I. **POLICY**

Subtalar arthroereisis is considered **investigational** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

II. **PRODUCT VARIATIONS**

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO*

* Refer to FEP Medical Policy Manual MP-7.01.104 Subtalar Arthroereisis. The FEP Medical Policy manual can be found at: [www.fepblue.org](http://www.fepblue.org)

III. **DESCRIPTION/BACKGROUND**

Arthroereisis (also referred to as arthroisis) is the limitation of movement across a joint. Subtalar arthroereisis (STA) 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 it 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 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 (STA) has been performed for more than 50 years, with a variety of implants designs, and compositions. Currently, the Maxwell-Brancheau Arthroereisis (MBA) implant is favored due to the simple and reversible implantation procedure, although other devices such as the STA peg and Kalix are reported in the medical literature. The MBA implant is described as reversible and easy to insert, with the additional advantage that it does not require bone cement. In children, insertion of the MBA implant may be offered as a stand-alone procedure, although children and adults often require adjunctive surgical procedures on bone and soft tissue to correct additional deformities.

**Regulatory Status**

A number of implants have received marketing clearance through the U.S. Food and Drug Administration’s (FDA) 510(k) pathway. For example, the SubFix™ arthroereisis implant (Memometal Technologies, Bruz, France) received FDA marketing clearance in 2010 (K093820) 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.” (1) 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. Predicate devices include the Osteomed Talar-Fit™ (K031155), Nexa Orthopedics Subtalar Peg (K032902 and K033046), Arthroereisis Implant Talus of Vilex (TOV, K041289),

**IV. RATIONALE**

The most recent literature review was performed through August 6, 2015. Following is a summary of the key literature to date.

There is 1 small controlled trial of STA compared with alternative treatments. The evidence base consists primarily of single-arm case series that report on success rates following this procedure.
Flatfoot

In 2015, Chong et al reported a small prospective nonrandomized trial that compared STA with lateral column calcaneal lengthening for the treatment of 24 painful flatfeet in children. Seven children (13 feet) enrolled at the Primary Children’s Medical Center were treated with arthroereisis and 8 children (11 feet) enrolled at the Shriners Hospital for Children were treated with lateral column lengthening. Children who underwent STA had a small incision with insertion of the implant and were placed in below-knee walking casts for 3 weeks. Children treated with lateral column lengthening had an opening wedge osteotomy with insertion of a wedge of cadaveric bone and were placed in non-weight-bearing casts for 1 month and walker type boots for another month. Outcomes at a mean of 12.7 months after surgery included radiographs, foot pressure, kinematic analysis and the Oxford Ankle-Foot Questionnaire for Children. The 2 groups showed similar improvements in the lateral talo-first metatarsal angle and talonavicular coverage and in kinematics. Both groups showed a statistically significant lateralization of the hindfoot and midfoot center of pressure (p<0.01). There were no between-group differences in any of the clinical or functional outcomes. On within-group comparison, only the STA group had a statistically significant reduction in time on the hindfoot (p=0.01). Both groups had improvements in the parental and child scores on the Oxford questionnaire, but only the STA group had a statistically significant improvement in this small sample. There were 2 complications in each group, with removal of the hardware in 1 patient and removal of the implant in 2 patients. The improvement in pain and foot position was retained following implant removal.

In 2011, Metcalfe et al published a systematic review of the literature on STA for pediatric flexible flatfoot. Seventy-six case series or case reports (no controlled trials) were identified. Ten of the studies (756 feet) provided clinician-based assessment of the surgical result graded from “excellent to poor” with follow-up between 36 and 240 months. Six studies (212 feet) included estimates of overall patient satisfaction using nonvalidated outcome measures, while 1 study (16 feet) found significant improvement using a validated foot-specific patient outcome measure. Data from 15 studies that reported radiographic values were combined for analysis. Although 8 of 9 radiographic parameters showed statistically significant improvements following arthroereisis procedures, the relationship between radiographic and clinical outcomes is uncertain. The procedure was associated with a number of complications including sinus tarsi pain, device extrusion, and undercorrection. Complication rates ranged from 4.8% to 18.6%, with unplanned removal rates between 7.1% and 19.3% across all device types. The influence of adjunctive procedures on outcomes was not addressed in this review.

One case series that was not confounded by adjunctive procedures and that had a relatively long follow-up was published by Graham et al in 2012. This study reported mean 51-month follow-up of talotarsal stabilization in 117 feet using the HyProCure device. Patients who received adjunctive procedures affecting the talotarsal joint were excluded from the analysis. Adult patients who met the inclusion/exclusion criteria were invited to participate in the study. Eighty-three patients gave consent to participate, and 78 completed the Maryland Foot Score
Questionnaire; 5 patients who had 7 implants (6%) removed did not complete the questionnaire. There were 16 revision surgeries with HyProCure; 9 involved repositioning of a partially displaced device or a change in size of the device. Of the patients who retained the device, 52% reported complete alleviation of foot pain, 69% had no limitations in their foot functional abilities, and 80% reported complete satisfaction with the appearance of their feet. This case series is notable for its assessment of functional outcomes at medium-term follow-up in patients who did not have adjunct procedures.

Other case series generally did not exclude the use of other adjunctive treatments. For example, in 1998 Vedantam et al reported on a series of 78 children (140 feet) with neuromuscular disease who underwent STA with an STA-peg. The stem of this implant is placed into the calcaneus with the collar abutting the inferior surface of the lateral aspect of the talus, thus limiting motion. All but 5 of the children had additional procedures to balance the foot. Satisfactory results were reported in 96.4% of patients, although the contribution of the STA-peg cannot be isolated. In 2004, Nelson et al reported on 37 patients (67 feet) who underwent Maxwell-Brancheau Arthroereisis (MBA) implant with an average of 18.4 months of follow-up. While this study reported various improvements in anatomic measurements, there were no data on improvement in symptoms. Another series from 2006 reported significant improvements in pain and function in 78% of patients (23 patients, 28 feet) with use of a subtalar implant as a component of reconstructive foot and ankle surgery. However, because results were not compared with controls receiving reconstructive surgery without STA, the contribution of the implants to these outcomes is unclear. In addition, the authors reported an overall complication rate of 46%, with surgical removal of 39% of the implants due to sinus tarsi pain. The authors also commented that postoperative sinus tarsi pain was unpredictable.

Cicchinelli et al reported on radiographic outcomes in a retrospective analysis of 28 feet in 20 pediatric patients treated with STA combined with gastrocnemius recession or with STA combined with gastrocnemius recession and medial column reconstruction. Lucaccini et al analyzed clinical and radiographic results of 14 patients (16 feet) with hallux valgus in abnormal pronation syndrome treated with distal osteotomy of the first metatarsal bone and STA performed in 1 stage. In a 2010 study, Scharer et al conducted a retrospective radiographic evaluation of 39 patients (68 feet) who had received the MBA implant for the treatment of painful pediatric flatfoot deformities. The average age of the patients at the time of surgery was 12 years (range, 6-16 years). Additional procedures included 12 (18%) gastrocnemius resections, 6 (9%) Achilles tendon lengthening, and 4 (6%) Kidner procedures. At an average 24-month follow-up (range, 6-61 months), there had been 10 (15%) complications requiring reoperation, including implant migration, undercorrection, overcorrection, and persistent pain. The implants were exchanged for either a larger or smaller implant. These case series do not allow comparison with nonsurgical interventions or with other surgical interventions.

An example of a case series with longer follow-up is a 2012 retrospective study by Branchéau et al, which reported mean 36-month follow-up (range, 18-48 months) in 35 patients (60 feet) after use of the MBA implant with adjunct procedures. The mean age of the patients was 14.3 years.
(range, 5-46 years). Significant changes were observed in radiographic measures (talocalcaneal angle, calcaneocuboid angle, first to second intermetatarsal angle, calcaneal inclination angle, and talar declination angle). Seventeen percent of patients reported that 9 implants (15%) were removed after the initial surgery. Of the 24 patients (68.6%) who answered a subjective questionnaire (in person or by telephone at a mean of 33 months postoperatively), 95.8% reported resolution of the chief presenting complaint, and 79.2% said they were 100% satisfied with their surgical outcome. The contribution of the MBA implant to these results cannot be determined by this study design.

Talotarsal Joint Dislocation
In 2013, Bresnahan et al reported a prospective study of talotarsal stabilization using HyProCure® in 46 feet of 35 patients diagnosed with recurrent and/or partial talotarsal joint dislocation. Patients who had the following characteristics were included: deformity characterized by talar displacement medially, plantarly, and/or anteriorly; collapse of the medial longitudinal arch; hyperpronation about the subtalar joint axis; ability to manipulate the foot to correct the deformity; a prolonged period of pronation or delayed resupination and/or flattening of the arch; and anteroposterior/dorsoplantar and lateral weight-bearing radiographs revealing talotarsal misalignment. No procedures besides insertion of the HyProCure® device were performed to address the talotarsal joint dislocation. At 1 year postoperatively, scores on the Maryland Foot Score had improved from a preoperative score of 69.53 to a postoperative score of 89.27 of 100 (n=30). Foot pain decreased by 37.0%, foot functional activities improved by 14.4%, and foot appearance improved by 29.5%. Implants were removed from 2 feet with no unresolved complications.

Adverse Events
Complications are frequently reported in the literature. Scher et al reported 2 cases of extensive implant reaction in 2 children 2 years after a STA-peg procedure. Due to the commonly seen complication of severe postoperative pain with failure to reconstitute the longitudinal arch on weight bearing and a residual flatfoot deformity, the authors do not recommend STA in the treatment of painful flexible flatfoot in children. A radiographic study on a bioabsorbable STA found poor outcomes in 3 of 6 patients who met the inclusion criteria and consented to additional imaging. Two patients requested implant removal; a third patient had persistent pain but refused explantation. Radiographic measurement (magnetic resonance imaging or computed tomography) found that these 3 patients had smaller tarsal canal widths than the diameter of the inserted interference screw. The authors noted that the implant length also had to be reduced before implantation. They concluded that the current width and length of commercially available implants may need to be modified and that more research and long-term clinical study are needed.

Cook et al conducted a retrospective case-control study to identify factors that may contribute to failure (explantation) of titanium arthroereisis implants. All patients who required removal of a self-locking wedge-type STA (n=22) were compared in a 1:2 ratio (n=44) with patients with
nonexplanted arthroereisis who were treated during the same time period. Subjects were matched for preoperative radiographic measurements, age, gender, presenting diagnosis, and length of follow-up. Multivariate logistic regression showed no significant effect of age, gender, implant size, shape, length of follow-up, implant position, surgeon experience, or concomitant procedures. Patients who required explantation had slightly greater odds of radiographic undercorrection (odds ratio [OR], 1.175) or residual transverse plane-dominant deformities (OR=1.096). The percentage of explantations in this retrospective analysis was not described.

**Ongoing and Unpublished Clinical Trials**
A search of ClinicalTrials.gov in August 2015 did not identify any ongoing or unpublished trials that would likely influence this review.

**Summary of Evidence**
The evidence for subtalar arthroereisis (STA) in patients with flatfoot or talotarsal joint dislocation includes mainly single-arm case series and 1 small nonrandomized controlled trial of STA compared 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 the effects of the technology on health outcome.

**Clinical Input Received From Physician Specialty Societies and Academic Medical Centers**
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

**2012 Vetting**
In response to requests, input was received through 2 physician specialty societies and 2 academic medical centers while this policy was under review in 2012. Input was mixed, with most reviewers considering this procedure to be investigational.

**2009 Vetting**
In response to requests, input was received through 1 physician specialty society (3 reviews) and 5 academic medical centers while this policy was under review in 2009. The input of reviewers was mixed regarding the medical necessity of arthroereisis.
Practice Guidelines and Position Statements

National Institute for Clinical Excellence
The 2009 Guidance from the U.K.’s National Institute for Clinical Excellence concluded that current evidence on the safety and efficacy of sinus tarsi implant insertion for mobile flatfoot is inadequate in quality and quantity. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit, or research.

American College of Foot and Ankle Surgeons
The American College of Foot and Ankle Surgeons (ACFAS) published practice guidelines for the diagnosis and treatment of adult and pediatric flatfoot in 2004 and 2005 (these are not included in the ACFAS library of current clinical practice guidelines).

The ACFAS guideline on adult flatfoot states:

“In the adult, arthroereisis is seldom implemented as an isolated procedure. Because of the long-term compensation and adaptation of the foot and adjunctive structures for flatfoot function, other ancillary procedures are usually used for appropriate stabilization. Long-term results of arthroereisis in the adult flexible flatfoot patient have not been established. Some surgeons advise against the subtalar arthroereisis procedure because of the risks associated with implantation of a foreign material, the potential need for further surgery to remove the implant, and the limited capacity of the implant to stabilize the medial column sag directly.”

The ACFAS guideline on pediatric flatfoot states: “proponents of this procedure (arthroereisis) argue that it is a minimally invasive technique that does not distort the normal anatomy of the foot. Others have expressed concern about placing a permanent foreign body into a mobile segment of a child’s foot. The indication for this procedure remains controversial in the surgical community.”

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD).

V. Definitions

Calcaneous is the largest of the tarsal bones situated at the lower and back part of the foot forming the heel.

Talus is the ankle bone; the bone of the tarsus which articulates with the tibia at the ankle.
VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational, therefore not covered:

<table>
<thead>
<tr>
<th>CPT Codes®</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0335T</td>
<td>28899</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2117</td>
<td>Arthroereisis, subtalar</td>
</tr>
</tbody>
</table>
IX. REFERENCES


7. Needleman RL. A surgical approach for flexible flatfeet in adults including a subtalar arthroereisis with the MBA sinus tarsi implant. Foot Ankle Int. Jan 2006;27(1):9-18. PMID 16442023


Other Sources:


X. POLICY HISTORY

<table>
<thead>
<tr>
<th>MP-1.114</th>
<th>CAC 9/25/07</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAC 9/30/08</td>
<td>Consensus Review</td>
</tr>
<tr>
<td>CAC 9/29/09</td>
<td>Adopted BCBSA Criteria</td>
</tr>
<tr>
<td>CAC 5/25/10</td>
<td>Consensus</td>
</tr>
<tr>
<td>CAC 4/26/11</td>
<td>Consensus, no change to policy statements. References updated.</td>
</tr>
<tr>
<td>CAC 6/26/12</td>
<td>Admin Coding Review complete</td>
</tr>
<tr>
<td>7/30/13</td>
<td>Top</td>
</tr>
<tr>
<td>Date</td>
<td>Summary</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>CAC 9/24/13</td>
<td>Consensus, no change to policy statements. References updated. Rational section added. Changed FEP variation to reference the FEP policy manual. 12/19/2013-2014 New code added to policy.</td>
</tr>
<tr>
<td>CAC 9/30/14</td>
<td>Consensus. No change to policy statements. References updated.</td>
</tr>
<tr>
<td>CAC 9/29/15</td>
<td>Consensus review. No change to the policy statement. Rationale and reference update. Coding Reviewed</td>
</tr>
<tr>
<td>CAC 9/27/16</td>
<td>Consensus review. No change to the policy statement. References and rationale updated. Variation reformatting. Coding reviewed.</td>
</tr>
</tbody>
</table>

*Top*

Health care benefit programs issued or administered by Capital BlueCross and/or its subsidiaries, Capital Advantage Insurance Company®, Capital Advantage Assurance Company® and Keystone Health Plan® Central. Independent licensees of the BlueCross BlueShield Association. Communications issued by Capital BlueCross in its capacity as administrator of programs and provider relations for all companies.