Introduction

Advanced end-stage arthritis in the ankle occurs when the cartilage that cushions the ankle joint wears down and bones grind together. This results in pain that limits daily activities. Treatments for arthritis of the ankle include non-steroidal anti-inflammatory drugs (NSAIDs), physical therapy (PT), splits, and devices to support the ankle (orthotics). Another treatment is total ankle replacement (TAR), which replaces the damaged bone and cartilage with new joint surfaces made of plastic or metal. This policy describes when total ankle replacement may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Total ankle replacement (TAR) for the treatment of advanced end stage arthritis of the ankle may be considered medically necessary when ALL of the following indications are met:

- The device must be U.S. Food and Drug Administration (FDA)-approved (see below)

AND

- The patient must be skeletally mature

AND

- 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

- There is moderate to severe ankle pain significantly limiting daily activity

AND

- Any one of the following is present:
  - Arthritis in adjacent joints (subtalor or midfoot) OR
  - Severe arthritis of the contralateral ankle OR
  - Arthrodesis of the contralateral ankle OR
  - Inflammatory arthritis (eg, RA)

TAR may be considered medically necessary for revision of prior total ankle replacement surgery if indicated (ie, for infection, inflammatory reaction, mechanical, or other complication) and the above indications are met.

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>Arthroplasty of ankle; with implant (total ankle)</td>
</tr>
<tr>
<td>27702</td>
<td>Arthroplasty of ankle; with implant (total ankle)</td>
</tr>
<tr>
<td>27703</td>
<td>Arthroplasty of ankle; revision, total ankle</td>
</tr>
</tbody>
</table>
Limitations

The 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’h. Poor skin and soft tissue quality around the surgical site (eg, 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

Evidence Review

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).

Regulatory Status

Current U.S. Food and Drug Administration (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.

References


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/16/19</td>
<td>New policy, approved August 13, 2019, effective January 1, 2020. Total ankle replacement (TAR) for the treatment of advanced end stage arthritis of the ankle may be considered medically when all criteria are met. TAR may be considered medically necessary for revision of prior total ankle replacement surgery if indicated (ie, for infection, inflammatory reaction, mechanical, or other complication) and criteria are met as listed for TAR.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2019 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy only applies to Individual Plans.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4537, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TTD)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):

بحث هذا الإشعار معلومات هامة. قد يحتوي هذا الإشعار معلومات مهمة بخصوص تلك أو هذه المعلومات التي لديك على موقع Premera Blue Cross. قد تكون هناك تأثيرات مختلفة على التأثر بالصحة أو المساعدة في هذا الإشعار. قد تكون هناك إجراءات خاصة في تأثيرات مختلفة على تأثيرات عدة لكن تلك الأخلاص الذي نحن ملتزمون نحن نحن ملتزمون في ذلك الإشعار. الإصل 800-722-1471 (TTY: 800-842-5357).

中文 (Chinese):

本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):


Deutsche (German):


Français (French):


Italiano (Italian):

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).