplasty includes prospective and retrospective studies that compare TAR to ankle arthrodesis (Almutairi, et al., 2023; Goldberg, et al., 2023; Sangeorzan, et al., 2021; Mehdi, et al., 2019; Merrill, et al., 2019; Norvell, et al., 2019; Veljkovic, et al., 2019; Wasik, et al., 2019; Segal, et al., 2018), compare TAR devices (King, et al., 2019; Nunley, et al., 2019; Queen, et al., 2017; Wood, et al., 2009), compare patient subpopulations undergoing TAR (e.g., degree of deformity, age of patient, etiology of osteoarthritis) (Tarricone, et al., 2022; Demetracopoulos, et al., 2019; Lee, et al., 2019; Usuelli, et al., 2019), compare primary TAR versus revision TAR (Lai, et al., 2019) and evaluate survivorship of the TAR implant (Loewy, et al., 2023; Koo et al., 2019; Lee, et al., 2019; Marks, 2019; Palanca, et al., 2018).

Li et al. (2020) conducted a meta-analysis of studies that compared TAR with ankle arthrodesis (AA). A total of 1280 patients were included in the seven studies selected, of which 927 were treated with TAR and 353 with AA. The follow-up cycles were provided in all seven studies, with the shortest one being 12 months and the longest being 77 months. This meta-analysis showed no statistically significant difference between TAR and AA in clinical outcomes, patient satisfaction, complications, and survival.

Undén et al. (2020) conducted an analysis of intermediate and long-term prosthetic survival of total ankle replacements (TAR) in Sweden. As an endpoint, the team analyzed the exchange or permanent extraction of TAR components for 1226 prostheses, with mean follow-up of seven years. Differences between current (Hintegra, Mobility, CCI, Rebalance, and TM Ankle) and early prosthetic designs (STAR, BP, and AES) were also examined. The authors found an overall prosthetic survival rate at five years of 0.85, at 10 years of 0.74, at 15 years of 0.63, and at 20 years of 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 $p<0.001$).

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 reoperation 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 reoperation 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 and Haverkamp (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 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.

Total Talar Prosthesis
Combined TAR with implantation of a total talar prosthesis (TTP) has been proposed for degenerative joint disease of the ankle, avascular osteonecrosis, talar collapse, and osteomyelitis. A talar prostheses is proposed to prevent leg length discrepancy, preserve the joint function, and allow early weight bearing.

U.S. Food and Drug Administration (FDA): On February 17, 2021, the FDA approved the Patient Specific Talus Spacer 3D-printed talus implant (Additive Orthopaedics, LLC; Monmouth Beach, NJ) through the humanitarian device exemption (HDE) process. The Patient Specific Talus Spacer is a talus prosthesis made of cobalt chromium alloy. It is intended for use in talus replacement surgery for the treatment of avascular necrosis (AVN) of the ankle joint, as an alternative to arthrodesis or amputation. The implant is designed from patient-specific imaging data (e.g., computed tomography [CT]; magnetic resonance imaging [MRI]), and 3D-printed via laser sintering. Contraindications for use of the implant include degenerative changes in the tibiotalar, subtalar or talonavicular joints; osteonecrosis of the calcaneus, distal tibia or navicular; and/or active infection. The FDA HDE approval of the Patient Specific Talus Spacer was based upon results of a single-center trial (n=32 cases) which assessed safety and benefit outcomes in patients with AVN who underwent talar replacement. A post-approval study is ongoing (FDA, 2021).

In November 2023, the FDA approved the restor3d Total Talus Replacement implant (restor3d, Inc., Durham, NC) via the HDE process. The implant is a patient-specific, additively manufactured (i.e., 3D-printed) implant made of cobalt chromium. The approved indications included avascular necrosis of the talus; avascular necrosis of the talus in addition to talar collapse, cysts or non-

union; large, uncontained, unstable, or cystic talar osteochondral defects with risk of collapse or talar osteochondral defects not responsive to traditional treatments; and non-union following talar fracture or talar extrusion, unresponsive to more conservative treatments. The supporting clinical information submitted in the FDA summary of safety and probable benefit consisted of a retrospective chart review of 27 patients who received a patient-specific total talus replacement for the treatment of talar dysfunction. A five year post-approval study is planned.

Literature Review: There is a lack of large, comparative prospective trials evaluating the long term outcomes and management of complications associated with total talar prosthesis, alone or in combination with total ankle replacement. Evidence consists primarily of case reports and small case series (Jennison, et al., 2023; Johnson, et al., 2022; Morita, et al., 2022; Abramson, et al., 2021; Morita, et al., 2020; West and Rush, 2020; Kanzaki, et al., 2019; Kurokawa, et al., 2019; Shnol and LaPorta, 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) noted 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. 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.

The ACFAS consensus statement on the diagnosis and treatment of ankle arthritis confirmed that total ankle arthroplasty is a viable option for the treatment of ankle arthritis. The panel noted there was no demonstrated superiority between mobile and fixed bearing prostheses (Shibuya, et al., 2020).

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 asserted that "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" (AOFAS, 2022).

Medicare Coverage Determinations

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

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
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®) ©2023 American Medical Association: Chicago, IL.**

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• Revised noncoverage policy statement.	2/15/2024