Corporate Medical Policy

Subtalar Arthroereisis

File Name: subtalar_arthroereisis
Origination: 6/2009
Last Review: 2/2024

Description of Procedure or Service

Arthroereisis (also referred to as arthroisis) is the limitation of excessive movement across a joint. Subtalar arthroereisis or extraosseous talotarsal stabilization (EOTTS) 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, inflammatory disorders, and other factors. Symptoms include dull, aching and 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 or extraosseous talotarsal stabilization is designed to correct the excessive talar displacement and calcaneal eversion by reducing pronation across the subtalar joint. Extraosseous talotarsal stabilization is also being evaluated as a treatment of talotarsal joint dislocation. It is performed by placing an implant in the sinus tarsi, a canal located between the talus and the calcaneus.

Subtalar arthroereisis has been performed for more than 50 years, with a variety of implant designs and compositions. The Maxwell-Brancheau Arthroereisis (MBA) implant is the most frequently reported, although other devices reported in the medical literature include the HyProCure, STA peg, and Kalix. 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.

A number of implants have received marketing clearance through the U.S. Food and Drug Administration's (FDA) 510(k) pathway. For example, the HyProCure® Subtalar Implant System/Extra Osseous Fixation Device (Graham Medical Technologies) received marketing clearance in 2004 (K042030) and the Arthrex ProStop Plus™ (Arthrex, Naples, FL) received marketing clearance in 2008 (K071456). The MBA® implant (now owned by Integra LifeSciences Corp., Plainsboro, NJ) received 510(k) marketing clearance in 1996 (K960692) 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 (K051611). 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. Some additional implants that received FDA clearance through the 501(k) process are

OsteoMed Subtalar Implant system (OsteoMed 2003), BioPro Subtalar Implant (BioPro 2004), and Subtalar Implant (Biomet Sports Medicine 2007). More recently, the Trilliant Surgical Subtalar Implant (Trilliant Surgical, 2011), the Metasurg Subtalar Implant (Metasurg, 2011), the NuGait™ Subtalar Implant System (Ascension Orthopedic, 2011), the Disco Subtalar Implant (Trilliant Surgical, 2011), the OsteoSpring FootJack Subtalar Implant System (OsteoSpring Medical, 2011), the IFS Subtalar Implant (Internal Fixation Systems, 2011), and the Life Spine Subtalar Implant System (Life Spine, 2016) have received FDA clearance.

******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

Subtalar arthroereisis is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

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 Subtalar Arthroereisis is covered

Not Applicable.

When Subtalar Arthroereisis is not covered

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

Policy Guidelines

For individuals who have flatfoot who receive STA, the evidence includes mainly single-arm case series and a small nonrandomized controlled trial comparing STA with lateral column calcaneal lengthening. Relevant outcomes are symptoms, functional outcomes, and quality of life. The small nonrandomized comparative trial (n=24 feet) is considered preliminary, and interpretation of the case series evidence is limited by the use of adjunctive procedures in addition to STA, creating difficulties in determining the extent to which each modality contributed to the outcomes. Another limitation of the published data is the lack of long-term outcomes, which is particularly important because the procedure is often performed in growing children. In addition, some publications report high rates of complications and implant removal. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have talotarsal joint dislocation who receive subtalar arthroereisis, the evidence consists of one prospective single-arm study of talotarsal stabilization using HyProCure. Relevant outcomes are symptoms, functional outcomes, and quality of life. Although improvements in pain and function were observed, the current evidence on the use of subtalar arthroereisis for treatment of talotarsal joint dislocation is insufficient to draw conclusions about treatment efficacy with certitude. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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, 0335T, 0510T, 0511T*

Physicians may be using an unlisted procedure code (28899 and 27899) 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

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. MBAResorb 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

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.104, 9/13/12

Specialty Matched Consultant Advisory Panel review 2/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.104, 9/12/13

Specialty Matched Consultant Advisory Panel review 2/2014

Medical Director review 2/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.104, 9/11/14

Specialty Matched Consultant Advisory Panel review 2/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.104, 9/10/15

Specialty Matched Consultant Advisory Panel review 2/2016

Specialty Matched Consultant Advisory Panel review 2/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.104, 8/10/2017

Specialty Matched Consultant Advisory Panel review 2/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.104, 4/12/2018

Specialty Matched Consultant Advisory Panel review 2/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.104, 4/8/2019

Specialty Matched Consultant Advisory Panel review 2/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.104, 4/16/2020

Specialty Matched Consultant Advisory Panel review 2/2021

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.104, 4/8/2021

Specialty Matched Consultant Advisory Panel review 2/2022

Specialty Matched Consultant Advisory Panel review 2/2023

Specialty Matched Consultant Advisory Panel review 2/2024

Medical Director review 2/2024

Policy Implementation/Update Information

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)

11/27/12 Policy Guidelines updated. References updated. No changes to Policy Statement. (mco)

3/12/13 Specialty Matched Consultant Advisory Panel review 2/2013. No changes to Policy Statement. (mco)

10/29/13 Description section updated. Policy Guidelines updated. References updated. No changes to Policy Statement. (mco)

12/31/13 CPT code 0335T added to Billing/Coding section. (mco)

3/11/14 Specialty Matched Consultant Advisory Panel review 2/2014. Medical Director review 2/2014. CPT code 27899 added to Billing/Coding section. (mco)

11/25/14 Reference added. No changes to Policy Statement. (sk)

4/28/15 Specialty Matched Consultant Advisory Panel review 2/2015. No change to Policy Statement. (sk)

10/30/15 Reference added. (sk)

4/1/16 Specialty Matched Consultant Advisory Panel review 2/24/2016. (sk)

3/31/17 Specialty Matched Consultant Advisory Panel review 2/22/2017. (sk)

9/29/17 Reference added. (sk)

4/27/18 Specialty Matched Consultant Advisory Panel review 2/28/2018. (sk)

7/13/18 Reference added. Additional implants added to Description section. (sk)

12/14/18 Codes 0510T and 0511T added to Billing/Coding section for effective date 1/1/2019. (sk)

3/12/19 Specialty Matched Consultant Advisory Panel review 2/20/2019. (sk)

7/1/19 Reference added. (sk)

3/10/20 Specialty Matched Consultant Advisory Panel review 2/19/2020. (sk)

8/25/20 Reference added. (sk)

3/9/21 Specialty Matched Consultant Advisory Panel review 2/17/2021. (sk)

1/11/22 Reference added. Policy Guidelines updated. (sk)

3/8/22 Specialty Matched Consultant Advisory Panel review 2/16/2022. (sk)

3/7/23 Specialty Matched Consultant Advisory Panel review 2/15/2023. (sk)

4/1/24 Updated Description section to add additional FDA approved Subtalar Implant Devices. Reference added. Specialty Matched Consultant Advisory Panel review 2/2024. Medical Director review 2/2024. (rp)