Total Ankle Arthroplasty/Replacement

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Related Coverage Resources
Physical Therapy - (CPG 135)

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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. 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.

Coverage Policy

Total ankle arthroplasty/replacement for a skeletally mature individual 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 limits activities of daily living
- 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).

Each of the following is considered experimental, investigational or unproven:

- total ankle arthroplasty/replacement for any other indication
- total ankle arthroplasty/replacement procedures customized to the individual, including the use of ANY of the following:
  - customized templates, and/or instrumentation
  - customized, individual-specific ankle implant
  - gender specific implant

Pre-operative imaging studies (e.g., CT scans, MRI) associated with customized ankle replacement and/or utilized as part of operative navigation guides (e.g., PROPHECY™ INBONE™ INFINITY™) is considered not medically necessary for a conventional total ankle replacement.

Overview

This Coverage Policy addresses total ankle arthroplasty.

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 arthroplasty has the potential to preserve range of motion, restore normal gait, and reduce progression of arthritis in adjacent joints. Since introduction in the 1970s, three generations of implants have been developed, with several total ankle arthroplasty systems approved for use in the United States by the US Food and Drug Administration (FDA) since 2005.

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 (Hayes, 2017; UpToDate, 2017).

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.

- Note: Hintermann Series H3™ mobile-bearing Total Ankle Replacement prosthesis is not FDA-approved at this time. It is a non-constrained, three-component total ankle replacement system (formerly known as HINGE TAR prosthesis) (DT MedTech LLC., Towson MD)

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)
- 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.,
  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; Hayes, 2017).

There have been several recall notices for various implants / implant components. 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 TAA may include ankle arthrodesis, revision arthroplasty, or amputation. Contraindications to revision TAA 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).

Literature Review
Hayes, Inc. published a Comparative Effectiveness Review on Total Ankle Replacement (TAR) (December 28, 2017). Hayes Rating = C for use of TAR as an alternative to conventional ankle arthrodesis (AA) for treating adult patients with end-stage ankle arthritis without contraindications to TAR. This Rating reflects an overall low-quality body of evidence that suggests that the effectiveness of TAR is at least comparable with AA for the treatment of adult patients with end-stage ankle arthritis. This Rating also reflects some uncertainties about rates of reoperation and complications due to inconsistencies in the evidence, the small number of studies reporting certain outcome measures, and questions regarding the long-term durability of TAR.

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

- TAA studies: Only studies including modern third-generation TAA 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 TAA (19.7%), with similar findings in the non-revision reoperation rate (12.9% for AA compared to 9.5% for TAA). The adjusted revision reoperation rate for TAA (7.9%) was higher than AA (5.4%). Analysis of results from ten studies directly comparing TAA to AA suggests a more symmetric gait and less impairment on uneven surfaces after TAA. The authors stated that pooled data analysis demonstrated a higher overall complication rate after AA, but a higher reoperation rate for revision after TAA. Based on the existing literature, the decision to proceed with TAA or AA for end-stage ankle arthritis should be made on an individual patient basis.

Kim et al. (2017) conducted a meta-analysis including comparative studies that assessed TAA 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 TAA 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.

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.
Lefrancois et al. (2017) conducted a prospective, comparative study with a mean follow-up of 4.5 years. Lefrancois et al. compared a total of 451 TAAs (Hintegra, Agility, Mobility, and STAR implants). The authors concluded that outcome results from patient-reported pain and disability scores were comparable between at least three of the four prostheses (the Hintegra, STAR, and Agility implants). The rates of complications and revisions were within the limits reported in the literature for similar prostheses.

Queen et al. (2017) conducted a small randomized trial to examine whether a fixed bearing (n=20) or mobile bearing (n=20) implant provides improved gait mechanics. Seven patients were not included in the analysis owing to cancelled surgery (one from each group) and five were lost to follow-up (four with fixed bearing and one with mobile bearing implants). The authors stated that the study was statistically powered to detect large effects and descriptively analyze observed effect sizes. They concluded there were no statistically or clinically meaningful differences between the fixed and mobile bearing implants when examining gait mechanics and pain one year after TAA.

Weme et al. (2015) prospective studied TAR performed for end-stage arthritis either because of fracture or ligamentous injury in 88 patients (50 post-fracture ankles and 40 ankles with instability arthritis [2 bilateral]) who. Mean follow-up for both groups was 5 years. At 6 years, survival with revision or salvage fusion as an endpoint was 87% in the post-fracture group and 79% in the instability group. The number of reoperations was similar in both groups.

Zaidi et al. (2013) performed a systematic review and meta-analysis of modern TARs, including 58 papers (7942 TARs). The overall survivorship was 89% at ten years with an annual failure rate of 1.2%. The mean total range of movement improved from 23° (95% CI 19 to 26) to 34° (95% CI 26 to 41) (p = 0.01). The authors stated the study demonstrates that TAR has a positive impact on patients’ lives, with benefits lasting ten years, as judged by improvement in pain and function, as well as improved gait and increased range of movement. However, the quality of evidence is weak and fraught with biases and high quality randomized controlled trials are required to compare TAR with other forms of treatment such as fusion.

van Heiningen et al. (2013) conducted a systematic review of retrospective and prospective studies including arthrodesis or three-component mobile bearing TAA or both. The 17 studies included 145 rheumatoid arthritis (RA) patients with talocrural arthrodesis and 260 RA patients with third generation total ankle prosthesis. For arthrodesis the mean follow up period was 3.8 years, and 4.5 years for TAA. The authors noted that the included studies had poor methodological design; however, they concluded both interventions show clinical improvement and in line with current literature neither procedure is superior to the other.

In 2014, Queen et al. prospectively reported two year results on 90 patients (49 mobile-bearing STAR and 41 fixed-bearing Salto Talaris). Queen et al. reported that in general, the group with a fixed-bearing implant demonstrated improvements in ankle moment and ground reaction forces, while the mobile-bearing-implant group demonstrated improvements in patient-reported pain outcome. There were few significant changes between the two implant types. The authors conclude that the fixed and mobile bearing prostheses resulted in comparable postoperative outcomes; the two implant types can be considered equal when choosing the type of implant to use to treat end-stage ankle osteoarthritis.

Schenk et al. (2011) prospectively evaluated 401 SALTO implants with a mean follow-up of 29 months. Schenk et al. reported the implant provided good clinical and functional results. Gougoulais et al (2010) published the results of systematic review of the literature evaluating the outcomes of TAA. The authors identified 13 studies published between 2003 and 2008 reporting on 1105 TAAs using various ankle prostheses. With revision, arthrodesis or amputation as the end point, the authors identified 108 failures (9.8%). The weighted follow-up for all prostheses was 5.2 years. The overall failure rate was approximately 10% at 5 years (range of 0% to 32%) with variation between different centers. Superiority of one type of design over another was not supported by the available data. Several limitations were noted regarding the literature reviewed and included surgeon experience, heterogeneity in study design, variable follow-up periods, variable assessment scales, clinical outcomes that were often not validated, methods to assess patient satisfaction were not rigorous, and measures regarding radiograph assessment varied and were often not standardized.
Using ankle fusion as the control, Saltzman et al. (2009) conducted a prospective controlled trial including results of three separate cohorts of patients. In the Pivotal Study, 158 ankle replacement and 66 arthrodesis procedures were performed; in the Continued Access Study, 448 ankle replacements were performed, of which 416 were at minimum 24 months post-surgery at time of the database closure. At 24 month follow-up, 16.5% of the Pivotal arthroplasty group required a secondary surgical intervention, of which 7.6% required revision or removal, compared to 10.6% of the fusion group who required secondary surgery, of which 10.6% required revision or removal. The Continued Access group required even less secondary surgical procedures (8.5%) compared to the Pivotal group. The authors conclude ankles treated with STAR ankle replacement (in both the Pivotal and Continued Access Groups) had better function and equivalent pain relief as ankles treated with fusion.

Haddad et al. (2007) conducted a systematic review of the literature addressing the intermediate and long-term outcomes of TAA and ankle arthrodesis in terms of ankle function, pain, revision, conversion to arthrodesis, implant survival and quality of life. The publications included in their review were published between 1990 and 2005 and included 49 primary studies (56 treatment arms, 2114 patients). Ten studies focused on TAA (n=852), and 39 studies focused on ankle arthrodesis (n=1262). No studies directly compared TAA and ankle arthrodesis. Follow-up time ranged from two to nine years in the TAA group of studies and two to 23 years in the arthrodesis group of studies, with an average of five years across both groups. The efficacy results associated with second-generation implants, including the Agility ankle, New Jersey Low Contact Stress Ankle, Buechel-Pappas, TNK, STAR, and Salto prosthesis were reported. The authors’ analysis was limited because efficacy outcomes were variable across the studies. The five- and ten-year implant survival rates following TAA were 78% and 77%, respectively. A revision was required in 7% of patients who underwent TAA, most commonly for loosening and/or subsidence. Five percent of the TAA patients were converted to arthrodesis. The review was limited by the variability of reported outcomes and the tools to assess outcomes, differences in patient populations, differences in study follow-up times, and lack of direct comparison between TAA and ankle arthrodesis. However, the authors acknowledged that although the evidence was limited, the intermediate results suggest the two procedures are comparable.

**Preoperative Imaging, Intraoperative Navigation, Customized Ankle Replacement**

Variations in ankle deformity may be considered a relative contraindication to ankle replacement surgery. As a result, total ankle replacement procedures employing the use of patient specific guides, preoperative computed tomography, and/or 3-dimensional navigation systems (e.g., Prophecy® INBONE® Preoperative Navigation Alignment Guides [intended for use with the INBONE® Total Ankle System], Wright Medical Technology, Arlington, TN) are under investigation as methods to improve the overall fit of the ankle implant. While these technologies may be considered an alternative to traditional methods of aligning the ankle implant device, evidence in the peer-reviewed published scientific literature consists primarily of case reports with few case series and is insufficient to support safety and improved clinical outcomes with the use of these technologies.

**Professional Societies/Organizations**

**American College of Foot and Ankle Surgeons (ACFAS):** The ACFAS Position Statement on Total Ankle Replacement Surgery (July 2016) 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. 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 (March 2014) supports the use of total ankle replacement for the treatment of ankle arthritis that has failed conservative management in select patients. To this end, the AOFAS considers total ankle replacement to be a treatment option with demonstrated improved outcomes. This position is based on multiple reports from the peer-reviewed scientific literature.

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

No relevant information.

**Use Outside of the US**

No relevant 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:**

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<th>CPT® Codes</th>
<th>Description</th>
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<tr>
<td>27700</td>
<td>Arthroplasty, ankle;</td>
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<tr>
<td>27702</td>
<td>Arthroplasty, ankle; with implant (total ankle)</td>
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<tr>
<td>27703</td>
<td>Arthroplasty, ankle; revision, total ankle</td>
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<tr>
<td>C1776</td>
<td>Joint device (implantable)</td>
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<td>L8699</td>
<td>Prosthetic implant, not otherwise specified</td>
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**Considered Not Medically Necessary when used to report pre-operative imaging studies (e.g., CT scans, MRI) associated with customized ankle replacement and/or utilized as part of operative navigation guides:**

<table>
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<th>Description</th>
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<td>73700</td>
<td>Computed tomography, lower extremity; without contrast material</td>
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<td>73701</td>
<td>Computed tomography, lower extremity; with contrast material(s)</td>
</tr>
<tr>
<td>73702</td>
<td>Computed tomography, lower extremity; without contrast material, followed by contrast material(s) and further sections</td>
</tr>
<tr>
<td>73721</td>
<td>Magnetic resonance (eg, proton) imaging, any joint of lower extremity; without contrast material</td>
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<td>76498</td>
<td>Unlisted magnetic resonance procedure (eg, diagnostic, interventional)</td>
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**References**


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