ANKLE ARTHROEREISIS AND SUBTALAR IMPLANT

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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ANKLE ARTHROEREISIS AND SUBTALAR IMPLANT (cont.)

Description:

Arthroereisis, also called arthroisis or arthroerisis, is a procedure designed to limit excessive motion across a joint. Subtalar Arthroereisis or extraosseous talotarsal stabilization (EOTTS), describes the use of an implant to correct flexible flatfoot (pes planus) which is described as excessive pronation during weight bearing due to displacement of the talus. Extraosseous talotarsal stabilization is also being evaluated as a treatment of talotarsal joint dislocation. Flatfoot may be congenital or acquired in adulthood because of Posterior Tibial Tendon Dysfunction (PTTD). PTTD may be caused by inflammatory disorders or trauma. Arthroereisis has also been investigated as a means to correct other disorders of the feet. Arthroereisis differs from arthrodesis, which is the immobilization of a joint.

Subtalar implants include, but are not limited to:

- Biopro® Subtalar Implant
- HyProCure® Subtalar Implant System
- Lundeen Subtalar Peg Implant
- Smith Subtalar Peg (also referred to as STA-peg)
- Subtalar MBA® System
- Subtalar Peg Implant
- Talar-Fit™ Subtalar Arthroereisis Implant
- The Kalix™ Implant
- Threaded Fixation Pin

Criteria:

FOOT CARE, INCLUDING THE TREATMENT OF FLAT FEET, IS NOT A COVERED BENEFIT FOR MANY PLANS. REFER TO THE MEMBER’S SPECIFIC BENEFIT PLAN BOOK.

- If benefit coverage for flat feet is available, subtalar arthroereisis and subtalar implant for individuals 4 years of age through 15 years of age are considered medically necessary with documentation of ANY of the following:

  1. Collapsing pes valgo planus
  2. Dorsolateral peritalar subluxation
  3. Hindfoot pronation
  4. Pes valgo planus deformity
  5. Planovalgus
  6. Subtalar instability
  7. Subtalar joint subluxation
ANKLE ARTHROEREISIS AND SUBTALAR IMPLANT (cont.)

Criteria: (cont.)

- **If benefit coverage for flat feet is available**, subtalar arthroereisis and subtalar implant for individuals 4 years of age through 15 years of age are considered *medically necessary* with documentation of ANY of the following: (cont.)

  8. Symptomatic pes valgus (also called talipes valgus)
  9. Tarsal coalitions between the calcaneus and navicular bones
  10. Unsuccessful long term orthopedic treatment (shoes, insoles, etc.)

- **If benefit coverage for flat feet is available**, subtalar arthroereisis and subtalar implant for all other indications not previously listed 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.

These indications include, *but are not limited to*:

- Paralytic flatfoot
- Posterior tibial tendon dysfunction
- Tibialis posterior dysfunction

**Resources:**

Literature reviewed 09/26/17. 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.

ANKLE ARTHROEREISIS AND SUBTALAR IMPLANT (cont.)

Resources: (cont.)


18. The Institute for Foot and Ankle Reconstruction at Mercy. Flat Feet in Childhood. Received 2006.
ANKLE ARTHROEREISIS AND SUBTALAR IMPLANT (cont.)

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: Dii kwe’ é atah nilińgįį Blue Cross Blue Shield of Arizona haada yit’éego bina’idilkiidgo éi doodago Háida bijá anílyeediįį t’aadoo le’é yina’idilkiidgo beehaz’á aními hólo dii t’aá hazaak’déhji háká a’dowlolo be be haz’a doo bąq łháñińgįį. Atá’ hainé’giį kojí bich’įj 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

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. Đề nghị chuyển với một thợ dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعد أسلاحة يشخص من Blue Cross Blue Shield of Arizona الضرورية، ينصح من دون أي تكلفة، للتحدث مع مرجم الفصل، ب 877-475-4799.
ANKLE ARTHROEREISIS AND SUBTALAR IMPLANT (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagsalan, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 이용 할수있게 할 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799로 전화하시는 것이 좋습니다.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizonaについてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi: اگر شما یا کسی که شما به آن کمک می‌کنید، سوال در مورد اطلاعات به زبان انگلیسی را به تماس‌گیری دریافت نمایید 877-475-4799. تیم کمک‌های رایگان در آمریکا ایرانی در دسترس است.

Assyrian: Blue Cross Blue Shield of Arizona، دانش‌های بالینی حق این را دارید که کمک و

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณ หรือคนใกล้ชิดประสบปัญหาเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์จะได้รับความช่วยเหลือและข้อมูลภาษาของคุณโดยไม่มีค่าใช้จ่าย ตลอดเวลา โทร 877-475-4799.