MEDICAL POLICY – 7.01.577
Total Ankle Replacement

Ref. Policy: PA-053

Effective Date: Jan. 1, 2020
Last Revised: Aug. 13, 2019
Replaces: N/A

RELATED MEDICAL POLICIES:
None

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Advanced end-stage arthritis in the ankle occurs when the cartilage that cushions the ankle joint wears down and bones grind together. This results in pain that limits daily activities. Treatments for arthritis of the ankle include non-steroidal anti-inflammatory drugs (NSAIDs), physical therapy (PT), splits, and devices to support the ankle (orthotics). Another treatment is total ankle replacement (TAR), which replaces the damaged bone and cartilage with new joint surfaces made of plastic or metal. This policy describes when total ankle replacement may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria
Total ankle replacement (TAR) for the treatment of advanced end stage arthritis of the ankle may be considered medically necessary when ALL of the following indications are met:

- The device must be U.S. Food and Drug Administration (FDA)-approved (see below)

AND

- The patient must be skeletally mature

AND

- The patient must have failed six months of conservative therapy including non-steroidal anti-inflammatory drugs (NSAID)s, physical therapy (PT), splints, or orthotic devices

AND

- There is moderate to severe ankle pain significantly limiting daily activity

AND

- Any one of the following is present:
  - Arthritis in adjacent joints (subtalor or midfoot) OR
  - Severe arthritis of the contralateral ankle OR
  - Arthrodesis of the contralateral ankle OR
  - Inflammatory arthritis (eg, RA)

Total ankle replacement, revision

TAR may be considered medically necessary for revision of prior total ankle replacement surgery if indicated (ie, for infection, inflammatory reaction, mechanical, or other complication) and the above indications are met.

### Coding

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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>27702</td>
<td>Arthroplasty of ankle; with implant (total ankle)</td>
</tr>
<tr>
<td>27703</td>
<td>Arthroplasty of ankle; revision, total ankle</td>
</tr>
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Related Information

Limitations

The device used for implant must be FDA-approved and contraindications to TAR include any of the following:

a. Active local or systemic infection

b. Hindfoot or forefoot mal-alignment which would prevent a plantigrade foot

c. Avascular necrosis of the talus

d. Charcot neuroarthropathy

e. Severe osteoporotic or osteopenic condition or prior surgery/injury resulting in poor bone quality and potential inadequate bony fixation

f. Patient age (less than 50 years of age), weight, or activity level that introduces unnecessary risk of failure (those less than 50 years of age with disabling arthritis, may be reviewed on a case-by-case basis for medical necessity)

g. Lower extremity vascular insufficiency demonstrated by Doppler arterial pressure

h. Poor skin and soft tissue quality around the surgical site (eg, scarring from multiple prior surgeries in the area)

i. Neuromuscular disease resulting in a lack of normal muscle function about the affected ankle

j. Severe sensorineural dysfunction of the foot/ankle

k. Prior arthrodesis of ankle joint

l. Severe mal-alignment (>15 degrees) not correctable by surgery
m. Insufficient ligament support that cannot be repaired with soft tissue stabilization

n. Surgeons without specific training/experience in the specific techniques of the device used

Evidence Review

Background

TAR designs are divided into two groups - fixed bearing designs (two component with a locked articulating surface between the components of the talus/tibia) and mobile bearing designs (three-component with a polyethylene bearing that glides between the talus component and tibia plate).

Regulatory Status

Current U.S. Food and Drug Administration (FDA)-approved fixed two-component implants include:

- Agility™ Total Ankle System by DePuy Orthopaedics, Inc. (Warsaw, IN) for patients with end stage ankle disorders as an alternative to ankle fusions

Semi-Constrained Cemented Prosthesis:

- INBONE™ Total Ankle System by Wright Medical Technology, Inc. (Arlington, TN) for patients with ankle joints damaged severe rheumatoid, post-traumatic, or degenerative arthritis

- Salto Talaris® Anatomic Ankle by Tornier, Inc. (France) for use as a total ankle replacement in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

- Eclipse Total Ankle Implant by Integra LifeSciences (Plainsboro, NJ) for patients affective with severe rheumatoid, post-traumatic, or degenerative arthritis

Current FDA approved three-part mobile bearing implant include:
• Scandinavian Total Ankle Replacement System (STAR Ankle) by Small Bone Innovations, Inc. (Morrisville, PA) for use as a non-cemented implant to replace a painful arthritic ankle joint due to osteoarthritis, post-traumatic arthritis or rheumatoid arthritis.

References


### History

<table>
<thead>
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<th>Date</th>
<th>Comments</th>
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<tr>
<td>09/16/19</td>
<td>New policy, approved August 13, 2019, effective January 1, 2020. Total ankle replacement (TAR) for the treatment of advanced end stage arthritis of the ankle may be considered medically when all criteria are met. TAR may be considered medically necessary for revision of prior total ankle replacement surgery if indicated (ie, for infection, inflammatory reaction, mechanical, or other complication) and criteria are met as listed for TAR.</td>
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Complaint forms are available at

200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

U.S. Department of Health and Human Services

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