Policy Statement

Subtalar arthroereisis is considered **investigational**.

Policy Guidelines

There is no specific CPT code for this procedure. It is possible that physicians may use any of the following codes to describe subtalar arthroereisis:

- **28725**: Arthrodesis; subtalar
- **28735**: Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (e.g., flatfoot correction)

**Note**: Arthrodesis describes joint fusion.

The following HCPCS code is specific for this procedure:

- **S2117**: Arthroereisis, subtalar

The following category III code is for insertion of the HyProCure® device:

- **0335T**: Insertion of sinus tarsi implant

The following category III codes are specific to the removal and reinsertion of a sinus tarsi implant:

- **0510T**: Removal of sinus tarsi implant
- **0511T**: Removal and reinsertion of sinus tarsi implant

Description

Arthroereisis is a surgical procedure that purposely limits movement across a joint. Subtalar arthroereisis or extraosseous talotarsal stabilization 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.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.
Regulatory Status

A number of implants have been cleared for marketing by the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
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<tr>
<td>Subtalar MBA®</td>
<td>Integra LifeSciences</td>
<td>07/96</td>
<td>K960692</td>
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<td>08/03</td>
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<td>BioPro</td>
<td>09/04</td>
<td>K041936</td>
</tr>
<tr>
<td>HyProCure Subtalar Implant System</td>
<td>Graham Medical Technologies</td>
<td>09/04</td>
<td>K042030</td>
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<td>MBA Resorb Implant</td>
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<td>K111265</td>
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</table>

*Rationale*

### Background

Subtalar arthroereisis has been performed for more than 50 years, with a variety of implant designs and compositions. The Maxwell-Brancheau Arthroereisis implant is the most frequently reported, although other devices such as the HyProCure, subtalar arthroereisis peg, and Kalix are also described in the medical literature. The Maxwell-Brancheau Arthroereisis 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 Maxwell-Brancheau Arthroereisis 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.

### Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 technology, two domains are examined: the relevance, and 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.

**Clinical Context and Therapy Purpose**

The purpose of subtalar arthroereisis in patients who have flatfoot or who have talotarsal joint dislocation is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does subtalar arthroereisis improve the net health outcome in patients with flatfoot or talotarsal joint dislocation?

The following PICO was used to select literature to inform this review.

**Patients**
The relevant population(s) of interest is individuals with flatfoot and individuals with talotarsal joint dislocation.

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, or it 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.

Talotarsal joint dislocation means that the joint surfaces of the talus are abnormally aligned on the heel and/or navicular bones.

**Interventions**
The therapy being considered is subtalar arthroereisis.

Arthroereisis is a surgical procedure that limits movement across a joint. subtalar arthroereisis (also called extraosseoustalotarsal stabilization) is designed to correct excessive talar displacement and calcaneal eversion by reducing pronation across the subtalar joint. The stabilization procedure is performed by placing an implant in the sinus tarsi, which is a canal located between the talus and the calcaneus.

**Comparators**
Surgical approaches for painful flatfoot deformities include tendon transfers, osteotomy, and arthrodesis. Conservative treatments include orthotics or shoe modifications.

**Outcomes**
The outcomes of interest are symptoms, functional outcomes, and quality of life.

**Flatfoot**
Literature searches on subtalar arthroereisis 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 that has compared subtalar arthroereisis with alternative treatments.

Chong et al (2015) reported on a small prospective nonrandomized trial that compared subtalar arthroereisis with lateral column calcaneal lengthening for the treatment of 24 painful flatfeet in children. Fourteen children (23 feet) enrolled at a children’s medical center were treated with arthroereisis and 8 children (11 feet) enrolled at another children’s hospital were treated with lateral column lengthening. Children who underwent subtalar arthroereisis received a subdermal...
Implant and were placed in below-knee walking casts for three weeks. Children treated with lateral column lengthening had an opening wedge osteotomy with the insertion of a wedge of cadaveric bone and were placed in non-weight-bearing casts for one month and “walker 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 kinematics. Both groups showed statistically significant lateralization of the hindfoot and midfoot center of pressure (p<0.01). There were no between-group differences for any clinical or functional outcomes. On within-group comparison, only the subtalar arthroereisis 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 subtalar arthroereisis group had a statistically significant improvement in this small sample. There were 2 complications in each group, with the 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.

Metcalfe et al (2011) published a systematic review of the literature on subtalar arthroereisis for pediatric flexible flatfoot. Seventy-six case series (none controlled) or case reports were identified. Ten of the studies (756 feet) provided a 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 eight of nine radiographic parameters showed statistically significant improvements following arthroereisis procedures, the relation 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.

Graham et al (2012) published a case series that was not confounded by adjunctive procedures and had a relatively long follow-up. 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 analysis. Adults who met the inclusion and 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 did not complete questionnaire because they had 7 (6%) implants removed. There were 16 revision surgeries with HyProCure; 9 of the surgeries called for the repositioning of a partially displaced device, or a change in the size of the device altogether. 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 have generally not excluded the use of other adjunctive treatments. For example, Vedantam et al (1998) reported on a series of 78 children (140 feet) with neuro-muscular disease who underwent subtalar arthroereisis with an subtalar arthroereisis-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 subtalar arthroereisis-peg cannot be isolated. Nelson et al (2004) reported on 37 patients (67 feet) who received a Maxwell-Brancheau Arthroereisis implant and had 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. In another series, Needleman (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 subtalar arthroereisis, the contribution of the implants to these outcomes is unclear. Also, Needleman (2006) reported an overall complication rate of 46% with surgical removal of 39% of the implants due to sinus tarsi pain; and that postoperative sinus tarsi pain was unpredictable.

Cicchinelli et al (2008) reported on radiographic outcomes in a retrospective analysis of 28 feet in 20 pediatric patients treated with subtalar arthroereisis combined with gastrocnemius recession or with subtalar arthroereisis combined with gastrocnemius recession and medial column reconstruction. Lucaccini et al (2008) 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 subtalar arthroereisis performed in 1 stage. Scharer et al (2010) conducted a retrospective radiographic evaluation of 39 patients (68 feet) who had received the Maxwell-Brancheau Arthroereisis implant to treat painful pediatric flatfoot deformities. Patients’ average age at the time of surgery was 12 years (range, 6-16 years). Additional procedures included 12 (18%) gastrocnemius recessions, 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 a larger or a smaller implant. None of these case series permitted comparison with nonsurgical interventions or with other surgical interventions.

An example of a case series with longer follow-up is the retrospective study by Brancheau et al (2012), which reported on a mean 36-month follow-up (range, 18-48 months) in 35 patients (60 feet) after use of the Maxwell-Brancheau Arthroereisis implant with adjunct procedures. Patients’ mean age 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, talar declination angle). Seventeen percent of patients reported that 9 (15%) implants were removed after the initial surgery. Of the 24 (68.6%) patients 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 Maxwell-Brancheau Arthroereisis implant to these results cannot be determined by this study design.

Section Summary: Flatfoot
The evidence evaluating the use of subtalar arthroereisis for treatment of flatfoot consists mainly of single-arm case series and a small nonrandomized controlled trial comparing subtalar arthroereisis 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 subtalar arthroereisis, 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 (on a score out of 100) for 30 patients had improved from 69.53 preoperatively to 89.17 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 subtalar arthroereisis 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 et al (2007) reported on 2 cases of extensive implant reaction in 2 children 2 years after a subtalar arthroereisis-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 flatfoot in children. In a radiographic study, Saxena and Nguyen (2007) evaluated a bioabsorbable subtalar arthroereisis and 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.

Cook et al (2011) conducted a retrospective case-control study to identify factors that might 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) with patients with nonexplanted arthroereisis who were treated during the same period. Subjects were matched for preoperative radiographic measurements, age, sex, presenting diagnosis, and length of follow-up. Multivariate logistic regression showed no significant effect of age, sex, 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, 1.175) or residual transverse plane-dominant deformities (odds ratio, 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 subtalar arthroereisis, the evidence includes mainly single-arm case series and a small nonrandomized controlled trial comparing subtalar arthroereisis 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 subtalar arthroereisis, 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information
Clinical Input 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 Input
In response to requests from Blue Cross Blue Shield Association, input was received through 2 physician specialty societies and 2 academic medical centers in 2012. Input was mixed, with most reviewers considering this procedure to be investigational.
2009 Input
In response to requests from Blue Cross Blue Shield Association, input was received through 1 physician specialty society (3 reviews) and 5 academic medical centers in 2009. Input was mixed regarding the medical necessity of arthroereisis.

Practice Guidelines and Position Statements
National Institute for Health and Care 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.15

American College of Foot and Ankle Surgeons
In 2004, the American College of Foot and Ankle Surgeons (ACFAS) published practice guidelines for the diagnosis and treatment of pediatric and adult flatfoot (neither is included in the ACFAS library of current clinical practice guidelines).16,17

The ACFAS guidelines on adult flatfoot have stated: “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 guidelines on pediatric flatfoot have stated: “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. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in January 2020 did not identify any ongoing or unpublished trials that would likely influence this review.

References

**Documentation for Clinical Review**

- No records required

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.
IE
The following services may be considered investigational.

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<th>Type</th>
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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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<td>04/03/2009</td>
<td>BCBSA Medical Policy adoption</td>
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Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member’s illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.
Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.