Protocol

Total Ankle Replacement

(70177)

Medical Benefit		**Effective Date**: 01/01/11	**Next Review Date**: 09/14
Preauthorization	No	**Review Dates**: 09/10, 09/11, 09/12, 09/13	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

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 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 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.

Related Protocol:

Subtalar Arthroereisis

Corporate Medical Guideline

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:

- 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.

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

Policy Guideline

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.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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