Subtalar Arthroereisis

Policy # 00592
Original Effective Date: 12/20/2017
Current Effective Date: 12/19/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers subtalar arthroereisis (STA) to be investigational.*

Background/Overview

FLATFOOT

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, 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.

Treatment

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.

STA has been performed for more than 50 years, with a variety of implant designs and compositions. The Maxwell-Brancheau Arthroereisis (MBA) implant is the most frequently reported, although other devices such as the HyProCure, STA peg, and Kalix are also described 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.

Flatfoot

Arthroereisis is the limitation of movement across a joint. STA (also called extraosseous talotarsal stabilization) is designed to correct excessive talar displacement and calcaneal eversion by reducing pronation across the subtalar joint.
Talotarsal Joint Dislocation
Extraosseous talotarsal stabilization is also being evaluated as a treatment of talotarsal joint dislocation. The stabilization procedure is performed by placing an implant in the sinus tarsi, which is a canal located between the talus and the calcaneus.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
A number of implants have been cleared for marketing by the U.S. 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 FDAa

<table>
<thead>
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<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>
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<td>09/04</td>
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<td>MBA™ resorb Implant</td>
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<td>09/05</td>
<td>K051611</td>
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<tr>
<td>Metasurg Subtalar Implant</td>
<td>Metasurg</td>
<td>05/07</td>
<td>K070441</td>
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<tr>
<td>Subtalar Implant</td>
<td>Biomet Sports Medicine</td>
<td>07/07</td>
<td>K071498</td>
</tr>
<tr>
<td>Arthrex ProStop Plus Arthroereisis Subtalar Implant</td>
<td>Arthrex</td>
<td>01/08</td>
<td>K071456</td>
</tr>
<tr>
<td>Trilliant Surgical Subtalar Implant</td>
<td>Trilliant Surgical</td>
<td>02/11</td>
<td>K103183</td>
</tr>
<tr>
<td>Metasurg Subtalar Implant</td>
<td>Metasurg</td>
<td>08/11</td>
<td>K111256</td>
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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).

Centers for Medicare and Medicaid Services (CMS)
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.

Rationale/Source
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.

Literature 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 that has compared STA with alternative treatments.

**FLATFOOT**

Chong et al (2015) reported on 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 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 STA received a subdermal implant and were placed in below-knee walking casts for 3 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 1 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 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 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 STA 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 8 of 9 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; nine 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 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. Nelson et al (2004) reported on 37 patients (67 feet) who received a Maxwell-Brancheau Arthroereisis (MBA) 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 STA, 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 STA combined with gastrocnemius recession or with STA 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 STA performed in 1 stage. Scharer et al (2010) conducted a retrospective radiographic evaluation of 39 patients (68 feet) who had received the MBA 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 MBA 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 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 et al (2007) reported on 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 flatfoot in children. In a radiographic study, Saxena and Nguyen (2007) evaluated a bioabsorbable STA 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 STA (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 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. 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.

References

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8. 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


Policy History
Original Effective Date: 12/20/2017
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12/07/2017 Medical Policy Committee review
12/20/2017 Medical Policy Implementation Committee approval. New policy.
12/06/2018 Medical Policy Committee review
12/19/2018 Medical Policy Implementation Committee approval. No change to coverage.
01/01/2019 Coding update
Next Scheduled Review Date: 12/2019

Coding
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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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<th>Code Type</th>
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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.
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For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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