

Total Ankle Replacement

Table of Content	Effective Date	1/2011
<u>Purpose</u> <u>Description & Definitions</u> <u>Criteria</u>	<u>Next Review Date</u>	6/15/2024
<u>Coding</u> <u>Document History</u>	<u>Coverage Policy</u>	Surgical 96
<u>References</u> <u>Special Notes</u> <u>Keywords</u>	<u>Version</u>	4

All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.<u>*</u>.

Purpose:

This policy addresses Total Ankle Replacements.

Description & Definitions:

Total Ankle Replacement is a surgical repair removal of the ankle joint and bones and replacement with a Federal Drug Administration (FDA) approved prosthetic device. The implanted device replaces the damaged articulating surfaces of the shin (tibia) and ankle (talus) bones.

Criteria:

Total ankle replacement or revisions are considered medical necessary with 1 or more of the following:

- Replacement with ALL of the following:
 - \circ $\;$ Individual is 18 years old or greater $\;$ and thus is considered skeletally mature $\;$
 - o Individual has ankle pain that significantly limits daily activity
 - o Device to be implanted is approved by the Federal Drug Administration (FDA)
 - Individual has tried and failed at least 6 months of conservative treatment (e.g. Anti-inflammatory medication, physical therapy, splints, orthotic devices, etc.)
 - Individual must have sufficient lower extremity vascular perfusion
 - o Individual has **1 or more of the following** conditions:
 - Arthritis in adjacent joints (subtalar or midfoot)
 - Arthrodesis of the contralateral ankle (other ankle)
 - Inflammatory arthritis (rheumatoid)
 - Severe arthritis of the contralateral ankle (other ankle)
- **Revision** of an already implanted device is considered medically necessary with **All of the following**:
 - The already implanted device has failed

- o Individual is 18 years old or greater and thus is considered skeletally mature
- o Individual has ankle pain that significantly limits daily activity
- Device to be implanted is approved by the Federal Drug Administration (FDA)
- Individual has tried and failed at least 6 months of conservative treatment (e.g. Anti-inflammatory medication, physical therapy, splints, orthotic devices, etc.)
- Individual must have sufficient lower extremity vascular perfusion
- Individual has **1 or more of the following** conditions:
 - Arthritis in adjacent joints (subtalar or midfoot)
 - Arthrodesis of the contralateral ankle (other ankle)
 - Inflammatory arthritis (rheumatoid)
 - Severe arthritis of the contralateral ankle (other ankle)

Total ankle replacements are considered not medically necessary for any use other than those indicated in clinical criteria.

Coding:

Medically necessary with criteria:

Coding	De	scription
27702	Art	hroplasty, ankle; with implant (total ankle)
27703	Art	hroplasty, ankle; revision, total ankle
27704	Re	moval of ankle implant

Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2022: June
- 2020: January
- 2015: April
- 2014: April
- 2013: April
- 2011: October

Reviewed Dates:

- 2023: June
- 2021: September
- 2020: September
- 2019: September
- 2018: March
- 2017: January
- 2012: April
- 2010: December

Effective Date:

• January 2011

Surgical 96

References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

(2023). Federal Register. Determination of Regulatory Review Period for Purposes of Patent Extension; HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM. (3.16.2021). Retrieved 6.13.2023. https://www.federalregister.gov/documents/2021/03/16/2021-05371/determination-of-regulatory-review-period-forpurposes-of-patent-extension-hintermann-series-h3

(2023). US Food and Drug Administration. FDA In Brief: FDA Advises Patients, Caregivers and Providers of Risk of Breakage of Total Ankle Replacement Device. (3.15.2021). Retrieved 6.13.2023. https://www.fda.gov/news-events/fda-brief/fda-brief/fda-advises-patients-caregivers-and-providers-risk-breakage-total-ankle-replacement-device

(2023). Comparative Effectiveness Review Of Total Ankle Replacement: A Review Of Reviews. Hayes, a symplr company. (2.2.2022). ARCHIVED 1.28.2023. Retrieved 6.13.2023. https://evidence.hayesinc.com/report/dir.total918

(2023). Musculoskeletal Surgery or Procedure GRG. GRG: SG-MS (ISC GRG). (2023). Retrieved 6.13.2023. https://careweb.careguidelines.com/ed26/index.html

(2023). Centers for Medicare and Medicaid Services. MCS.gov. Retrieved 6.13.2023. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=36039&ver=12&

(2023). Fee Schedule. Search CPT Codes. Virginia's Medicaid Program. Department of Medical Assistance Services. An Agency of the Commonwealth of Virginia. (2023). Retrieved 6.13.2023. https://www.dmas.virginia.gov/for-providers/rates-and-rate-setting/procedure-fee-files-cpt-codes/#searchCPT

(2023). Carelon. Small Joint Surgery. (11.05.2022). Retrieved 6.13.2023. https://guidelines.carelonmedicalbenefitsmanagement.com/small-joint-surgery-2023-11-05/?highlight=ankle+arthritis&hilite=ankle+arthritis

(2023). Arthritis of the Foot and Ankle. American Academy of Orthopedic Surgeons. (9.2019). Retrieved 6.13.2023. https://orthoinfo.org/en/diseases--conditions/arthritis-of-the-foot-and-ankle/

(2023). Barg, A., Wimmer, M. D., Wiewiorski, M., Wirtz, D. C., Pagenstert, G. I., & Valderrabano, V. Total ankle replacement. Deutsches Arzteblatt international. PubMed. National Library of Medicine. (3.13.2015). Retrieved 6.13.2023. https://doi.org/10.3238/arztebl.2015.0177

(2022). Retrieved June 10, 2022, from Optum EncoderPro Professional. 2022: https://www.encoderpro.com

(2022). Retrieved June 10, 2022, from DynaMed Plus, Ehrlich, A., Osteoarthritis (OA) of the Ankle. (2022): https://www.dynamed.com/condition/osteoarthritis-oa-of-the-ankle#SURGERY_AND_PROCEDURES

(2022). Retrieved June 10, 2022, from PubMed, Journal of Orthopedic Surgery, Li, Y., He, J., Hu, Y., Comparison of the Efficiency and Safety of Total Ankle Replacement and Ankle Arthrodesis in the Treatment of Osteoarthritis: An Updated Systematic Review and Meta-analysis. (3/29/2020): https://pubmed.ncbi.nlm.nih.gov/32227465/

(2022). Retrieved June 10, 2022, from DynaMed Plus, the Journal of Bone & Joint, Zaidi, R., Cro, S., Gurusamy, K, Macgregor, A., Henricson, A., Goldberg, A., The outcome of total ankle replacement: a systematic review and meta-analysis. (11/2013): https://pubmed.ncbi.nlm.nih.gov/24151270/ Surgical 96 (2022). Retrieved June 10, 2022, from PubMed, Journal of Orthopedic Surgery and Research, Lawton, C., Butler, B., Dekker, R., Prescott, A., Kadakia, A., Total ankle arthroplasty versus ankle arthrodesis-a comparison of outcomes over the last decade. (5/18/2017): https://pubmed.ncbi.nlm.nih.gov/28521779/

(2022). Retrieved June 10, 2022, from UpToDate, Rinaldi, R., Total joint replacement for severe rheumatoid arthritis. (5/12/2022): <u>https://www.uptodate.com/contents/total-joint-replacement-for-severe-rheumatoid-arthritis?search=total%20ankle%20replacement&source=search_result&selectedTitle=1~12&usage_type=default&display_rank=1#H18</u>

Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

Keywords:

SHP Total Ankle Replacement, SHP Surgical 96, arthroplasty, Arthritis, Arthrodesis, Inflammatory arthritis, rheumatoid arthritis, Hintermann Series H2 Total Ankle System, Invision Total Ankle Revision System, Salto Xt, Vantage Total Ankle System, Integra Total Ankle Replacement System, Infinity Total Ankle System, Inbone Total Ankle, Salto Talaris Total Ankle Prosthesis, Agility LP Total Ankle Replacement System, Eclipse Total Ankle Implant, Topez Total Ankle Replacement