BlueCross BlueShield of Alabama

Name of Policy:

Subtalar Arthroereisis

Policy #: 357
Category: Surgery

Latest Review Date: April 2018
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. 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.

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 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:

The most recent literature review was performed through February 5, 2018. Searches on subtalar arthroereisis (STA) have identified few published studies, primarily consisting of single-institution case series and individual case reports, reporting on success rates following this

procedure. There is a small controlled trial of STA compared with alternative treatments. The following is a summary of the key literature to date.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function- including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

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 eight 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 three 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 one 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 two 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 two complications in each group, with removal of the hardware in one patient and removal of the implant in two 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 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.

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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 calcaneus 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 Brancheau 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.

Section Summary: Flatfoot

The evidence evaluating the use of STA for treatment of flatfoot consists mainly of single-arm case series and a small nonrandomized controlled trial comparing STA with lateral column calcaneal lengthening. 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 of particular importance because the procedure is often performed in growing children. Also, some studies have reported high rates of complications and implant removal.

Talotarsal Joint Dislocation

Bresnahan et al (2013) reported on a prospective study of talotarsal stabilization using HyProCure in 46 feet of 35 patients diagnosed with recurrent and/or partial talotarsal joint dislocation. 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 (/100) for 30 patients had improved from 69.53 preoperatively to 89.27 postoperatively. 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.

Section Summary: Talotarsal Joint Dislocation

The current evidence on the use of STA for treatment of talotarsal joint dislocation is insufficient to draw conclusions about treatment efficacy with certitude.

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.

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 non-explanted 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.

Summary of Evidence
For individuals who have flatfoot or talotarsal joint dislocation 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 of particular importance because the procedure is often performed in growing children. In addition, some studies have reported high rates of complications and implant removal. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
National Institute for Clinical Excellence
Guidance from the National Institute for Health and Care Excellence (2009) concluded that current evidence on the safety and efficacy of sinus tarsi implant insertion for mobile flatfoot was inadequate in quality and quantity.

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.

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

Approved by Governing Bodies:

A number of implants have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process, and are summarized in Table 1. In general, these devices are indicated for insertion into the sinus tarsi of the foot, allowing normal subtalar joint motion while blocking excessive pronation.

Table 1. Representative Subtalar Implant Devices Cleared by FDA[a]

Device	Manufacturer	Date Cleared	510(k) No.
Subtalar MBA®	Integra LifeSciences	07/96	K960692
OsteoMed Subtalar Implant System	OsteoMed	08/03	K031155
BioPro Subtalar Implant	BioPro	09/04	K041936
HyProCure Subtalar Implant System	Graham Medical Technologies	09/04	K042030
MBA $_{resorb}$ Implant	Kinetikos Medical	09/05	K051611
Metasurg Subtalar Implant	Metasurg	05/07	K070441
Subtalar Implant	Biomet Sports Medicine	07/07	K071498
Arthrex ProStop Plus Arthroereisis Subtalar Implant	Arthrex	01/08	K071456
Trilliant Surgical Subtalar Implant	Trilliant Surgical	02/11	K103183
Metasurg Subtalar Implant	Metasurg	08/11	K111265
NuGait™ Subtalar Implant System	Ascension Orthopedic	08/11	K111799
Disco Subtalar Implant	Trilliant Surgical	12/11	K111834
OsteoSpring FootJack Subtalar Implant System	OsteoSpring Medical	12/11	K112658
IFS Subtalar Implant	Internal Fixation Systems	12/11	K113399
The Life Spine Subtalar Implant System	Life Spine	06/16	K160169

FDA: Food and Drug Administration.

[a] FDA 510(k) database search product code HWC (03/08/18).

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:

0335T Extra-osseous subtalar joint implant for talotarsal stabilization

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.

28725 Arthrodesis, subtalar

28735 Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (e.g., flatfoot correction)

28740 Arthrodesis, midtarsal or tarsometatarsal, single joint

29907	Arthroscopy, subtalar joint, surgical; with subtalar arthrodesis
28899	Unlisted procedure, foot or toes

HCPCS:

S2117	Arthroereisis, subtalar

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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 Panel, 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
Medical Policy Panel, September 2015
Medical Policy Group, October 2015 (**2**): 2015 Updates to Key Points, Current Coding, and References, no change in policy statement.
Medical Policy Panel, August 2017
Medical Policy Group, August 2017 **(7)**: Updates to Key Points. No change in Policy Statement.
Medical Policy Panel, April 2018
Medical Policy Group, April 2018 **(7)**: Updates to Key Points and Approved by Governing Bodies. 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.