**Name of Policy:**
Subtalar Arthroereisis

Policy #: 357
Category: Surgery

Latest Review Date: September 2014
Policy Grade: B

**Background/Definitions:**
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**
Arthroereisis (also referred to as arthrosis) is the limitation of excessive movement across a joint. Subtalar arthroereisis (STA) or extraosseous talotarsal stabilization (EOTTS) is designed to correct excessive talar displacement and calcaneal eversion by reducing pronation across the subtalar joint.

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.

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, which is a canal located between the talus and the calcaneus.

Subtalar arthroereisis has been performed for over 50 years, with a variety of implants designs and compositions. The Maxwell-Brancheau Arthroereisis (MBA) implant is the most frequently reported, although other devices such as the HyProCure, STA peg and Kalix device are also described in the medical literature. 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, while adults often require adjunctive surgical procedures on bone and soft tissue to correct additional deformities.

**Policy:**
Subtalar arthroereisis does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

**Key Points:**
Periodic literature searches of the MEDLINE database on subtalar arthroereisis (STA) have identified minimal published studies, primarily consisting of single institution case series and
individual case reports. The most recent literature update, using the MEDLINE database, was performed through July 25, 2014. Following is a summary of the key literature to date.

There are no controlled trials of subtalar arthroereisis compared to alternative treatments. The evidence base consists entirely of single-arm case series that report on success rates following this procedure. Interpretation of the current case series evidence is limited by the use of adjunctive procedures in addition to subtalar arthroereisis, creating difficulties in determining the extent to which each modality contributed to the outcomes. The evidence base is also limited by the lack of long-term follow-up, which may be particularly important for a procedure performed in children.

**Flatfoot**

In 2011, Metcalfe et al published a systematic review of the literature on subtalar arthroereisis 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 non-validated outcome measures, while one 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 eight of nine 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; five patients who had seven implants (6%) removed did not complete the questionnaire. There were 16 revision surgeries with HyProCure; nine 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 and colleagues 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 calcaneous with the collar abutting the inferior surface of the lateral aspect of the talus, thus limiting motion. All but five 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 and colleagues 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, since 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 one stage. In a 2010 study, Scharer and colleagues 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 to 16 years). Additional procedures included 12 (18%) gastrocnemius recessions, six (9%) Achilles tendon lengthening, and four (6%) Kidner procedures. At an average 24-month follow-up (range: 6 to 61 months), there had been ten (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 Branchau et al, which reported mean 36-month follow-up (range 18 to 48 months) in 35 patients (60 feet) after use of the Maxwell-Brancheau Arthroereisis (MBA) implant with adjunct procedures. The mean age of the patients was 14.3 years (range, 5 to 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 nine 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 one 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 two feet with no unresolved complications.

**Adverse Events**
Complications are frequently reported in the literature. Scher and colleagues reported two cases of extensive implant reaction in two children two 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 subtalar arthroereisis in the treatment of painful flexible flatfoot in children. A radiographic study on a bioabsorbable STA found poor outcomes in three of six 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 three 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 prior to 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 subtalar arthroereisis (n=22) were compared in a 1:2 ratio (n=44) to patients with nonexplanted arthroereises 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.

**Summary**
The evidence in the published medical literature on subtalar arthroereisis is inadequate to permit scientific conclusions. The main limitation is the lack of controlled studies comparing use of the implants with other surgical procedures, alone or in combination. Other limitations of the published data is the lack of long-term outcomes, particularly important since the procedure is often performed in growing children, and the difficulty in separating the effect of this procedure from that of other adjunctive treatments. In addition, some publications report high rates of complications and implant removal. Therefore, subtalar arthroereisis is considered investigational.
Practice Guidelines and Position Statements
2009 Guidance from the United Kingdom’s National Institute for Clinical Excellence (NICE) 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.

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
STA is not a preventive service.

Key Words:
Arthroereisis, Subtalar, MBA Implant, Subtalar Arthroereisis

Approved by Governing Bodies:
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 Osseos Fixation Device (GraMedica) received marketing clearance in 2004 (K042030), 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.” The MBA_{Resorb} 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), Instrateck (K080280), and Wright Medical Smith Sta-Peg (K792670).

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

**Current Coding:**
CPT Codes:
For the insertion of the HyProCure® device use the following:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0335T</td>
<td>Extra-osseous subtalar joint implant for talotarsal stabilization (Effective 01/01/2014)</td>
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</table>

There are no specific CPT codes for this procedure or any of the other implants. Physicians may use any of the following codes to file subtalar arthroereisis.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>28735</td>
<td>Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (e.g., flatfoot correction)</td>
</tr>
<tr>
<td>28740</td>
<td>Arthrodesis, midtarsal or tarsometatarsal, single joint</td>
</tr>
<tr>
<td>29907</td>
<td>Arthroscopy, subtalar joint, surgical; with subtalar arthrodesis</td>
</tr>
<tr>
<td>28899</td>
<td>Unlisted procedure, foot or toes</td>
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HCPCS:

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>S2117</td>
<td>Arthroereisis, subtalar</td>
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</tbody>
</table>

**References:**
**Policy History:**
Medical Policy Group, June 2009 (3)
Medical Policy Administration Committee, July 2009
Available for comment July 1-August 14, 2009
Medical Policy Group, August 2009 (3)
Medical Policy Group, September 2010 (3)
Medical Policy Administration Committee October 2010
Available for Review October 21 through December 6, 2010
Medical Policy Group, September 2011(3): Updated Key Points and References
Medical Policy Group, October 2012 (3): 2012 Update to Key Points and References
Medical Policy Group, September 2013
Medical Policy Group, September, 2013 (3): Updates to Description, Key Points, Approval by Governing Bodies; no change in policy statement
Medical Policy Group, December 2013 (1) 2014 Coding Update: added new code 0335T for the insertion of the HyProCure device, effective 01/01/2014
Medical Policy Panel, September 2014
Medical Policy Group, September 2014 (3): 2014 Updates to Description, Key Points & References; no change in policy statement

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.