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 5, 2018
Next Review Date: June 2019

Policy contains:
- Ankle arthroplasty.
- Ankle arthrodesis.
- Arthritis.

Related policies:
None.

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’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 Prestige Health Choice 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. Prestige Health Choice’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. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review as medical science evolves. Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers total ankle replacement to be clinically proven and, therefore, medically necessary as an alternative to ankle fusion when all of the following criteria are met (American College of Foot and Ankle Surgeons, 2016; American Orthopaedic Foot & Ankle Society, 2014):

- Skeletally mature members.
- Operative weight not greater than 250 lbs. (U.S. Food and Drug Administration, 2017 and b).
- End-stage ankle disorders caused by severe rheumatoid arthritis, severe osteoarthritis, or posttraumatic osteoarthritis of the ankle.
- Either (American Orthopaedic Foot & Ankle Society, 2014):
  - Moderate to severe ankle pain with loss of mobility and function of the involved ankle.
  - Previous hind foot fusion or significant arthritic change in neighboring joints.
- Failure to obtain adequate relief from more than 12 weeks of conservative therapy, including physical therapy, anti-inflammatory medications, activity modification, and orthotic devices (Interqual®, 2017).
• U.S. Food and Drug Administration (2018a and b) 501(k) cleared or premarket approved prosthetic device.
• Consultation with a board-certified or board-qualified foot and ankle surgeon who has training and experience in this procedure.

Prestige Health Choice considers total ankle replacement revision to be clinically proven and, therefore, medically necessary for individuals with a failed total ankle replacement.

Limitations:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

All other uses of total ankle replacement are not medically necessary.

Absolute contraindications to the procedure include but are not limited to (U.S. Food and Drug Administration, 2016a and b):
• 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 perioperative period.

Alternative covered services:

• Medications (analgesics, biological response modifiers, disease-modifying antirheumatic drugs, glucocorticoids, hyaluronic acid injections, immunosuppressants, low-molecular-weight heparin injection, and nonsteroidal anti-inflammatory drugs).
• 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 Orthopaedic Surgeons, 2015). Arthritis in the ankle joint can lead to decreased range of motion, swelling, stiffness, increased pain with any weight-bearing activity, a limp, a feeling of instability secondary to pain, and a visible deformity of the ankle joint itself. The major types of arthritis that affect the foot and ankle are osteoarthritis, rheumatoid arthritis, and posttraumatic osteoarthritis. Trauma (e.g., dislocation and fracture) is the dominant etiology in the general population, while osteoarthritis and rheumatoid arthritis in the ankle are more common in the elderly (Valderrabano, 2009; Saltzman, 2005).

Treatment options for ankle arthritis include nonsurgical and surgical interventions (American Academy of Orthopaedic Surgeons, 2015). Nonsurgical 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 total ankle replacement a viable option for many people. The U.S. Food and Drug Administration (2017a and b) has approved several total ankle replacement systems. Total ankle replacement 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 total ankle replacement systems are fixed-bearing intended for cemented use in which the articulating surface is molded, locked, or attached to one of the metallic components. One mobile bearing device, the Scandinavian Total Ankle Replacement (STAR) System (Stryker Corp., Morrisville, Pennsylvania), relies on bearings that move across a flexible, polyethylene surface and is a noncemented implant; as a condition of approval, the company will evaluate the safety and effectiveness of the device through 2017.

Searches

Prestige Health Choice searched PubMed and the databases of:
- 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 18, 2018. Search terms were: “Ankle Joint/surgery” (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 (Hayes, 2015; Gross, 2015), two professional society consensus statements (American College of Foot and Ankle Surgeons, 2016; American Orthopaedic Foot & Ankle Society, 2014) and no cost-effectiveness analyses for this policy. The evidence base consists of one randomized controlled trial comparing two mobile-bearing ankle implants, four prospective nonrandomized controlled studies comparing total ankle replacement to ankle fusion, and multiple uncontrolled observational studies.

Low-quality evidence suggests total ankle replacement 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 total ankle replacement compared with arthrodesis. Results of nonrandomized controlled studies suggest total ankle replacement is an acceptable alternative treatment to ankle fusion, and total ankle replacement can be revised successfully to fusion if needed. However, long-term studies with 10- to 15-year follow-ups and randomized controlled trials comparing total ankle replacement to ankle fusion are needed.

Total ankle replacement 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 total ankle replacement include skeletally mature patients with primary osteoarthritis, posttraumatic osteoarthritis, and rheumatoid arthritis, 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 total ankle replacement.

No absolute cutoffs have been established for weight or age. Some manufacturer data submitted for U.S. Food and Drug Administration (2016a and b) 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. Where reported, studies published since approval have included
patients weighing more than 250 pounds, but any correlation between operative weight and outcome has not been determined. Absolute contraindications to total ankle replacement 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 and the American Orthopaedic Foot & Ankle Society endorse the use of total ankle replacement surgery for treatment of arthritic conditions of the ankle in carefully selected patients who have failed nonsurgical treatment (American College of Foot and Ankle Surgeons, 2016; American Orthopaedic Foot & Ankle Society, 2014). Because total ankle replacement is a technically demanding procedure, the American College of Foot and Ankle Surgeons (2016) 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.

Policy updates:

In 2017, we found no new information for this policy.

In 2018, we added Interqual (2017) criteria and one systematic review and pooled analysis that provided both direct and indirect comparison of surgical outcomes following total ankle arthroplasty and ankle arthrodesis (Lawton, 2017). Lawton et al. concluded no superiority of one procedure over the other, and treatment choice should be on a case-by-case basis. The policy statement was revised to align more closely with both Interqual (2017) and the American Orthopaedic Foot & Ankle Society (2014) criteria.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td><strong>Lawton (2017)</strong></td>
<td><strong>Key points:</strong></td>
</tr>
</tbody>
</table>
| Total ankle arthroplasty versus ankle arthrodesis—a comparison of outcomes over the last decade | - Quasi-systematic review included six studies of total ankle arthroplasty, five studies of ankle arthrodesis, and 10 studies directly comparing the two procedures. Criteria: published in the past 10 years; used only modern third-generation implants approved for use in the United States; included ≥ 80 ankles in each study; and reported surgical outcomes.  
  - Results (ankle arthrodesis versus total ankle arthroplasty):  
    - Adjusted overall complication rate 26.9% versus 19.7%.  
    - Non-revision reoperation rate 12.9% versus 9.5%.  
    - Adjusted revision reoperation rate 5.4% versus 7.9%.  
  - Direct comparison studies suggest a more symmetric gait and less impairment on uneven surfaces after total ankle arthrodesis. |
| **Hayes (2011; updated 2015)** | **Key points:** |
| Total ankle replacement | - Systematic review of one randomized controlled trial, four prospective nonrandomized controlled studies (total ankle replacement versus ankle fusion), 66 uncontrolled studies, and three systematic reviews (>8,000 total patients.)  
  - Overall quality: Low with high risk of bias. One randomized controlled trial of high |
Citation | Content, Methods, Recommendations
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- Follow-up: One year to 12 years, average <5 years.
- Estimated prosthetic survival rates: 54% at 5 years to 92% at 12 years.
- 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.
- Consistent improvements in clinical ankle-hindfoot outcomes, sustained pain relief, and patient satisfaction regardless of scoring system or implant type.
- Compared with ankle fusion, total ankle replacement improves function but with higher complication and reoperation rates.

Gross (2015) | Key points:
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Salvage ankle arthrodesis after failed total ankle replacement

- Systematic review of 16 observational studies (193 total patients).
- 41% underwent the index total ankle replacement for rheumatoid arthritis.
- 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%.

References

Professional society guidelines/other:


Peer-reviewed references:


CMS National Coverage Determinations (NCDs):

No NCDs identified as of the writing of this policy.

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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