BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Total Ankle Replacement

Policy #: 339
Category: Surgery

Latest Review Date: October 2019
Policy Grade: **Effective July 24, 2014: Active Policy but no longer scheduled for regular literature reviews and updates.**

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after November 10, 2009:

Blue Advantage will treat **total ankle replacement** using an FDA-approved device as a **covered** benefit in skeletally mature patients with moderate to severe ankle (tibiotalar) pain that limits daily activity and who have 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 absence 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.

Revision or replacement of an implanted total ankle prosthesis may be considered medically necessary for failure of a previously implanted ankle prosthesis (e.g., implant loosening, malpositioning, periprosthetic, infection, or periprosthetic fracture).

Effective for dates of service on or after June 6 through November 9, 2009:

Blue Advantage will treat **total ankle replacement** as a **covered** benefit when the following criteria are met:

- Patient is over 50 years of age, except patients with rheumatoid arthritis.
- Patient has ankle and adjacent subtalar and/or transverse tarsal arthritis.
- Patient has failed at least a 3-month trial of adequate bracing, i.e., high unweighting Arizona brace, PTB brace, or calf lacer brace.
- Patient has no evidence of prior or current ankle infection, no avascular necrosis of the talus, and no neuropathy of the foot or ankle.
- Patient's intra-articular varus or valgus cannot exceed 15 degrees.

Also, the revision surgery should be considered on a case-by-case basis for reimplantation of a new polyethylene bearing, component, or entire total ankle.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

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 main alternative to total ankle replacement is arthrodesis. While both procedures are designed to reduce pain, the total ankle replacement is also intended to improve function and reduce stress on adjacent joints. TAR has been investigated since the 1970s, but the procedure was essentially abandoned in the 1980s due to a high long-term failure rate, both in terms of pain control and improved function. Newer models have since been developed, which can be broadly subdivided into two design types, fixed-bearing and mobile-bearing. More than twenty different ankle replacement systems are currently being evaluated worldwide.

Total ankle replacement has been performed in patients with severe rheumatoid arthritis, severe osteoarthritis, or post-traumatic osteoarthrosis. 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 > 50), thin, low-demand individuals with minimal deformity. Patients should have no functional barriers to participation in a rehabilitation program.

KEY POINTS:

Summary of Evidence

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 Orthopaedic Foot and Ankle Society (AOFAS)

The AOFAS Position Statement on The Use of Total Ankle Replacement for the Treatment of Arthritic Conditions of the Ankle (March 2014, updated April 2018) states that the AOFAS endorses the use of total ankle replacement surgery as an option for treatment of arthritic conditions of the ankle in select patients with this condition who have failed nonoperative treatment. The AOFAS does not consider this procedure to be experimental.

American College of Foot and Ankle Surgeons (ACFAS)
The ACFAS Position Statement on Total Ankle Replacement Surgery (July 2016) notes that not every patient with end-stage arthritis of the ankle is a sound candidate for ankle replacement. A surgeon experienced in total ankle surgery can make this determination through careful history and physical evaluation. In the United States, total ankle replacement surgery is currently a safe and effective treatment option for select patients with end stage ankle arthritis. Studies have shown total ankle replacement surgery improves patient function, reduces pain, and promotes improved quality of life.

American 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. 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 is 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 patients characteristics, provide conflicting results.

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.

KEY WORDS:
Agility ankle, ankle replacement, total ankle arthroplasty, ankle, total ankle replacement, ankle arthrodesis

APPROVED BY GOVERNING BODIES:
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. In 2002, the U.S. Food and Drug Administration (FDA) approved the Agility® Ankle Revision Prosthesis (DePuy Orthopaedics),

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 System (Wright Medical Technology, Arlington, TN). This device 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 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. 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 eight years. The Mobility™ Total Ankle System is currently being evaluated in a FDA-regulated investigational device exemption (IDE) trial. The Ankle Evolution System (AES), Buechel-Pappas, Mobility, Salto Total Ankle, BOX Ankle, CCI Evolution Ankle, Zenith, and the TNK ankle are not currently used in the United States.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

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

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POLICY HISTORY:

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