

POLICY NUMBER	EFFECTIVE DATE	APPROVED BY
MG.MM.SU.48C8	02/01/2020	MPC (Medical Policy Committee)

#### IMPORTANT NOTE ABOUT THIS MEDICAL POLICY:

Property of ConnectiCare, Inc. All rights reserved. The treating physician or primary care provider must submit to ConnectiCare, Inc. the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, ConnectiCare will not be able to properly review the request for prior authorization. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. The clinical review criteria expressed below reflects how ConnectiCare determines whether certain services or supplies are medically necessary. ConnectiCare established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based quidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). ConnectiCare, Inc. expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Each benefit plan defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by ConnectiCare, as some plans exclude coverage for services or supplies that ConnectiCare considers medically necessary. If there is a discrepancy between this guideline and a member's benefits plan, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of the State of CT and/or the Federal Government. Coverage may also differ for our Medicare members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including including National Coverage Determinations (NCD), Local Coverage Determinations (LCD) and/or Local Medical Review Policies(LMRP). All coding and web site links are accurate at time of publication.

#### **Definitions**

Total Ankle Replacement (TAA)

Total ankle replacement (aka total ankle arthroplasty [TAA]) consists of replacing a diseased ankle joint with a prosthetic plastic and metal joint. The procedure has been proposed as an alternative to ankle arthrodesis (fusion) for conditions such as severe osteoarthritis (OA), post-traumatic arthritis and rheumatoid arthritis.

#### Guideline

Members with a severely degenerative ankle or severe inflammatory arthritis (e.g., OA, post-traumatic or rheumatoid), who are skeletally mature with sufficient bone stock, are eligible for TAA with an FDA- approved device when the following criteria are met:

- Loss of ankle mobility and function
- Moderate to severe pain unrelieved by ≥ 6 months of conservative therapy (e.g., anti- inflammatory medications, orthotics, activity modification, physical



therapy)

#### AND ANY OF THE FOLLOWING

- Arthritis in adjacent joints of the involved extremity (i.e., subtalar, midfoot)
- Severe arthritis of the contralateral ankle
- Previous arthrodesis of the contralateral ankle

## **Limitations/Exclusions**

TAA is not considered medically necessary when any of the following are applicable:

- Active infection in the joint or adjacent bones
- Insufficient bone stock/osteonecrosis
- Loss of musculature in the affected limb/insufficient ligament support that is not repairable
- Lower extremity vascular insufficiency
- Neurologic impairment affecting muscle function about the ankle/peripheral neuropathy
- Severe ankle deformity
- Malalignment/severe deformity of involved or adjacent anatomic structures (e.g. hindfoot, forefoot, knee)

## **Applicable Coding**

To access the codes, please download the policy to your computer, and click on the paperclip icon within the policy



**Applicable CPT and Diagnosis Codes** 

### References

American Orthopaedic Foot & Ankle Society. Position statement on Total Ankle Replacement Surgery. April 2018. <a href="https://www.aofas.org/docs/default-source/research-and-policy/total-ankle-replacement-position-statement.pdf?sfvrsn=9a9512c7">https://www.aofas.org/docs/default-source/research-and-policy/total-ankle-replacement-position-statement.pdf?sfvrsn=9a9512c7</a> 4. Accessed September 17, 2019.

Anderson T, Montgomery F, Carlsson A. Uncemented STAR total ankle prosthesis. Three to eight-year follow-up of fifty-one consecutive ankles. J Bone Joint Surg Am. 2003; 85-A(7):1321-1329.

Bonnin M, Judet T, Colombier JA, et al. Midterm results of the Salto Total Ankle Prosthesis. Clin Orthop Relat Res. 2004; (424):6- 18.

Buechel FF Sr, Buechel FF Jr, Pappas MJ. Ten-year evaluation of cementless Buechel-Pappas meniscal bearing total ankle replacement. Foot Ankle Int. 2003; 24(6):462-472.

Colman AB, Pomeroy GC. Transfibular ankle arthrodesis with rigid internal fixation: an assessment of outcome. Foot Ankle Int. 2007; 28(3):303-307.

Conti SF, Wong YS. Complications of total ankle replacement. Foot Ankle Clin. 2002; 7(4):791-807.

Doets H, Brand R, Nelissen R. Total ankle arthroplasty in inflammatory joint disease with use of two mobile-bearing designs. J Bone Joint Surg Am. 2006; 88(6):1272-1284.

Dyrby C, Chou LB, Andriacchi TP, Mann RA. Functional evaluation of the Scandinavian total ankle



replacement. Foot ankle Int. 2004; 25(6):377-381.

Easley ME, Vertullo CJ, Urban WC, Nunley JA. Total ankle arthroplasty. J Am Acad Orthop Surg.

2002; 10(3):157-167.

Gill LH. Challenges in total ankle arthroplasty. Foot Ankle Int. 2004; 25(4):195-207.

Guyer AJ, Richardson G. Current concepts review: total ankle arthroplasty. Foot Ankle Int. 2008; 29(2):256-264.

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; 89(9):1899-1905.

Hintermann B, Valderrabano V. Total ankle replacement. Foot Ankle Clin 2003; 8(2):375-405.

Hopgood P, Kumar R, Wood PL. Ankle arthrodesis for failed total ankle replacement. 2006; 88(8):1032-1038.

Hurowitz EJ, Gould JS, Fleisig GS, Fowler R. Outcome analysis of agility total ankle replacement with prior adjunctive procedures: two to six year followup. Foot Ankle Int. 2007; 28(3):308-312.

Knecht SI, Estin M Callaghan JJ, et al. The Agility total ankle arthroplasty. Seven to sixteen-year follow-up. J Bone Joint Surg Am. 2004; 86-A(6):1161-1171.

Kopp FJ, Patel MM, Deland JT, O'Malley MJ. Total ankle arthroplasty with the Agility prosthesis: clinical and radiographic evaluation. Foot Ankle Int. 2006; 27(2):97-103.

Kotnis R, Pasapula C, Anwar F, et al. The management of failed ankle replacement. J Bone Joint Surg Br.

2006; 88(8):1039-1047. Morse KR, Flemister AS, Baumhauer JF, DiGiovanni BF. Distraction arthroplasty.

Foot Ankle Clin. 2007; 12(1):29-39.

Pyevich MT, Saltzman CL, Callaghan JJ, Alvine FG. Total ankle arthroplasty: a unique design. Two to twelve-year follow-up. J Bone Joint Surg Am. 1998; 80(10):1410-1420.

Raikin SM, Myerson MS. Avoiding and managing complications of the Agility Total Ankle Replacement system. Orthopedics. 2006; 29(10):930-938.

Saltzman CL, Mann RA, Ahrens JE, et al. Prospective Controlled Trial of STAR Total Ankle Replacement Versus Ankle Fusion: Initial Results. Foot Ankle Int. 2009; 30(7):579-596.

San Giovanni TP, Keblish DJ, Thomas WH, Wilson MG. Eight-year results of a minimally constrained total ankle arthroplasty. Foot Ankle Int. 2006; 27(6):418-426.

Schuberth JM, Patel S, Zarutsky E. Perioperative complications of the Agility total ankle replacement in 50 initial, consecutive cases. J Foot Ankle Surg. 2006; 45(3):139-146.

Slobogean GP, Younger A, Apostle KL, et al. Preference-based quality of life of end-stage ankle arthritis treated with arthroplasty or arthrodesis. Foot Ankle Int. 2010; 31(7):563-566.

Smith R, Wood PL. Arthrodesis of the ankle in the presence of a large deformity in the coronal plane. J Bone Joint Surg. Br. 2007; 89(5):615-619.

Soohoo NF, Zingmond DS, Ko CY. Comparison of reoperation rates following ankle arthrodesis and total ankle arthroplasty. J Bone Joint Surg Am. 2007; 89(10):2143-2149.

Spirt AA, Assal M, Hansen ST Jr. Complications and failure after total ankle arthroplasty. J Bone Joint Surg Am. 2004; 86- A(6):1172-1178.

Stamatis ED, Myerson MS. How to avoid specific complications of total ankle replacement. Foot Ankle Clin.



2002; 7(4):765-789. Stengel D, Bauwens K, Ekkernkamp A, Cramer J. Efficacy to total ankle replacement with meniscal-bearing devices: a systemic review and meta-analysis. Arch Orthop Trauma Surg. 2005; 125(2):109-119

Vickerstaff JA, Miles AW, Cunningham JL. A brief history of total ankle replacement and a review of the current status. Med Eng Phys. 2007; 29(10):1056-1064.

U.S. Food and Drug Administration Premarket Approvals. Scandinavian Total Ankle Replacement System (STAR Ankle). P050050. Rockville, MD: FDA. May 29, 2009. Available at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm1665 50.htm. Accessed August 22, 2012.

Wood PL, Deakin S. Total ankle replacement. The results in 200 ankles. J Bone Joint Surg Br. 2003; 85(3):334-341.

Wood PL, Prem H, Sutton C. Total ankle replacement: medium-term results in 200 Scandinavian total ankle replacements. J Bone Joint Surg Br. 2008; 90(5):605-609.

Specialty matched clinical peer review.

## **Revision history**

DATE	REVISION	
09/13/2019	<ul> <li>New Policy.</li> <li>ConnectiCare, Inc. has adopted the clinical criteria of its parent corporation, EmblemHealth. Reformatted and reorganized policy, transferred content to new CCI template</li> </ul>	