TOTAL ANKLE REPLACEMENT (TAR)

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**Table of Contents:**

<table>
<thead>
<tr>
<th>POLICY DESCRIPTION</th>
<th>Page: 2</th>
<th>Cross Reference Policy: Mechanical Stretching And Continuous Passive Motion Devices, 2013M0012A</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVERAGE RATIONALE/CLINICAL CONSIDERATIONS</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>BACKGROUND</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>REGULATORY STATUS</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>CLINICAL EVIDENCE</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>APPLICABLE CODES</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>REFERENCES</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>POLICY HISTORY/REVISION INFORMATION</td>
<td>12</td>
<td></td>
</tr>
</tbody>
</table>

**INSTRUCTIONS:**

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:

This policy describes the use of ankle replacement which involves the surgical removal of a dysfunctional, painful ankle joint and its replacement with a prosthetic device. The purpose of total ankle replacement (TAR) is to relieve pain and restore joint function in patients with end-stage degenerative joint disease resulting from conditions such as osteoarthritis or rheumatoid arthritis, and who have failed conservative methods of treatment.

COVERAGE RATIONALE/CLINICAL CONSIDERATIONS:

Total ankle replacement, using an FDA-approved device, as an alternative to ankle fusion may be considered MEDICALLY NECESSARY for treating older individuals with end-stage ankle joint disorder, damaged by severe rheumatoid arthritis (RA), posttraumatic osteoarthritis (PTOA), or degenerative arthritis, when pain limits daily activity and any of the following criteria set is met:

1. The member has a confirmed diagnosis by x-rays of severe or end stage rheumatoid arthritis, osteoarthritis, or post-traumatic osteoarthritis:
   a. The member experiences significant pain at the ankle (tibiotalar joint), and
   b. Patient experiences loss of ankle mobility and/or function, limiting activity levels
   c. Optimal medical management has been tried and failed, including:
      • NSAIDS, and
      • Pain relievers, and
      • Physical Therapy, and
      • External support (e.g., shoe insert, AFO, brace), and
      • Disease Modifying Antirheumatic Drugs (e.g., Imuran, Enbrel, Humira).

2. Previously fused ankle:
   a. The fusion has failed as demonstrated by a non union or malunion of the ankle joint and; 
   b. It has been at least a year from the date of the fusion during which time the Member was fully mobile and ambulatory.

3. Failed total ankle replacement.

Total ankle replacement is considered EXPERIMENTAL AND INVESTIGATIONAL for treating conditions other than those listed above.

Clinical Considerations:

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, 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:

• Osteonecrosis/avascular necrosis of the talus
• Compromised bone stock or soft tissue (including skin and muscle)
Clinical & Quality Management

MEDICAL POLICY

- Severe malalignment (e.g., > 15 degrees) not correctable by surgery
- Active ankle joint infection
- Peripheral vascular disease or insufficient blood supply in the involved ankle
- Charcot neuroarthropathy
- Insufficient bone or soft tissue to ensure proper implant positioning

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
- Severe non-correctable hind foot varus/valgus deformity
- Morbidly obese (e.g., body mass index [BMI] > 40 kg/m²)
- Participates in high impact activities
- Prior infection or septic arthritis

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

Postoperative Care: Postoperatively the ankle is immobilized in a splint that protects it against eversion, inversion, and plantar flexion movements for 6 weeks. Whether patients are allowed to walk full weight bearing during this period depends on center-specific protocols and the recommendations of the manufacturer. ROM exercises are initiated once the operative incision has healed (Pyevich et al., 1998; Buechel et al., 2004; Hintermann et al., 2004; Spirt et al., 2004; Doets et al., 2006; San Giovanni et al., 2006; Hurowitz et al., 2007; Wood et al., 2008; Saltzman et al., 2009; Wood et al., 2009).

BACKGROUND:

Arthritis is one of the most prevalent chronic health problems and one of the most common causes of disability in the United States. Nearly 19 million adults report activity limitations because of arthritis each year. The prevalence of arthritis is projected to increase significantly to 64.9 million by 2030, and disabilities arising from arthritis are estimated to affect approximately 20 million individuals (Arthritis Foundation, 2008a; CDC, 2011).

The ankle joint is composed of three bones: the distal tibia, the talus, and the distal fibula. In a healthy ankle, the joint surfaces of the distal tibia, the talus, and the distal fibula are covered with cartilage that enables the joint to move through a painless range of motion (ROM). Disruption of this cartilaginous surface of the ankle joint leads to the development of arthritis, which results in decreased ROM, swelling, stiffness, increased pain with any weight-bearing activity, a limp, a feeling of instability secondary to pain, and/or a visible deformity of the ankle joint itself. Ankle joint arthritis occurs mainly in the elderly population due to primary osteoarthritis (OA) or rheumatoid arthritis (RA), and in the general population after severe trauma to the ankle joint. Each year more than 50,000 new cases of ankle joint arthritis are reported in the United States (Easley et al., 2002; Brown et al., 2006; Pfeiff, 2006; Arthritis Foundation, 2008b; Helmick et al., 2008).
Conservative treatments used for arthritis depend on the type and severity of disease. OA may be treated conservatively with physical and occupational therapy, weight reduction, analgesics, nonsteroidal anti-inflammatory drugs, and glucocorticoid injections. Treatment options for RA include immunosuppressants, biological response modifiers, and disease-modifying antirheumatic drugs. The use of a soft brace, such as a Scott ankle brace, is recommended to give extra support around the ankle.

When conservative methods of treatment fail, surgery is often recommended. The conventional surgical treatment for ankle joint arthritis has been ankle joint fusion, or arthrodesis. However, significant drawbacks of ankle joint fusion have led to the development of the ankle prosthesis, as an alternative treatment for end-stage ankle arthritis. Ankle fusion often has good short- and mid-term results, but longer-term data have identified concerns such as progressive arthritis of adjacent joints. Theoretically, total ankle replacement (TAR) offers advantages of gait preservation and conservation of the adjacent joints of the lower extremities. Most contemporary TAR designs are uncemented, three-component, mobile-bearing implants.

**Agility Total Ankle System:** The Agility prosthesis is a fixed-bearing two-piece device with an upper metal segment that attaches to the tibia and fibula. Implantation of the Agility ankle requires resurfacing of the bone to accommodate the prosthesis components. Different implant sizes are available, and two thicknesses (standard and standard plus 2 millimeters [mm]) of polyethylene inserts allow the surgeon to recreate appropriate ligamentous tension. A fourth-generation implant was introduced in 2007. This newest version features a redesigned, broad-based talar component, the ability to mismatch component sizes, and a front-loading polyethylene bearing (Easley et al., 2002; Cerrato and Myerson, 2008).

**Scandinavian Total Ankle Replacement System (STAR):** The STAR prosthesis is a mobile-bearing three-piece prosthesis consisting of a flat tibial component with two anchorage bars, a high-density polyethylene sliding core, and a convex cylindrical talar component resurfacing the entire talus. The metallic components are made of cobalt-chromium alloy and coated with a layer of hydroxyapatite or calcium phosphate and titanium. The polyethylene bearing varies in thickness from 6 to 10 mm; the talus is available in four sizes and the tibia in three. Implantation of the prosthesis requires 10 to 12 mm of bone, to be resected from the talus and the tibial plafond. The medial and lateral aspects of the talus are resurfaced to allow for maximal talar fixation and improved load distribution. The prosthesis is press fit with a titanium porous coating that allows for bony ingrowth of the prosthesis (Easley et al., 2002).

**Buechel-Pappas (BP):** The BP prosthesis is available in six sizes and is based on improvements made on the first generation of New Jersey Low Contact Stress (LCS) devices. It is a mobile-bearing implant consisting of a three-piece congruent bearing matching the curved talar component and the flat tibial and a shallow-sulcus talar component. Implantation of the BP TAR requires some bone resection and resurfacing. The prosthesis is made of titanium alloy and is coated with Ultracoat® to reduce joint friction between the plastic and metal components, and BioCoat®, a porous coating for enhancing bone ingrowth fixation (Nelissen et al., 2006).

**Ankle Evolutive System (AES):** The AES is derived from the BP prosthesis. Although the shapes of the components are similar, the tibial and talar components of the AES prosthesis are made of cobalt-chrome rather than titanium alloy. As of August 2004, the parts of the tibial component that contact bone were coated by spraying with titanium followed by hydroxyapatite (Besse et al., 2009).

**Hintegra:** The Hintegra prosthesis is a mobile-bearing prosthesis that includes a cobalt-chromium tibial component, a UHMWPE mobile-bearing component, and a cobalt-chromium talar component, all available
in five sizes. The anatomically sized flat surface allows for optimal contact to the subchondral bone and optimal support of the cortical bone ring, providing a maximal load transfer area; and minimizes bony resection to 2 to 3 mm of the subcortical bone. The flat resection allows intact preservation of the anterior tibial bone, which is mostly of better strength in patients with OA or RA of the ankle (Hintermann et al., 2004).

**Salto Talaris Anatomic Ankle:** The Salto Talaris prosthesis has cobalt-chromium tibial and talar components and a mobile UHMWPE component that is inserted between the metallic components. To create a porous surface, faces of the tibial and talar components that contact bone are sprayed with titanium and hydroxyapatite, which promotes osseous integration (Bonnin et al., 2004; Reuver et al., 2010).

**Mobility Total Ankle System:** The Mobility prosthesis has a mobile-bearing design with three components that are not cemented to the bone. Both the tibial and talar components are made of a cobalt-chromium alloy and the faces of these components that lie against bone are porous coated to encourage ingrowth of bone (Wood et al., 2010).

**REGULATORY STATUS:**

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):**

Total ankle replacement (TAR) is indicated for use in patients who have end-stage ankle disorders as an alternative to ankle fusion. TAR is intended to allow for greater rotation and movement in the joint by reducing pain, restoring alignment, and replacing the flexion and extension movement in the ankle joint. This procedure is indicated for patients with ankle joints damaged by severe rheumatoid arthritis (RA), posttraumatic osteoarthritis (PTOA), or degenerative arthritis in elderly individuals with reduced activity levels (CDRH, 2011a).

Five fixed-bearing ankle systems have been cleared for marketing by the FDA’s 510(k) process:

- The Alvine Ankle/Agility™ Total Ankle system (K020541; approved on May 20, 2002) was replaced by the newer Agility™ LP Total Ankle Replacement System (K051023; approved on March 31, 2006), manufactured by DePuy Orthopaedics Inc. (a Johnson & Johnson company);

- The Eclipse Total Ankle Implant, manufactured by Kinetikos Medical Inc. (K061749; approved on November 22, 2006); [http://www.accessdata.fda.gov/cdrh_docs/pdf6/K061749.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf6/K061749.pdf)


- The Topez Total Ankle Replacement, manufactured by Topez Orthopedics Inc. (K051023; approved on November 15, 2005);


- The Inbone II Total Ankle Replacement prosthesis, manufactured by Wright Medical Inc. (K100886; approved August 26, 2010). Fixed-bearing ankle systems are intended for cemented use only; the articulating surface is molded, locked, or attached to one of the metallic components (CDRH, 2011a); [http://www.accessdata.fda.gov/cdrh_docs/pdf10/K100886.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf10/K100886.pdf)
The mobile-bearing Scandinavian Total Ankle Replacement (STAR®) system, manufactured by Small Bone Innovations Inc., received FDA premarket approval (PMA) on May 27, 2009 (CDRH, 2011b). This prosthesis relies on bearings that move across a surface of polyethylene, a flexible plastic. STAR is indicated for use as a noncemented implant to replace a painful arthritic ankle joint due to osteoarthritis (OA), PTOA, or RA. As a condition of FDA approval, the company will evaluate the safety and effectiveness of the device during the next 8 years. STAR is currently the only FDA-approved mobile-bearing ankle device (CDRH, 2009); http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm166550.htm

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):
CMS has not established a National Coverage Determination (NCD) for TAR (CMS, 2013).

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):
Minnesota DHS does not have a policy statement regarding total ankle replacement in its Provider Manual or other specific provider references.

CLINICAL EVIDENCE:

Summary:

Study Design: The body of evidence concerning total ankle replacement (TAR) is large in size and almost entirely very low in quality since 35 of the 38 reviewed studies were uncontrolled and some of these uncontrolled studies had other shortcomings such as small sample size, retrospective analysis, incomplete reporting of patient demographics, and limited follow-up. Only one study was good in quality—a randomized controlled trial that compared the Scandinavian Total Ankle Replacement (STAR) prosthesis with the Buechel-Pappas (BP) prosthesis. The other two controlled studies compared ankle replacement with ankle fusion, but were poor in quality due to nonrandomized design and other shortcomings such as small sample size, demographic differences between the treatment groups, and limited follow-up.

Efficacy: In the reviewed studies, TAR was associated with consistent improvements in overall clinical ankle-hindfoot outcomes, regardless of the scoring system or type of implant. TAR also provided consistent, sustained pain relief in the majority of patients, as shown by medium- and long-term results. Although estimated prosthetic survival rates ranged from 54% at 5 years follow-up to 92% at 12 years follow-up, the available studies do not provide sufficient evidence to determine relative survival rates for the various prostheses.

Failure: Failure of implanted ankle prosthesis can occur due to poor prosthetic design or implantation technique, or to biological incompetence of the bone. The rates of failure of the different implants ranged from 3% to 34% after various lengths of follow-up, using different definitions of implant failure.

Quality of Life: An SF-36 Health Survey (see Appendix I) was administered in four of the reviewed studies, providing limited evidence with respect to a potential improvement in quality of life (QOL) after surgery. Two of the studies evaluated the Agility prosthesis and in one of these studies, the average SF-36 Physical and Mental Component Summary scores after ankle replacement were 49.5 and 56.1, respectively. These scores compare favorably with the general U.S. population, which has a mean score of 50 on each of these
SF-36 components (Kopp et al., 2006). In the other Agility prosthesis study, patients with rheumatoid arthritis (RA) reported more limitations because of pain compared with patients who had osteoarthritis (OA) or PTOA. The patients with RA also scored consistently lower in the categories of General Health, Vitality, and Physical Summary when compared with the other causes of arthritis (Hurowitz et al., 2007).

APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<td>Osteoarthritis and allied disorders</td>
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<td>27703</td>
<td>Arthroplasty, ankle; revision, total ankle</td>
</tr>
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CPT® is a registered trademark of the American Medical Association.

REFERENCES:


22. Center for Devices and Radiological Health (CDRH). 510(k) Premarket Approval Notification Database


64. Mann R, Mann J, Reddy S, Mangold DR. Correction of moderate to severe coronal plane deformity with the STAR ankle prosthesis. Foot Ankle Int. 2011b;32(7):659-664.
83. St. Michael's Hospital, Toronto. Gait Analysis of Ankle Arthroplasty and Arthrodesis. National Library of

POLICY HISTORY:

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