

MedStar Health, Inc.

POLICY AND PROCEDURE MANUAL

Policy Number: PA.053.MH
Last Review Date: 05/10/2018
Effective Date: 07/01/2018

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
- 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

PA.053.MH – Total Ankle Replacement

Policy Number: PA.053.MH
Last Review Date: 05/10/2018
Effective Date: 07/01/2018

- 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.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description

PA.053.MH – Total Ankle Replacement

Policy Number: PA.053.MH
Last Review Date: 05/10/2018
Effective Date: 07/01/2018

27702	Arthroplasty of ankle; with implant (total ankle)
27703	Arthroplasty of ankle; revision, total ankle

References

1. American College of Foot and Ankle Surgeons (ACFAS): Position Statement Total Ankle Replacement Surgery. March 2010.
<http://www.acfas.org/Physicians/Content.aspx?id=1933>
2. American Orthopaedic Foot & Ankle Society (AOFAS): Position Statement- The Use of Total Ankle Replacement for the Treatment of Arthritic Conditions of the Ankle. March 31, 2014. <http://www.aofas.org/medical-community/health-policy/Documents/Total%20Ankle%20Replacement%20Position%20Statement%20203-2014%20FINAL.pdf>
3. American Orthopaedic Foot & Ankle Society (AOFAS): Total ankle replacement (TAR). OrthopaedicsOne: Chapter 66:318-359. Posted January 31, 2013.
<http://www.aofas.org/education/OrthopaedicArticles/Total-ankle-replacement.pdf>
4. AOFAS Position Statement: Total Ankle Replacement Surgery; Dated: Aug. 4, 2009. Available at: <http://www.saintalphonsus.org/documents/AOFAS-PositionStatement.pdf>
5. Bonasia DE, Dettoni F, Femino JE, et al. Total Ankle Replacement: Whey, When and How? Iowa Orthop J. 2010; 30; 19-130.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2958283/>
6. Conti SF, Wong YS. Complications of the total ankle replacement. Clin Orthop Relat Res. 2001 Oct; (391):105-114. http://ovidsp.tx.ovid.com/sp-3.12.0b/ovidweb.cgi?WebLinkFrameset=1&S=HLCAFPPMAIDDBHNENCMKKDFBEADCAA00&returnUrl=ovidweb.cgi%3f%26Full%2bText%3dL%257cS.sh.22.23%257c0%257c00003086-200110000-00011%26S%3dHLCAFPPMAIDDBHNENCMKKDFBEADCAA00&directlink=http%3a%2f%2fgraphics.tx.ovid.com%2fovftpdfs%2fFPDDNCFBKDNEAI00%2ffs046%2fovft%2flive%2fgv023%2f00003086%2f00003086-200110000-00011.pdf&filename=Complications+of+Total+Ankle+Replacement.&pdf_key=FPDDNCFBKDNEAI00&pdf_index=/fs046/ovft/live/gv023/00003086/00003086-200110000-00011
7. Haddad SL, Coetzee JC, Estok R, et al. Intermediate and long-term outcomes of total ankle arthroplasty and ankle. arthrodesis. A systematic review of the literature. J Bone Joint Surg Am. 2007 Sep; 89(9):1899-1905.
<http://www.jbjs.org/content/jbjsam/89/9/1899.full.pdf>
8. McKee J. What's the latest word in joint replacement?. AAOSNOW: 01/2009 Issue.
http://www6.aaos.org/news/PDFopen/PDFopen.cfm?page_url=http://www.aaos.org/news/aaosnow/jan09/clinical8.asp

PA.053.MH – Total Ankle Replacement

Policy Number: PA.053.MH

Last Review Date: 05/10/2018

Effective Date: 07/01/2018

9. Stanton T. Ten “takes” on the future of the total ankle. American Academy of Orthopaedic Surgeons (AAOS). AAOSNOW. 10/2010 Issue.
http://www6.aaos.org/news/PDFopen/PDFopen.cfm?page_url=http://www.aaos.org/news/aaosnow/oct10/clinical6.asp
10. Wood PLR, Deakin S. Total ankle replacement. J Bone Joint Surg (Br). 2003; (85): 334-341. <http://www.bjj.boneandjoint.org.uk/content/85-B/3/334.full.pdf>
11. U.S. Food and Drug Administration (FDA), Centers for Devices and Radiological Health, Summary of the Orthopaedic and Rehabilitation Devices Panel Meeting – April 24, 2007.
<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/ucm124865.htm>
12. U.S. Food and Drug Administration (FDA), Centers for Devices and Radiological Health. Device Approvals, Denials and Clearances. Scandinavian Total Ankle Replacement System (STAR Ankle) - P050050. Issued: May 27, 2009.
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P050050>
13. U.S. Food and Drug Administration (FDA), Centers for Devices and Radiological Health. Device Approvals, Denials and Clearances. INFINITY Total Ankle System. Issued: April 1, 2013, 2009
http://www.accessdata.fda.gov/cdrh_docs/pdf12/K123954.pdf
14. U.S. Food and Drug Administration (FDA), Centers for Devices and Radiological Health. Device Approvals, Denials and Clearances. Tonier. Issued March 17, 2009. http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090076.pdf

Disclaimer:

MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

These policies are the proprietary information of Evolent Health. Any sale, copying, or dissemination of said policies is prohibited.

PA.053.MH – Total Ankle Replacement

Policy Number: PA.053.MH
Last Review Date: 05/10/2018
Effective Date: 07/01/2018