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Total Ankle Replacement (TAR)

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

1. Total ankle replacement using a U.S. Food and Drug Administration (FDA) approved replacement device **may be 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 the following criteria are met:
   A. Skeletally mature patient with moderate to severe ankle (tibiotalar) pain that limits daily activity; AND
   B. Failure of conservative treatment (i.e., anti-inflammatory medications, orthotic devices, activity modification, physical therapy) for a minimum of 6 months; AND
   C. Any ONE of the following conditions:
      - Arthritis in adjacent joints (i.e., subtalar or midfoot); OR
      - Severe arthritis of the contralateral ankle; OR

- Arthrodesis of the contralateral ankle; OR
- Inflammatory (e.g., rheumatoid) arthritis; AND

D. Does NOT HAVE ANY of the following contraindications:
- Extensive avascular necrosis of the talar dome;
- Compromised bone stock or soft tissue (including skin and muscle);
- Severe malalignment (e.g., > 15 degrees) not correctable by surgery;
- Active ankle joint infection;
- Peripheral vascular disease;
- Charcot neuroarthropathy;
- Peripheral neuropathy;
- Ligamentous instability;
- Subluxation of the talus;
- History of ankle joint infection;
- Presence of severe deformities above or beneath the ankle.

2. A revision to a total ankle replacement using a U.S. FDA approved device **may be considered medically necessary** when:
   A. The implanted device has failed; AND
   B. All the criteria in section I are met EXCEPT IB (failure of conservative treatment [i.e., anti-inflammatory medications, orthotic devices, activity modification, and physical therapy] for a minimum of 6 months).

3. Total ankle replacement, revision of a total ankle replacement, or total ankle replacement combined with 3-D total talar prosthesis **is considered experimental, investigational and/or unproven** for all other indications.

Policy Guidelines

None.

Description

A variety of total ankle replacement (TAR) system designs are being utilized for the management of moderate-to-severe tibiotalar pain. TAR (arthroplasty) is being evaluated as an alternative to tibiotalar fusion (arthrodesis) in patients with arthritis.

Background

The ankle joint is a comparatively small joint relative to the weight bearing and torque it must withstand. These factors have made the design of total ankle joint replacements technically challenging. The alternative to total ankle replacement (TAR) is arthrodesis, which may lead to alterations in gait and onset of arthrosis in joints adjacent to the fusion.TAR has been performed in patients with severe rheumatoid arthritis, severe osteoarthritis (OA), or posttraumatic OA. While both procedures are designed to reduce pain, TAR is also intended to

improve function and reduce stress on adjacent joints. TAR has been investigated since the 1970s, but in the 1980s the procedure was essentially abandoned due to high long-term failure rates, both in terms of pain control and function. (1) Due to evolving techniques and improved implant design, TAR implant devices have reemerged as a viable option in select individuals. (2, 3)

Devices

There are multiple implant devices currently available. Implant survivorship varies among prosthesis types and generations, with improved outcomes reported with use of the more recent third- and fourth-generation ankle implants. (2)

Fixed-Bearing

Fixed-bearing designs lock the polyethylene component into the baseplate, which provides greater stability but increases constraint and edge-loading stress at the bone implant interface, potentially increasing risk of early loosening and failure. The first fixed-bearing devices are implanted with cement fixation (cement fixation requires more removal of bone). (1)

Mobile-Bearing

Three-piece mobile-bearing systems have a polyethylene component that is unattached and articulates independently with both the tibial and talar components. The 3-piece mobile-bearing prostheses are designed to reduce constraint and edge-loading but are less stable than fixed-bearing designs and have the potential for dislocation and increased wear of the polyethylene component. Mobile-bearing designs are intended for uncemented implantation and have a porous coating on the components to encourage osseointegration. (1)

Total Talar Prosthesis

Combined TAR with implantation of a three-dimensional (3D) printed total talar prosthesis (TTP) is a technology which is being proposed for restoring normal joint anatomy throughout the hindfoot. The goal of this 3D technology is to provide a custom implant that mimics the individual patient's anatomy while restoring normal anatomical relationships. (4)

Patient Selection

In general, patients selected for total ankle arthroplasty would not be good candidates for arthrodesis due to the presence of end stage arthritis. Optimal candidates for TAR are considered to be older (age >50 years), thin, low-demand individuals with minimal deformity. Patients should have no functional barriers to participation in a rehabilitation program. Total ankle arthroplasty should also be performed by surgeons who are adequately trained and experienced in the specific techniques and devices used. Non-surgical options including but not limited to injections, physical therapy and bracing should be attempted prior to surgical intervention. Some suggested contraindications to TAR may include but are not limited to individuals with peripheral neuropathy, vascular insufficiency, severe ankle instability, significant bone loss and infection. (3, 5)

Regulatory Status

The United States (U.S.) Food and Drug Administration (FDA) approved indications vary depending on device type: fixed-bearing versus mobile-bearing. In general, these devices are intended for adult patients with reduced activity levels, who have severe rheumatoid arthritis, post-traumatic arthritis, or OA of the ankle.

Fixed-Bearing Devices

Fixed-bearing TAR (Class II devices, product code HSN) include but are not limited to the following U.S. FDA approved devices:

- Agility™ LP Total Ankle (DePuy Orthopaedics Inc., Warsaw, IN). (6)
- Cadence® Total Ankle System (Integra Lifesciences Corporation, Ascension Orthopedics, Inc., Austin, Texas). (7)
- Eclipse Total Ankle Implant (Kinetikos Medical Inc., Carlsbad, CA). (8)
- Hintermann Series H2™ Total Ankle System (DT MedTech LLC, Towson, MD). (9)
- Inbone™ Total Ankle (I and II) (Wright Medical Technology Inc., Memphis, TN) (10)
- Infinity™ Total Ankle System (Wright Medical Technology Inc., Arlington, TN). (11)
- Integra® Total Ankle Replacement System (Ascension Orthopedics, Austin, TX). (12)
- Invision™ Total Ankle Revision System (Wright Medical Technology Inc., Memphis, TN). (13)
- Salto Talaris® (14, 15), Salto XT (Tornier/Tornier SAS, France). (16)
- Topez Total Ankle Replacement (Topez Orthopedics Inc, Boulder, CO.) (17)
- Exactech Vantage® Total Ankle System (Exactech Inc., Gainsville, FL) (18)

Mobile-Bearing Devices

Mobile-bearing devices are Class III devices and are considered under a different regulatory pathway (premarket approval) than the fixed component devices described above, which were cleared for marketing under the 510(k)-regulatory pathway. Premarket approval (PMA) requires demonstration of clinical efficacy in FDA-regulated trials conducted under an investigational device exemption (IDE).

The following mobile-bearing TAR devices are available in the U.S. under FDA product code NTG:

- Scandinavian Total Ankle Replacement (STAR®) system (DJO Global, Austin, TX; P050050): This device was approved by the FDA for use as a non-cemented implant to replace a painful arthritic ankle joint due to OA, post-traumatic arthritis, or rheumatoid arthritis. (19) As a condition of the PMA approval, the device maker was required to evaluate the safety and effectiveness of the device over 8 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. (3, 19)
- Hintermann Series H3™ mobile-bearing Total Ankle Replacement 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 OA, post-traumatic OA or arthritis secondary to inflammatory disease. (20, 21)

The Ankle Evolution System, the Buechel-Pappas, the Mobility, the Salto Total Ankle, the BOX Ankle, the CCI Evolution Ankle, the Zenith and the TNK ankle are not currently used in the U.S.

Total Talar Prosthesis

On February 17, 2021, the FDA granted the humanitarian device exemption (HDE) for the patient specific talus spacer 3D-printed talus implant (Additive Orthopaedics, LLC.). This implant is the first 3-D implant to replace the talus bone in patients with avascular necrosis (AVN) of the ankle joint. FDA Product code: QNN (22, 23)

A comprehensive list of all U.S. FDA approved devices with their specific FDA approved indication(s) can be found on the FDA website at <https://www.FDA.gov>.

Rationale

This policy was created in August 2003 and updated periodically with literature reviews. The most recent literature update covered through December 18, 2023.

The following outcomes are relevant to the analysis of safety and efficacy of total ankle replacement (TAR), compared to ankle arthrodesis, the standard treatment alternative:

- Resolution of pain;
- Function of both the ankle and the proximal joint in various activities, such as gait walking on flat or irregular surfaces, or walking upstairs, and return to recreational activities;
- Long-term outcomes, including time to revision, and the development of arthritis in the tarsus, knee, or hip related to strain on adjacent joints.

In 2007, Haddad et al. conducted a systematic review and meta-analysis of 10 studies (including 2 abstracts) on TAR (852 patients) and 39 studies on ankle arthrodesis (1262 patients). (24) No studies that directly compared the 2 procedures were identified. The patients treated with TAR were older (58 vs 50 years, respectively), and the primary indication was rheumatoid arthritis (39%), whereas posttraumatic arthritis was the primary indication for arthrodesis (57%). The meta-analysis found similar overall scores for the Ankle-Hindfoot Scale (78 for TAR vs 76 for arthrodesis) and revision rates (7% vs 9%, respectively), although these results are limited due to the quality of the included studies, heterogeneity of results, variability in reporting of outcomes of interest, different populations for the 2 procedures, and different durations of follow-up. Loosening (28%), wear (15%), and dislocation/migration (11%) were the most frequently reported reasons for revision of ankle arthroplasty (n=46), while revision of ankle arthrodesis (n=66) was predominantly due to nonunion (65%) and infection (26%). Conversion from arthroplasty to arthrodesis was reported in 5% of 572 patients. Below-the-knee

amputations were reported in 1 of 126 (0.8%) patients who had an ankle replacement and 12 of 242 (5%) patients who had undergone ankle fusion.

SooHoo et al. conducted a review of California's hospital discharge database to compare short- and long-term outcomes of patients who had undergone TAR (n=480) or ankle arthrodesis (n=4705) during a 10- year period (1995-2004). (25) The type of prosthesis was not specified. At 90 days, there were more device-related complications (hazard ratio [HR], 2.68) and major revisions (HR=3.65) in the TAR group in comparison with those who had undergone arthrodesis. For example, there were 6 (1%) major revision procedures by 90 days in the TAR group, including 3 revision arthroplasties, 2 implant removals, and 2 ankle fusions. In comparison, additional fusion was performed in 16 (0.35%) of the ankle arthrodesis patients. At 5 years after surgery, major revision rates were 23% for TAR and 11% for arthrodesis (HR=1.93), with reduced survival rates according to Kaplan-Meier analysis. There was a 2% lower rate of Subtalar fusion following TAR compared with ankle arthrodesis (0.7% vs 2.8%; HR=0.28). Patients treated with ankle fusion were more likely to have lower median income and safety-net insurance, complicated diabetes, and osteonecrosis, whereas patients with ankle replacement were more likely to have rheumatoid arthritis.

A comparison of complications between TAR and arthrodesis was reported by Krause et al. in 2011. (26) From 2002 through 2007, data collected from 516 patients following TAR or ankle arthrodesis were entered into the database. Indications for ankle arthrodesis were severe deformity and instability, poor ankle motion, no or mild adjacent joint arthritis, and younger age. Indications for TAR were older age, severe adjacent joint arthritis, a diagnosis of rheumatoid arthritis, and no or only mild deformity or instability. Patient preference was also a factor. A total of 114 TARs and 47 ankle fusions met the inclusion criteria for the study, with a complete data set and minimum 2-year follow-up. Sixty-one of the TARs were performed with the fixed-bearing Agility prosthesis, while the remaining 53 were performed with 1 of 3 types of mobile-bearing prostheses (HINTEGRA, STAR, Mobility). The mean age was 64 years for the patients who underwent TAR and 59 years for the patients who underwent arthrodesis. The validated self-administered Ankle Osteoarthritis Scale (AOS) was used to evaluate all patients at 6, 12, and 24 months and 3.5, 5, and 10 years postoperatively. Radiographic evaluations were performed at a mean of 39 months following TAR and 37 months following arthrodesis. Both groups had significant improvement in the validated AOS (30.9 points for TAR, 30.6 for arthrodesis, $p<0.001$ for pre- /post comparison). There were significantly more complications following TAR than ankle arthrodesis (54% vs 21%, respectively, $p=0.003$). Aseptic loosening occurred in 17 (15%) of the 114 TARs, and 11 of these had revision surgery. A technical error occurred in 17 (15%) of the TARs, which included lateral gutter impingement, excessive polyethylene wear or breakage, and malalignment. There were 8 (7%) intraoperative fractures, which were treated during the index operation, and 7 cases (6%) of deep infection. The highest rate of complications was reported for the Agility prosthesis (61%), followed by the Mobility (47%), the STAR (44%), and the HINTEGRA (18%). Complications in patients treated with arthrodesis included adjacent joint arthritis (6%), nonunion (4%), and technical error (2%). Other complications (9%) included medial-gutter-related discomfort and nonspecific ongoing pain. For both groups, there was a significant impact of major complications on the AOS

outcome score. The comparison of adverse rates between groups is limited by differences in the patient populations selected for each procedure.

Schuh et al. in 2011 retrospectively compared 21 patients receiving ankle arthrodesis with 20 patients receiving TAR on the outcome of percent of patients participating in sports and recreational activities. (27) At an average of 34.5 months after surgery, there was no significant difference between TAR and arthrodesis in activity levels as measured by the University of California at Los Angeles (UCLA) activity scale (6.8 vs 7.0), participation in sports activities (76% vs 75%), or the American Orthopaedic Foot and Ankle Society (AOFAS) hindfoot score (75.6 vs 75.6). Prospective controlled trials directly comparing TAR with the established alternative of fusion are lacking. Therefore, relevant publications reporting outcomes of ankle arthrodesis and ankle arthroplasty are reviewed below.

In 2017, Lawton et al. (28) conducted a systematic review to assess outcomes and complications following ankle arthrodesis and TAR in patients with symptomatic tibiotalar arthritis. Six studies reporting on outcomes following TAR and 5 studies reporting on outcomes following ankle arthrodesis met inclusion criteria and were included for pooled data analysis. Evaluation of TAR studies only included studies using modern third-generation TAR implants approved for use in the US. 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. The evaluated ankle arthrodesis studies were all retrospective in nature and reported on a total of 635 ankles operated on from 1993 to 2013. Arthrodesis was performed through an open approach in 577 ankles and through an arthroscopic approach in 58 ankles. Three of the studies reported an adjusted mean follow-up of 4.3 years. The adjusted overall complication rate was higher for ankle arthrodesis (26.9%) compared to TAR (19.7%), with similar findings in the non-revision reoperation rate (12.9% for ankle arthrodesis compared to 9.5% for TAR). The adjusted revision reoperation rate for TAR (7.9%) was higher than ankle arthrodesis (5.4%). The analysis of results from 10 studies directly comparing TAR to ankle arthrodesis 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 ankle arthrodesis, but a higher reoperation rate for revision after TAR. Based on existing literature, the decision to proceed with TAR or ankle arthrodesis for end-stage ankle arthritis should be individualized.

In 2017, Kim et al. (29) conducted a meta-analysis including comparative studies that assessed TAR versus ankle arthrodesis 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 (4 prospective and 6 retrospective studies). There were no significant differences between the two procedures in the AOFAS ankle-hindfoot score, Short Form-36 physical component summary and mental component summary scores, visual analogue scale (VAS) 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 most of the

included studies were retrospective in design. The authors stated that further studies of high methodological quality with long-term follow-up are needed.

In 2020, Li et al. (30) 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.

Undén et al. (2020) conducted an analysis of intermediate and long-term prosthetic survival of TAR. (31) As an endpoint, the team analyzed the exchange or permanent extraction of TAR components for 1226 prostheses, with mean follow-up of 7 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 5 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 $p<0.001$).

Total Ankle Replacement versus Ankle Arthrodesis for Patients Aged 50 to 85 Years with End-Stage Ankle OA

In 2022, Goldberg (32) performed a multi-center, parallel-group, non-blinded, RCT that compared the clinical effectiveness and complication rates of TAR with those of arthrodesis (i.e., ankle fusion) in the treatment of end-stage ankle OA in individuals aged 50 to 85 years. Individuals were suitable for both procedures and were recruited from 17 U.K. hospitals and randomized using minimization. The primary outcome was the change in the Manchester-Oxford Foot Questionnaire walking/standing domain scores between the pre-operative baseline and 52 weeks post-surgery. Between March 2015 and January 2019, a total of 303 participants were randomized using a minimization algorithm: 152 to TAR and 151 to ankle fusion. At 52 weeks, the mean (standard deviation) Manchester-Oxford Foot Questionnaire walking/standing domain score was 31.4 (30.4) in the TAR arm (n = 136) and 36.8 (30.6) in the ankle fusion arm (n = 140); the adjusted difference in the change was -5.6 (95 % CI: -12.5 to 1.4; p = 0.12) in the intention-to-treat (ITT) analysis. By week 52, 1 patient in the TAR arm required revision. Rates of wound-healing issues (13.4 % versus 5.7 %) and nerve injuries (4.2 % versus less than 1 %) were higher and the rate of thrombo-embolic events was lower (2.9 % versus 4.9 %) in the TAR arm than in the ankle fusion arm. The bone non-union rate (based on plain radiographs) in the ankle fusion arm was 12.1 %, but only 7.1 % of patients had symptoms. A post-hoc analysis of fixed- bearing TAR showed a statistically significant improvement over ankle fusion in Manchester- Oxford Foot Questionnaire walking/standing domain score (-11.1, 95 % CI: -19.3 to -2.9; p = 0.008). The authors concluded that both TAR and ankle fusion improved patients' QOL at 1 year, and both appeared to be safe. When TAR was compared with ankle fusion overall, these investigators were unable to show a statistically significant difference between the 2 arms in terms of the primary outcome measure. The TAR versus ankle

arthrodesis (TARVA) trial was inconclusive in terms of superiority of TAR, as the 95 % CI for the adjusted treatment effect included both a difference of 0 and the minimal important difference of 12, but it could rule out the superiority of ankle fusion. A post-hoc analysis comparing fixed-bearing TAR with ankle fusion showed a statistically significant improvement of TAR over ankle fusion in Manchester-Oxford Foot Questionnaire walking/standing domain score. This study had several drawbacks as the initial report contained 52-week data, which should be interpreted with caution. There was also heterogeneity between surgical implants and techniques which was performed across 17 NHS centers to ensure that decision-making streams reflected the standard of care in the NHS as closely as possible.

Ankle Arthrodesis

Coester et al. reported 22-year follow-up with clinical and radiologic evaluation on 23 patients who had ankle arthrodesis for the treatment of painful posttraumatic arthritis of the ankle. (33) A chart review of arthrodesis procedures at the author's institution identified 64 patients who met the inclusion/exclusion criteria of isolated ankle arthrodesis, 48 (75%) of whom were located. Thirteen of these 48 patients had died, 4 (8%) had a below-the-knee amputation, 2 (4%) had an additional midfoot arthrodesis, and 6 (13%) declined to participate, resulting in 23 patients included in the follow-up evaluation (range, 12-44 years). The mean age of the study group at the time of the operation was 41 years (range, 12-70 years), and 64 years (range, 38-89 years) at follow-up. Twenty-two (96%) of the patients demonstrated a slight-to moderate limp on clinical evaluation, with no range of motion (ROM) present in 39% and motion less than half the range of the contralateral side in 57%. Eleven patients (48%) had tenderness and swelling in the hindfoot and 9 (39%) in the midfoot. Six patients (26%) used a cane and 2 (9%) used a walker or other assistance for support. Self-reported questionnaire results indicated more foot pain (38 vs 11 points, respectively), foot disability (47 vs 15 points, respectively), and more severe activity limitation on the ipsilateral than contralateral side (27 vs 10 points, respectively). Twenty-three patients (96%) reported limitations in vigorous activities, and 20 patients (83%) reported difficulty walking more than 1 mile. For the uninvolved ankle, most of the patients (87%) had full and painless motion. Pain did not differ significantly between the ipsilateral and contralateral knee. Radiographic evaluation of other joints showed more degeneration in the ipsilateral than the contralateral foot. For example, 21 patients had moderate or severe osteoarthritis (OA) in the ipsilateral but not the contralateral subtalar joint and 13 patients had moderate or severe OA in the ipsilateral but not the contralateral talonavicular joint. No differences were found in the level of OA in the ipsilateral and contralateral knees. The effects of ankle fusion on other joints of the foot may be underestimated in this study due to the exclusion of patients who underwent additional procedures.

Buchner and Sabo evaluated long-term outcomes of 48 patients at an average 9 years after ankle arthrodesis. (34) From a cohort of 60 patients who underwent fusion between 1979 and 1997, 7 patients were excluded, 3 died, and 2 were lost to follow-up, leaving 45 patients who had clinical and radiologic evaluation and 3 patients who responded to questionnaires only. The average age of the patients at the time of surgery was 51 years (range, 20-74 years). Before surgery, 34 patients (71%) reported severe pain that was almost always present, 12 (25%)

reported moderate daily pain and 2 (4%) had mild occasional pain. At follow-up, 10 (21%) patients reported moderate-to-severe pain, and 38 (79%) reported mild-to-no pain. The VAS for pain improved from an average of 8.8 before surgery to 3.0 at follow-up. Nine patients (19%) had revision surgery due to infection (n=4), nonunion (n=4), and malposition (n=1). Clinical evaluation at 9 years (range, 3-21 years) revealed that 4 patients (8%) had a marked gait abnormality and limp, 26 (54%) had some gait abnormality, and 18 patients (38%) had no abnormality while walking. The average postoperative score on the AOFAS Ankle and Hindfoot Scale was 74 out of 100. Thirty-four patients (73%) scored as good-to-excellent and 13 (27%) as fair-to-poor. Arthrosis in the subtalar joint was severe in 4, moderate in 17, and mild in 17. The average tarsal mobility of the surgically treated foot was 54% of the contralateral side, and restriction of tarsal mobility was correlated with worse clinical outcome.

Takakura et al. reported on a 7-year follow-up (average range, 2-15 years) on 42 patients who underwent arthrodesis for primary or secondary OA of the ankle. (35) Of 48 patients treated between 1979 and 1995, 3 patients died, and 3 did not return for the clinical evaluation or radiography, resulting in 88% follow-up. The average age of the patients at the time of surgery was 58 years (range, 25-79 years). The clinical score improved from 54 to 78 points (out of 100), with the pain subscore improving from 18 to 35 (out of 40). No association was found between postoperative pain and ROM. Nonunion was detected in 3 ankles (7%). Degenerative arthritis developed and advanced in the subtalar joint in 33% of the patients. The severity of arthritis in the subtalar and Chopart joints was exacerbated if patients had arthritis before surgery. Based on these findings, the authors concluded that a treatment method that allows mobility of the ankle, such as total ankle arthroplasty, is indicated for patients in whom degenerative changes are detected in adjoining joints before surgery.

Section Summary: Ankle Arthrodesis

The literature indicates that treatment of a painful arthritic joint with arthrodesis can significantly reduce pain. However, nonunion and malposition may require additional surgery, and as many as 5% of patients have been reported to choose amputation due to continuing pain or loss of function. With longer term follow-up, increasing foot pain and degenerative changes in adjoining joints have been observed. These longer-term changes are associated with reduced ROM in the fused ankle joint and have been shown to be most severe in patients with preexisting OA of the subtalar joint.

Total Ankle Replacement

Gougoulias et al. published a 2010 systematic review on outcomes from ankle replacement. (36) Thirteen level IV (case series) studies were published between 2003 and 2008 that included at least 20 subjects and had at least 2 years of follow-up. The studies included a total of 1105 total ankle replacements (TARs) (including 234 Agility, 344 STAR, 153 Buechel-Pappas, 152 HINTEGRA, 70 TNK, 54 Mobility). The failure rate, with revision, arthrodesis, or amputation as an endpoint, was 9.8%, with a weighted follow-up of 5.2 years. The available evidence was insufficient to determine superiority of any implant design over another.

Fixed-Bearing Total Ankle Replacement

Roukis reported a systematic review of articles published between 1998 and 2011 in which the Agility TAR was used. (37) Included were 14 studies (2312 ankles) that had a mean follow-up of 12 months or longer and had details of the revisions performed. Reasons for revisions were aseptic loosening, ballooning osteolysis, cystic changes, malalignment, or instability. The methodologic quality of the included studies was considered generally poor. At a weighted mean follow-up of 22.8 months, 224 (9.7%) had undergone revision, of which 182 (81.3%) underwent implant component replacement, 34 (15.2%) underwent arthrodesis, and 8 (3.6%) underwent below-knee amputation. No significant effect from the surgeon's learning curve on the incidence of revision or the type of revision surgery performed was identified. Causes of revision included malalignment, subsidence, migration, aseptic loosening/osteolysis, instability of the talar component, and "undersizing" the implant components. The conclusions of this systematic review are limited by the poor quality of the individual studies and the short follow-up.

One of the studies included in the systematic review was by Spirt et al. reporting outcomes from 306 consecutive TARs (303 patients) with the Agility Ankle system performed between 1995 and 2001. (38) The majority of the patients had posttraumatic osteoarthrosis (65%) or primary osteoarthrosis (25%) and had an average age of 54 years (range, 19-85 years). Loosening of the talar component was observed in 22 joints. (7%) At an average follow-up of 33 months, 40% of cases had required reoperation, and 33 TARs (11%) were considered to have failed. The 5-year implant survival rate was 80%. Age at the time of the primary total ankle arthroplasty was the only covariate related to the rate of reoperation and failure, with each 1-year increase in age associated with a 3.5% decrease in the hazard of failure. Another case series of 100 consecutive total ankle replacements with the Agility Ankle, implanted between 1984 and 1993, reported follow-up of 2 to 12 years. (39) Patients were evaluated with an interview focusing on pain and activities of daily living, and clinical and radiologic examination. Of the 85 ankles in 83 patients that were available for follow-up, 98% were associated with some level of pain relief. A total of 74% of patients reported an increase in their functional level. Based on radiologic exam, 36% of prostheses were associated with a delayed union or nonunion. Migration of talar or tibial components of the prosthesis were also noted; migration of the tibial component was associated with nonunion. Nonunion was associated with ballooning lysis at the interface between the bone and tibial component, although lysis was also seen in cases when a solid union was present. The authors conclude that these intermediate results are encouraging, although the radiographic findings created concerns about long-term outcomes.

Kopp et al. reported minimum 2-year follow-up (range, 26-64 months) on 43 consecutive ankle replacements with the Agility prosthesis; 2 patients were lost to follow-up and 1 patient required revision due to aseptic loosening. (40) Pain was reported to have improved in all patients, rated postoperatively as "none" in 16 patients, "mild, occasional" in 21 patients, and "moderate, daily" in 3 patients. Twelve perioperative and 12 postoperative complications occurred (60%), requiring additional operative procedures. The authors note that the high rate of complications and need for reoperation is consistent with other reports on the Agility prosthesis, but most of the complications can be adequately treated. Radiolucency or lysis was

noted at follow-up in 34 of 40 ankles, and migration or subsidence of components was noted in 18. The authors concluded that, "the overall intermediate-term clinical results of total ankle replacement using the Agility prosthesis are promising, but the longevity of the prosthesis is questionable because of the frequency of periprosthetic lucency, lysis, and component subsidence." In other case series, failure rates for the Agility prosthesis have been reported to range from 10.6% at 108 months to 32.3% at 40 months. (41)

In 2009, Jensen and Linde reported follow-up of up to 23 years for 26 patients (33 ankles) with rheumatoid arthritis who had received a TAR between 1980 and 1993. (42) The median age of the patients was 60.5 years (range, 31-75 years) at the time of surgery. At the latest follow-up, prostheses in 4 patients had been removed (15%; 4-13 years after implantation); 2 patients with 3 prostheses were alive at 23 years after surgery. Two patients had received amputation due to unrelated causes, and the remaining 18 patients had died with the prosthesis in place (median 9.5 years after TAR; range, 0.5-23.3 years). Survival based on radiographic loosening was 64% at 10 years, while the prosthesis survival rate was 85% at 10 years.

In 2017, Queen et al. (43) 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 total ankle arthroplasty.

Mobile-Bearing Total Ankle Replacement

The STAR prosthesis received final FDA approval in 2009. The pivotal trial for the STAR prosthesis, reported to the FDA in 2007, was a 2-year noninferiority design with 158 patients from 10 sites treated with arthroplasty and 66 patients from 5 additional sites treated with arthrodesis. (19) Results from this trial, and from 435 patients enrolled in the FDA-regulated, multicenter, continued-access registry, were published in 2009. (44) Patients were included if they had primary ankle arthritis, posttraumatic arthritis, or rheumatoid arthritis, moderate-to-severe pain (Buechel-Pappas pain score of 20 or less), loss of mobility and function (total Buechel-Pappas score <50/100), and a minimum of 6 months of conservative treatment including a 3-month trial of orthosis and/or analgesic medication. Exclusion criteria included hindfoot or forefoot malalignment, avascular necrosis, severe osteopenia or inadequate bone stock, insufficient ligament support, neuropathy, or neuromuscular impairment. There were no differences between groups in the operative time, estimated blood loss, or length of stay. In the STAR arm, 142 patients (90%) completed the 24-month follow-up; 3 patients died, and 2 were transferred to a bilateral treatment study. Only 78% completed 24-month follow-up in the arthrodesis arm due to noncompliance by patients and investigators. The average total Buechel-Pappas score increased from 41 to 82 in the STAR group and from 43 to 70 in the arthrodesis arm, achieving noninferiority for this outcome. Statistical superiority was driven primarily by the improvement in ROM, with slight improvements in deformity (increased by 1.9

vs 0.4 for arthrodesis) and function (increased by 13.4 vs 9.7 for arthrodesis). Safety success was achieved in fewer STAR patients (71%) than arthrodesis patients (83%). Major adverse events were reported in 9% of STAR patients and 1.5% of controls. Implant-related adverse events included bone fracture (18%), bony changes (8%), nerve injury (20%), soft tissue edema (16%) decreased ROM (6%), and wound problems (20%). Pain adverse events were similar in the 2 groups (44% for STAR, 49% for arthrodesis). Surgical instrumentation and technique were modified during the study to address the wound problems and sensory loss from damage to a branch of the peroneal nerve. In the continued access study, there was a 5.3% major complication rate (wound problems, infection, bone problems), 1 ankle replacement resulted in a below knee amputation due to infection, and 98 of 435 patients (22.5%) had perioperative nerve injury. (21) At 24-month follow-up, 37 patients (8.5%) in the continued access group required revision, removal, or other intervention (compared to 16.5% in the pivotal STAR group and 10.6% in the pivotal fusion group). As in the pivotal trial, efficacy (76%, with ≥40-point improvement in the Buechel-Pappas score) was driven primarily by the improvement in ROM.

Wood et al. reported mid-term outcomes from 200 patients who had been randomized to receive 1 of 2 mobile-bearing ankle replacement systems (STAR or Buechel-Pappas) between 2000 and 2003. (45) The mean follow-up (date last seen for surviving ankles or for failure) was 49 months, with a range of 1 to 85 months. At the time of follow-up, 163 implants had survived, 21 patients had died, and 16 (8%) implants had failed (12 Buechel-Pappas, 4 STAR). These were treated with fusion (n=14) or revision (n=2). There was a trend toward higher failure with the Buechel-Pappas ankle compared with the STAR (p=0.09), with a hazard ratio of 2.7. The presence of a varus or valgus deformity before surgery was associated with failure for either prosthesis, with a hazard ratio of 1.64 for every 5° increment in deformity. Edge-loading was observed in 12 Buechel-Pappas and 6 STAR prostheses, 39% of which were subsequently revised. A patient who had a varus or valgus deformity of 15º or more had a 6.5 greater likelihood of developing edge-loading than if the ankle was well-aligned before surgery. Pain and function, measured by the AOFAS hindfoot score, improved to a similar extent in the 2 groups. The study found that few patients (<20%) had marked increases (≥10º) in range of ankle movement with either prosthesis. Results were not compared with arthrodesis.

In 2019 Nunley et al. (46) competed a prospective, single institution, randomized trail comparing the use of the mobile bearing (STAR device) and fixed bearing (Salto-Talaris) device in the treatment of end-stage ankle arthritis. Between November 2011 and November 2014, adult patients with end-stage ankle OA failing nonoperative treatment were introduced to the study. With informed consent, 100 patients (31 male and 69 female, average age 65 years, range 35-85 years) were enrolled; a demographic comparison between the 2 cohorts was similar. Exclusion criteria included inflammatory arthropathy, neuropathy, weight exceeding 250 pounds, radiographic coronal plane deformity greater than 15 degrees, or extensive talar dome wear pattern ("flat-top talus"). Prospective patient-reported outcomes, physical examination, and standardized weightbearing ankle radiographs were obtained preoperatively, at 6 and 12 months postoperatively, and then at yearly intervals. Data collection included visual analog pain score, Short Form 36, Foot and Ankle Disability Index, Short Musculoskeletal Functional Assessment, and AOFAS ankle-hindfoot score. Surgeries were performed by a non-

design team of orthopedic foot and ankle specialists with TAR expertise. Statistical analysis was performed by a qualified statistician. At average follow-up of 4.5 years (range, 2-6 years) complete clinical data and radiographs were available for 84 patients; 7 had incomplete data, 1 had died, 4 were withdrawn after enrolling but prior to surgery, and 4 were lost to follow-up. In all outcome measures, the entire cohort demonstrated statistically significant improvements from preoperative Status to postoperative follow-up with no statistically significant difference between the 2 groups. Radiographically, tibial lucency/cyst formation was 26.8% and 20.9% for mobile bearing TAR and fixed bearing TAR, respectively. Tibial settling/subsidence occurred in 7.3% of mobile bearing. Talar lucency/cyst formation occurred in 24.3% and 2.0% of mobile bearing TAR and fixed bearing TAR, respectively. Talar subsidence was observed in 21.9% and 2.0% of mobile bearing TAR and fixed bearing TAR, respectively. Reoperations were performed in 8 mobile bearing TARs and 3 fixed bearing TAR, with the majority of procedures being to relieve impingement or treat cysts and not to revise or remove metal implants. With a high level of evidence, our study found that patient-reported and clinical outcomes were favorable for both designs and that there was no significant difference in clinical improvement between the 2 implants. The incidence of lucency/cyst formation was similar for mobile bearing TAR and fixed bearing TAR for the tibial component, but the mobile bearing TAR had greater talar lucency/cyst formation and tibial and talar subsidence. As has been suggested in previous studies, clinical outcomes do not necessarily correlate with radiographic findings. Reoperations were more common for mobile bearing TAR and, in most cases, were to relieve impingement or treat cysts rather than revise or remove metal implants.

In 2011, Zhao et al. reported 5- to 10-year survival outcomes in a meta-analysis of 16 studies with 2088 STAR ankle replacements. (47) At a mean follow-up of 52 months, the pooled rate of failure was 11.1%; 41% of these failures occurred within 1 year of initial operation. The pooled mean 5- year survival rate (10 studies) was 85.9%, and the pooled mean 10-year survival rate (5 studies) was 71.1%. The major reasons for implant failure were aseptic loosening and malalignment.

One of the studies included in the systematic review was a consecutive series of 200 implants (184 patients) with the STAR prosthesis reported by Wood et al. (48, 49) The cumulative 5-year survival rate was 93%, and the 10-year survival rate was 80%. Twenty-four ankles (12%) failed at a mean of 48 months (range, 1-108). The authors suggested that survivorship figures are similar to those of early reports of total knee replacement when techniques and designs were being developed.

Other observational studies report the probability of STAR implant survival to range between 70% and 90% at 10 years. (41, 50-52) Survival of the first generation single-coated STAR prosthesis (used until 1999) was found to be significantly lower than survival of the double-coated STAR prosthesis. (53) In 1 study, survival of the first generation single-coated STAR prosthesis was reported to be 70.7% at 10 years and 45.6% at 10 years. (54) Women younger than age 60 years with OA or posttraumatic arthritis have been shown to have a higher risk for revision than women older than 60 years. (53) Another study that used a 2-component device before 1985 and a 3-component device from 1986 to 1997 found that survival at 15 years was

75% in patients younger than 50 years and 81% for patients 50 or older, although this difference was not significant. (55)

Quality of life (QOL), function, and pain were prospectively evaluated in 82 consecutive patients who had received a STAR prosthesis. (52) Patients were evaluated pre- and postoperatively by the same surgeon, with a mean follow-up of 61 months (range, 24-108 months). Significant improvement between preoperative and last follow-up were found in all outcome categories, including visual analog scale (VAS) for pain, the 36-Item Short-Form Health Survey QOL scale, the AOFAS hindfoot scale, the Buechel-Pappas pain and function scores, and ankle ROM.

Short- to mid-term follow-up from large case series have been reported for the 3-component mobile bearing Salto, Mobility and BOX prostheses. (57-59) Two smaller case series have reported a high rate of osteolysis with the Ankle Evolutive System (AES) total ankle in mid-term follow-up. (60, 61). Outside of an investigational device exemption (FDA-regulated) trial for the Mobility total ankle system, these devices are not available for use in the United States (U.S.) Mid-term survival (8-12 years) of the Buechel-Pappas TAR has been reported to range from 84% to 93%. (62-65) The Buechel-Pappas TAR system is no longer available for use in the U.S. (3)

In 2018, Palanca et al. (66) acknowledged that total ankle arthroplasty (TAA) has become a mainstay in the treatment of end-stage ankle OA. Currently in its fourth generation, the Scandanavian total ankle replacement (STAR) reports implant survivorship at 15 years. In this study, eighty- four TAAs were performed between 1998 and 2000. Metal component survivorship at 15 years was calculated with a Kaplan-Meier curve. Twenty-four (29%) of 84 patients were available for participation with a minimum 15-year follow-up. Any radiographic changes were documented. All additional procedures and complications were recorded. Clinical findings, self-reported performance, and pain evaluations, and AOFAS ankle/hindfoot scores were noted. Metal implant survival was 73% at 15 years. Of the 24 patients available for clinical evaluation, 18 of 24 patients (70.7%) had no change in prosthetic alignment from the immediate postoperative radiograph. Only 1 subtalar fusion was required for symptomatic adjacent joint arthritis. Three patients sustained a broken polyethylene component. AOFAS scores improved from an average of 39.6 points preoperatively, to an average of 71.6. More than half (52.4%) of patients with retained implants required an additional surgical procedure; 3 required 2 additional procedures. The average time to subsequent procedure was 10.2 years. This small cohort demonstrated STAR ankles with retention at 9 years were highly likely to survive to 15 years, and patients continued to have significant improvement in pain relief and minimal decrease in function. At 15 years from TAA, metal survivorship was 73%. As with all ankle replacements, supplementary procedures were common.

Section Summary: Total Ankle Replacement

Total ankle systems are continuing to evolve, although long-term evidence is limited, short term results suggest similar improvements in pain and function in comparison with arthrodesis. Mid-term results indicate 70% survival with first-generation mobile-bearing TAR and up to 90% survival at 8 to 12 years with second-generation devices.

TAR with Implantation of a 3-Dimensional (3-D) Total Talar Prosthesis (TTP)
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 in 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 randomized trials evaluating the long-term outcomes of total talar prosthesis, alone or in combination with total ankle replacement. Larger long-term RCTs are needed to determine the impact on health outcomes. (67-71)

Ongoing and Unpublished Clinical Trials
Some currently ongoing and/or unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04594993	INFINITY™ With ADAPTIS™ Technology Total Ankle Replacement Follow-Up	206	Nov 2035
NCT01620541	Comparing Ankle Fusion to Ankle Replacement	516	May 2027
NCT02038140	Prospective Post Market Clinical Follow-Up (PMCF) Study of the Zimmer® Trabecular Metal™ Total Ankle	120	Mar 2027
NCT02128555	Total Ankle Replacement Versus Arthrodesis Trial (TARVA)	303	Feb 2029
NCT03277989	INFINITY™ Total Ankle Replacement Follow-up (ITAR)	200	Oct 2032 (recruiting)
NCT03247023	Long Term Follow-up of Integra® Cadence™ Total Ankle System in Primary Ankle Joint Replacement	61	Sept 2029
NCT03142958	A Post-Market, Prospective, Non-Randomized, Multi-Center, Open- Label, Clinical Evaluation of the Integra® Cadence™ Total	132	Feb 2029

	Ankle System in Primary Ankle Joint Replacement		

NCT: national clinical trial.

Summary of Evidence

The established standard for the painful arthritic ankle is ankle arthrodesis (fusion), which usually results in a pain-free but rigid ankle in the short term. Complications associated with ankle fusion are nonunion, an increase in arthrosis, and pain in adjoining joints, and not uncommonly, amputation. For specific conditions, including presence of bilateral, subtalar or midfoot arthritis, fusion is not indicated. Therefore, in the absence of an established alternative for specific conditions, total ankle replacement may be considered medically necessary when specified conditions are met.

Total ankle prosthesis (TAR) with implantation of a 3-D total talar prosthesis (TTP) has been proposed for some patients with stage 3 and 4 osteonecrosis and in patients with talar collapse. To date, there is a lack of large, well-designed randomized trails evaluating the long-term outcomes of total talar prosthesis therefore total ankle prosthesis (TAR) with implantation of a 3-D total talar prosthesis (TTP) is considered experimental, investigational, and/or unproven. Larger long-term RCTs are needed to determine the impact on health outcomes.

Practice Guidelines and Position Statements

American College of Foot and Ankle Surgeons (ACFAS)

In 2020, the ACFAS updated their position statement that states 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 evaluation of patient 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, TAR 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 QOL. (72)

The 2020 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 (73).

American Orthopaedic Foot and Ankle Society (AOFAS)

The 2022 AOFAS position statement states that ankle arthritis is a condition that can result in substantial pain and dysfunction. The AOFAS 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 demonstrated improved outcomes in multiple peer reviewed publications." (74)

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	27702, 27703, 27704
HCPCS Codes	C1776

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/31/2025	Document became inactive.
07/15/2024	Reviewed. No changes.
02/15/2024	Document updated with literature review. The following change(s) were made in Coverage. 1) Added “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” to the medically necessary statement for total ankle replacement. 2) Moved section III up to section 1D as part of the total ankle criteria which included “Does not have any of the following contraindications” 3) Reformatted the existing experimental, investigational and/or unproven statement from section IV to section III. Added references 2, 5, 7, 21, 23, 31, 32.70, 71, 73: others updated, some removed.
01/01/2023	Reviewed. No changes.
05/15/2022	Document updated with literature review. The following change was made in Coverage: expanded experimental, investigational and/or unproven statement to include total ankle replacement combined with 3-D total talar prosthesis. Added references 2, 15, 17, 18, 24-26, 40, 60-62: others updated.
09/01/2020	Reviewed. No changes.

02/15/2019	Document updated with literature review. Coverage unchanged. Added references 1-15 and 31; some references removed.
04/15/2017	Reviewed. No changes.
06/15/2016	Document updated with literature review. The following was added to Coverage: Section II: A revision to a total ankle using a U.S. Food and Drug Administration (FDA) approved device may be considered medically necessary when A) the implanted device has failed; AND B) All of the criteria in section I are met EXCEPT IB (failure of conservative treatment [i.e., anti- inflammatory medications, orthotic devices, activity modification, and physical therapy] for a minimum of 6 months). Editorial change to Section III: Added total ankle replacement to coverage statement. Section IV: added "or revision of a total ankle replacement" is considered experimental, investigational and/or unproven for all other indications.
05/01/2015	Document updated with literature review. The following was added to conditional coverage: Failure of conservative treatment (i.e., anti-inflammatory medications, orthotic devices, activity modification, physical therapy) for a minimum of 6 months. CPT/HCPCS code(s) updated.
01/01/2012	Document updated with literature review, no coverage changes. Rationale updated. CPT/HCPCS code(s) updated.
12/15/2009	Document updated with literature review. Coverage changed to state total ankle replacement may be considered medically necessary when specified criteria are met. All other cases remain experimental, investigational and unproven.
06/15/2008	Revised/updated entire document.
09/01/2007	Revised/updated entire document.
08/15/2003	New medical document