Medical Coverage Policy

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Subtalar Arthroereisis

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INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses subtalar arthroereisis, also referred to as extraosseous subtalar joint implantation, a surgical procedure in which an implant is inserted into the sinus tarsi. The procedure has been proposed for the treatment of pes planus, posterior tibial tendon dysfunction, and talotarsal joint dislocation.

Coverage Policy

Subtalar arthroereisis/extraosseous talotarsal stabilization is considered experimental, investigational or unproven for ANY indication, including but not limited to treatment of any of the following:

- rigid or flexible pes planus (i.e., flatfoot)
- posterior tibial tendon dysfunction
- talotarsal joint subluxation/dislocation

General Background

Pes planus (i.e., flatfoot), also referred to as pes planovalgus, is defined as the loss of the normal medial longitudinal arch, and may be characterized as flexible or rigid. Most cases of pes planus are flexible, with

presence of a normal arch during non-weight bearing that flattens when weight bearing. If an acceptable medial longitudinal arch does not appear with non-weight bearing, pes planus is considered to be rigid. Anatomical abnormalities that may be associated with pes planus include a valgus posture of the heel; mild subluxation of the subtalar joint; eversion of the calcaneus at the subtalar joint; lateral angulation at the midtarsal joint; supination of the forefoot relative to the hindfoot; and shortening of the Achilles tendon. Pes planus may be congenital or acquired. The condition often begins in childhood or adolescence and may persist into adulthood, although many children with pes planus outgrow the condition with no treatment. The occurrence of flatfeet can be caused by many factors. It could be present at birth (congenital pes planus) or develop later in life (acquired pes planus). Congenital flatfeet is found to be highest in African-American women. Acquired flatfeet can be caused by age, obesity and not wearing footwear in early childhood. In addition, improper function of extrinsic and intrinsic foot muscles at birth or later in life has been reported to cause flat foot (Kodithuwakku Arachchige, et al., 2019). Pes planus may be associated with pain in the heel, arch, ankle, or along the outside of the foot, pain from shin splints, and weakness or fatigue in the foot or leg.

Treatment options for symptomatic pes planus include foot orthoses, stretching, shoe modification, nonsteroidal anti-inflammatory drugs (NSAIDS), physical therapy, and corticosteroid injections. Surgery may be considered when conservative treatment does not adequately alleviate symptoms. Surgical options include arthrodesis, osteotomy, excision of bone or bone spurs, synovectomy, or tendon transfer. Operative management usually involves a combination of bony and soft-tissue procedures performed during the same operation, and rarely involves an isolated procedure. Arthroereisis (i.e. stabilization of the joint using an implant), also referred to as extraosseous subtalar joint implantation, has been investigated as a surgical treatment of pes planus, posterior tibial tendon dysfunction and talotarsal joint dislocation. Arthroereisis may be performed alone or in combination with other procedures. Arthroereisis is intended to decrease subtalar range of motion, improve the weight-bearing position during the gait cycle, and limit calcaneal eversion, by the insertion of an implant into the sinus tarsi. Implant devices can be classified into the following three categories based on their biomechanical properties: self-locking wedges, axis-altering devices, and implant blocking devices. Complications of subtalar arthroereisis include persistent sinus tarsi pain, foreign body reaction, implant failure, talar fracture and osteonecrosis of the talus (Campbell's Operative Orthopaedics, 2017; Soomekh and Baravarian, 2006; Pinney and Linn, 2006; Lee, et al., 2005; Harris et al., 2004).

U.S. Food and Drug Administration (FDA)
Numerous implants have received U.S. FDA approval through the 510(k) process, including but not limited to the following:

- Arthrex ProStop Plus™ Arthroereisis Subtalar Implant (Arthrex, Inc., Naples, FL)
- HyProCure Subtalar Implant System (Graham Medical Technologies, LLC, Shelby Township, MI)
- MBA Resorb Implant (Kinetikos Medical Inc. Carlsbad, CA)
- OsteoMed Subtalar Implant System (OsteoMed L.P., Addison TX)
- STA-Peg Implant (Wright Medical, Arlington,TN)
- SubFix™ Arthroereisis Implant (Memometal Technologies, Bruz, France)
- Subtalar Arthrorisis Implant (Nexa Orthopedics, Inc., Vista, CA)
- Subtalar Lok Implant (Instratek, Inc., Spring, TX)
- Subtalar MBA System (KMI [Kinetikos Medical Inc.], San Diego, CA)
- Subtalar Peg Implant (Nexa Orthopedics, Inc., Vista, CA)
- Talus of Vilex (TOV) (Vilex, Inc., Pittsburgh, PA)
- The Life Spine Subtalar Implant System (Life Spine Incorporated, Huntley, IL)

Literature Review
A Hayes Medical Technology Directory report evaluated the evidence (n=7 studies/161 patients) on subtalar arthroereisis (SA) for the correction adult-acquired flatfoot deformity (AAFD). The review included a prospective pretest/posttest study, a retrospective cohort study and retrospective studies evaluating the procedure performed in adults. Follow-up timeframes ranged from 1.25 to 76 months. In general, patients were included who had painful flatfoot deformity refractory to non-surgical management. Definitive patient selection for the use of SA for the treatment of AAFD were not determined due to insufficient published evidence. There were no studies found that compared subtalar arthroereisis to established surgical procedures. Infrequent complications included superficial wound infection and implant dislocation or fracture and resolved with removal of the implant without

irreversible sequelae. The report summarized that the studies consistently demonstrated positive effects such as improved pain and functionality after subtalar arthroereisis. However, the overall body of evidence was found to be of insufficient for adults limiting the ability to draw conclusions regarding safety and efficacy (Hayes, 2012).

A Hayes Medical Technology Directory report evaluated the evidence on subtalar arthroereisis for the correction of pediatric flexible flatfoot (FFF) (n=11 studies/893 patients) and pediatric spastic flatfoot (n=2 studies/41 patients). The FFF studies included a prospective comparative cohort study; a retrospective comparative cohort study and nine retrospective cohort studies and spastic FF studies included two retrospective comparative cohort studies. Follow-up timeframes for pediatric flexible flatfoot (FFF) ranged from 1.1 year to 12.6 years, although some findings were reported at a follow-up of three months. Follow-up timeframes for spastic flat foot (FF) ranged from 2.3–6.0 years. In general patients were included who had painful flatfoot deformity refractory to non-surgical management. Definitive patient selection criteria were not determined due to insufficient evidence in the published literature. Additionally, it is difficult to specify the necessity for surgical correction as FFF trends toward gradual resolution with age in a large majority of cases. Implant removal or revision due to pain, implant dislocations, or fractures occurred in 2.3%–28.6% of patients with idiopathic FFF. One study in patients spastic FF reported a revision rate of 38.5% due to implant fracture or displacement of which 50%–83% occurred in patients who did not undergo Achilles tendon lengthening. No deaths related to SA were reported. The report summarized the overall body of evidence was found to be of low-quality for children with FFF limiting the ability to draw firm conclusions regarding safety and efficacy. For children with spastic FF, there is a lack of evidence and the overall quality of evidence is very low. The report concluded there is a need for additional well-designed studies evaluating the long-term efficacy and safety of SA and to define patient selection criteria (Hayes, 2012).

A prospective case series conducted by Saxena et al. (2016) evaluated the rate and risk factors for implant removal due to sinus tarsi pain following subtalar joint arthroereisis (STA) in adults treated for acquired flatfoot deformity including posterior tibial tendon dysfunction (PTTD). The inclusion criteria were an arthroereisis procedure for adult acquired flatfoot deformity (AAFD)/PTTD, age > 18 years and a follow-up period of two years. Patients (n=100) underwent 104 STA procedures. The mean follow-up period was 6.5 (range 2–17) years with two patients lost to follow-up. The outcome measured the incidence of STA implant removal patients treated for AAFD/PTTD. The study also assessed whether age, size of implant or endoscopic gastrocnemius recession (EGR) affected the incidence of implant removal. The overall incidence of implant removal was 22.1%. Patient age was not clinically significant (p=0.09) however, implant size was clinically significant (p=0.02) with 11-mm implants removed more frequently. Endoscopic gastrocnemius recession did not exert any influence on the rate of implant removal (p=0.19). The author noted limitation of the study was the lack of some follow-up data, such as removal of the STA implant elsewhere after our evaluation and lack of radiographic analysis pre- and postoperatively. Other factors that were not considered in the study might have contributed to implant removal, including body mass index and the severity of the deformity. Future studies should consider evaluation of these factors. The authors concluded that removal of the implant is common due to sinus tarsi pain.

Bresnahan et al. (2013) reported preliminary outcomes of a prospective case series to evaluate subjective outcomes after extraosseous talotarsal stabilization using the HyProCure stent as a standalone procedure for treatment of recurrent and/or partial talotarsal joint dislocation (35 patients/46 feet). Pediatric (> three years old) and adult patients 18 years or older were included. Inclusion criteria were kept intentionally broad to an effort to promote external validity. The Maryland Foot Score (MFS) questionnaire was used to evaluate outcomes and patient satisfaction. At one year, the mean MFS score improved from 69.53 ± 19.56 to 89.17 ± 14.41. Foot pain decreased by 63.97%, foot functional activities improved by 14.39%, and foot appearance improved by 25.49%. Implants were removed in two patients; one due to discomfort when walking and during activates and one due to failure to relieve symptoms. At six months, four patients (six feet) showed no improvement in MFS scores, and at one year, three patients (six feet) showed no improvement. At one year, 14 of 35 patients (16 of 30 feet) were lost to follow-up.

A retrospective review by Graham et al. (2012) was conducted to determine long-term functional outcomes and device-tolerance following treatment of flexible talotarsal joint deformity using the HyProCure device (n=83, 117 feet). The mean postoperative Maryland Foot Score (MFS) was 88 out of 100; 52% of patients reported complete alleviation of foot pain, 69% had no limitations on their feet functional abilities, and 80% were completely satisfied with the appearance of their feet. The implant was removed in seven of 117 feet (6%) due to prolonged pain (4), psychogenic reaction (3), and postoperative infection (1). The authors stated that, based on positive

long-term subjective outcomes, this procedure may be a treatment option for stabilizing the talotarsal joint and eliminating pain and improving quality of life. The authors acknowledged limitations of this study, including the inability to quantify improvement in terms of preoperative subjective patient satisfaction scores due to the study's retrospective nature.

Brancheau et al. (2012) published a retrospective review of 35 consecutive patients with flexible flatfoot treated with the Maxwell-Brancheau Arthroereisis (MBA) implant from 1996 to 2000. The mean age at the time of treatment was 14.3 years (range 5–46 years). Sixty adjunct procedures were performed in the 35 included patients in conjunction with the implant procedure. Preoperative and postoperative anteroposterior and lateral radiographs of angles (talocalcaneal, calcaneocuboid, first to second intermetatarsal angle, calcaneal inclination, and talar declination) were compared at a mean of 36 months (range 18–48 months) and improvements were all considered to be statistically significant ($p<0.001$) The authors noted that correction of radiographic parameters is not always a reliable predictor of patient satisfaction with a surgical outcome, and that the presence of pain or disability is a more reliable indicator of surgical success. A subgroup of 24 patients also answered a subjective questionnaire at a mean of 33 months (range 12–55 months) postoperatively. The presenting chief complaints were resolved in 23 of the 24 patients. Patients reported no pain in 24 of 40 feet, moderate pain in two feet, and mild pain in 13 feet. There was an 11.9% complication rate. Pain and restricted motion of the subtalar joint was the most common complaint requiring implant removal; implants were removed in nine patients. The authors noted limitations of the study, included inclusion of patients of all ages without survey validated for all age groups, significant numbers of patients lost to follow-up, and lack of statistical analysis that may have allowed associations between variables and specific outcomes.

Metcalfe et al. (2011) conducted a meta-analysis to evaluate arthroereisis in the treatment of pediatric flatfoot. Seventy-six studies met the inclusion criteria. Data could not be pooled for statistical analysis due to several factors; the literature consists primarily of ad hoc case reports and retrospective case series; methodological variations (e.g. device type, inclusion criteria, surgical technique, adjunctive procedures, and outcome measures). Few studies applied validated clinical or patient reported outcome measures. Eight of the nine radiographic parameters reported showed significant improvement following arthroereisis reflecting increased static arch height and joint congruency. Only small increases were seen in calcaneal inclination angle. Arthroereisis is associated with a number of complications, including sinus tarsi pain, device extrusion, and under-correction. Complication rates ranged between 4.8% and 18.6%, with unplanned removal rates between 7.1% and 19.3%. The authors stated that although literature suggests high patient satisfaction rates, qualitative outcome data based on disease specific, validated outcome tools may improve current evidence and permit comparison of future study data.

Scharer et al. (2010) conducted a retrospective review to evaluate outcomes of pediatric patients who received Maxwell-Brancheau arthroereisis (MBA) subtalar implants for treatment of painful flatfoot deformities. The authors reviewed charts and radiographs of 39 patients (68 feet) treated between 2000 and 2006. The mean age was 12 years (range 6–16 years), and the mean period of follow-up was 24 months (range 6–61 months). The surgical procedures consisted of 68 MBA implants, 12 gastrocnemius recessions, six Achilles tendon lengthenings, and four Kidner procedures. There were ten (15%) complications, consisting of ten re-operations in ten feet. Implants were exchanged in nine feet due to implant migration, under-correction, and overcorrection. One reoperation was performed for implant removal due to persistent sinus tarsi pain. Radiographic evaluation demonstrated an improvement in talonavicular joint coverage and lateral and anterior-posterior talocalcaneal angles. The authors noted that significantly more study is needed on subtalar arthroereisis; additional studies should evaluate long-term follow-up in pediatric patients to assess the longevity of correction and need for future treatment.

Needleman (2006) conducted a case series to determine the functional outcomes and radiographic results of reconstructive foot and ankle surgery that included arthroereisis with the Maxwell-Brancheau Arthroereisis (MBA) sinus tarsi implant. A total of 23 patients (28 feet) were treated between 1998 and 2003. Indications for surgery and study inclusion were failure of nonoperative management to relieve foot pain and restriction of activity because of flexible flatfoot in adult patients. The average follow-up was 44 months. The average preoperative American Orthopaedic Foot and Ankle Society (AOFAS) score was 52, improving to 87 at final follow-up ($p<0.00001$). The average overall satisfaction was 8.3 on a 10-point scale, and 18 patients (78%) said they

would have the surgery again. The MBA implant was surgically removed in 11 of 28 feet (39%) because of sinus tarsi pain. In 9 of these 11 feet, the implant was removed eight months or more after the procedure.

A retrospective review conducted by Nelson et al. (2004) evaluated the results of arthroereisis with the MBA implant in 37 patients (67 feet) treated for flexible flatfoot by a single surgeon between 1998 and 2002. Included patients had failed an average of eight months of conservative therapy consisting of any combination of shoe-gear modifications, activity modifications, physical therapy, stretching exercises, oral anti-inflammatory medication, over the counter shoe inserts, and prescription orthotics. The average age at the time of surgery was 13.7 years (range 6–45), and the average age of pediatric patients was 11.9 years (range 6–17). Radiographic measurements showed significant improvement in the talo-first metatarsal angle, lateral talar declination angle and talocalcaneal angle. Of the 37 patients, 34 were pediatric, and 27 returned a postoperative Child Health Questionnaire (CHQ). The questionnaire was completed by a parent. Preoperative CHQs were not completed. The postoperative results were therefore compared to population norms. The results of the CHC, demonstrated scores better than population norms in the role emotional behavior domain, global behavior domain, and parent time domain, with no difference in the remaining domains. Two patients with pain due to sinus tarsi syndrome required implant removal, and two patients required implant readjustment because of poor positioning.

Available evidence on the safety and efficacy of subtalar arthroereisis for the treatment of pes planus consists primarily of case series and retrospective analyses with limited follow-up (Indino, et al., 2020; Junxian, et al., 2020; Walley, et al., 2019; Caravaggi, et al., 2018; Viladot Voegeli, et al., 2018). There is insufficient evidence in the published medical literature to compare the safety, efficacy, and long-term outcomes of this procedure with the results of conservative treatment or alternative surgical procedures.

Professional Societies/Organizations
American College of Foot and Ankle Surgeons (ACFAS): The ACFAS published a consensus statement on the appropriate clinical management of adult-acquired flatfoot deformity (AAFD). The consensus statement stated that the following is neither appropriate nor inappropriate: subtalar arthroereisis should not be considered as a single corrective procedure for stage IIB AAFD. There is limited literature demonstrating the use of a subtalar implant alone to address pronation of the foot in type IIa deformity. The ACFAS also stated that the most identified complication is sinus tarsi pain due to presence of the implant; explantation resolves the pain (Piraino, et al., 2020).

Use Outside the U.S.
National Institute for Health and Clinical Excellence (NICE) (United Kingdom): NICE interventional procedure guidance issued in 2009 stated that current evidence on the safety and efficacy of sinus tarsi implant insertion for mobile flatfoot is inadequate in quality and quantity, and encourages further research to define patient selection criteria, address uncertainties about using the procedure in children and adults, include descriptions of adjunctive procedures, and provide long-term outcome data. Studies comparing the outcomes of the procedure with the natural history of mobile flatfoot would also be useful.

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Experimental/Investigational/Unproven/Not Covered when used to report subtalar arthroereisis/extra-osseous talotarsal stabilization.

CPT®* Codes	Description
28899	Unlisted procedure, foot or toes
0335T	Insertion of sinus tarsi implant

HCPCS Codes	Description
S2117	Arthroereisis, subtalar

***Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.**

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