Medical Coverage Policy

Effective Date.....3/15/2026
Next Review Date.....3/15/2027
Coverage Policy Number..... 0285

Total Ankle Arthroplasty/Replacement

Table of Contents

Related Coverage Resources

Hip Replacement/Arthroplasty
Knee Replacement/Arthroplasty
Physical Therapy
Subtalar Joint Implantation (Subtalar Arthroereisis)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses total ankle arthroplasty/replacement, revision total ankle arthroplasty, and total talar replacement.

Coverage Policy

Total Ankle Arthroplasty/Replacement

Total ankle arthroplasty/replacement with a U.S. Food and Drug Administration (FDA)-approved/cleared device* is considered medically necessary as an alternative to ankle arthrodesis when ALL of the following criteria have been met:

- individual is skeletally mature
- presence of **ONE** of the following in the affected ankle:
  - severe inflammatory arthritis (e.g., rheumatoid arthritis)
  - severe osteoarthritis
  - post-traumatic arthritis
- individual has moderate to severe ankle pain that:
  - is function-limiting at short distances (e.g., walking less than ¼ mile, limiting activity to two city blocks, the equivalent to walking the length of a shopping mall) for at least three (3) months duration
  - interferes with the ability to carry out age appropriate activities of daily living and/or demands of employment
- failure of at least six months of conservative therapy (i.e., anti-inflammatory medications, orthotic devices, activity modification, physical therapy)
- individual has **NONE** of the following contraindications to total ankle arthroplasty:
  - active infection
  - insufficient bone/osteonecrosis
  - loss of musculature in the affected limb/insufficient ligament support
  - vascular insufficiency in the affected limb
  - Charcot's or other peripheral neuropathy
  - neurological impairment
  - severe ankle deformity precluding proper alignment
  - malalignment or severe deformity of involved or adjacent anatomic structures (e.g. hindfoot, forefoot, knee)
  - absence of medial or lateral malleolus, or both
  - poor skin conditions secondary to surgical scars or trauma

*See Appendix for a list of FDA-approved/cleared devices.

Total ankle arthroplasty/replacement for any other indication is considered not medically necessary.

Revision Total Ankle Arthroplasty

Revision total ankle arthroplasty is considered medically necessary for moderate to severe ankle pain secondary to failure of an implanted device (e.g., implant loosening, malpositioning, periprosthetic infection, periprosthetic fracture).

Revision total ankle arthroplasty for any other indication is considered not medically necessary.

Total Talar Replacement

Total talar replacement (i.e., prosthesis), alone or in combination with total ankle arthroplasty or revision total ankle arthroplasty, is considered experimental, investigational or unproven.

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Total Ankle Arthroplasty/Replacement/Revision

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
27702	Arthroplasty, ankle; with implant (total ankle)
27703	Arthroplasty, ankle; revision, total ankle

Total Talar Replacement

Considered Experimental/Investigational/Unproven when used to report total talar replacement (i.e., prosthesis), alone or in combination with total ankle arthroplasty/replacement or revision total ankle arthroplasty:

CPT®* Codes	Description
27899	Unlisted procedure, leg or ankle

HCPCS Codes	Description
L8699	Prosthetic implant, not otherwise specified

General Background

Total ankle arthroplasty (TAA), also known as total ankle replacement (TAR), is the process of replacing a diseased or injured ankle with a prosthetic ankle. The procedure has been proposed as an alternative to ankle arthrodesis (i.e., ankle fusion) for non-inflammatory arthritic conditions such as severe osteoarthritis (OA) or post-traumatic arthritis, and for inflammatory arthritic conditions, such as rheumatoid arthritis (RA) of the ankle. Arthritic ankle (tibiotalar) joints frequently result in decreased range of motion, swelling, joint stiffness, pain with weight-bearing activity, instability secondary to pain, and in some cases visible joint deformity. Conservative management typically consists of medications for pain control, limiting activity, the use of ankle braces to stabilize the joint, shoe modifications, heat, and physical therapy to control the pain associated with ankle arthrosis.

When conservative management fails, ankle arthrodesis (AA) (fusion) has been the standard surgical treatment of choice to control the pain of severe ankle arthritis. During an ankle arthrodesis, the joint is fused together, limiting up-and-down movement. While pain may be relieved with ankle arthrodesis, the main drawback is the later development of arthrosis in the adjacent joints, particularly in fusion of the subtalar joint.

Total ankle replacement (TAR) is a viable and sometimes preferable option to ankle arthrodesis for individuals with end-stage ankle disease. The decision between ankle arthroplasty and arthrodesis should be made on a case-by-case basis; there are no consensus guidelines. Mobile-bearing prostheses are most commonly used in Europe, while the majority of implants used in the United States are fixed-bearing cemented designs. Pre-existing ipsilateral hindfoot or hip or knee arthritis may make total ankle arthroplasty more desirable than ankle fusion in certain patient groups. Historically, the suggested ideal individual for an ankle replacement is a person who is fifty years of age or older, has a body mass index (BMI) of less than 30, undertakes low demand physical activity, and who has a manageable deformity.

Contraindications to TAR include active infection; insufficient bone/osteonecrosis (avascular necrosis); loss of musculature/insufficient ligament support or vascular insufficiency in the affected limb; Charcot's or other peripheral neuropathy; neurological impairment; severe ankle deformity which precludes proper alignment; malalignment or severe deformity of the involved or adjacent anatomic structures; absence of the medial and/or lateral malleolus; and poor skin condition due to surgical scars or trauma. Other relative contraindications for TAR include uncontrolled diabetes and/or hypertension; active smoking; and unrealistic patient goals (e.g., expectation to participate in high-demand physical activities) (Le, et al., 2025; Haskell, 2024; Murphy, 2021; Adukia, et al., 2020).

Revision Surgery
Revision surgery may be necessary in the presence of failed arthroplasty. Failed arthroplasty is typically suspected when pain occurs progressively over time and is persistent, indicating implant loosening and collapse. Periprosthetic infection should be ruled out early. Bone scans or computed tomography (CT) scans may be performed to evaluate the implant, with some individuals requiring surgical evaluation. Surgical management of failed TAR may include ankle arthrodesis, revision arthroplasty, or amputation. Absolute contraindications to revision TAR include deep infection, neuropathic joint, insufficient bone stock, and soft-tissue breakdown. Relative contraindications to revision TAR include absence of the distal part of the fibula, instability resulting from incompetent ligaments, severe malalignment, peripheral vascular disease, significant bone loss, and morbid obesity (Murphy, 2021).

U.S. Food and Drug Administration (FDA)
First generation TARs (developed in the 1970s and 1980s) were constrained and cemented in design, and had a very high rate of aseptic loosening. Second-generation TARs employed bone conserving surgery without cementation and with less constraint between components. They have

demonstrated upwards of 89% survival at 10 years, were developed to more closely mimic physiologic movement and stability, and avoid the osteolytic issues of the early designs. Newer, third generation implants feature a metallic baseplate fixed to the tibia and a domed component resurfacing the talus, with ultra-high molecular weight polyethylene (UHMWPE) bearings to avoid the stability issues of previous implants due to increased polyethylene wear. The choice of implant depends on the clinical scenario and the surgeon's training and experience.

Mobile-bearing (non-constrained) ankle prostheses are regulated by the FDA via the premarket approval (PMA) pathway, and are considered Class III devices. Fixed-component (semi-constrained) cemented ankle joint prostheses are regulated via the FDA 510(k) premarket notification pathway, as Class II devices.

FDA-approved indications vary depending on device type: fixed-bearing or mobile-bearing. Generally, these devices are intended for adults with reduced activity levels, who have severe rheumatoid arthritis, post-traumatic arthritis, or osteoarthritis of the ankle. Contraindications also vary depending on device type, but may include the following:

- active infection
- insufficient bone/osteonecrosis
- loss of musculature in the affected limb/insufficient ligament support
- vascular insufficiency in the affected limb
- Charcot's or other peripheral neuropathy
- neurological impairment
- severe ankle deformity precluding proper alignment
- malalignment or severe deformity of involved or adjacent anatomic structures (e.g., hindfoot, forefoot, knee)
- absence of medial or lateral malleolus, or both
- poor skin conditions secondary to surgical scars or trauma
- patient age, weight or activity levels that introduces unnecessary risk of failure
- skeletal immaturity

See Appendix for a list of FDA-approved/cleared devices.

Literature Review
The available published peer-reviewed literature on total ankle arthroplasty includes prospective and retrospective studies and meta-analyses that compare TAR to ankle arthrodesis (Almutairi, et al., 2023; Goldberg, et al., 2023; Glazebrook, et al., 2021; Sangeorzan, et al., 2021; Lawton, et al., 2020; Mehdi, et al., 2019; Merrill, et al., 2019; Norvell, et al., 2019; Veljkovic, et al., 2019; Wasik, et al., 2019; Segal, et al., 2018; Daniels, et al., 2014), compare TAR devices (González-Alonso, et al., 2024; King, et al., 2019; Nunley, et al., 2019; Queen, et al., 2017; Wood, et al., 2009), compare patient subpopulations undergoing TAR (e.g., degree of deformity, age of individual, etiology of osteoarthritis) (Kipp, et al., 2024; Mousavian, et al., 2022; Tarricone, et al., 2022; Demetracopoulos, et al., 2019; Lee, et al., 2019; Usuelli, et al., 2019), compare primary TAR versus revision TAR (Lai, et al., 2019) and evaluate survivorship of the TAR implant (Ashy, et al., 2025; St Mart, et al., 2024; Sundet, et al., 2024; Loewy, et al., 2023; McKenna, et al., 2020; Koo et al., 2019; Lee, et al., 2019; Marks, 2019; Palanca, et al., 2018; Mann, et al., 2011).

Li et al. (2020) conducted a meta-analysis of studies that compared TAR with ankle arthrodesis (AA). A total of 1280 individuals were included in the seven studies selected, of which 927 were treated with TAR and 353 with AA. The follow-up cycles were provided in all seven studies, with the shortest one being 12 months and the longest being 77 months. This meta-analysis showed no statistically significant difference between TAR and AA in clinical outcomes, patient satisfaction, complications, and survival.

Undén et al. (2020) conducted an analysis of intermediate and long-term prosthetic survival of total ankle replacements (TAR) in Sweden. As an endpoint, the team analyzed the exchange or permanent extraction of TAR components for 1226 prostheses, with mean follow-up of seven years. Differences between current (Hintegra, Mobility, CCI, Rebalance, and TM Ankle) and early prosthetic designs (STAR, BP, and AES) were also examined. The authors found an overall prosthetic survival rate at five years of 0.85, at 10 years of 0.74, at 15 years of 0.63, and at 20 years of 0.58. For early prosthetic designs the 5- and 10-year survival rates were 0.81 and 0.69 respectively, while the corresponding rates for current designs were 0.88 and 0.84. Current prosthetic designs had better survival (log rank test $p<0.001$).

Kim et al. (2017) conducted a meta-analysis including comparative studies that assessed TAR versus AA for the treatment of end-stage ankle arthritis. The primary outcomes were clinical scores and patient satisfaction and secondary outcomes were the prevalence of complications and the reoperation rate. Ten comparative studies were included (four prospective and six retrospective studies). There were no significant differences between the two procedures in the American Orthopaedic Foot and Ankle Society ankle-hindfoot score, Short Form-36 physical component summary and mental component summary scores, visual analogue scale for pain, and patient satisfaction rate. The risk of reoperation and major surgical complications were significantly increased in the TAR group. A limitation of this meta-analysis is the majority of included studies were retrospective design. The authors stated that further studies of high methodological quality with long-term follow-up are needed.

Total Talar Prosthesis (TTP)
Due to its limited blood supply, the talus is at risk of avascular necrosis (AVN), or bone death due to lack of adequate blood supply. AVN of the talus may be caused by trauma (fractures) or atraumatic causes (e.g., corticosteroid use, irradiation). Treatment of early talar AVN may include conservative measures like non- or protective weightbearing, or joint-sparing procedures (e.g., core decompression, bone grafting). For more advanced disease (i.e., talar collapse with adjacent joint arthritis), joint-sacrificing procedures (e.g., ankle arthrodesis) are typically needed (Adams, 2024). Total talar prosthesis (TTP), alone or combined with TAR has been proposed for degenerative joint disease of the ankle, avascular osteonecrosis, talar collapse, and osteomyelitis. The proposed advantages of a TTP include preventing leg length discrepancy, preserving joint function, and allowing early weight bearing.

U.S. Food and Drug Administration (FDA): On February 17, 2021, the FDA approved the Patient Specific Talus Spacer 3D-printed talus implant (Paragon 28, Inc. [formerly Additive Orthopaedics, LLC]) through the humanitarian device exemption (HDE) process. The Patient Specific Talus Spacer is a talus prosthesis made of cobalt chromium alloy. It is intended for use in talus replacement surgery for the treatment of avascular necrosis (AVN) of the ankle joint, as an alternative to arthrodesis or amputation. The implant is designed from patient-specific imaging data (e.g., computed tomography [CT]; magnetic resonance imaging [MRI]), and 3D-printed via laser sintering. Contraindications for use of the implant include degenerative changes in the tibiotalar, subtalar or talonavicular joints; osteonecrosis of the calcaneus, distal tibia or navicular; and/or active infection. The FDA HDE approval of the Patient Specific Talus Spacer was based upon results of a single-center trial (n=32 cases) which assessed safety and benefit outcomes in individuals with AVN who underwent talar replacement. A post-approval study is ongoing.

In November 2023, the FDA approved the restor3d Total Talus Replacement implant (restor3d, Inc.) via the HDE process. The implant is a patient-specific, additively manufactured (i.e., 3D-printed) implant made of cobalt chromium. The approved indications included avascular necrosis of the talus; avascular necrosis of the talus in addition to talar collapse, cysts or non-union; large, uncontained, unstable, or cystic talar osteochondral defects with risk of collapse or talar

osteochondral defects not responsive to traditional treatments; and non-union following talar fracture or talar extrusion, unresponsive to more conservative treatments. The supporting clinical information submitted in the FDA summary of safety and probable benefit consisted of a retrospective chart review of 27 individuals who received a patient-specific total talus replacement for the treatment of talar dysfunction. A five-year post-approval study is planned.

Literature Review: There is a lack of large, comparative prospective trials evaluating the long-term outcomes and management of complications associated with total talar prosthesis, alone or in combination with total ankle replacement. Evidence consists primarily of case reports and small case series. Complications following total talus replacement, including fracture, heterotopic ossification, infection, prolonged wound healing, and implant failure with persistent pain necessitating subsequent surgery have been reported in the literature (Mitra, et al., 2025; Anastasio, et al., 2024; Wang, et al., 2024; Jennison, et al., 2023; Johnson, et al., 2022; Morita, et al., 2022; Abramson, et al., 2021; Morita, et al., 2020; West and Rush, 2020; Kanzaki, et al., 2019; Kurokawa, et al., 2019; Shnol and LaPorta, 2018; Taniguchi, et al., 2015).

Professional Societies/Organizations
American College of Foot and Ankle Surgeons (ACFAS): The ACFAS Position Statement on Total Ankle Replacement Surgery noted that not every individual with end-stage arthritis of the ankle is a sound candidate for ankle replacement. A surgeon experienced in total ankle surgery can make this determination through careful history and physical evaluation. As with any total joint replacement, individuals who are candidates for this procedure should be made aware of alternative treatments and expected outcomes. Furthermore, adjunctive procedures are often necessary as part of the surgical plan to ensure proper device function. Total ankle replacement surgery is currently a safe and effective treatment option for select individuals with end stage ankle arthritis. Studies have shown total ankle replacement surgery improves patient function, reduces pain, and promotes improved quality of life (ACFAS, 2023).

The ACFAS consensus statement on the diagnosis and treatment of ankle arthritis confirmed that total ankle arthroplasty is a viable option for the treatment of ankle arthritis. The panel noted there was no demonstrated superiority between mobile and fixed bearing prostheses. Regarding total talus implants, the statement noted "custom cobalt chrome total talus replacement has been successfully performed, although without a long-term duration of follow-up or data from a large sample of patients" (Shibuya, et al., 2020).

American Orthopaedic Foot & Ankle Society (AOFAS): The AOFAS Position Statement on The Use of Total Ankle Replacement for the Treatment of Arthritic Conditions of the Ankle asserted that "ankle arthritis is a condition that can result in substantial pain and dysfunction. The American Orthopaedic Foot & Ankle Society supports the use of total ankle replacement as an option for the treatment of ankle arthritis that has failed conservative management in select patients due to its demonstrated improved outcomes in multiple peer reviewed publications" (AOFAS, 2022).

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job

opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

A 2020 study found that, compared to white individuals, Black individuals who underwent TAR had an increased risk of in-hospital complications and longer length of stay, and were more likely to be discharged to an inpatient rehabilitation facility. Hispanic individuals who underwent TAR were more likely than white individuals to experience an in-hospital infection, and to have higher hospital charges. Overall, factors which increased healthcare utilization and/or in-hospital complications after TAR included: age over 50 years, non-white race/ethnicity, Medicaid payer status, and higher comorbidity (Singh and Cleveland, 2020).

A study by Brodeur et al. (2022) found that, in New York state, the use of arthroplasty to treat ankle osteoarthritis had increased by 757% over the course of nine years, overtaking arthrodesis as the preferred surgical management modality. Compared with ankle arthroplasty, ankle arthrodesis was found to be associated with increased rates of hospital readmission, surgical site infection, acute renal failure, cellulitis, urinary tract infection, and deep vein thrombosis. Further, African American race, federal insurance, workers compensation, presence of comorbidities, and higher social deprivation index (SDI) score were associated with increased odds of having an ankle arthrodesis versus an ankle arthroplasty.

Appendix

FDA Approved/Cleared Devices

Ankle Joint Prostheses

Device or Product	Identifier	Manufacturer
APEX 3D™ Total Ankle Replacement System	K192994	Paragon 28, Inc.
Cadence® Total Ankle System	K201507	Integra LifeSciences Corp. (Smith & Nephew)
Hintermann Series H2® Total Ankle System	K171004	DT MedTech, LLC (Vilex, LLC)
Hintermann Series H3® Total Ankle Replacement System	P160036	DT MedTech, LLC (Vilex, LLC)
Inbone® Total Ankle System	K100886	Wright Medical Technology Inc. (Stryker)
Incompass™ Total Ankle System	K250037	Wright Medical Technology Inc. (Stryker)
Infinity® Total Ankle System	K123954	Wright Medical Technology Inc. (Stryker)
Invision® Total Ankle Revision System	K142117	Wright Medical Technology Inc. (Stryker)
Kinos Axiom® Total Ankle System	K192778	Kinos Medical (restor3d)
Quantum® Total Ankle System	K191380	In2Bones (ConMed)

Device or Product	Identifier	Manufacturer
Salto Talaris Total Ankle Prosthesis	K060544	Tornier (Smith & Nephew)
Salto XT Ankle Prosthesis (XT Revision System)	K153452	Tornier (Smith & Nephew)
Scandinavian Total Ankle Replacement (STAR™ Ankle)	P050050	DJO Global (Stryker)
Trabecular Metal™ Total Ankle	K120906	Zimmer Biomet
Vantage® Total Ankle System	K152217	Exactech, Inc.

*FDA product codes: HSN, NTG

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

References

1. Abramson M, Hilton T, Hosking K, Campbell N, Dey R, McCollum G. Total Talar Replacements Short-Medium Term Case Series, South Africa 2019. J Foot Ankle Surg. 2021 Jan-Feb;60(1):182-186.

2. Adams SB. Avascular Necrosis and Total Talus Replacement. In: Haskell A, Coughlin MJ. Coughlin and Mann's Surgery of the Foot and Ankle. Philadelphia, PA: Elsevier; 2024. 1006-1019.

3. Adukia V, Mangwani J, Issac R, Hussain S, Parker L. Current concepts in the management of ankle arthritis. J Clin Orthop Trauma. 2020 May-Jun;11(3):388-398.

4. Almutairi TA, Ragab KM, Elsayed SM, Elsnhory AB, Elhady MM, Gamal MH, Fathallah AH. Safety and efficacy of total ankle arthroplasty versus ankle arthrodesis for ankle osteoarthritis: A systematic review and meta-analysis. Foot (Edinb). 2023 May;55:101980.

5. American College of Foot and Ankle Surgeons (ACFAS). Position Statement on Total Ankle Replacement Surgery.Nov 2023. Accessed Jan 22, 2026. Available at URL address: https://www.acfas.org/policy-advocacy/policy-position-statements

6. American Orthopaedic Foot & Ankle Society (AOFAS). Position Statement: The Use of Total Ankle Replacement for the Treatment of Arthritic Conditions of the Ankle. Approved Jul 29, 2022. Accessed Jan 22, 2026. Available at URL address: https://www.aofas.org/research-policy/position-statements-clinical-guidelines

7. Anastasio AT, Bagheri K, Johnson L, Hubler Z, Hendren S, Adams SB. Outcomes following total ankle total talus replacement: A systematic review. Foot Ankle Surg. 2024 Apr;30(3):245-251.

8. Ashy CC, Reid JJ, Morningstar JL, Brennan E, Scott DJ, Gross CE. A systematic review of outcomes of total ankle arthroplasty with INBONE II. Foot Ankle Surg. 2025 Apr;31(3):190-198. doi: 10.1016/j.fas.2024.11.001. Epub 2024 Nov 6. PMID: 39547917.

9. Barg A, Bettin CC, Burstein AH, Saltzman CL, Gililland J. Early Clinical and Radiographic Outcomes of Trabecular Metal Total Ankle Replacement Using a Transfibular Approach. J Bone Joint Surg Am. 2018 Mar 21;100(6):505-515.

10. Brodeur PG, Walsh DF, Modest JM, Salameh M, Licht AH, Hartnett DA, Gil J, Cruz AI Jr, Hsu RY. Trends and Reported Complications in Ankle Arthroplasty and Ankle Arthrodesis in the State of New York, 2009-2018. Foot Ankle Orthop. 2022 Aug 23;7(3):24730114221117150.

11. D'Ambrosi R, Tiusanen HT, Ellington JK, Kraus F, Younger A, Usuelli FG. Fixed-Bearing Trabecular Metal Total Ankle Arthroplasty Using the Transfibular Approach for End-Stage Ankle Osteoarthritis: An International Non-Designer Multicenter Prospective Cohort Study. JB JS Open Access. 2022 Sep 22;7(3):e21.00143.

12. Daniels TR, Younger AS, Penner M, et al. Intermediate-term results of total ankle replacement and ankle arthrodesis: A COFAS multicenter study. J Bone Joint Surg Am. 2014;96(2):135-142.

13. Demetracopoulos CA, Cody EA, Adams SB Jr, DeOrio JK, Nunley JA et al. Outcomes of Total Ankle Arthroplasty in Moderate and Severe Valgus Deformity. Foot Ankle Spec. 2019 Jun;12(3):238-245.

14. Gajebasia S, Jennison T, Blackstone J, Zaidi R, Muller P, Goldberg A. Patient reported outcome measures in ankle replacement versus ankle arthrodesis - A systematic review. Foot (Edinb). 2022 May;51:101874.

15. Glazebrook M, Burgesson BN, Younger AS, Daniels TR. Clinical outcome results of total ankle replacement and ankle arthrodesis: a pilot randomised controlled trial. Foot Ankle Surg. 2021 Apr;27(3):326-331.

16. Goldberg AJ, Chowdhury K, Bordea E, Blackstone J, Brooking D, Deane EL, Hauptmannova I, Cooke P, Cumbers M, Skene SS, Doré CJ. Total ankle replacement versus ankle arthrodesis for patients aged 50-85 years with end-stage ankle osteoarthritis: the TARVA RCT. Health Technol Assess. 2023 Mar;27(5):1-80.

17. González-Alonso M, Trapote-Cubillas AR, Madera-González FJ, Fernández-Hernández Ó, Sánchez-Lázaro JA. Fixed-bearing versus mobile-bearing total ankle replacement survivorship. A meta-analysis. Foot Ankle Surg. 2024 Jun;30(4):275-284.

18. Haskell A. Ankle replacement. In: Haskell A, Coughlin MJ. Coughlin and Mann's Surgery of the Foot and Ankle. 10th ed. Philadelphia, PA: Elsevier; 2024. Ch 23, 920-1005.

19. Hermus JP, Voesenek JA, van Gansewinkel EHE, Witlox MA, Poeze M, Arts JJ. Complications following total ankle arthroplasty: A systematic literature review and meta-analysis. Foot Ankle Surg. 2022 Dec;28(8):1183-1193.

20. Jennison T, Dalgleish J, Sharpe I, Davies M, Goldberg A. Total Talus Replacements. Foot Ankle Orthop. 2023 Jan 27;8(1):24730114221151068.

21. Johnson LG, Anastasio AT, Fletcher AN, Hendren S, Adams SB. Outcomes following total talus replacement: A systematic review. Foot Ankle Surg. 2022 Dec;28(8):1194-1201.

22. Kanzaki N, Chinzei N, Yamamoto T, Yamashita T, Ibaraki K, Kuroda R. Clinical Outcomes of Total Ankle Arthroplasty With Total Talar Prosthesis. Foot Ankle Int. 2019 Aug;40(8):948-954.

23. Kim HJ, Suh DH, Yang JH, Lee JW, Kim HJ, et al. Total ankle arthroplasty versus ankle arthrodesis for the treatment of end-stage ankle arthritis: a meta-analysis of comparative studies. Int Orthop. 2017 Jan;41(1):101-109.

24. King A, Bali N, Kassam AA, Hughes A, Talbot N, Sharpe I. Early outcomes and radiographic alignment of the Infinity total ankle replacement with a minimum of two year follow-up data. Foot Ankle Surg. 2019 Dec;25(6):826-833.

25. Kipp JA, Vesely BD, Lance TA, White BN, Medda AW, Scott AT. Age Influence on Total Ankle Arthroplasty Outcomes: A Systematic Review. J Foot Ankle Surg. 2024 Nov-Dec;63(6):765-768.

26. Koo K, Liddle AD, Pastides PS, Rosenfeld PF. The Salto total ankle arthroplasty - Clinical and radiological outcomes at five years. Foot Ankle Surg. 2019 Aug;25(4):523-528.

27. Kurokawa H, Taniguchi A, Morita S, Takakura Y, Tanaka Y. Total ankle arthroplasty incorporating a total talar prosthesis: a comparative study against the standard total ankle arthroplasty. Bone Joint J. 2019 Apr;101-B(4):443-446.

28. Lai WC, Arshi A, Ghorbanifarajzadeh A, Williams JR, Soohoo NF. Incidence and predictors of early complications following primary and revision total ankle arthroplasty. Foot Ankle Surg. 2019 Dec;25(6):785-789.

29. Lawton CD, Prescott A, Butler BA, Awender JF, Selley RS, Dekker Ii RG, Balderama ES, Kadakia AR. Modern total ankle arthroplasty versus ankle arthrodesis: A systematic review and meta-analysis. Orthop Rev (Pavia). 2020 Nov 30;12(3):8279.

30. Le YTT, Tran DNA, Nguyen BTT, Nguyen TT, Chen YP, Kuo YJ. Is smoking a risk factor for complications following total ankle arthroplasty? A meta-analysis. Foot Ankle Surg. 2025 Jan;31(1):50-57.

31. Lee GW, Lee KB. Outcomes of Total Ankle Arthroplasty in Ankles with >20° of Coronal Plane Deformity. J Bone Joint Surg Am. 2019 Dec 18;101(24):2203-2211.

32. Lee GW, Santoso A, Lee KB. Comparison of Intermediate-term Outcomes of Total Ankle Arthroplasty in Primary and Ligamentous Post-traumatic Osteoarthritis. Foot Ankle Int. 2019 Nov;40(11):1273-1281.

33. Lee GW, Seon JK, Kim NS, Lee KB. Comparison of Intermediate-Term Outcomes of Total Ankle Arthroplasty in Patients Younger and Older Than 55 Years. Foot Ankle Int. 2019 Jul;40(7):762-768

34. 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. Orthop Surg. 2020 Apr;12(2):372-377.

35. Loewy E, Conti MS, Jones CP, Cohen BE, Anderson RB, Irwin TA, Davis WH. Midterm Outcomes of the INBONE™ II Total Ankle Arthroplasty. J Foot Ankle Surg. 2023 Jul-Aug;62(4):651-656.

36. Mann JA, Mann RA, Horton E. STAR™ ankle: long-term results. Foot Ankle Int. 2011 May;32(5):S473-84.

37. Marks RM. Mid-Term Prospective Clinical and Radiographic Outcomes of a Modern Fixed-Bearing Total Ankle Arthroplasty. J Foot Ankle Surg. 2019 Nov;58(6):1163-1170.

38. McAlister JE, Duelfer KA. Updates on Total Ankle Arthroplasty. Clin Podiatr Med Surg. 2023 Oct;40(4):725-733.

39. McKenna BJ, Cook J, Cook EA, Crafton J, Knabel M, Swenson E, Miner S, Manning E, Basile P. Total Ankle Arthroplasty Survivorship: A Meta-analysis. J Foot Ankle Surg. 2020 Sep-Oct;59(5):1040-1048.

40. Mehdi N, Bernasconi A, Laborde J, Lintz F. Comparison of 25 ankle arthrodeses and 25 replacements at 67 months' follow-up. Orthop Traumatol Surg Res. 2019 Feb;105(1):139-144.

41. Merrill RK, Ferrandino RM, Hoffman R, Ndu A, Shaffer GW. Comparing 30-day all-cause readmission rates between tibiotalar fusion and total ankle replacement. Foot Ankle Surg. 2019 Jun;25(3):327-331.

42. Morita S, Taniguchi A, Miyamoto T, Kurokawa H, Takakura Y, Takakura Y, Tanaka Y. The Long-Term Clinical Results of Total Talar Replacement at 10 Years or More After Surgery. J Bone Joint Surg Am. 2022 May 4;104(9):790-795.

43. Morita S, Taniguchi A, Miyamoto T, Kurokawa H, Tanaka Y. Application of a Customized Total Talar Prosthesis for Revision Total Ankle Arthroplasty. JB JS Open Access. 2020 Oct 28;5(4):e20.00034.

44. Mousavian A, Baradaran A, Schon LC, Daniel J, Pedowitz D, Kachooei AR. Total Ankle Replacement Outcome in Patients With Inflammatory Versus Noninflammatory Arthritis: A Systematic Review and Meta-analysis. Foot Ankle Spec. 2022 Nov 22:19386400221136591.

45. Murphy GA. Total Ankle Arthroplasty. In: Azar FM, Beaty JH, editors. Campbell's Operative Orthopaedics. 14th ed. Philadelphia, PA: Elsevier; 2021. 526-562.

46. Norvell DC, Ledoux WR, Shofer JB, Hansen ST, Davitt J, et al. Effectiveness and Safety of Ankle Arthrodesis Versus Arthroplasty: A Prospective Multicenter Study. J Bone Joint Surg Am. 2019 Aug 21;101(16):1485-1494

47. Nunley JA, Adams SB, Easley ME, DeOrio JK. Prospective Randomized Trial Comparing Mobile-Bearing and Fixed-Bearing Total Ankle Replacement. Foot Ankle Int. 2019 Nov;40(11):1239-1248.

48. Onggo JR, Nambiar M, Phan K, Hickey B, Galvin M, Bedi H. Outcome after total ankle arthroplasty with a minimum of five years follow-up: A systematic review and meta-analysis. Foot Ankle Surg. 2019 Jul 25. pii: S1268-7731(19)30111-0.

49. Palanca A, Mann RA, Mann JA, Haskell A. Scandinavian Total Ankle Replacement: 15-Year Follow-up. Foot Ankle Int. 2018 Feb;39(2):135-142.

50. Queen RM, Franck CT, Schmitt D, Adams SB. Are There Differences in Gait Mechanics in Patients With A Fixed Versus Mobile Bearing Total Ankle Arthroplasty? A Randomized Trial. Clin Orthop Relat Res. 2017 Oct;475(10):2599-2606.

51. Sangeorzan BJ, Ledoux WR, Shofer JB, Davitt J, Anderson JG, Bohay D, Coetzee JC, Maskill J, Brage M, Norvell DC. Comparing 4-Year Changes in Patient-Reported Outcomes Following Ankle Arthroplasty and Arthrodesis. J Bone Joint Surg Am. 2021 May 19;103(10):869-878.

52. Segal AD, Cyr KM, Stender CJ, Whittaker EC, Hahn ME, et al. A three-year prospective comparative gait study between patients with ankle arthrodesis and arthroplasty. Clin Biomech (Bristol, Avon). 2018 May;54:42-53.

53. Shibuya N, McAlister JE, Prissel MA, Piraino JA, Joseph RM, Theodoulou MH, Jupiter DC. Consensus Statement of the American College of Foot and Ankle Surgeons: Diagnosis and Treatment of Ankle Arthritis. J Foot Ankle Surg. 2020 Sep-Oct;59(5):1019-1031.

54. Shnol H, LaPorta GA. 3D Printed Total Talar Replacement: A Promising Treatment Option for Advanced Arthritis, Avascular Osteonecrosis, and Osteomyelitis of the Ankle. Clin Podiatr Med Surg. 2018 Oct;35(4):403-422.

55. Singh JA, Cleveland JD. Age, race, comorbidity, and insurance payer type are associated with outcomes after total ankle arthroplasty. Clin Rheumatol. 2020 Mar;39(3):881-890.

56. St Mart JP, Goh EL, Hay D, Pilkington I, Bednarczuk N, Ahluwalia R. Contemporary modern total ankle arthroplasty (TAA): A systematic review and meta-analysis of indications, survivorship and complication rates. Surgeon. 2024 Jun;22(3):174-181.

57. Sundet M, Gyllensten KS, Dybvik E, Eikvar KH, Hallan G, Lillegraven S, Lund Eriksen M. Five-Year Results of the Salto XT Revision Ankle Arthroplasty. Foot Ankle Int. 2024 Oct;45(10):1083-1092.

58. Taniguchi A, Takakura Y, Tanaka Y, Kurokawa H, Tomiwa K, et al. An Alumina Ceramic Total Talar Prosthesis for Osteonecrosis of the Talus. J Bone Joint Surg Am. 2015 Aug 19;97(16):1348-53.

59. Tarricone A, Gee A, Chen S, De La Mata K, Muser J, Axman W, Krishnan P, Perake V. A Systematic Review and Meta-analysis of Total Ankle Arthroplasty or Ankle Arthrodesis for Treatment of Osteoarthritis in Patients With Diabetes. Foot Ankle Orthop. 2022 Jul 26;7(3):24730114221112955.

60. Undén A, Jehpsson L, Kamrad I, Carlsson Å, Henricson A, Karlsson MK, Rosengren BE. Better implant survival with modern ankle prosthetic designs: 1,226 total ankle prostheses followed for up to 20 years in the Swedish Ankle Registry. Acta Orthop. 2020 Apr;91(2):191-196.

61. U.S. Food and Drug Administration (FDA). 510(k) premarket notification database. Product code(s): HSN. Page Last Updated: Jan 19, 2026. Accessed Jan 22, 2026. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

62. U.S. Food Drug Administration (FDA). Humanitarian Device Exemption (HDE) database. Product code(s): QNN. Page Last Updated: Jan 19, 2026. Accessed Jan 22, 2026.

Available at URL address:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/hde.cfm

63. U.S. Food Drug Administration (FDA). Premarket approval (PMA) database. Product code(s): NTG. Page Last Updated: Jan 19, 2026. Accessed Jan 22, 2026. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm

64. Usuelli FG, Di Silvestri CA, D'Ambrosi R, Orenti A, Randelli F. Total ankle replacement: is pre-operative varus deformity a predictor of poor survival rate and clinical and radiological outcomes? Int Orthop. 2019 Jan;43(1):243-249.

65. Vale C, Almeida JF, Pereira B, Andrade R, Espregueira-Mendes J, Gomes TM, Oliva XM. Complications after total ankle arthroplasty- A systematic review. Foot Ankle Surg. 2023 Jan;29(1):32-38.

66. Veljkovic AN, Daniels TR, Glazebrook MA, Dryden PJ, Penner MJ, et al. Outcomes of Total Ankle Replacement, Arthroscopic Ankle Arthrodesis, and Open Ankle Arthrodesis for Isolated Non-Deformed End-Stage Ankle Arthritis. J Bone Joint Surg Am. 2019 Sep 4;101(17):1523-1529.

67. Wang JE, Day J, McCann J, Cooper P. Early results of combined total ankle total talus replacement in the revision setting. Foot Ankle Surg. 2024 Aug;30(6):493-498.

68. Wasik J, Stołtny T, Pasek J, Szyluk K, Pyda M, et al. Effect of Total Ankle Arthroplasty and Ankle Arthrodesis for Ankle Osteoarthritis: A Comparative Study. Med Sci Monit. 2019 Sep 10;25:6797-6804.

69. West TA, Rush SM. Total Talus Replacement: Case Series and Literature Review. J Foot Ankle Surg. 2020 Aug 26:S1067-2516(20)30320-3.

70. Wood PL, Sutton C, Mishra V, Suneja R. A randomised, controlled trial of two mobile-bearing total ankle replacements. J Bone Joint Surg Br. 2009 Jan;91(1):69-74.

71. Zygogiannis K, Thivaios GC, Kouramba A, Drakou A, Vlasis K, Panayiotidis P, Kalatzis D, Koulalis D. comparison of postoperative gait parameters after total ankle arthroplasty and ankle fusion: A systematic review. Medicine (Baltimore). 2024 Jul 5;103(27):e38727.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• Added not medically necessary statement for revision total ankle arthroplasty. • Revised policy statement for total talar replacement.	3/15/2026
Annual Review	• Revised policy statement for total ankle arthroplasty/replacement.	3/15/2025
Annual Review	• Revised noncoverage policy statement.	2/15/2024