



Louisiana

Subtalar Arthroereisis

Policy # 00592

Original Effective Date: 12/20/2017

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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.

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.

Treatment

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.

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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. For example, in 2004, the HyProCure^{®†} Subtalar Implant System/Extra Osseous Fixation Device (GraMedica, Macomb, MI) was cleared for marketing by FDA through the 510(k) process (K042030); in 2010, the SubFix^{™‡} arthroereisis implant (Memometal Technologies, Bruz, France) was cleared (K093820); and, in 2008, the Arthrex ProStop Plus^{™‡} (Arthrex, Naples, FL) was cleared (K071456). In 1996, the Subtalar MBA^{®‡} Implant (now owned by Integra LifeSciences, Plainsboro, NJ) was cleared for marketing by FDA through the 510(k) process (K960692). FDA determined that the Subtalar MBA Implant was substantially equivalent to existing devices on the market before device regulation. According to the FDA summary, the primary indication for the Subtalar MBA Implant 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.” In 2005, the Subtalar MBA Implant was cleared for marketing by FDA through the 510(k) process (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, K033046), arthroereisis implant Talus of Vilex (TOV; K041289), Instrateck (K080280), and Wright Medical Smith Sta-Peg (K792670). FDA product code: HWC.

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

Searches on 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.

FLATFOOT

In 2015, Chong et al 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 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 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

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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 STA for pediatric flexible flatfoot. Seventy-six case series (none controlled) or case reports were identified. Ten of the studies (756 feet) provided clinician-based assessment of the surgical result graded from “excellent to poor” with follow-up between 36 and 240 months. Six studies (212 feet) included estimates of overall patient satisfaction using nonvalidated outcome measures, while 1 study (16 feet) found significant improvement using a validated foot-specific patient outcome measure. Data from 15 studies that reported radiographic values were combined for analysis. Although 8 of 9 radiographic parameters showed statistically significant improvements following arthroereisis procedures, the 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 published a case series in 2012 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 the 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 implants (6%) 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 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, in 1998 Vedantam et al reported on a series of 78 children (140 feet) with neuromuscular disease who underwent STA with an STA-peg. The stem of this implant is placed into the calcaneus with the collar abutting the inferior surface of the lateral aspect of the talus, thus limiting motion. All but 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 et al reported on 37 patients (67 feet) who underwent 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,

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because results were not compared with controls receiving reconstructive surgery without STA, the contribution of the implants to these outcomes is unclear. In addition, the authors reported an overall complication rate of 46%, with surgical removal of 39% of the implants due to sinus tarsi pain. The authors also commented that postoperative sinus tarsi pain was unpredictable.

Cicchinelli et al (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. In a 2010 study, Scharer et al conducted a retrospective radiographic evaluation of 39 patients (68 feet) who had received the MBA implant to treat painful pediatric flatfoot deformities. The average age of the patients at the time of surgery was 12 years (range, 6-16 years). Additional procedures included 12 (18%) gastrocnemius 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 a 2012 retrospective study by Brancheau et al, 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, and 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.

TALOTARSAL JOINT DISLOCATION

In 2013, Bresnahan et al 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. Patients who had the following characteristics were included: deformity characterized by talar displacement medially, plantarly, and/or anteriorly; collapse of the medial longitudinal arch; hyperpronation about the subtalar joint axis; ability to manipulate the foot to correct the deformity; a prolonged period of pronation or delayed resupination and/or flattening of the arch; and anteroposterior/dorsoplantar and lateral weight-bearing radiographs revealing talotarsal misalignment. No procedures besides insertion of the HyProCure device were performed to address the talotarsal joint dislocation. At 1 year postoperatively, scores on the Maryland Foot Score (/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.

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ADVERSE EVENTS

Complications are frequently reported in the literature. Scher et al (2007) reported on 2 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 STA in the treatment of painful flatfoot in children. A radiographic study (2007) on a bioabsorbable STA found poor outcomes in 3 of 6 patients who met the inclusion criteria and consented to additional imaging. Two patients requested implant removal; a third patient had persistent pain but refused explantation. Radiographic measurement (magnetic resonance imaging or computed tomography) found that these 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 before implantation. They concluded that the current width and length of commercially available implants may need to be modified and that more research and long-term clinical study would be needed.

Cook et al (2011) conducted a retrospective case-control study to identify factors that may contribute to failure (explantation) of titanium arthroereisis implants. All patients who required removal of a self-locking wedge-type STA (n=22) were compared in a 1:2 ratio (n=44) with patients with nonexplanted arthroereisis who were treated during the same time period. Subjects were matched for preoperative radiographic measurements, age, sex, 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, 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. 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.

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Policy History

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12/07/2017 Medical Policy Committee review

12/20/2017 Medical Policy Implementation Committee approval. New policy.

08/14/2018 Coding update

Next Scheduled Review Date: 12/2018

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Code Type	Code
CPT	0335T, 28899
HCPCS	S2117
ICD-10 Diagnosis	M21.40-M21.42, Q66.50-Q66.52

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- 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:
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- 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.

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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