

MedStar Health, Inc.

POLICY AND PROCEDURE MANUAL

Policy Number: PA.053.MH
Last Review Date: 08/26/2021
Effective Date: 10/01/2021

PA.053.MH – Total Ankle Replacement

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers a **Total Ankle Replacement (TAR)** for the treatment of advanced end stage arthritis of the ankle medically necessary when ALL of the following indications are met:

1. The device must be FDA approved; and
2. The patient must be skeletally mature; and
3. **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
4. There is moderate to severe ankle pain significantly limiting daily activity; and
5. Any one of the following is present:
 - a. Arthritis in adjacent joints (subtalar or midfoot) or
 - b. Severe arthritis of the contralateral ankle or
 - c. Arthrodesis of the contralateral ankle or
 - d. Inflammatory arthritis (e.g. RA)

TAR may also be used for revision of prior total ankle replacement surgery if indicated (i.e. for infection, inflammatory reaction, mechanical, or other complication) and the above indications are met.

Limitations

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

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- 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 (e.g. 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

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).

Current 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.

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Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
27702	Arthroplasty of ankle; with implant (total ankle)
27703	Arthroplasty of ankle; revision, total ankle

References

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April 24, 2007. <https://www.fda.gov/advisory-committees/medical-devices-advisory-committee/orthopaedic-and-rehabilitation-devices-panel>

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13. U.S. Food and Drug Administration (FDA), Centers for Devices and Radiological Health. Device Approvals, Denials and Clearances. Tonier. Issued March 17, 2009. https://www.accessdata.fda.gov/cdrh_docs/pdf9/K090076.pdf

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