

Coverage of any medical intervention discussed in a Prevea360 Health Plan medical policy is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

Total Ankle Replacement

MP9363

Covered Service: Yes

Prior Authorization

Required: No

Additional Information:

The criteria in this policy do not apply to those devices which have been granted a humanitarian device exemption (HDE) by the FDA, which are considered medically necessary when all FDA-required criteria are met. This includes Patient Specific Talus Spacer (Additive Orthopaedics, LLC) indicated for avascular necrosis of the ankle joint.

For a current list of HDE approved devices, refer to the FDA HDE database at: <u>Listing of CDRH Humanitarian Device</u>

Exemptions | FDA

Restricted to Orthopedic Surgeons or Podiatrists

Prevea360 Health Plan Medical Policy:

- 1.0 Total ankle replacement surgery **does not require** prior authorization and may be considered medically necessary when **ALL** of the following criteria are met:
 - 1.1 Moderate or severe pain related to osteoarthritis, post traumatic arthritis or rheumatoid arthritis; AND
 - 1.2 Failed conservative treatment; AND
 - 1.3 No contraindications are noted; AND
 - 1.4 An FDA-approved device is used.
- 2.0 .Total ankle replacement surgery is considered experimental and investigational, and therefore not medically necessary for all other indications.



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