

**Policy terminated because Medicaid covers codes in the same manner as  
Health Choice.**

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## **1.0 Description of the Procedure, Product, 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 recipients 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 recipients 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 posttraumatic 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 recipients with severe rheumatoid arthritis, severe osteoarthritis, or post-traumatic osteoarthritis.

## 1.1 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:

- a. Class I - these devices present minimal potential for harm.
- b. Class II - these devices are subject to special controls as general controls alone are insufficient to ensure safety and effectiveness.
- c. 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.

## 2.0 Eligible Recipients

### 2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

## 3.0 When the Procedure, Product, or Service Is Covered

### 3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

### 3.2 Specific Criteria

Total ankle replacement is covered by the NC Health Choice Program when it is determined to be medically necessary and when the following criteria and guidelines are met. Total ankle replacement using an FDA-approved device may be considered medically necessary in skeletally mature recipients with moderate to severe ankle (tibiotalar) pain that limits daily activity and who have the following conditions:

- a. Arthritis in adjacent joints (i.e., subtalar or midfoot);
- b. Severe arthritis of the contralateral ankle;
- c. Arthrodesis of the contralateral ankle; **OR**
- d. Inflammatory (e.g., rheumatoid) arthritis

### 3.3 Policy Guidelines

In general, recipients 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 recipients with minimal deformity. Recipients should have no functional barriers to participation in a rehabilitation program.

- a. Absolute contraindications to ankle arthroplasty include any of the following:
  1. Extensive avascular necrosis of the talar dome;
  2. Compromised bone stock or soft tissue (including skin and muscle);
  3. Severe malalignment (e.g., > 15 degrees) not correctable by surgery;
  4. Ankle joint infection;
  5. Peripheral vascular disease;
  6. Charcot neuroarthropathy.
- b. Relative contraindications to ankle arthroplasty include:
  1. Peripheral neuropathy;
  2. Ligamentous instability;
  3. Subluxation of the talus;
  4. History of ankle joint infection;
  5. 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.

## 4.0 When the Procedure, Product, or Service Is Not Covered

### 4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;

- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

#### 4.2 Specific Criteria

Total ankle replacement is considered investigational for all other indications. Refer to **Subsection 3.2**.

### 5.0 Requirements for and Limitations on Coverage

#### 5.1 Prior Approval

Prior approval is not required for total ankle replacement.

### 6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

### 7.0 Additional Requirements

#### 7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

### 8.0 Policy Implementation/Revision Information

**Original Effective Date:** July 1 2010

**Revision Information:**

Date	Section Revised	Change
July 1 2010	Throughout	Policy Conversion: Implementation of Session Law 2009-451, <b>Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."</b>
February 29, 2012	Throughout	Policy Termination

## Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

### A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

### B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

### C. Procedure Code(s)

CPT Code(s)
27702
27703

### D. Modifiers

Providers are required to follow applicable modifier guidelines.

### E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

### F. Place of Service

Inpatient Hospital and outpatient hospital.

### G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

### H. Reimbursement

Providers must bill their usual and customary charges.