Clinical Policy Title: Total ankle replacement

Clinical Policy Number: 14.03.04

Effective Date: October 1, 2016
Initial Review Date: June 15, 2016
Most Recent Review Date: June 15, 2016
Next Review Date: June 2017

Related policies:

None.

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers total ankle replacement (TAR) to be clinically proven and, therefore, medically necessary as an alternative to ankle fusion when all of the following criteria are met:

- Skeletally mature members
- Operative weight not greater than 250 lbs.
- End-stage ankle disorders caused by severe rheumatoid arthritis (RA), severe osteoarthritis (OA) or posttraumatic osteoarthritis (PTOA) of the ankle.
- Moderate to severe ankle pain that limits activities of daily living.
- Failure to obtain adequate relief from ≥ six months of conservative therapy, including physical therapy, anti-inflammatory medications, activity modification and orthotic devices.
- Arthrodesis or severe arthritis of the contralateral ankle, or arthritis in an adjacent joint such as the subtalar or midfoot joint of the affected ankle.
- Food and Drug Administration (FDA) 501(k) cleared or pre-market approved prosthetic device.
- Consultation with a board-certified or board-qualified foot and ankle surgeon who has training and experience in this procedure.

Keystone First considers TAR revision to be clinically proven and, therefore, medically necessary for individuals with failed TAR.
Limitations:

- All other uses of TAR are not medically necessary.
- Absolute contraindications to the procedure include but are not limited to:
  - Active infection.
  - Extensive avascular necrosis of the talar dome.
  - Compromised bone stock or soft tissue.
  - Peripheral neuropathy.
  - Peripheral vascular disease.
  - Charcot neuroarthropathy.
  - Prior surgery or injury that has adversely affected ankle bone quality.
  - Psychiatric problems that hinder adequate cooperation during peri-operative period.

NOTE: The following codes are not included in the Medicaid medical fee schedule in Pennsylvania

28780 - Arthrodesis, ankle, open

Alternative covered services:

- Nonpharmacologic therapies:
  - Physical or occupational therapy.
  - Splints or joint assistive aids.
  - Patient education and support.
  - Weight loss.
- Surgery (e.g., arthroscopic debridement, joint distraction arthroplasty, supramalleolar osteotomies and ankle arthrodesis).

Background

Arthritis is common in the small joints of the foot and ankle (American Academy of Osteopaedic Surgeons [AAOS], 2015). Arthritis in the ankle joint can lead to decreased range of motion (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. The major types of arthritis that affect the foot and ankle are OA, RA, and PTOA. Trauma (e.g., dislocation and fracture) is the dominant etiology in the general population, while OA and RA in the ankle are more common in the elderly (Valderrabano, 2009; Saltzman, 2005).

Treatment options for ankle arthritis include non-surgical and surgical interventions (AAOS, 2015). Non-surgical treatment comprises lifestyle modifications, physical therapy, assistive devices such as canes and braces and anti-inflammatory medications. Surgery may be an option if conservative measures fail to relieve the pain and discomfort. The type of surgery will depend on the type and location of the arthritis and the impact of the disease on the ankle joint. In some cases, more than one type of surgery may be needed.

Historically, the established surgical option for patients with painful end-stage ankle arthritis has been ankle fusion (arthrodesis). While ankle fusion can successfully relieve the pain within the joint, the resulting range
of motion restriction can shift motion stresses to the adjacent joints, which in time may become arthritic. Advances in implant design have made TAR a viable option for many people.

The FDA has approved several TAR systems for use in the United States (FDA, 2016a; FDA, 2016b). TAR is indicated for patients with end-stage ankle disorders caused by severe RA, PTOA or OA with reduced activity levels. TAR is an implant intended to replace the ankle joint and is an alternative to ankle fusion. It allows for greater rotation and movement in the joint by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint. Most TAR systems are fixed-bearing intended for cemented use in which the articulating surface is molded, locked or attached to one of the metallic components (FDA, 2016a). One mobile bearing device, the Scandinavian Total Ankle Replacement System (STAR) (Stryker Corp., Morrisville, PA), relies on bearings that move across a flexible, polyethylene surface and is a non-cemented implant; as a condition of FDA approval, the company will evaluate the safety and effectiveness of the device through 2017 (FDA, 2016b).

**Searches**

Keystone First searched PubMed and the following databases:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality's National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on April 28, 2016. Search terms were: "Arthroplasty, Replacement"[Mesh], "Arthroplasty, Replacement, Ankle"[Mesh] and free text terms "total ankle replacement" and "total ankle arthroplasty".

We included:

- Systematic reviews, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- Guidelines based on systematic reviews.
- Economic analyses, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

We identified two systematic reviews, two professional society consensus statements and no cost-effectiveness analyses for this policy. The evidence base consists of one randomized controlled trial (RCT) comparing two mobile-bearing ankle implants, four prospective nonrandomized controlled studies comparing TAR to ankle fusion and multiple uncontrolled observational studies.

Low quality evidence suggests TAR of any type is an effective and safe surgical option for properly selected patients who have end-stage arthritis. Studies report up to 90 percent decreased pain and high patient satisfaction. There is insufficient evidence to determine relative prosthetic survival rates for various prostheses or the relative efficacy and safety of TAR compared with ankle fusion (arthrodesis). Results of nonrandomized controlled studies suggest TAR is an acceptable alternative treatment to ankle fusion, and
TAR can be revised successfully to fusion if needed. However, long-term studies with 10- to 15-year follow-ups and RCTs comparing TAR to ankle fusion are needed.

TAR is associated with a wide range of complications. Serious complications required revision or salvage, ankle fusion or below-the-knee amputation. Other complications were related to the anterior surgical approach and the articulating nature of the prosthetic device. Device-related complications often necessitated surgical revision or removal of the prosthesis.

Candidates for TAR include skeletally mature patients with primary OA, posttraumatic OA and RA, who have moderate to severe pain, loss of mobility and loss of function of the involved ankle. Patients should have completed several months of conservative treatment, have satisfactory vascular perfusion in the involved extremity, and have adequate soft-tissue coverage about the ankle that affords a safe surgical approach to TAR. No absolute cutoffs have been established for weight or age. Some manufacturer data submitted for FDA approval indicated no patient weighing more than 250 pounds had been evaluated, but available studies provide little guidance due to incomplete reporting of patient characteristics or inclusion criteria (FDA 2016a; FDA, 2016b). Where reported, studies published since FDA approval have included patients weighing more than 250 pounds, but any correlation between operative weight and outcome has not been determined. Absolute contraindications to TAR include active infection, extensive avascular necrosis of the talar dome, compromised bone stock or soft tissue, peripheral neuropathy, peripheral vascular disease and Charcot neuroarthropathy.

Both the American College of Foot and Ankle Surgeons (ACFAS) and the American Orthopaedic Foot & Ankle Society (AOFAS) endorse the use of TAR surgery for treatment of arthritic conditions of the ankle in carefully selected patients who have failed non-surgical treatment (ACFAS, 2013: AOFAS, 2014). Because TAR is a technically demanding procedure, the ACFAS recommends consulting with a board-certified or board-qualified foot and ankle surgeon who has training and experience in this procedure to ensure optimal patient selection and outcomes (ACFAS, 2013).

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hayes (2011; updated 2015)</td>
<td>Key points:</td>
</tr>
<tr>
<td>TAR</td>
<td></td>
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<tr>
<td></td>
<td>• Systematic review of one RCT, four prospective nonrandomized controlled studies (TAR versus ankle fusion), 66 uncontrolled studies and three systematic reviews. (&gt; 8,000 total patients.)</td>
</tr>
<tr>
<td></td>
<td>• Overall quality: Low with high risk of bias. One RCT of high quality.</td>
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<td></td>
<td>• Follow up: One year to 12 years, average &lt; 5 years.</td>
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<td></td>
<td>• Estimated prosthetic survival rates: 54% at 5 years to 92% at 12 years.</td>
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<td>• Complications were related mostly to the anterior surgical approach and articulating nature of the prosthetic device. Device-related complications were common, requiring surgical revision or removal of the prosthesis.</td>
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<td></td>
<td>• Consistent improvements in clinical ankle-hindfoot outcomes, sustained pain relief and patient satisfaction regardless of scoring system or implant type.</td>
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<tr>
<td></td>
<td>• Compared with ankle fusion, TAR improves function but with higher complication and reoperation rates.</td>
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</table>
Gross (2015)  
Salvage ankle arthrodesis after failed TAR

**Key points:**
- Systematic review of 16 observational studies (193 total patients).
- 41% underwent the index TAR for RA.
- Majority of revisions were secondary to component loosening, frequently of the talar component (38%).
- For those who underwent ankle arthrodesis, 81% fused after first arthrodesis procedure.
- First attempt fusion rate 100% in patients with intercalary bone graft and blade plate, but only 50% following tibiotalocalcaneal fusion with cage.
- The overall complication rate 18.2%, overall nonunion rate 10.6%.

**Glossary**

**Arthritis** — Acute or chronic inflammation and stiffness of the joints usually accompanied by pain and stiffness.

**Arthrodesis** — Surgical immobilization of a joint by fusion of the adjacent bones.

**Arthroplasty** — The surgical reconstruction or replacement of a joint.

**Debridement (cleansing)** — Removal of loose cartilage, inflamed synovial tissue and bone spurs from around the joint.

**References**

**Professional society guidelines/other:**

Arthritis of the Foot and Ankle. American Academy of Orthopaedic Surgeons website.  


FDA 510(k) Premarket Notification. Searched using product code "HSN". FDA website.  

FDA Premarket Approval (PMA) database searched using product code "NTG". FDA website.  


**Peer-reviewed references:**


**Clinical trials:**

Searched clinicaltrials.gov on May 3, 2016 using terms ankle AND (arthroplasty OR replacement) | Open Studies. 23 studies found, 3 relevant.


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**CMS Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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