# Medical Policy

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## Title: Total Ankle Replacement

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## DESCRIPTION

A variety of total ankle replacement (TAR) system designs, including fixed-bearing and mobile-bearing, are being investigated 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. 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 a high long-term failure rate, both in terms of pain control and function. Newer models have since been developed, which can be broadly subdivided into two design types, fixed-bearing and mobile-bearing. More than 20 different ankle replacement systems are being evaluated worldwide.

**Regulatory Status**

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 were implanted with cement fixation (cement fixation requires more removal of bone). In 2002, the U.S. Food and Drug Administration (FDA) approved the Agility® Ankle Revision Prosthesis (DePuy Orthopaedics, Warsaw, IN), which is intended for cemented use only in patients with a failed previous ankle surgery. In 2005, the FDA reviewed a 510(k) marketing clearance application for the Topez™ Total Ankle Replacement (Topez Orthopedics, Inc., Boulder, Colorado) and determined that it was substantially equivalent to the existing DePuy Agility device. The Topez Ankle is now called the Inbone™ Total Ankle (Wright Medical Technology, Arlington, TN) and is also intended for cemented use only. The Agility LP (DePuy Orthopaedics) and the Eclipse (Kinetikos Medical, Carlsbad, CA) received 510(k) marketing clearance in 2006. The Salto Talaris® (Tornier, Edina, MN) received 510(k) marketing clearance in 2006 and 2009. These semi-constrained cemented prostheses are indicated in patients with end-stage ankle disorders (e.g., affected with severe rheumatoid, post-traumatic, or degenerative arthritis) as an alternative to ankle fusion.

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. They include the Ankle Evolution System (AES, Biomet, Whippany, NJ), Buechel-Pappas system, HINTEGRA® Total Ankle Prosthesis (New Deal), Mobility™ Total Ankle System (DePuy), Salto Total Ankle Prosthesis (Tornier), Scandinavian Total Ankle Replacement (STAR, Small Bone Innovations, Morrisville, PA), Bologna and Oxford Universities (BOX) Ankle (MAT Ortho), CCI Evolution Ankle (Van Straten), Zenith (Corin) and the TNK ankle (Kyocera Corporation, Kyoto, Japan). Three-component mobile-bearing systems 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). In May 2009, the FDA approved the STAR ankle as an alternative to fusion for replacing an ankle joint deformed by rheumatoid arthritis, primary arthritis, or post-traumatic arthritis. As a condition of the approval, the device maker must evaluate the safety and effectiveness of the device over the next 8 years. The Mobility™ Total Ankle System is currently being evaluated in an FDA-regulated investigational device exemption (IDE) trial. The AES, Buechel-Pappas, Mobility, Salto Total Ankle, BOX Ankle, CCI Evolution Ankle, Zenith and the TNK ankle are not currently used in the U.S.

Total ankle replacement has been performed in patients with severe rheumatoid arthritis, severe osteoarthritis, or post-traumatic osteoarthrosis.

## POLICY

A. Total ankle replacement using an FDA-approved device may be considered **medically necessary** in skeletally mature patients with moderate-to-severe ankle (tibiotalar) pain that limits daily activity and who have the following conditions:
   1. Arthritis in adjacent joints (i.e., subtalar or midfoot); OR
   2. Severe arthritis of the contralateral ankle; OR
   3. Arthrodesis of the contralateral ankle; OR
   4. Inflammatory (e.g., rheumatoid) arthritis

   Note: **Absolute contraindications** to ankle arthroplasty include any of the following:
   1. Extensive avascular necrosis of the talar dome
   2. Compromised bone stock or soft tissue (including skin and muscle)
   3. Severe malalignment (e.g., >15 degrees) not correctable by surgery
   4. Active ankle joint infection
   5. Peripheral vascular disease
   6. Charcot neuroarthropathy

   Note: **Relative contraindications** to ankle arthroplasty include:
   1. Peripheral neuropathy
   2. Ligamentous instability
   3. Subluxation of the talus
   4. History of ankle joint infection
   5. Presence of severe deformities above or beneath the ankle

B. Total ankle replacement is considered **experimental / investigational** for all other indications.

Policy Guidelines

In general, patients selected for arthroplasty would not be good candidates for arthrodesis due to the presence of bilateral or subtalar arthritis or Chopart arthrosis. Optimal candidates for total ankle replacement are considered to be older (age older than 50 years), thin, low-demand individuals with minimal deformity. (1) Patients should have no functional barriers to participation in a rehabilitation program.

Ankle arthroplasty should be performed by surgeons who are adequately trained and experienced in the specific techniques and devices used.

## RATIONALE

This policy was updated periodically with literature review. The most recent literature update covered the period of August 2012 through July 12, 2013.

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 up stairs, 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.

Numerous reviews have detailed the technical challenges of TAR, which include evolving prosthetic designs, optimizing biomechanics, and surgical complications. A 2008 evidence-based review concluded that the literature on TAR for any prosthesis consists of level IV evidence (case series). (2) No randomized trials comparing arthrodesis to arthroplasty were identified, and 2 small, nonrandomized studies had conflicting results. The review indicates that, in general, older, thin, low-demand individuals are considered optimal candidates for TAR, but specific criteria have not been established. Absolute contraindications were listed as extensive avascular necrosis of the talar dome, compromised bone stock or soft tissue, peripheral neuropathy, peripheral vascular disease, and Charcot neuroarthropathy. Ligamentous instability, subluxation of the talus, and presence of severe deformities above or beneath the ankle were listed as relative contraindications to arthroplasty. The authors noted that in 2007, the Canadian Orthopaedic Foot and Ankle Society launched a multi-center, randomized case-controlled trial comparing the clinical and radiographic outcomes of the 2 procedures in order to provide evidence for future clinical decision making.

Haddad and colleagues conducted a systematic review and meta-analysis of 10 studies (including 2 abstracts) on TAR (852 patients) and 39 studies on ankle arthrodesis (1,262 patients). (3) 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 post-traumatic 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 and colleagues 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=4,705) during a 10-year period (1995-2004). (4) 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 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. (5) From February 2002 through August 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, and 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 and 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 were 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%), non-union (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. (6) 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 Orthopedic 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.

**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 post-traumatic arthritis of the ankle. (7) 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 in the ipsilateral but not the contralateral subtalar joint, and 13 patients had moderate or severe osteoarthritis in the ipsilateral but not the contralateral talonavicular joint. No differences were found in the level of osteoarthritis 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. (8) 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 visual analog scale (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), non-union (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 American Orthopaedic Foot and Ankle Society (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.

Another study reported average 7-year follow-up (range: 2–15 years) on 42 patients who underwent arthrodesis for primary or secondary osteoarthritis of the ankle. (9) 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 sub score improving from 18 to 35 (out of 40). No association was found between postoperative pain and ROM. Non-union 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*. The literature indicates that treatment of a painful arthritic joint with arthrodesis can significantly reduce pain. However, non-union 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 pre-existing osteoarthritis of the subtalar joint.

**Total Ankle Replacement**

Gougoulias and colleagues published a 2010 systematic review on outcomes from ankle replacement. (10) 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 1,105 total ankle replacements (TARs) (including 234 Agility, 344 STAR, 153 Buechel-Pappas, 152 HINTEGRA, 70 TNK, and 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. Studies of fixed-bearing and mobile-bearing devices are described below.

Fixed-Bearing Total Ankle Replacement

Roukis reported a systematic review of articles published between 1998 and 2011 in which the Agility TAR was used. (11) Included were 14 studies (2,312 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 and colleagues reporting outcomes from 306 consecutive TARs (303 patients) with the Agility Ankle system performed between 1995 and 2001. (12) The majority of the patients had post-traumatic 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 33 months' follow-up, 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. (13) 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. Another case series of 86 cases has been published and reported similar results. (14) While 79 of the 86 cases (92%) reported a favorable outcome, there were similar radiographic findings. A total of 22% of prosthetic components had migrated, and 8 of the 12 tibial components that had migrated involved a delayed union or nonunion. Kopp and colleagues reported minimum 2-year follow-up (range: 26 to 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. (15) 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 are 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. (16)

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. (17) The median age of the patients was 60.5 years (range: 31 to 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 to 23.3 years). Survival based on radiographic loosening was 64% at 10 years, while the prosthesis survival rate was 85% at 10 years.

Mobile-Bearing Total Ankle Replacement

*Randomized Controlled Trials*. 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. (18) Results from this trial, and from 435 patients enrolled in the FDA-regulated, multicenter, continued-access registry, were published in 2009. (19) Patients were included if they had primary ankle arthritis, post-traumatic arthritis, or rheumatoid arthritis, moderate-to-severe pain (Buechal-Pappas pain score of 20 or less), loss of mobility and function (total Buechal-Pappas score of less than 50 out of 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 non-compliance by patients and investigators. The average total Buechal-Pappas score increased from 41 to 82 in the STAR group and from 43 to 70 in the arthrodesis arm, achieving non-inferiority 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 and 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. (19) 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 equal to or greater than 40-point improvement in the Buechal-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 Buechal-Pappas) between 2000 and 2003. (20) 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 Buechal-Pappas and 4 STAR). These were treated with fusion (n=14) or revision (n=2). There was a trend toward higher failure with the Buechal-Pappas ankle compared to 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-degree increment in deformity. Edge-loading was observed in 12 Buechal-Pappas and 6 STAR prostheses, 39% of which were subsequently revised. A patient who had a varus or valgus deformity of 15 degrees 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 American Orthopaedic Food and Ankle Society (AOFAS) hindfoot score, improved to a similar extent in the 2 groups. The study found that few patients (less than 20%) had marked increases (10 degrees or more) in range of ankle movement with either prosthesis. Results were not compared with arthrodesis.

*Observational Studies*. In 2011, Zhao et al. reported 5- to 10-year survival outcomes in a meta-analysis of 16 studies with 2,088 STAR ankle replacements. (21) At a mean follow-up of 52 months, the pooled rate of failure was 11.1%; 41% of these failures occurred within one 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 and colleagues. (22, 23) 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 to 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. (16, 24-26) 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. (27) In one study, survival of the first generation single-coated STAR prosthesis was reported to be 70.7% at 10 years and 45.6% at 14 years. (28) Women younger than age 60 years with osteoarthritis or post-traumatic arthritis have been shown to have a higher risk for revision than women older than 60 years. (27) 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. (29)

Quality of life, function, and pain were prospectively evaluated in 82 consecutive patients who had received a STAR prosthesis. (26) Patients were evaluated pre- and post-operatively by the same surgeon, with a mean follow-up of 61 months (range, 24 to 108 months). Significant improvement between preoperative and last follow-up were found in all outcome categories, including visual analog scale (VAS) for pain, the Short Form-36 (SF-36) quality-of-life scale, the AOFAS hindfoot scale, the Buechel-Pappas pain and function scores, and ankle range of motion.

Short- to mid-term follow-up from large case series have been reported for the 3-component mobile-bearing Salto, Mobility and BOX prostheses. (30-33) Two smaller case series have reported a high rate of osteolysis with the Ankle Evolutive System (AES) total ankle in mid-term follow-up. (34, 35). Outside of an investigational device exemption (FDA-regulated) trial for the Mobility total ankle system, these devices are not available for use in the U.S. Mid-term survival

(8-12 years) of the Buechel-Pappas TAR has been reported to range from 84% to 93%. (36-39) The Buechel-Pappas TAR system is no longer available for use in the U.S.

*Section Summary*. Although total ankle systems are continuing to evolve, and 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 8-12 years with second-generation devices.

**Ongoing Clinical Trials**
Identified at online site: www.clinicaltrials.gov in July 2013 were the following trials:

Total Ankle Replacement Versus Ankle Arthrodesis (TARVA) trial: A Pragmatic, Prospective Randomized Controlled Trial (NCT01518361). This trial evaluates pain, quality-of-life, revision and complication rate in a randomized trial comparing all TAR systems (chosen based on physician preference) with fusion. A total of 188 study subjects are estimated for accrual. The estimated completion date is July 2015.

Prospective randomized trial of 2- and 3-piece total ankle replacement (NCT01504438). This study will randomize patients to either the STAR or Salto-Talaris prosthesis. A total of 80 patients are expected to be enrolled with an estimated completion date in February 2016,

Comparing Ankle Arthrodesis to Ankle Arthroplasty (NCT01620541) trial. This multi-center randomized trial compares change in overall physical function, activity levels, pain, patient satisfaction, and general health between TAR and fusion. A total of 512 study subjects are estimated for accrual. The estimated completion date is July 2016.

**Clinical Input Received through Physician Specialty Societies and Academic Medical Centers**
While the various Physician Specialty Societies and Academic Medical Centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the Physician Specialty Societies or Academic Medical Centers, unless otherwise noted.

In response to requests, input was received through 1 Physician Specialty Society and 5 Academic Medical Centers while this policy was under review in 2009. Clinical input supported use of total ankle replacement as a surgical option for selected patients in situations when fusion is not indicated. The consensus of the experts supported the specific indications for total ankle replacement as listed in the policy statement.

**Summary**
The established standard for the painful arthritic ankle is fusion, which usually results in a pain-free but rigid ankle in the short term. Complications associated with ankle fusion are non-union, 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 those specified conditions are met.

## Practice Guidelines and Position Statements

American Academy of Orthopaedic Surgeons (AAOS)
AAOS published a 2010 technology overview of surgical treatment options for patients with ankle arthritis in whom nonoperative treatment has failed. (40) The report concluded that based on low- and very low-quality evidence, treatment of ankle arthritis with either a generation 2 or generation 3 total ankle arthroplasty results in an improvement in pain and function. The literature does not conclusively demonstrate predictors of better or worse patient-oriented outcomes (e.g., device failure, reoperation, pain relief, patient satisfaction, walking ability) for total ankle arthroplasty.

Additionally, the report concluded that there are limited data from multiple studies directly comparing the efficacy of total ankle arthroplasty to arthrodesis in patients with arthritis. The disparate preoperative ankle function scores and demographic characteristics between the groups enrolled in the relevant comparative studies prohibit meaningful comparisons and confound the interpretation of the data. Analysis of adverse events that corrected for preoperative differences in patient's characteristics, provide conflicting results.

American College of Foot and Ankle Surgeons (ACFAS)
An ACFAS 2010 position statement on total ankle replacement states that "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 that total ankle replacement surgery improves patient function, reduces pain, and promotes improved quality-of-life." (41)

American Orthopaedic Foot and Ankle Society (AOFAS)
In 2009, the American Orthopaedic Foot and Ankle Society (AOFAS) issued the following position statement on total ankle arthroplasty (42): "Over the past decade, total ankle replacement surgery has evolved as an acceptable and viable alternative to ankle arthrodesis in select patients with ankle arthritis. These include adult patients with primary, post-traumatic, and rheumatoid arthritis who have moderate or severe pain, loss of mobility, and loss of function of the involved ankle. Before considering total ankle replacement, patients should have completed several months of conservative treatment, should have satisfactory vascular perfusion in the involved extremity, and must have adequate soft-tissue coverage about the ankle that affords a safe surgical approach to total ankle replacement. In such patients, high-level evidence indicates that total ankle replacement safely relieves pain and may provide superior functional results when compared to ankle fusion. Additional concomitant or sequential surgical procedures may be required in some patients to optimize outcome."

National Institute for Health and Clinical Excellence (NICE)
NICE considers total ankle replacement surgery standard clinical practice with an efficacy and safety profile that is sufficiently well-known. (43)

## CODING

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

CPT/HCPCS

| | |
|---|---|
| 27702 | Arthroplasty, ankle; with implant (total ankle) |
| 27703 | Arthroplasty, ankle; revision, total ankle |

ICD-9 Diagnoses (Effective October 1, 2015)

| | |
|---|---|
| M00.071 | Staphylococcal arthritis, right ankle and foot |
| M00.072 | Staphylococcal arthritis, left ankle and foot |
| M00.171 | Pneumococcal arthritis, right ankle and foot |
| M00.172 | Pneumococcal arthritis, left ankle and foot |
| M00.271 | Other streptococcal arthritis, right ankle and foot |
| M00.272 | Other streptococcal arthritis, left ankle and foot |
| M00.871 | Arthritis due to other bacteria, right ankle and foot |
| M00.872 | Arthritis due to other bacteria, left ankle and foot |
| M01.x71 | Direct infection of right ankle and foot in infectious and parasitic diseases classified elsewhere |
| M01.x72 | Direct infection of left ankle and foot in infectious and parasitic diseases classified elsewhere |
| M02.171 | Postdysenteric arthropathy, right ankle and foot |
| M02.172 | Postdysenteric arthropathy, left ankle and foot |
| M02.371 | Reiter's disease, right ankle and foot |
| M02.372 | Reiter's disease, left ankle and foot |
| M02.871 | Other reactive arthropathies, right ankle and foot |
| M02.872 | Other reactive arthropathies, left ankle and foot |
| M05.471 | Rheumatoid myopathy with rheumatoid arthritis of right ankle and foot |
| M05.472 | Rheumatoid myopathy with rheumatoid arthritis of left ankle and foot |
| M05.49 | Rheumatoid myopathy with rheumatoid arthritis of multiple sites |
| M05.571 | Rheumatoid polyneuropathy with rheumatoid arthritis of right ankle and foot |
| M05.572 | Rheumatoid polyneuropathy with rheumatoid arthritis of left ankle and foot |
| M05.59 | Rheumatoid polyneuropathy with rheumatoid arthritis of multiple sites |
| M05.771 | Rheumatoid arthritis with rheumatoid factor of right ankle and foot without organ or systems involvement |
| M05.772 | Rheumatoid arthritis with rheumatoid factor of left ankle and foot without organ or systems involvement |
| M05.79 | Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement |
| M05.871 | Other rheumatoid arthritis with rheumatoid factor of right ankle and foot |
| M05.872 | Other rheumatoid arthritis with rheumatoid factor of left ankle and foot |
| M05.89 | Other rheumatoid arthritis with rheumatoid factor of multiple sites |
| M05.9 | Rheumatoid arthritis with rheumatoid factor, unspecified |
| M06.071 | Rheumatoid arthritis without rheumatoid factor, right ankle and foot |

| | |
|---|---|
| M06.072 | Rheumatoid arthritis without rheumatoid factor, left ankle and foot |
| M06.09 | Rheumatoid arthritis without rheumatoid factor, multiple sites |
| M06.271 | Rheumatoid bursitis, right ankle and foot |
| M06.272 | Rheumatoid bursitis, left ankle and foot |
| M06.29 | Rheumatoid bursitis, multiple sites |
| M06.371 | Rheumatoid nodule, right ankle and foot |
| M06.372 | Rheumatoid nodule, left ankle and foot |
| M06.39 | Rheumatoid nodule, multiple sites |
| M06.871 | Other specified rheumatoid arthritis, right ankle and foot |
| M06.872 | Other specified rheumatoid arthritis, left ankle and foot |
| M06.89 | Other specified rheumatoid arthritis, multiple sites |
| M19.071 | Primary osteoarthritis, right ankle and foot |
| M19.072 | Primary osteoarthritis, left ankle and foot |
| M19.171 | Post-traumatic osteoarthritis, right ankle and foot |
| M19.172 | Post-traumatic osteoarthritis, left ankle and foot |
| M19.271 | Secondary osteoarthritis, right ankle and foot |
| M19.272 | Secondary osteoarthritis, left ankle and foot |
| M19.90 | Unspecified osteoarthritis, unspecified site |
| M35.2 | Behcet's disease |

## REVISIONS

| | |
|---|---|
| 06-29-2010 | Policy added to the bcbsks.com web site. |
| 10-26-2010 | Description Section updated. |
| | Rationale Section updated. |
| | References Section updated. |
| 12-07-2012 | Description Section updated. |
| | In Coding section:<br>▪ Corrected code 715.37 which was incorrectly reflected as 175.37 in a prior revision. |
| | Rationale Section updated. |
| | References Section updated. |
| 02-05-2014 | Description section updated. |
| | Rationale section updated |
| | In Coding section:<br>▪ Added ICD-10 Diagnoses Codes |
| | References updated |
| 03-01-2018 | Medical Policy reviewed with no updates needed. |
| 04-10-2019 | Medical Policy reviewed with no updated needed. |
| 02-01 2021 | Description Section updated. |
| | Rationale Section updated. |
| | References Section updated. |

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