Medical Affairs Policy

**Service:** Total Ankle Arthroplasty (Total Ankle Replacement)

*PUM 250-0009-1706*

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<th>Medical Policy Committee Approval</th>
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<td>Effective Date</td>
<td>10/01/17</td>
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<tr>
<td>Prior Authorization Needed</td>
<td>Yes</td>
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**Disclaimer:** This policy is for informational purposes only and does not constitute medical advice, plan authorization, an explanation of benefits, or a guarantee of payment. Benefit plans vary in coverage and some plans may not provide coverage for all services listed in this policy. Coverage decisions are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations, and to applicable state and federal law. Some benefit plans administered by the organization may not utilize Medical Affairs medical policy in all their coverage determinations. Contact customer services as listed on the member card for specific plan, benefit, and network status information.

Medical policies are based on constantly changing medical science and are reviewed annually and subject to change. The organization uses tools developed by third parties, such as the evidence-based clinical guidelines developed by MCG to assist in administering health benefits. This medical policy and MCG guidelines are intended to be used in conjunction with the independent professional medical judgment of a qualified health care provider. To obtain additional information about MCG, email medical.policies@wpsbc.com.

**Description:**

Total Ankle Arthroplasty (TAA) is a surgical procedure for arthritis in which the ankle joint is replaced with a prosthetic two or three-part (typically plastic and metal) joint. Joint fusion has been the primary surgical treatment for ankle joint arthritis. The sequelae of fusion include non-union of the joint, development of arthritis in adjacent joints, and gait abnormalities secondary to the loss of ankle mobility. TAA is used as an alternative to surgical fusion.

Ankle joint arthritis occurs most commonly due to osteoarthritis (OA) or rheumatoid arthritis (RA) in older individuals and after severe trauma (post traumatic arthritis) in younger individuals. Conservative medical treatment varies with the type and severity of the joint disease and includes anti-inflammatory drugs, physical and occupational therapies, bracing, and specialty medications for RA.

The FDA has approved various prosthetic ankle implants as class II devices, class III devices and 510 premarketing cleared devices.

**Indications of Coverage:**

A. TAA with an FDA approved implant is considered medical necessary in a skeletally mature individual when **all criteria 1-5 below** are met:

- Note: It is the responsibility of the surgeon to choose an FDA approved device with proven safety and efficacy.
1. The individual has moderate to severe pain, and loss of mobility and function, in the joint to be treated.

2. **At least one** of the following conditions is present:
   a. Severe osteoarthritis of the joint
   b. Inflammatory (e.g. rheumatoid) arthritis of the joint
   c. Post traumatic arthritis of the joint

3. **At least one** of the following is present:
   a. Severe arthritis of the contralateral ankle
   b. Arthrodesis of the contralateral ankle
   c. Arthritis in an adjacent joint (such as the subtalar joint)
   d. History of arthroplasty of the adjacent (ipsilateral) knee

4. Failure of at least 6 months of conservative therapy including **all** the following:
   a. Physical therapy **and**
   b. Non-steroidal anti-inflammatory drugs (or other analgesics if NSAIDS are not tolerated/indicated) **and**
   c. Orthoses or bracing as indicated (when the device is a covered benefit)

5. Weight under 250 lbs.

**B.** TAA revision is considered medically necessary for individuals with a failed total ankle prosthesis (e.g. loosening / malposition/ periprosthetic fracture/ or infection) provided that the original replacement was an approved service.

**Limitations of Coverage:**

**A.** Review health plan and endorsements for exclusions and prior authorization or benefit requirements

**B.** If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental, investigational, and unproven to affect health outcomes.
C. If used for a condition/diagnosis that is listed in the Indications of Coverage but the criteria are not met, deny as not medically necessary

D. TAA is considered experimental, investigational, and unproven to affect health outcomes when used for ANY of the following indications:

1. Active or prior deep infection in the ankle joint or adjacent bones
2. Avascular necrosis of the talus
3. Charcot joint (Charcot or other neuropathy)
4. Hindfoot or forefoot mal-alignment precluding plantigrade foot
5. Insufficient ligament support that cannot be corrected with soft tissue stabilization
6. Lower extremity vascular insufficiency
7. Neuromuscular disease resulting in lack of normal muscle function about the affected ankle
8. Peripheral neuropathy (may lead to Charcot joint of the affected ankle)
9. Poor skin and soft tissue quality about the surgical site
10. Prior arthrodesis (fusions) at the ankle joint
11. Prior surgery or injury that has adversely affected ankle bone quality
12. Psychiatric problems that hinder adequate cooperation during the perioperative period
13. Severe ankle deformity (e.g. severe varus or valgus deformity) that would not normally be eligible for ankle arthroplasty
14. Severe osteoporosis, osteopenia, or other conditions resulting in poor bone quality, as this may result in inadequate bony fixation
15. Significant mal-alignment of the knee joint
16. Skeletal maturity not yet reached
17. Customized TAA procedures, customized templates and/or instrumentation, or gender specific implants as they are not supported by the American Academy of Orthopedic Surgeons (AAOS)
18. Pre-operative imaging studies (e.g., CT scans, MRI) associated with customized ankle replacement and/or utilized as part of operative navigation guides (e.g., PROPHECY® INBONE®) because it is considered not medically necessary for a conventional total ankle replacement as they are not supported by the AAOS.

19. Viscosupplementation injections (e.g. Hyaluronan [Hyalgan] and hylan-GF-20 [Synvisc]) are considered experimental, investigational, and unproven to affect health outcomes. Synvisc is not approved by the FDA for use in the ankle.

**Documentation Required:**

- Office notes documenting the physical findings, diagnosis, nicotine status, and conservative treatment history

**References:**


3. UpToDate Total joint replacement for severe rheumatoid arthritis. Literature review current through Apr 2017. Topic last updated Nov 5, 2016

4. MCG 21st ed. ACG: A-00306 Hyaluronic Acid, Intra-articular Injection


WPS/Arise Review History:

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Approved by the Medical Director