Prior Authorization Review  
Panel MCO Policy Submission  

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

<table>
<thead>
<tr>
<th>Plan: Aetna Better Health</th>
<th>Submission Date: 11/01/2018</th>
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<tbody>
<tr>
<td><strong>Policy Number:</strong> 0669</td>
<td><strong>Effective Date:</strong></td>
</tr>
<tr>
<td><strong>Policy Name:</strong> Subtalar Implant for Foot Deformity</td>
<td><strong>Revision Date:</strong></td>
</tr>
</tbody>
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**Type of Submission – Check all that apply:**
- [ ] New Policy
- [x] Revised Policy*
- [ ] Annual Review – No Revisions

*All revisions to the policy must be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:

**CPB 0669 Subtalar Implant for Foot Deformity**

Clinical content was last revised 09/15/2016. Additional non-clinical updates were made by Corporate since the last PARP submission, as documented below.

Revision and Update History since last PARP submission:
11/16/2017 - This CPB has been updated with additional background information and references.
07/12/2018 – Next tentative scheduled review date by Corporate (not yet released by corporate).

Name of Authorized Individual (Please type or print):

Dr. Bernard Lewin, M.D.

Signature of Authorized Individual:
Subtalar Implant for Foot Deformity

Policy

Aetna considers subtalar implants experimental and investigational for the treatment of subtalar instability, talipes equinovarus deformity (club foot), foot drop (dangle foot), and flatfoot deformity including congenital and adult-onset (acquired) flatfoot deformity (e.g., pes planus, pes planovalgus, pes valgus) and posterior tibial tendon dysfunction) or any other conditions because their clinical value has not been established.

Aetna considers the following subtalar implants experimental and investigational because their effectiveness has not been established:

- Angled Subtalar Implant (ASI)
- Arthrex Prostop and Arthrex Prostop Plus Subtalar Arthroereisis Implant
- Bioarch Subtalar Arthroereisis Implant
- bioBLOCK Resorbable Subtalar Implant
- BioPro Horizon Subtalar Implant

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Policy History

Last Review
11/16/2017
Effective: 08/22/2003
Next Review: 07/12/2018

Definitions

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Please see amendment for Pennsylvania Medicaid at the end of this CPB.
▪ Conical Subtalar Implant (CSI)
▪ Disco Subtalar Implant
▪ Extraosseous Talotarsal Stabilization (EOTTS)
▪ Futura Angled Subtalar Implant
▪ Futura Conical Subtalar Implant
▪ HyProCure Sinus Tarsi Implant
▪ IFS Subtalar Implant
▪ Instratek Sub-Talar Lok Arthroereisis Implant System
▪ Kalix II
▪ Lundeen Subtalar Implant
▪ Maxwell-Brancheau arthroereisis (MBA) Implant
▪ MBA Resorb Implant
▪ MetaSurg BioArch Subtalar Implant System
▪ Nexa Orthopedics Subtalar Peg
▪ Normed Vario Subtalar Screw
▪ OsteoMed Talar-Fit Subtalar Implant System
▪ OsteoSpring Footjack Subtalar Implant System
▪ Smith Subtalar Arthroereisis Implant
▪ Solana Surgical Gaitway Implant
▪ STA-Peg
▪ SubFix Arthroereisis Implant
▪ Subtalar Maxwell-Brancheau Arthroereisis (MBA) Implant System
▪ Sub-Talar Lok Arthroereisis Subtalar Implant System
▪ Talus of Vilex (TOV) Subtalar Implant
▪ Trilliant Twist Subtalar Implant.

Background

Flatfoot (hyperpronation and flattening-out of the longitudinal arch) (also known as pes planus or pes planovalgus) is a common deformity among children and adults. Another cause of flatfoot can be attributed to posterior tibial tendon dysfunction. Conservative treatments to relieve pain from the foot and leg associated with flatfoot include orthotics, stretching exercises, and medication (e.g., non-steroidal anti-inflammatory drugs). Corticosteroid injections continue to be controversial. These methods may fail to provide relief and do
not provide any correction at the point of contact. Various surgical techniques of subtalar joint arthroereisis have been used in the treatment of patients who have failed conservative approaches. Some surgeons use bone blocks and bone grafts placed into the sinus tarsi to limit excessive subtalar joint pronation. Others advocate the use of endoprosthetic devices.

Arthroereisis is the limitation of exogenous joint motion without complete arthrodesis. Subtalar arthroereisis is a surgical procedure that involves placing an implant that has the appearance of a threaded cylinder into the sinus tarsi between the talus and calcaneus (heel) to stabilize the foot. It may be performed on both children and adults for congenital and adult onset flatfoot (eg, pes planus, pes planovalgus and pes valgus) deformities.

Examples of U.S. Food and Drug Administration (FDA) cleared implants utilized during subtalar arthroereisis include, but may not be limited to: Arthrex ProStop Plus Arthroereisis subtalar implant; HyProCure subtalar implant system; OsteoMed Subtalar implant; Solana Surgical Gaitway implant; subtalar arthroereisis peg; Silastic silicone sphere; SubFix arthroereisis implant; Sub Talar Lok implant; Subtalar Maxwell-Brancheau Arthroereisis (MBA) system; and Trilliant Surgical subtalar implant.

The Subtalar MBA implant (KMI - Kinetikos Medical Incorporated, San Diego, CA) was cleared by the U.S. Food and Drug Administration (FDA) via a 510(k) premarket notification in 1996. It is an "internal orthotic" designed for correction of pediatric pes valgus and adult posterior tibial dysfunction deformity. There are 5 different MBA implant sizes: 6, 8, 9, 10, and 12 mm in diameter. The implant is a soft-threaded titanium device that is inserted into the sinus tars. It aims to restore the arch by blocking the anterior and inferior displacement of the talus and by preventing the foot from pronating; thus allowing normal subtalar joint motion.
Tissue grows normally around the implant and aids in holding it in place. In adults, ancillary procedures may be performed simultaneously (e.g., an Achilles tendon lengthening if an equines deformity is present). The patient can ambulate the day after surgery in a Cam Walker for approximately 3 weeks. Thereafter, regular shoes can be worn with an ankle brace for an additional 2 to 3 weeks.

Husain and Fallat (2002) performed biomechanical analysis of MBA implants in fresh-frozen cadaver limbs to quantitate the effects on subtalar joint motion restriction and radiographic angles. This study did not contain any clinical data on the value of MBA implants.

Well-designed studies are needed to ascertain the effectiveness and durability of the Subtalar MBA implant for the treatment of pathologic flatfoot.

Needleman (2006) ascertained the functional outcomes as well as radiographical results of adult patients who had an operation for flexible flatfeet without any hind-foot osteotomies or fusions. A total of 28 feet in 23 patients with problems caused by their flexible flatfoot deformities had reconstructive foot and ankle surgery that included a subtalar arthroereisis with the MBA sinus tarsi implant. The American Orthopedic Foot and Ankle Society (AOFAS) Hind-foot Scale and a patient assessment questionnaire were obtained from all patients before surgery and at final follow-up. Pre-operative and post-operative standing radiographs were analyzed to determine radiographical correction of the deformities. The average follow-up was 44 months. The MBA implant was surgically removed in 11 of 28 feet (39%) because of sinus tarsi pain. The average pre-operative AOFAS score was 52 and had improved to 87 ($p < 0.00001$) at final follow-up. The average response to 4 of 5 questions in the patient assessment had significantly improved ($p < 0.05$). On a 10-point scale, average patient satisfaction was 8.3 points; 78% said that they would have the surgery again. Correction after surgery was
significant (p < 0.0001) in each of the 3 radiographical parameters evaluated for ‘correction with MBA’ and “final correction”. With the numbers available, no significant differences could be detected after the MBA was removed. Complications included sinus tarsi pain in 46% (13) of the 28 feet in this study; after implant removal, 73% (8) of 11 feet had less discomfort than before surgery with AOFAS scores 80 or better. The author concluded that reconstructive foot and ankle surgery that included a subtalar arthroereisis with the MBA sinus tarsi implant resulted in favorable clinical outcomes and patient satisfaction in 78% (18) of 23 patients. In spite of the high incidence of temporary sinus tarsi pain until the implant was removed, this operative approach compares favorably with other operations for flexible flatfoot deformities in adults. The major drawbacks of this study were its small sample size as well as the multiple etiologies of the flexible flatfoot deformity (13 feet had congenital etiologies and 15 feet had acquired etiologies). Other pitfalls of this study included the 42% occurrence of sinus tarsi discomfort and the associated 8 post-operative months of pain until the implant was removed.

In a review on acquired adult flatfoot deformity (AAFD), Pinney and Lin (2006) described the key elements of AAFD and outlined therapeutic options based on the peer-reviewed literature. The authors stated that the limited research on subtalar arthroereisis (the use of a sinus tarsi plug or implant to restrict eversion of the subtalar joint) in adult patients with AAFD means that there is insufficient evidence to make a recommendation for or against this treatment option.

The Interventional Procedures Advisory Committee of the National Institute for Clinical Excellence (NICE, 2008) examined sinus tarsi implant insertion for mobile flatfoot. Provisional recommendations from the Committee stated “[c]urrent evidence on the safety and efficacy of sinus tarsi implant for mobile flatfoot is inadequate in quality and quantity”. Furthermore, a review of the published literature on
this procedure that was commissioned by NICE (2008) identified 8 case series and 4 case reports (643 feet) of sinus tarsi implant insertion for mobile flatfoot; no prospective comparative data were found. The published literature focused mainly on the pediatric population. Only 1 case series (n = 23) was reported in adults. The provisional review found that the procedures described in the studies varied significantly, particularly in relation to the design, size and instrumentation/insertion of the implant(s). The Committee recommended that this procedure should only be used with special arrangements for clinical governance, consent and audit or research. Formal guidance on this procedure (NICE, 2009) concluded: "Current evidence on the safety and efficacy of sinus tarsi implant insertion for mobile flatfoot is inadequate in quality and quantity. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research."

In a retrospective study, Scharer et al (2010) evaluated the outcome of pediatric patients who have undergone MBA subtalar implants for the treatment of painful pediatric flatfoot deformities. A total of 39 patients (68 feet) were evaluated clinically and radiographically. The mean age of the patients was 12 years (range of 6 to 16 years). The mean period of follow-up was 24 months (range of 6 to 61 months). Statistical evaluation was performed on all radiographical measurements. Additional surgical procedures (gastrocnemius recession, Achilles tendon lengthening, Kidner posterior tibial tendon advancement) were performed in 22 of 68 feet. There were 10 (15 %) complications, which consisted of 10 re-operations in 10 feet. Implants were exchanged in 9 feet because of implant migration, under-correction, and over-correction. There was 1 re-operation (in 1 foot) for implant removal because of persistent sinus tarsi pain. Radiographical evaluation demonstrated an improvement of all parameters determined. The parameters that were evaluated include talo-navicular joint coverage, as well as lateral and anterior-posterior talo-calcaneal angles. There were significant
changes noted in pre- and post-operative measurements ($p < 0.001$). The authors concluded that the MBA implant is effective for the correction of painful, flexible flatfoot deformity in children in short-term follow-up. However, this is a multi-planar deformity, and additional procedures may be needed in addition to the MBA.

Yu et al (2011) reviewed the application progress of subtalar arthroereisis for the correction of pediatric flatfoot in children and analyzed the problems at present as well as to predict the trend of development in the field. Domestic and abroad literature concerning the methods of subtalar arthroereisis applied in pediatric flatfoot in recent years was reviewed extensively and thoroughly analyzed. Subtalar arthroereisis has proved to yield good results for correction of the flatfoot in children. In addition to the advantages of subtalar arthroereisis for pediatric flatfoot treatment (simple procedure, mature technology, and less complications), it allows further surgery if needed. The authors concluded that subtalar arthroereisis is a simple and effective way to treat flatfoot in children, however, its biomechanics mechanism and managements to complication need to be explored further.

Metcalf et al (2011) noted that pediatric flexible flatfoot is a common deformity for which a small, but significant number undergo corrective surgery. Arthroereisis is a technique for treating flexible flatfoot by means of inserting a prosthesis into the sinus tarsi. The procedure divides opinion in respect of both its effectiveness and safety. A database search up until 2010 was used to find articles regarding arthroereisis in pediatric patients. These researchers summarized the findings of this study. A total of 76 studies were identified; 8 of the 9 radiographical parameters reported show significant improvement following arthroereisis reflecting both increased static arch height and joint congruency. Calcaneal inclination angle demonstrated the least change with only small increases following arthroereisis. Arthroereisis remains associated with a number of complications including sinus tarsi pain, device
extrusion, and under-correction. Complication rates range between 4.8 % and 18.6 % with unplanned removal rates between 7.1 % and 19.3 % across all device types. The authors concluded that current evidence is limited to consecutive case series or ad hoc case reports. Limited evidence exists to suggest that devices may have a more complex mode of action than simple motion blocking or axis altering effects. The interplay between osseous alignment and dynamic stability within the foot may contribute to the effectiveness of this procedure. They stated that although literature suggests patient satisfaction rates of between 79 % to 100 %, qualitative outcome data based on disease specific, validated outcome tools may improve current evidence and permit comparison of future study data.

In a retrospective study, Graham et al (2012a) determined the long-term functional outcomes and device tolerance achieved in adult patients who chose to undergo an extra-osseous talotarsal stabilization (EOTTS) procedure HyProCure for the treatment of flexible talotarsal joint deformity. A total of 83 adult patients participated in this study. Post-operative subjective assessment of device performance was evaluated using Maryland Foot Scores, which were collected at a mean follow-up period of 51 months. The mean post-operative Maryland Foot Score was 88 out of 100; post-operatively, 52 % of cases reported complete alleviation of foot pain, 69 % of cases had no limitations on their foot functional abilities, and 80 % of cases reported complete satisfaction with the appearance of their feet. The implant was removed in 7 out of 117 cases (removal rate: 6 %) due to prolonged pain of the anterior talofibular ligament (4 cases), psychogenic reaction (2 cases), and post-operative infection (1 case). The authors concluded that the long-term positive subjective outcomes and excellent patient satisfaction obtained in this study may imply that EOTTS was effective in stabilizing the talotarsal joint complex and eliminating excessive abnormal pronation, thus reducing pain and improving quality of life of the patients; it represents a possible treatment option for partial talotarsal
dislocation in cases with flexible and reducible deformity. This study had several major drawbacks: (i) 16 subjects underwent revision surgeries, (ii) the effectiveness of the HyProCure device as a stand-alone procedure is unclear since 32% of the cases (35 of 110 feet in whom the implants were not removed) were performed with adjunctive procedures to achieve the desired amount of correction, and (iii) these researchers failed to quantify the improvement in terms of pre-operative subjective participant satisfaction scores.

Graham et al (2012b) determined radiographic correction achieved in adult patients treated with an EOTTS procedure. Patients diagnosed with flexible/reducible talotarsal joint dislocation (partial) underwent surgical correction with the HyProCure EOTTS device. Pre-operative and post-operative weight-bearing radiographs taken in the antero-posterior (AP) and lateral views for a total 95 feet (in 70 patients) were analyzed to determine standardized radiographic angles, and to quantify the correction obtained after the EOTTS procedure. Post-operative radiographs were taken at an average follow-up of 17 days from the surgery date. The mean pre-operative and post-operative talar 2nd metatarsal angles (measured from the AP radiographs) were 24.8° ± 1.0° and 5.8° ± 0.9°, respectively, that is, mean decrease by 19°. The mean pre-operative and post-operative talar declination angles (measured from the lateral radiographs) were 25.1° ± 0.7° and 19.4° ± 0.5°, respectively, that is, mean decrease by 5.7°. The mean pre-operative and post-operative calcaneal inclination angles (measured from the lateral radiographs) were 21° ± 0.7° and 21.8° ± 0.7°, respectively, that is, mean increase by 0.8°. Post-operatively, the talar 2nd metatarsal and talar declination angles were reduced to average values reported in the literature for normal feet. The authors concluded that the findings of this study showed the effectiveness of a minimally invasive EOTTS procedure in restoring the normal angular relationships between hind-foot
and fore-foot osseous structures on weight-bearing, in both the transverse and sagittal planes. They noted that this indicated that stabilization of the talotarsal joint complex and elimination of hyper-pronation, which may lead to reduced pain, improved foot functional abilities, and patient satisfaction. The drawbacks of this study included (i) its retrospective nature, and (ii) the lack of pre-operative lateral radiographs in the talotarsal joint neutral position, which resulted in an inability to determine whether the HyProCure device was completely successful in re-aligning the talonavicular joint to its maximally neutral position.

In a prospective, multi-center, case-series study, Bresnahan et al (2013) evaluated the subjective outcomes in patients after EOTTS using the HyProCure stent as a stand-alone procedure for the treatment of recurrent and/or partial talotarsal joint dislocation (RTTD) in a population of pediatric and adult patients. Recurrent and/or partial talotarsal joint dislocation has been cited as a possible etiology for a number of foot ailments and might contribute to the development of pathologic features localized more proximally in the weight-bearing musculoskeletal chain. Correction of RTTD might, therefore, lead to the reduction of pathologic features associated with this deformity. A total of 46 feet in 35 patients were included in the present study. Subjective evaluation used the Maryland Foot Score assessment, which was obtained pre-operatively and 1, 2, and 3 weeks, 1, 2, 3, and 6 months, and 1 year post-operatively. The mean overall scores improved from a pre-operative value of 69.53 ± 19.56 to a post-operative value of 89.17 ± 14.41 at the 1-year follow-up. Foot pain decreased by 36.97 %, foot functional activities improved by 14.39 %, and foot appearance improved by 29.49 %. The greatest magnitude of improvement occurred 4 weeks post-operatively, with gradual improvement continuing through to the 1-year follow-up. Implants were removed from 2 patients (2 feet, 4.35 %). No unresolved complications were observed. The authors concluded that the positive subjective outcomes resulting from
the EOTTS procedure suggested that the intervention employing the HyProCure device alleviated pain and improved foot function and appearance in patients with RTTD. The drawbacks of this study included (i) the broad nature of the inclusion and exclusion criteria, including a lack of measurement of certain variables (e.g., the planar dominance of the recurrent talotarsal deformity, the presence of certain secondary conditions, as well as the relative activity level, all of which could have affected the subjective outcomes), and (ii) there was a significant number of subjects lost to follow-up and incomplete data at the 1-year post-operative assessment, as 46 feet in 35 pre-operative subjects decreased to 30 feet in 21 subjects.

Shah and colleagues (2015) noted that subtalar arthroereisis (SA) has been a procedure used for the correction of painful flexible flatfoot deformity in adults and children. Clinical studies of patients who had a SA are sparse and with mixed results and variable indications. These researchers determined the current practice among orthopedic foot and ankle specialists regarding SA. Web-based questionnaires were e-mailed to members of the AOFAS. Requested information included demographics and practice patterns in regard to performing SA surgery. A total of 572 respondents completed the survey (32 % response rate). A total of 273 respondents (48 %) have performed SA. Of this group, 187 respondents (69 %) still perform this procedure (33 % of total respondents currently perform SA). Of the respondents, 401 (70 %) practice in the United States, 40 % have performed SA, and 60 % of those still perform this procedure. Of non-US respondents, 66 % have performed SA, and 80 % of those still perform it. The most common US indications are painful congenital flatfoot, posterior tibial tendon dysfunction, and flatfoot associated with accessory navicular. The authors concluded that many doctors have performed SA, and a significant number no longer perform this procedure for various reasons. A greater percentage of non-US practitioners have performed and
continue to perform SA than their counterparts in the US. There is a common list of surgical indications. Most doctors who still perform this procedure have removed the implants, commonly for pain.

Gross and colleagues (2015) noted that as the number of total ankle replacements (TARs) performed has risen, so has the need for revision. These investigators performed a systematic review of clinical outcomes following a salvage ankle arthrodesis from a failed TAR to identify patient- and technique-specific prognostic factors and determined the clinical outcomes and complications following an ankle arthrodesis for a failed TAR. They searched PubMed, Medline, EMBASE, and the Cochrane Central Register of Controlled Trials for studies that analyzed ankle fusion after failed TAR with a minimum follow-up of 1 year. These investigators included 16 studies (193 patients). The majority of patients (41%) underwent the index TAR for rheumatoid arthritis. The majority of these revision surgeries were secondary to component loosening, frequently of the talar component (38%). In the cases that were revised to an ankle arthrodesis, 81% fused after their first arthrodesis procedure. The intercalary bone graft group and the blade plate group had the highest rate of fusion after the first attempt at fusion at 100%, whereas the tibiotalocalcaneal fusion with cage group had the lowest fusion rate at 50%. The overall complication rate was 18.2%, whereas the overall nonunion rate was 10.6%. The authors concluded that a salvage ankle arthrodesis for a failed TAR resulted in favorable clinical end-points and overall satisfaction at short-term follow-up if the patients achieve fusion. The bone graft fusion and blade plate group resulted in the highest first-attempt fusion rate, with a low complication rate. Moreover, they stated that future studies should include prospective, comparative control or surgical groups and use standardized outcome measurements that will make direct comparisons easier.
Saxena and colleagues (2016) noted that the implant used for subtalar joint arthroereisis (STA) often needs to be removed because of sinus tarsi pain. They reported that endoscopic gastrocnemius recession did not exert any influence on the rate of implant removal \((p = 0.19)\). After STA for adult acquired flatfoot deformity, 22% of the implants were removed. No significant difference was found in the incidence of removal according to patient age or endoscopic gastrocnemius recession. However, a significant difference was found for implant size, with 11-mm implants explanted most frequently.

### CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

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<th>Code</th>
<th>Code Description</th>
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<td>CPT codes not covered for indications listed in the CPB:</td>
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<td>0335T</td>
<td>Extra-osseous subtalar joint implant for talotarsal stabilization</td>
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<td>29907</td>
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<td>HCPCS codes not covered for indications listed in the CPB:</td>
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<td>Q66.80 - Q66.89</td>
<td>Other congenital deformities of feet</td>
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The above policy is based on the following references:


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Amendment to
Aetna Clinical Policy Bulletin Number:
0669 Subtalar Implant for Foot Deformity

There are no amendments for Medicaid.

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