

Corporate Medical Policy

Subtalar Arthroereisis

File Name:	subtalar_arthroereisis
Origination:	6/2009
Last CAP Review:	2/2012
Next CAP Review:	2/2013
Last Review:	2/2012

Description of Procedure or Service

Arthroereisis (also referred to as arthroisis) is the limitation of excessive movement across a joint. Subtalar arthroereisis is performed by placing an implant in the sinus tarsi (a canal located between the talus and the calcaneus) and is designed to correct excessive talar displacement and calcaneal eversion.

Flexible flatfoot is a common disorder, anatomically described as excessive pronation during weight bearing due to anterior and medial displacement of the talus. It may be congenital in nature, or may be acquired in adulthood due to posterior tibial tendon dysfunction, which in turn may be caused by trauma, overuse, and inflammatory disorders, among others. Symptoms include dull aching throbbing cramping pain, which in children may be described as growing pains. Additional symptoms include refusal to participate in athletics or walking long distances. Conservative treatments include orthotics or shoe modifications. Surgical approaches for painful flatfoot deformities include tendon transfers, osteotomy, and arthrodesis. Arthroereisis with a variety of implant designs has also been investigated. Subtalar arthroereisis is designed to correct the excessive talar displacement and calcaneal eversion by placing an implant in the sinus tarsi, a canal located between the talus and the calcaneus.

Subtalar arthroereisis has been performed for some 50 years, with a variety of implants designs and compositions. The Maxwell-Brancheau Arthroereisis (MBA) implant is currently favored due to the simple and reversible implantation procedure, although other devices reported in the medical literature include the STA peg and a Kalix device. The MBA implant is described as a reversible and easy to insert device with the additional advantage that it does not require bone cement. In children, insertion of the MBA implant is frequently offered as a stand-alone procedure, however, adults and children often require adjunctive surgical procedures on bone and soft tissue to correct additional deformities.

The SubFix™ arthroereisis implant (Memometal Technologies, Bruz, France) received U.S. Food and Drug Administration (FDA) marketing clearance in 2010 and the Arthrex ProStop Plus™ (Arthrex, Naples, FL) received marketing clearance in 2008. The MBA® implant (now owned by Integra LifeSciences Corp.) received 510(k) marketing clearance in 1996 because it was substantially equivalent to products on the market prior to device regulation. According to the FDA summary, the primary indication for the Subtalar MBA device is “as a spacer for stabilization of the subtalar joint. It is designed to block the anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.” The MBAResorb Implant received 510(k) marketing clearance in 2005. This implant employs the same basic mechanical features as the predicate MBA implant, but is composed of a material (poly l-lactic acid) that is resorbed by the body. Predicate devices include the Osteomed Talar-Fit™, Nexa Orthopedics Subtalar Peg, Arthroereisis Implant Talus of Vilex, Instrateck and Wright Medical Smith Sta-Peg.

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*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will not provide coverage for subtalar arthroereisis. It is considered investigational. BCBSNC does not cover investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When it is covered

Not Applicable

When it is not covered

Subtalar arthroereisis is not covered. It is considered investigational for all clinical applications.

Policy Guidelines

Data in the published medical literature is inadequate to permit scientific conclusions. More research and long-term clinical study are needed. The lack of long-term outcomes is particularly important since the procedure is often performed in growing children. Another limitation is the lack of controlled studies comparing use of the implants with other surgical procedures (alone or in combination). Subtalar arthroereisis has not been shown to be as beneficial as established alternatives.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: S2117

There is no specific CPT for this procedure. Physicians may be using an unlisted procedure code (28899) to describe subtalar arthroereisis. CPT code 28725 describes subtalar arthrodesis which is a significantly different procedure.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Subtalar Arthroereisis

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.104, 5/08/08

Lee MS, Vanore JV, Thomas JL, Catanzariti AR, Kogler G, Kravitz SR, Miller SJ, Gassen SC.

Diagnosis and treatment of adult flatfoot. J Foot Ankle Surg 2005 Mar-Apr;44(2):78-113.

FDA [Webpage] Center for Devices and Radiological Health (CDRH). 510(k) Premarket Notification Database. 510(k) summary K960692. MBA System. Issued 07/23/1996. Retrieved June 2009 from <http://www.fda.gov/cdrh/pdf/k960692.pdf>

FDA [Webpage] Center for Devices and Radiological Health (CDRH). 510(k) Premarket Notification Database. 510(k) summary K051611. MBA Resorb Implant. Issued 09/06/2005. Retrieved June 2009 from <http://www.fda.gov/cdrh/pdf/k051611.pdf>

Senior Medical Director review 7/2009

National Institute for Clinical Excellence (NICE). Guidance on Sinus tarsi implant insertion for mobile flatfoot. Interventional Procedure Guidance 305. London, UK: NICE July 2009. Retrieved on June 3, 2010 from <http://www.nice.org.uk/nicemedia/live/12080/44910/44910.pdf>

Specialty Matched Consultant Advisory Panel review 7/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.104, 9/16/10

Specialty Matched Consultant Advisory Panel review 2/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.104, 9/1/11

Specialty Matched Consultant Advisory Panel review 2/2012

Policy Implementation/Update Information

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| 7/20/09 | Notification of new policy titled "Subtalar Arthroereisis." BCBSNC will not provide coverage for subtalar arthroereisis for the treatment of flatfoot deformity. It is considered investigational. Notification given 7/20/09. Effective date 10/26/09. (adn) |
| 8/17/10 | Specialty Matched Consultant Advisory Panel review 7/2010. References updated. Medical Policy number removed. (mco) |
| 3/15/11 | Specialty Matched Consultant Advisory Panel review 2/2011. Description section updated. Policy Guidelines updated. References updated. (mco) |
| 11/8/11 | References updated. No changes to Policy Statements. (mco) |
| 12/6/11 | Policy Statement revised. "for treatment of flatfoot deformity" removed. New policy statement as follows: "BCBSNC will not provide coverage for subtalar arthroereisis. It is considered investigational. BCBSNC does not cover investigational services." "When not Covered" section revised to state: "Subtalar arthroereisis is not covered. It is considered investigational for all clinical applications." Medical Director review 11/2011. (mco) |
| 3/20/12 | Specialty Matched Consultant Advisory Panel review 2/2012. No changes to policy statements. (mco) |

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.