KAISER PERMANENTE®

Review Criteria
Georgia Region

Title:	**Total Ankle Arthroplasty**		
Department:	QUALITY RESOURCE MANAGEMENT	**Page:**	1 of 5
Section:	UTILIZATION MANAGEMENT	**Policy Number:**	01-51
Type:	() New	**Effective Date:**	3/10/2014
	(X) Reviewed / Revised	**Date:**	1/22/2018 1/22/2019 1/27/2020 1/21/2021 1/10/2022 2/21/2023

Purpose
This policy provides the indications and contraindications necessary for the Quality Resource Management staff to make the most appropriate decision related to the medical necessity of the procedure listed.

DIAGNOSIS/CONDITION:
CPT-4/ HCPCS CODE AND DESCRIPTION: 27702, 27703, 27870; L8699
INDICATORS
(QRMMD note: please discuss these requests with – TSPMG COS Podiatry

1.0 INDICATIONS:

Total ankle arthroplasty (TAA) using a Food and Drug Administration-cleared implant (e.g., the Agility LP Total Ankle, the Eclipse Total Ankle, the INBONE Total Ankle, the STAR system, the Salto Talaris Total Ankle Prosthesis, and the Zimmer Trabecular Metal Total Ankle) may be considered medically necessary to replace an arthritic or severely degenerated ankle in skeletally mature persons with moderate or severe pain with loss of ankle mobility and function due to osteoarthritis, post-traumatic arthritis and rheumatoid arthritis and who have failed at least 6 months of conservative management (including physical therapy, non-steroidal anti-inflammatory drugs, and orthoses as indicated).

2.0 CONTRAINDICATIONS:

- Absence of the medial or lateral malleolus;
- Active or prior deep infection in the ankle joint or adjacent bones;
- Avascular necrosis of the talus;
- Charcot joint;
- Hindfoot or forefoot mal-alignment precluding plantigrade foot;

- Insufficient bone or musculature such that proper component positioning or alignment is not possible;
- Insufficient ligament support that cannot be repaired with soft tissue stabilization;
- Lower extremity vascular insufficiency;
- Neuromuscular disease resulting in lack of normal muscle function about the affected ankle;
- Osteonecrosis;
- Peripheral neuropathy (may lead to Charcot joint of the affected ankle);
- Poor skin and soft tissue quality about the surgical site;
- Prior arthrodesis (fusion) at the ankle joint;
- Prior surgery or injury that has adversely affected ankle bone quality;
- Psychiatric problems that hinder adequate cooperation during peri-operative period;
- Severe anatomic deformity in adjacent ankle structures, including hindfoot, forefoot and knee joint;
- Severe ankle deformity (e.g., severe varus or valgus deformity) that would not normally be eligible for ankle arthroplasty;
- Severe osteoporosis, osteopenia or other conditions resulting in poor bone quality, as this may result in inadequate bony fixation;
- Significant mal-alignment of the knee joint;
- Skeletal maturity not yet reached;
- Vascular insufficiency in the affected limb; *or*
- Weight greater than 250 lbs.

VIEWS OF THE SOUTHEAST PERMANENTE MEDICAL GROUP- Total Ankle Arthroplasty is an option for patients that have severe arthritis, with persistent pain and decreased mobility that have failed at least 6 months of conservative therapy i.e. physical therapy, NSAIDs and orthotics. This procedure should be done by a surgeon with experience in this procedure.

4.0 CLINICAL SUMMARY:

Total ankle replacement is a procedure in which an injured ankle joint is replaced with a plastic and metal joint. The procedure has been used as an alternative to surgical fusion in patients with loss of ankle function and pain that is refractory to medications, especially because of rheumatoid arthritis. Arthritis from other causes is rarely a reason to do ankle replacement.

Conservative management of ankle pain includes acetaminophen, aspirin, or other medication for pain and inflammation, limiting activity, wearing an ankle brace, shoe modifications, application of heat, and physical therapy.

When conservative measures of treatment fail to provide adequate pain relief, either an ankle fusion or total ankle replacement (ankle arthroplasty) may be considered. Ankle fusion has been the traditional method of treating arthritis of the ankle. In recent years, total ankle replacement has developed as another option. However, there are limited long-term data on the effectiveness of total ankle replacement. Available data suggest that total ankle replacement has a relatively short lifespan. For this reason, ankle replacements are not usually recommended for people under the age of 50.

The procedure is performed under general or spinal anesthesia. Patients are generally hospitalized for 1 to 4 days. A period of physical therapy is often required after ankle replacement. The patient is able to ambulate within a few weeks following the procedure. The most common complications include thrombophlebitis and pulmonary embolism. Swelling or pressure as a result of the procedure may injure the nerves in the ankle. The new joint can be dislocated rather easily. In addition, there is a risk of infection and hemorrhage.

5.0REVIEW OF THE LITERATURE: N/A

6.0REFERENCES:

Aetna CPB- Total Ankle Arthroplasty – 9/2019, 12/2020, 11/2021
Hayes Tech: gives this procedure a C: potential but unproven benefit. March 2019

Hayes Review – Total Ankle Replacement: A Review of Reviews 3/2019

A low-quality body of evidence suggests that TAR may be comparable with AA for some clinical effectiveness outcomes and provides an equivalent patient satisfaction rate in patients with end-stage ankle arthritis. However, evidence regarding rates of reoperation and the safety of TAR remain unclear. TAR implants evaluated in this evidence base include STAR, Hintegra, Mobility, Salto

Talaris, Agility, and AES, but there is limited and insufficient evidence to inform conclusions regarding the comparative effectiveness and safety of different TAR implants.

Hayes update 2021:

2021

Summary

Based on a review of abstracts, there are 18 newly published studies that may meet the inclusion criteria set out in the report, which was published in 2017.

Impact on Hayes Rating

Impact of Newly Published Studies	
Indication	*Impact on Current Hayes Rating*
For use of total ankle replacement (TAR) as an alternative to conventional ankle arthrodesis (AA) for treating adult patients with end-stage ankle arthritis without contraindications to TAR.	***No change in current Rating of C.***

This Annual Review is based on a review of study abstracts only. A formal review of the full text of the studies containing new evidence is required to confirm content and to draw conclusions regarding the quality, strength, and direction of effects of the new evidence and its impact on the existing Hayes Rating(s) in the report. Refer to the regulation and guidance sections of this Annual Review for updated information on the regulatory status, key payer coverage policies, and professional organization guidelines related to this topic.

Summary of Evidence in Study Abstracts

EFFECTIVENESS: Evaluation of the literature indicates that new evidence regarding efficacy is available since publication of the 2017 Directory Report.

PATIENT SELECTION CRITERIA: Evaluation of the literature indicates that evidence on patient selection criteria is unchanged since publication of the 2017 Directory Report.

SAFETY: Evaluation of the literature indicates that new evidence regarding safety is available since publication of the 2017 Directory Report.

LONG-TERM FOLLOW-UP: Evaluation of the literature identified new evidence with longer-term follow-up (up to 8.2 years) since publication of the 2017 Directory Report.

New Applications of the Technology

Evaluation of the literature indicates that no new applications of the technology have been identified since publication of the 2017 Directory Report.

Research Findings

Search Strategy

An update literature search was performed in PubMed on February 2, 2022. The search string replicates the search string employed in the report.

Database	***Date of Search***	***Terms***	***Search Limits***	***Rationale***	***Results***

Search Results

Twenty-nine abstracts were retrieved, including 2 randomized controlled trials, 16 nonrandomized comparative studies, 6 systematic reviews and meta-analyses, and 5 cost-utility analyses.

Key Study Abstracts

Two key study abstracts were identified.

Study Author(s) (Year)	*Study Design*	*Efficacy/ Effectiveness*	*Safety*	*Long-Term Follow-Up*	*Patient Selection Criteria*
Goldberg et al. (2022)	*Randomized controlled trial (RCT)*	✓	✓		
Glazebrook et al. (2021)	*RCT*	✓	✓		

Regulatory Information

Regulation

Food and Drug Administration (FDA)

Since the 2017 publication of the report, additional clearances for the FDA 510(k) Product Code HSN have been identified: 2017, 2018, 2019, 2020, 2021: click here.

Since the 2017 publication of the report, additional approvals for the PMA Product Code NTG have been identified: 2018, 2019, 2020, 2021: click here.

A search of the MAUDE database by 510(k) Product Code HSN for the year spanning 2/2/2021 – 2/2/2022 identified more than 500 events. A search using the PMA product code NTG for the same timespan identified 89 events.

CE Marking

No additional CE marking noted.

Coverage Policy

Centers for Medicare & Medicaid Services (CMS)

No National Coverage Determination (NCD) for total ankle replacement was identified on the CMS website on February 2, 2022 (search National Coverage Documents by keywords ankle or arthroplasty or replacement or 27702 in all documents at: CMS Advanced Search Database). In the absence of an NCD, coverage is left to the discretion of local Medicare carriers.

Payer Policies

The following payer sites were searched using the keywords ankle or arthroplasty or replacement on February 2, 2022.

Key: FDA, Food and Drug Administration; TAA, total ankle arthroplasty; TAR, total ankle replacement

Payer	*Policy*	*Review Date*	*Coverage Details*
Aetna	*Total Ankle Arthroplasty* *No. 0645*	*Last review: 11/12/2021* *Next review: 7/14/2022*	*TAA using an FDA-cleared implant is medically necessary when criteria are met.*
Cigna	*Total Ankle Arthroplasty/Replacement* *No 0285*	*Effective date: 2/15/2022* *Next review: 2/15/2023*	*TAA/TAR is medically necessary for skeletally mature patients for the treatment of severe inflammatory arthritis, severe osteoarthritis, or posttraumatic arthritis of the ankle, as an alternative to ankle arthrodesis, when all criteria have been met.*

Payer	Policy	Review Date	Coverage Details
Highmark Blue Shield	Total Ankle Replacement No. S-202-007	Effective date: 7/23/2018 Next review: Not applicable	The policy was archived on July 23, 2018.
UnitedHealthcare	Surgery of the Ankle No. 2022T0622B	Effective date: 2/1/2022 Next review: Not stated	Surgery of the ankle is proven and medically necessary in certain circumstances. The reader is referred to an outside vendor for eligibility criteria.
Blue Shield of California	None identified.		
Humana	None identified.		

Position Statements and Guidelines

Professional Organization Guideline Update

Searches were conducted on the Internet on February 2, 2022, using the terms total ankle replacement AND guideline, to identify new or updated guidelines or position statements from relevant organizations, which are summarized below.

Key: TAR, total ankle replacement

Organization	Latest Update	Guideline Information
American College of Foot and Ankle Surgeons (ACFAS)	*2/2020*	*Not every patient 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. This position statement recommends that patients who are considering TAR consult with a board-certified or board-qualified foot and ankle surgeon who has training and experience in this procedure.* *The 2016 ACFAS Position Statement Total Ankle Replacement Surgery was updated in February 2020.*
American Orthopaedic Foot and Ankle Society (AOFAS)	*4/12/2018*	*The AOFAS endorses the use of TAR surgery as an option for treatment of arthritic conditions of the ankle in select patients with this condition who have failed nonoperative treatment.* *The 2014 Position Statement was updated April 12, 2018, and is now titled The Use of Total Ankle Replacement for the Treatment of Arthritic Conditions of the Ankle.*

Other Payer Coverage Policy:

Aetna: Total Ankle Arthroplasty CPB- December 2020

Aetna considers total ankle arthroplasty (TAA) using a Food and Drug Administration-cleared implant (e.g., the Agility LP Total Ankle, the Eclipse Total Ankle, the INBONE Total Ankle, the STAR system, the Salto Talaris Total Ankle Prosthesis, and the Zimmer Trabecular Metal Total Ankle) medically

necessary to replace an arthritic or severely degenerated ankle in skeletally mature persons with moderate or severe pain with loss of ankle mobility and function due to osteoarthritis (degenerative arthritis), post-traumatic arthritis and rheumatoid arthritis and who have failed at least 6 months of conservative management (including physical therapy, non-steroidal anti-inflammatory drugs, and orthoses as indicated), who have none of the contraindications to TAA listed below, and who have one of the following: arthritis in adjacent joints (i.e., subtalar or midfoot), inflammatory (e.g., rheumatoid) arthritis, arthrodesis of the contralateral ankle, or severe arthritis of the contralateral ankle.

Aetna considers revision TAA medically necessary for individuals with failed total ankle prosthesis.

Aetna considers TAA experimental and investigational for persons who have one or more of the following contraindications:

- Absence of the medial or lateral malleolus;
- Active or prior deep infection in the ankle joint or adjacent bones;
- Avascular necrosis of the talus;
- Charcot joint;
- Hindfoot or forefoot mal-alignment precluding plantigrade foot;
- Insufficient bone or musculature such that proper component positioning or alignment is not possible;
- Insufficient ligament support that cannot be repaired with soft tissue stabilization;
- Lower extremity vascular insufficiency;
- Neuromuscular disease resulting in lack of normal muscle function about the affected ankle;
- Osteonecrosis;
- Peripheral neuropathy (may lead to Charcot joint of the affected ankle);
- Poor skin and soft tissue quality about the surgical site;

- Prior arthrodesis (fusion) at the ankle joint;
- Prior surgery or injury that has adversely affected ankle bone quality;
- Psychiatric problems that hinder adequate cooperation during peri-operative period;
- Severe anatomic deformity in adjacent ankle structures, including hindfoot, forefoot and knee joint;
- Severe ankle deformity (e.g., severe varus or valgus deformity) that would not normally be eligible for ankle arthroplasty;
- Severe osteoporosis, osteopenia or other conditions resulting in poor bone quality, as this may result in inadequate bony fixation;
- Significant mal-alignment of the knee joint;
- Skeletal maturity not yet reached;
- Vascular insufficiency in the affected limb; *or*
- Weight greater than 250 lbs.

Aetna considers TAA experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established.

American Orthopedic Foot and Ankle Society (AOFAS)- 2020

Position Statement The American College of Foot and Ankle Surgeons (ACFAS) is a professional society of more than 7,700 foot and ankle surgeons. Founded in 1942, ACFAS seeks to promote the art and science of foot, ankle, and related lower extremity surgery, address the concerns of foot and ankle surgeons, advance and improve standards of education and surgical skill, and advance and advocate for the highest standards of patient care and safety.

ACFAS member physicians are doctors of podiatric medicine who are graduates ofaccredited U.S. podiatric medical schools. ACFAS members have completed surgical residency programs of up to four years, and all Fellows of the College are certified by the American Board of Foot and Ankle Surgery (the surgical board of foot and ankle surgeons recognized by the Joint Committee on the Recognition of Specialty Boards). Many have additional fellowship trainingin various aspects of foot, ankle, and lower extremity surgery, including total ankle replacement.

End stage arthritis of the ankle is a leading cause of chronic disability in North America.[1] Historically,

the prevailing option for patients with painful end-stage ankle arthritis has been ankle fusion.[2] While ankle fusion can successfully relieve the pain within the joint, the resulting range of motion restriction can shift motion stresses to the adjacent joints, which in time also become arthritic.[3] In more recent years, total ankle replacement has been refined and now has become a viable option to ankle fusion and has high patient acceptance. In a survey of the world literature on ankle fusion versus ankle replacement surgery, the safety profile of the two procedures are comparable.[4]

Not every patient 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.[5] As with any total joint replacement, patients 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.[6]

In the United States, total ankle replacement surgery is currently a safe and effective treatment option for select patients with end stage ankle arthritis. Studies have shown total ankle replacement surgery improves patient function, reduces pain, and promotes improved quality of life.[7]

Patients should consider consulting with a surgeon who is board certified or board qualified in foot and ankle surgery with experience and training in total ankle replacement when considering this procedure.

UptoDate: Total Joint Replacement for Severe RA- May 2022

Total ankle replacement — Because the ankle is a hinged joint, and normal gait requires only 10 to 12 degrees of ankle extension and 20 degrees of ankle flexion, loss of motion is not critical to function, and ankle arthrodesis (AA) can result in a stable, pain-free ankle and improve quality of life. It has remained the treatment of choice for relief of severe ankle and hindfoot pain in patients with RA [40]. The main drawback is the later development of arthrosis in the adjacent joints, particularly fusion of the subtalar joint. Total ankle replacement (TAR) has the potential to preserve range of motion, restore normal gait, and protect adjacent joints.

TAR was introduced in the 1970s, but initially high failure and complication rates were noted. Since that time, three generations of implants have been developed, with several total ankle arthroplasty systems approved for use in the United States by the US Food and Drug Administration (FDA) since 2005. Third-generation systems feature a metallic baseplate fixed to the tibia and a domed component resurfacing the talus, with a polyethylene bearing surface interposed between the two.

Although there is an impression that the two procedures have similar outcomes, there is no conclusive evidence. A 2014 systematic review of data comparing TAR with arthrodesis found three retrospective studies and only one prospective study, which was non-randomized [41]. There were multiple other methodological problems noted with the studies. Two of the studies showed statistically significant improvements in the TAR group, but the other two studies showed no

differences between the two procedures. Careful selection of patients for either procedure is important. Younger, heavy, physically active males might be better candidates for arthrodesis, and patients with preexisting subtalar arthritis or hip or knee impairment that would be worsened by loss of ankle joint motion might be better candidates for TAR, but randomized trials are needed to confirm these preferences.

Approval

2/14/2023

Luke Beno MD
Physician Program Director, Quality Resource Management

Date

Date