



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 09/17/13
LAST REVIEW 08/07/18
LAST CRITERIA REVISION DATE: 08/19/14
ARCHIVE DATE:

TOTAL ANKLE REPLACEMENT

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

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.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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.

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TOTAL ANKLE REPLACEMENT (cont.)

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 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.

Device names intended for cemented use only include, *but are not limited to:*

- Agility® Ankle Revision Prosthesis
- Eclipse Total Ankle Implant
- Inbone® and Infinity® Total Ankle Systems
- Integra Total Ankle Replacement System
- Invision® Total Ankle Revision System
- Salto Talaris® Total Ankle
- Exactech® Vantage™ Total Ankle System

Device names intended for non-cemented use only include, *but are not limited to:*

- Scandinavian Total Ankle Replacement System (S.T.A.R.® Ankle)



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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)
 - Arthrodesis of the contralateral ankle
 - Inflammatory (e.g., rheumatoid) arthritis
 - Severe arthritis of the contralateral ankle
 4. Absence of **ALL** the following absolute contraindications:
 - Active ankle joint infection
 - Charcot neuroarthropathy
 - Compromised bone stock or soft tissue (including skin and muscle)
 - Extensive avascular necrosis of the talar dome
 - Peripheral vascular disease
 - Severe malalignment (e.g., >15 degrees) not correctable by surgery
- Medical director and/or clinical advisor review is required for **ANY** of the following relative contraindications:
 - History of ankle joint infection
 - Ligamentous instability
 - Peripheral neuropathy
 - Presence of severe deformities above or beneath the ankle
 - Subluxation of the talus
 - 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.



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TOTAL ANKLE REPLACEMENT (cont.)

Resources:

Literature reviewed 08/15/17. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

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Resources: (cont.)

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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ 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: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's 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, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilínígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'idííkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowolgo bee haz'á doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

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