BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

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TOTAL ANKLE REPLACEMENT

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Total ankle replacement or revision with implant of artificial ankle prosthesis. Total ankle replacement may also be referred to as total ankle arthroplasty.

In general, individuals selected for arthroplasty would not be good candidates for arthrodesis (joint fusion) due to the presence of bilateral or subtalar arthritis or Chopart arthrosis. Optimal candidates for total ankle replacement are considered to be older (age older than 50), thin, low-demand individuals with minimal deformity. Individuals should have no functional barriers to participation in a rehabilitation program.

TOTAL ANKLE REPLACEMENT (cont.)

Criteria:

- Total ankle replacement using an FDA-approved device is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Individual is skeletally mature (radiographic evidence of epiphyseal closure)
  2. Moderate to severe ankle (tibiotalar) pain that limits daily activity
  3. **ANY** of the following:

     - Arthritis in adjacent joints (i.e., subtalar or midfoot)
     - Severe arthritis of the contralateral ankle
     - Arthrodesis of the contralateral ankle
     - Inflammatory (e.g., rheumatoid) arthritis

  4. Absence of **ALL** the following absolute contraindications:

     - Extensive avascular necrosis of the talar dome
     - Compromised bone stock or soft tissue (including skin and muscle)
     - Severe malalignment (e.g., >15 degrees) not correctable by surgery
     - Active ankle joint infection
     - Peripheral vascular disease
     - Charcot neuroarthropathy

- Medical director and/or clinical advisor review is required for **ANY** of the following relative contraindications:

  - Peripheral neuropathy
  - Ligamentous instability
  - Subluxation of the talus
  - History of ankle joint infection
  - Presence of severe deformities above or beneath the ankle
  - Vascular insufficiency

- Total ankle replacement for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

TOTAL ANKLE REPLACEMENT (cont.)

Resources:

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TOTAL ANKLE REPLACEMENT (cont.)

Resources: (cont.)

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TOTAL ANKLE REPLACEMENT (cont.)

Resources: (cont.)

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TOTAL ANKLE REPLACEMENT (cont.)

Resources: (cont.)

FDA Summary Statements for ankle prosthesis. Device names include, *but are not limited to*:

Agility® Ankle Revision Prosthesis
Eclipse Total Ankle Implant
Inbone ™ Total Ankle System
Salto Talaris®

- FDA-approved indication: Total ankle arthroplasty is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint. Total ankle arthroplasty is indicated for patients with ankle joints damaged by severe rheumatoid, post traumatic or degenerative arthritis. Additionally indicated for patients with a failed previous ankle surgery. Intended for cemented use only.

FDA Premarket Approval Database for Scandinavian Total Ankle Replacement System (S.T.A.R.® Ankle):

- FDA-approved indication: For use as a non-cemented implant to replace a painful arthritic ankle joint due to osteoarthritis, post-traumatic arthritis or rheumatoid arthritis.