



Cigna Medical Coverage Policy

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Subject **Subtalar Arthroereisis**

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. 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. 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. Proprietary information of Cigna. Copyright ©2014 Cigna

Coverage Policy

Cigna does not cover subtalar arthroereisis/extracapsular talotarsal stabilization for the treatment of any condition, including but not limited to treatment of the following because it is considered experimental, investigational or unproven (this list may not be all inclusive):

- 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. 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, and osteonecrosis of the talus (Lee et al., 2005; Harris et al., 2004; Soomekh and Baravarian, 2006; Pinney and Linn, 2006; Campbell's Operative Orthopaedics, 2012).

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)

Literature Review

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 activities 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 7 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 ($p < .0001$). 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 2 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, including 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.

Metcalf 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.

Vedantam et al. (1998) conducted a retrospective review to evaluate the results of 140 arthroereisis procedures using ultrahigh-molecular-weight polyethylene (UHMWPE) STA-peg implants in 78 ambulatory children. The majority of included patients (78) had cerebral palsy. The indications for surgery were a progressive hindfoot valgus deformity associated with a neuromuscular disorder, with difficulty in shoe or orthotic wear resulting in poor gait. The average age of included patients was seven years, nine months. The average follow-up was four years, six months. The majority of patients had at least one concomitant surgical procedure to balance the soft tissue and muscles involved in foot motion. Patients were evaluated based on the presence of pain and hindfoot valgus deformity. Satisfactory results were seen in 135 feet (96.4%). The results were unsatisfactory in one foot of each of the five patients who received bilateral implants, resulting in implant removal.

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. 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

A clinical practice guideline on the diagnosis and treatment of adult flatfoot disorders published by the American College of Foot and Ankle Surgeons (ACFAS), states that long-term results of arthroereisis have not been established. The guideline also states that some surgeons advise against the subtalar arthroereisis procedure because of the risks associated with implantation of a foreign material, the potential need for further surgery to remove the implant, and the limited capacity of the implant to stabilize the medial column sag directly.

An ACFAS practice guideline on pediatric flatfoot states that proponents of this procedure argue that it is a minimally invasive technique that does not distort the normal anatomy of the foot, while others have expressed concern about placing a permanent foreign body into a mobile segment of a child's foot. The guideline further states that the indication for this procedure remains controversial in the surgical community.

Use Outside the U.S.

National Institute for Health and Clinical Excellence (NICE) (United Kingdom)

NICE interventional procedure guidance issued in 2009 states 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.

Summary

Treatment options for symptomatic pes planus (i.e., flatfoot) include foot orthoses, stretching, shoe modification, nonsteroidal anti-inflammatory drugs (NSAIDs), physical therapy, and corticosteroid injections. Surgical options, including arthrodesis, osteotomy, excision of bone or bone spurs, synovectomy, or tendon transfer, may be considered when conservative treatment does not adequately alleviate symptoms. Subtalar arthroereisis, also referred to as extraosseous subtalar joint implantation, a surgical procedure in which an implant is inserted into the sinus tarsi, has been investigated in the treatment of pes planus in children and adults, and has also been proposed for the treatment of posterior tibial tendon dysfunction and talotarsal joint dislocation. Evidence published to date consists primarily of case series and retrospective analyses with limited follow-up. 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.

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	Extra-osseous subtalar joint implant for talotarsal stabilization

HCPCS Codes	Description
S2117	Arthroereisis, subtalar

*Current Procedural Terminology (CPT®) © 2013 American Medical Association: Chicago, IL.

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