GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Total Ankle Replacement (TAR) involves the surgical removal of a dysfunctional, painful ankle joint and its replacement with a prosthetic device. The purpose of TAR is to relieve pain and restore joint function in patients with medically refractory, end-stage degenerative joint disease resulting from conditions such as osteoarthritis, posttraumatic osteoarthritis, or rheumatoid arthritis. Conservative treatments for ankle arthritis include pain medications, weight loss, activity limitations, ankle braces, use of orthotics and physical therapy. When conservative methods of treatment fail and symptoms are severe or cause loss of function, surgery may be considered.

Examples of US Food and Drug Administration (FDA) approved total ankle replacement devices include, but may not be limited to:

- Agility™ LP Total Ankle (Alvine Ankle) (DePuy Orthopaedics Inc., Jacksonville, FL)
- Eclipse Total Ankle Implant (Kinetics Medical Inc.; Integra Lifesciences Corporation, Plainsboro, NJ)
- Hintermann Series H2™ Total Ankle System (DT MedTech LLC.)
- Inbone™ Total Ankle (including I and II) (Wright Medical Technology Inc., Memphis, TN)
- Infinity™ Total Ankle System (Wright Medical Technology Inc.)
- Integra® Cadence™ Total Ankle Replacement System (Ascension Orthopedics) (Integra Lifesciences Corp.)
- Invision™ Total Ankle Revision System (Wright Medical Technology Inc.,
- Salto XT, Salto Talaris® (Tornier SAS, France; Integra Lifesciences Corp.)
- Scandinavian total ankle replacement system (STAR)
- Topez Total Ankle Replacement (Topez Orthopedics Inc.)
- Vantage® Total Ankle System (Exactech Inc. Gainesville, FL)
- Zimmer® Trabecular Metal™ Total Ankle

When compared to other joint replacement procedures such as hip and knee, the reported outcomes from TAR such as device durability and stability, complication and failure rates have not been as favorable. Complications such as wound infection, delayed healing and poor implant survival are associated with TAR. In addition, patient selection criteria have not been clearly defined and there is some debate regarding the optimal candidate. Evidence in the medical literature suggests the lifespan of the device is short-term and therefore not practical for use in younger patients or those who are very active. For this reason, ankle replacements are not usually recommended for people under the age of 50.

POLICY
Total Ankle Replacement (TAR) (27702, 27703) requires prior authorization.

Procedure 27700 does not require prior authorization.

HMO, PPO, Individual Marketplace, Elite, Advantage
Paramount considers Total Ankle Replacement (TAR) using a FDA cleared implant 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, 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).

Paramount considers TAR experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established.
Paramount considers revision TAR medically necessary for individuals with failed total ankle prosthesis.

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

- 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 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
- 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 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
- Weight greater than 250 lbs.

CODING/BILLING INFORMATION

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>CPT CODES</th>
<th>Description</th>
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<tbody>
<tr>
<td>27700</td>
<td>Arthroplasty, ankle</td>
</tr>
<tr>
<td>27702</td>
<td>Arthroplasty, ankle; with implant (total ankle)</td>
</tr>
<tr>
<td>27703</td>
<td>Arthroplasty, ankle; revision, total ankle</td>
</tr>
</tbody>
</table>

TAWG REVIEW DATES: 08/13/2013, 07/18/2014, 06/18/2015, 06/24/2016, 08/25/2017, 08/23/2018

REVISION HISTORY EXPLANATION

04/30/09: No change
07/18/14: Policy title changed from Ankle Arthroplasty with Implant or Revision to Total Ankle Replacement. TAR (27702, 27703) now covered with prior authorization for all product lines. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
06/18/15: Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
06/24/16: Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
08/25/17: Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
08/23/18: Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid http://jfs.ohio.gov/
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
Industry Standard Review
Hayes, Inc.