

Total Ankle Arthroplasty	
Type: Medical Necessity and Investigational / Experimental	Policy Specific Section: Surgery
Original Policy Date: December 7, 2006	Effective Date: April 2, 2010

Description

A total ankle arthroplasty (TAA) replaces the diseased ankle joint with a plastic and metal joint. 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 arthroplasty technically challenging. The alternative to TAA is arthrodesis or fusion, 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, TAA is also intended to improve function and reduce stress on adjacent joints.

Total ankle arthroplasties have been performed on patients with severe rheumatoid arthritis, severe osteoarthritis or post-traumatic osteoarthritis.

Policy

Total ankle arthroplasty using a United States Food and Drug Administration-approved device is considered **medically necessary** when **all** of the following criteria are met:

- Skeletally mature
- No functional barrier to participation in a rehabilitation program
- Moderate to severe ankle (tibiotalar) pain that limits daily activities and **one** of the following:
 - Arthritis in adjacent joints (i.e., subtalar or midfoot)
 - Arthrodesis of the contralateral ankle
 - Severe arthritis of the contralateral ankle
 - Inflammatory (e.g., rheumatoid) arthritis

Total ankle arthroplasty is considered **investigational** for all other indications

Policy Guideline

Absolute contraindications to ankle arthroplasty include any of the following:

- 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

Relative contraindications to ankle arthroplasty include:

- Peripheral neuropathy
- Ligamentous instability
- Subluxation of the talus
- History of ankle joint infection
- Presence of severe deformities above or beneath the ankle

Internal Information

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:

http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

Rationale

Total ankle arthroplasty (TAA) 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 prosthetic ankle joints have since been developed, which can be broadly subdivided into two design types, fixed-bearing and mobile-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 following are current United States Food and Drug Administration (FDA)-approved fixed-bearing prosthetic ankle designs:

- Agility Ankle Revision Prosthesis (DuPuy Orthopaedics)
- Inbone™ Total Ankle (INBONE Technologies)
- The Agility LP (DuPuy Orthopaedics)
- Eclipse (Kinetikos Medical)
- The Salto Talaris (Tornier)

Mobile-bearing systems have a polyethylene component that is unattached and articulates independently with both the tibial and talar components. The three 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. The following is the current FDA approved mobile-bearing prosthetic ankle design:

- Scandinavian Total Ankle Replacement (STAR, Small Bone Innovations)

Note: The TNK ankle (Kyocera Corporation) and the Buechel-Pappas system (Endotec) are not currently approved in the United States.

A 2003 position statement on total ankle arthroplasty from the American Orthopaedic Foot and Ankle Society (AOFAS) states:

Ankle arthritis has many treatment options, both operative and non-operative. Operative treatment is available for patients with persistent symptoms. Surgical options for ankle arthritis include joint debridement, distraction arthroplasty, osteotomy, and ankle arthrodesis and TAA. Total ankle arthroplasty is a viable option for the treatment of ankle arthritis.

Numerous reviews have detailed the technical challenges of TAA, including the evolving prosthetic designs, optimizing biomechanics, and surgical complications. Haddad et al., (2007) conducted a systematic review and meta-analysis of 10 studies on TAA (852 patients) and 39 studies on ankle arthrodesis (1262 patients). The patients treated with TAA were older (58 years versus 50 years) and the primary indication was rheumatoid arthritis (39%) whereas post-traumatic arthritis was the primary indication for arthrodesis (57%). 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 non-union (65%) and infection (26%). Conversion from arthroplasty to arthrodesis was reported in 5% of 572 patients.

SooHoo et al., (2007) conducted a review of California's hospital discharge database to compare short- and long-term outcomes of patients who had undergone TAA (n=480) or ankle arthrodesis (n=4705) during a 10-year period (1995 to 2004). The type of prosthesis was not specified. At 90 days, there were more device-related complications (hazard ratio of 2.68) and major revisions (hazard ratio of 3.65) in comparison with arthrodesis. At five years after surgery, major revision rates were 23% for TAA and 11% for arthrodesis (hazard ratio of 1.93). There was a 2% lower rate of subtalar fusion following TAA compared with ankle arthrodesis (0.7% versus 2.8%, hazard ratio of 0.28).

Guyer and Richardson (2008) concluded in an evidence-based review the current literature on TAA for any prosthesis consists of level IV evidence (case series). No randomized trials comparing arthrodesis to arthroplasty were identified, and two small, non-randomized studies had conflicting results. The review indicates that in general, older, thin, low-demand individuals are considered optimal candidates for TAA, 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.

Prospective controlled trials directly comparing TAA 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., (2001) reported 22-year follow-up with clinical and radiological evaluation on 23 patients who received ankle arthrodesis for the treatment of painful post-traumatic arthritis of the ankle. Post surgery, all 23 patients reported limitations in vigorous activities and 20 patients (83%) reported difficulty walking more than one mile. For the uninjured 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 contralateral foot. 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 (2003) evaluated long-term outcomes of 48 patients at an average nine years after ankle arthrodesis. From a cohort of 60 patients who underwent fusion between 1979 and 1997, seven patients were excluded, three died and two were lost to follow-up, leaving 45 patients who had clinical and radiologic evaluation and three patients who responded to questionnaires only. The average age of the patients at the time of surgery was 51 years (range, 20 - 74). Before surgery, 34 patients (71%) reported severe pain that was almost always present, 12 (25%) reported moderate daily pain and two (4%) had mild occasional pain. At follow-up, 10 (21%) patients reported moderate-to-severe pain and 38 (79%) reported mild-to-no pain. Nine patients (19%) had revision surgery due to infection (n = 4), non-union (n=4), and malposition (n = 1). Clinical evaluation at nine years (range, 3 - 21) revealed that four patients (8%) had a marked gait abnormality and limp, 26 (54%) had some gait abnormality, and 18 patients (38%) had no abnormality while walking. Thirty-four patients (73%) scored as good-to-excellent and 13 (27%) as fair-to-poor. 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.

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 range of motion in the fused ankle joint, and have been shown to be most severe in patients with pre-existing osteoarthritis of the subtalar joint.

Fixed-Bearing Total Ankle Arthroplasty

Spiert and colleagues (2004) reported outcomes from 306 consecutive TAAs (303 patients) with the Agility ankle system performed between 1995 and 2001. The majority of the patients had post-traumatic osteoarthritis (65%) or primary osteoarthritis (25%), and had an average age of 54 years (range of 19 to 85). 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 TAAs (11%) were considered to have failed. Age at the time of the primary TAA was the only covariate related to the rate of reoperation and failure, with each one-year increase in age associated with a 3.5% decrease in the hazard of failure. Kopp and colleagues (2006) reported minimum two year follow-up (range of 26 to 64 months) on 43 consecutive ankle arthroplasties with the Agility prosthesis. 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 three patients. Twelve perioperative and 12 postoperative complications occurred (60%), requiring additional operative procedures. The authors concluded that, "the overall intermediate-term clinical results of TAA 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."

Mobile-Bearing Total Ankle Arthroplasty

The pivotal trial for the STAR prosthesis, reported to the FDA in 2007, was a two year non-inferiority design with 158 patients from 10 sites treated with arthroplasty and 66 patients from five additional sites treated with arthrodesis. Patients were included if they had primary ankle arthritis, posttraumatic arthritis, or rheumatoid arthritis, moderate to severe pain, loss of mobility and function, and a minimum of six months of conservative treatment including a three month trial of orthosis and/or analgesic medication. In the STAR arm, 142 patients (90%) completed the 24-month follow-up. Only 78% completed 24-month follow-up in the arthrodesis arm. Statistical superiority was driven primarily by the improvement in range of motion (ROM), with slight improvements in deformity (increased by 1.9 versus 0.4 for arthrodesis) and function (increased by 13.4 versus 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 two groups.

The largest consecutive series of 200 implants (184 patients) with the STAR prosthesis was reported by Wood and colleagues (2003; 2008). Eighty-one patients had osteoarthritis (25 fracture-related) and 119 had inflammatory joint disease (112 with rheumatoid arthritis). The authors suggested that survivorship figures are similar to those of early reports of total knee arthroplasty when techniques and designs were being developed. A Swedish group reported median 52 month follow-up on 51 consecutive ankle arthroplasties with the STAR prosthesis implanted between 1993 and 1999 (Anderson et al., 2003). Valderrabano et al., (2004) reported outcomes of 68 patients with TAA using the STAR prosthesis and followed up for an average of 3.7 years. The authors reported that 35 patients (51%) were completely free of pain and 67 ankles were graded as good or excellent by overall clinical score. The estimated five-year survival rate was 70%, with significant improvement in survival after the first 20 cases were performed. Fevang et al., (2007) reported analysis of 257 primary ankle arthroplasties from the Norwegian arthroplasty registry between 1994 and 2006, with 82% of all TAAs being registered.

The cementless STAR prosthesis was used in 82% of the cases; 14% were with the fixed-bearing Norwegian TPR prosthesis. The five-year survival for all prostheses was 89%, with a 10-year survival of 76%, rates the authors considered low compared to survival of hip and knee prostheses in Norway.

Wood et al., (2009) reported mid-term outcomes from 200 patients who had been randomized to receive one of two mobile-bearing ankle arthroplasty systems (STAR or Buechal-Pappas) between 2000 and 2003. At the time of follow-up, 163 implants had survived, 21 patients had died, and 16 (8%) implants had failed (12 Buechal-Pappas and four 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. 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.

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. Total ankle arthroplasty is in the development stage with designs that are continuing to evolve. Although long-term evidence is lacking, short-term results suggest similar improvements in pain and function in comparison with arthrodesis, and mid-term results indicate 75% to 80% survival at 10 years to 15 years.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement Policy

Type	Number	Description
CPT	27702	Arthroplasty, ankle; with implant (total ankle)
	27703	Arthroplasty, ankle; revision, total ankle
HCPC	None	
ICD9 Procedure	81.56	Total ankle replacement
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-343-1691 or visit the Provider Portal www.blueshieldca.com/provider.

Documentation Required for Clinical Review

- History and physical including: previous treatment plan and response

Documentation Required for Clinical Review

- Progress notes for the past three months
- Radiology report(s) for the past three months

Post Service

- Operative report(s)

Tables

N/A

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

N/A

Definitions

Arthrodesis - The ends of two bones are fused together with screw fixation and possible bone grafting. The bones are aligned in the most functional position, but lose their natural motion. The procedure does eliminate motion in the joint.

Hazard ratio - The hazard ratio is an estimate of the ratio of the hazard rate in the treated versus the control group. The hazard rate is the probability that if the event in question has not already occurred, it will occur in the next time interval, divided by the length of that interval. A hazard ratio of one means that there is no difference between the two groups.

Arthrosis - Any degenerative disease of a joint e.g. osteoarthritis

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Key / Related Searchable Words

N/A

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
12/7/2006	BCBSA Medical Policy adoption	Medical Policy Committee

Effective Date	Action	Reason
4/2/2010	BCBSA Medical Policy adoption with title change from Total Ankle Replacement	Medical Policy Committee

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.