

**Policy#: 193**

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**Title**

**Total Ankle Replacement**

**Description**

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 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, total ankle replacement is also intended to improve function and reduce stress on adjacent joints. Total ankle replacement 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.

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 (DuPuy 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 (INBONE Technologies) and is also intended for cemented use only. The Agility LP (DuPuy Orthopaedics) and the Eclipse (Kinetikos Medical) received 510(k) marketing clearance in 2006. The Salto Talaris (Tornier) 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.

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 Scandinavian Total Ankle Replacement (STAR, Small Bone Innovations) the TNK ankle (Kyocera Corporation) and the Buechel-Pappas system. Three-component mobile-bearing systems are Class III devices, and are considered under a different regulatory pathway (pre-market approval) than the fixed component devices described above, which were cleared for marketing under the 510(k) regulatory pathway. Pre-market 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 TNK and Buechel-Pappas systems 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 osteoarthritis.

**When services are covered for commercial products and for Medicare HMO Blue and Medicare PPO Blue<sup>1</sup>**

We cover total ankle replacement, using a device which the FDA has approved or cleared for marketing, 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

**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.

**When services are not covered for commercial products or for Medicare HMO Blue and Medicare PPO Blue<sup>1</sup>**

We do not cover total ankle replacement for all other indications because it is considered investigational as it does not meet our Medical technology Assessment Guidelines #350.

**Individual consideration**

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

**For services already billed**

Blue Cross Blue Shield of Massachusetts  
Provider Appeals  
PO Box 986065  
Boston, MA 02298

**Prior to performance of service**

Blue Cross Blue Shield of Massachusetts  
Case Creation/Medical Policy  
One Enterprise Drive  
Quincy, MA 02171  
Tel: 1-800-327-6716  
Fax: 1-888-282-0780

**Authorization Information**

**For Managed Care members:**

- Authorization is required for this service; see *Managed Care Guidelines* for additional requirements.

**For Indemnity and PPO members:**

- Authorization is required for this service; *see Indemnity and PPO Guidelines for additional requirements.*

**Managed Care Guidelines**

All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan description, however;

- **For Medicare HMO Blue members:** The service must meet the criteria for coverage noted in this policy, be medically necessary, prescribed by a plan physician and provided by a network provider.
- **For Medicare HMO Blue members:** Referrals are required for all visits to a specialist.
- For all other Managed Care plans, any specialist visit requires a referral, except for visits performed by OB/GYN specialists.
- Authorization is required for an inpatient admission.

**Indemnity and PPO Guidelines**

All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan description, however;

- Authorization is required for an inpatient admission.
- Authorizations are not required for most outpatient services as determined by the individual's subscriber certificate.
- Referrals to a specialist are not required.

**Coding information**

*Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code 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 as it applies to an individual member.*

**CPT codes:**

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

**Policy update history**

New policy, effective 6/01/10. Reviewed 7/2010 MPG – Orthopedics, Rehabilitation Medicine and Rheumatology, no changes in coverage were made. Updated 1/2011 with added references. Reviewed 6/2011 MPG – Orthopedics, Rehabilitation and Rheumatology, no changes in coverage were made. Updated 5/2012 with additional references based on BCBSA national policy, reviewed 9/2011.

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This document is designed for informational purposes only and is not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

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#### **Footnotes**

<sup>1</sup> Based on BCBSA national policy #7.01.77, Total Ankle Replacement, reviewed September 2011.