

An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES

SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 11/14/07 LAST REVIEW DATE: 10/29/13 LAST CRITERIA REVISION DATE: 10/29/13 ARCHIVE DATE:

ANKLE ARTHROEREISIS AND SUBTALAR IMPLANT

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 "<u>Description</u>" 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 "<u>Criteria</u>" 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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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. 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.

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Description: (cont.)

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
- Talar-Fit[™] Subtalar Arthroereisis Implant
- Subtalar Peg 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
 - 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.)

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ANKLE ARTHROEREISIS AND SUBTALAR IMPLANT (cont.)

Criteria: (cont.)

- 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:
 - 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:

- 1. 7.01.104 BCBS Association Medical Policy Reference Manual. Subtalar Arthroereisis. Re-issue date 09/12/2013, issue date 12/14/2005.
- 2. Alfahd U, Roth SE, Stephen D, Whyne CM. Biomechanical comparison of intramedullary nail and blade plate fixation for tibiotalocalcaneal arthrodesis. *J Orthop Trauma*. 2005 Nov-Dec 2005;19(10):703-708.
- 3. American Academy of Orthopaedic Surgeons. Spectrum of Flexible Flatfoot: Calcaneal Osteotomy and FDL Transfer with Subtalar Arthroreisis. 02/24/2005, accessed 06/04/2007 2005.
- 4. American Academy of Orthopaedic Surgeons. Flexible Flatfoot in Children. 08/2007, accessed 10/16/2007 2007.
- 5. American Podiatric Medical Association. Treating Severely Flat Arches in Children's Feet Early Avoids Complication Later. Accessed 06/04/2007.
- 6. Arangio GA, Reinert KL, Salathe EP. A biomechanical model of the effect of subtalar arthroereisis on the adult flexible flat foot. *Clin Biomech (Bristol, Avon)*. 2004 Oct 2004;19(8):847-852.
- 7. Brancheau S, Maxwell, J, et, al,. The Valenti STJ Arthroereisis Implant: A Ten Year Retrospective Study. Chapter 8:44-53.

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ANKLE ARTHROEREISIS AND SUBTALAR IMPLANT (cont.)

Resources: (cont.)

- 8. De Pellegrin M. [Subtalar screw-arthroereisis for correction of flat foot in children]. *Orthopade*. 2005 Sep 2005;34(9):941-953, quiz 954.
- Dellon AL, Barrett SL. Sinus tarsi denervation: clinical results. J Am Podiatr Med Assoc. 2005 Mar-Apr 2005;95(2):108-113.
- 10. External Consultant. Podiatry. 10/2007, 11/2007.
- 11. Lepow, G, Jex, J. A New Generation of Subtalar Implants. *Podiatry Management*. 10/2004 2004:143-148.
- 12. Miller S. Treatment of the Adult Flexible Flatfoot: Long-Term Follow-Up of the MBA Arthroereisis Implant. Rec'd 08/30/2006: Chapter 35: 184-187.
- 13. Needleman RL. A surgical approach for flexible flatfeet in adults including a subtalar arthroereisis with the MBA sinus tarsi implant. *Foot Ankle Int.* 2006 Jan 2006;27(1):9-18.
- 14. Nelson SC, Haycock DM, Little ER. Flexible flatfoot treatment with arthroereisis: radiographic improvement and child health survey analysis. *J Foot Ankle Surg.* 2004 May-Jun 2004;43(3):144-155.
- 15. Soomekh DJ, Baravarian B. Pediatric and adult flatfoot reconstruction: subtalar arthroereisis versus realignment osteotomy surgical options. *Clin Podiatr Med Surg.* 2006 Oct 2006;23(4):695-708, v.
- 16. Su EP, Kahn B, Figgie MP. Total ankle replacement in patients with rheumatoid arthritis. *Clin Orthop Relat Res.* 2004 Jul 2004(424):32-38.
- 17. TEC Clearinghouse News. Subtalar Arthroereisis. 09/23/2005 2005.
- 18. The Institute for Foot and Ankle Reconstruction at Mercy. Flat Feet in Childhood. Received 2006.

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