

Corporate Medical Policy

Ankle Replacement, Total

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Policy Number: SUR6029
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Description of Procedure or Service

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.

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

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Total Ankle Replacement when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

When Ankle Replacement, Total is covered

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

When Ankle Replacement, Total is not covered

Total ankle replacement is considered 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 > 50), thin, low-demand individuals with minimal deformity. Patients should have no functional barriers to participation in a rehabilitation program.

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;
- Ankle joint infection;
- Peripheral vascular disease;

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- 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.

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

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 27702, 27703

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Medical Term Definitions

The FDA has established 3 regulatory classes for medical devices based on the degree of control necessary to assure the various types of devices are safe and effective:

Class I - these devices present minimal potential for harm.

Class II - these devices are subject to special controls as general controls alone are insufficient to ensure safety and effectiveness.

Class III - these devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury.

Section **510(k)** of the Food, Drug and Cosmetic Act requires those device manufacturers who must register to notify FDA their intent to market a medical device (**Premarket Notification**). Under 510(k), before a manufacturer can market a medical device, they must demonstrate to FDA's satisfaction that the device is substantially equivalent to, and as safe and effective as, a device already on the market.

The FDA requires that manufacturers must submit a **Premarket Approval (PMA)** application if they wish to market any new products that contain new materials or differ in design from products already on the market. A PMA submission must provide valid scientific evidence collected from human clinical trials showing the device is safe and effective for its intended use.

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Scientific Background and Reference Sources

- BCBSA Medical Policy Reference Manual, 7.01.77; 5/31/01
- Specialty Matched Consultant Advisory Panel - 8/2001
- Specialty Matched Consultant Advisory Panel - 5/2003
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.77, 7/15/04
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.77, 10/10/06
- Doets HC, Brand R, Nelissen RG. Total ankle arthroplasty in inflammatory joint disease with use of two mobile-bearing designs. *J Bone Joint Surg Am* 2006; 88(6):1272-84
- Haddad SL, Coetzee R, Estok K, Fahrback D, Banel D, Nalysnyk L. Intermediate and long-term outcomes of total ankle arthroplasty and ankle arthrodesis. A systematic review of the literature. *J Bone Joint Surg Am* 2007; 89: 1899-1905
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.77, 4/24/09
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.77, 9/10/09
- Senior Medical Director Review - 11/2009

Policy Implementation/Update Information

- 10/01 Original policy issued. Specialty Matched Consultant Advisory Panel - 8/01. Approved.
- 01/03 System coding changes.
- 05/03 Specialty Matched Consultant Advisory Panel review. No criteria changes. Format changes.
- 12/03 Benefits Application and Billing/Coding sections updated for consistency.
- 6/2/2005 Specialty Matched Consultant Advisory Panel review on 5/23/2005. No changes made to the policy statement. Reference added. SUR6029 added as key word. CPT code 27703 added to Billing/Coding section. Notification given 6/2/2005. Effective date 8/4/2005.
- 6/18/07 Information added to description of procedure for clarity. Rationale for continued investigational status added to Policy Guidelines section. References updated. Specialty Matched Consultant Advisory Panel review 5/18/07. No changes to policy coverage criteria. (adn)
- 7/6/09 Description section expanded. Specialty Matched Consultant Advisory Panel review 5/21/09. No change to policy statement. (adn)
- 12/7/09 Description section extensively revised. Policy statement changed to read: "BCBSNC will provide coverage for Total Ankle Replacement when it is determined to be medically necessary because the medical criteria and guidelines shown below are met." 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. Policy Guidelines updated to include absolute and relative contraindications to total ankle replacement surgery. (adn)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.