SUBTALAR ARTHROEREISIS

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
**POLICY DESCRIPTION:**

This policy describes the use of subtalar arthroereisis (also referred to as arthroisis) and extrosseous talotarsal stabilization (EOTTS), as surgical interventions designed to correct painful flatfoot, stabilize and prevent redislocation of the talotarsal joint, and improve overall foot alignment.

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 may be acquired in adulthood due to posterior tibial tendon dysfunction, which in turn may be caused by trauma, overuse, and inflammatory disorders, among others. Symptoms include a dull aching throbbing cramping pain that may be described as growing pains, gait disturbance, and heel cord tightness which causes withdrawal from physical activity. Conservative treatments for painful flatfoot deformities include orthotics, foot exercises and/or shoe modifications. Surgical approaches include tendon transfers, osteotomy, and arthrodesis.

Subtalar arthroereisis may be performed alone or in combination with other comprehensive surgical procedures for ankle and foot conditions.

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**COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:**

Subtalar arthroereisis is considered **EXPERIMENTAL AND/OR INVESTIGATIONAL** and **NOT MEDICALLY NECESSARY** for all indications, including but not limited to the treatment of flatfoot conditions, symptomatic flexible flatfoot deformity, and posterior tibial tendon dysfunction (PTTD).

Extraosseous subtalar joint implantation is considered **EXPERIMENTAL AND/OR INVESTIGATIONAL** and **NOT MEDICALLY NECESSARY** for all indications, including but not limited to, talotarsal joint stabilization.

The evidence in the published medical literature on subtalar arthroereisis is inadequate to permit scientific conclusions. The main limitation is the lack of controlled studies comparing the use of the implants with other surgical procedures, alone or in combination. Other limitations of the published data are the lack of long-term outcomes, particularly important since the procedure is often performed in growing children, and the difficulty in separating the effect of this procedure from that of other adjunctive treatments. In addition, some publications report high rates of complications and implant removal. Therefore, subtalar arthroereisis is considered investigational.

Clinical Considerations:

In adults, a compression dressing is followed by a cast for 4 to 6 weeks, an ankle walker boot for 2 to 4 weeks, and the transition between boot and full-time use of supportive footwear with an arch support as the final step. Time to weight bearing depends on the associated procedures (from ≥ 2 weeks).

In children, allowed walking with full weight bearing as soon as possible unless gastrocnemius lengthening was performed, which required the use of a walker in the neutral position for 2 to 4 weeks. A walking cast must be applied for 4 weeks postoperatively, with weight-bearing mobilization 1 week postoperatively.

Possible Complications: The most common complication appears to be continued postoperative pain. Complications also include implant dislocations (van Ooij et al., 2012) or implant fractures, pain, sinus tarsi tenderness/tarsitis (approximately 20% to 45% of patients in some studies), mild stiffness and transient decrease in power at the ankle joint, forefoot supinatus, and superficial infections. Talus fracture, implant...
reactions, and migration have been reported (Evans and Rome, 2011; Corpuz et al., 2012).

**Contraindications:**
- Active local infection and/or any evidence of infection.
- Allergic reaction to foreign bodies.
- Poor or insufficient bone stock.
- The presence of any clinical or functional abnormalities that would preclude the potential of achieving a good result for the patient.
- Other conditions that may place the patient at risk (physiologically).

**BACKGROUND:**

Flatfoot (FF) is a progressive developmental or acquired deformity characterized by plantar medial rotation of the talus, decrease in medial arch height, and abduction of the forefoot. FF is the most frequent condition seen in pediatric orthopedic clinics (Evans and Rome, 2011). In the pediatric population, estimation of prevalence is difficult due to variations in the specific definitions. Some reports noted prevalence ≥ 2.7% to 18%, and prevalence differs between age groups. A certain degree of flatness of the foot in children is considered physiological; in such cases, the medial arch height appears to be a function of weight, age, gender, hypermobility, and footwear. An inverse relationship between age and FF has been suggested, and boys are more often affected compared with girls. Prevalence increases with body weight and generalized joint hypermobility (Evans, 2008; Evans and Rome, 2011). Compared with whites, prevalence is higher among African Americans and lower among Asian Americans (Shibuya et al., 2010). FF may be an isolated clinical entity or it may be a finding associated with local or systemic abnormalities such as posterior tibial tendon dysfunction (PTTD), generalized ligamentous laxity, neurological or muscular disorders, genetic syndromes, or collagen disorders. In adults, conditions such as PTTD may lead to weight shift medially, followed by elongation of the supporting structures of the medial longitudinal arch, loss of arch height, and eventually rearfoot valgus (Adelman et al., 2008).

Diagnosis focuses on measurements of arch height, heel eversion angle, and establishment of level of FF flexibility by means of footprint assessment, x-rays, and visual observation. Clinical categories of FF include flexible flatfoot (FFF), characterized by a normalization of arch during non weight-bearing, and rigid flatfoot (RFF). FF may not always be associated with symptoms and may or may not lead to functional defects. The signs and symptoms include pain along the medial side of the foot, pain in the sinus tarsi, knee pain, decreased endurance, gait disturbances, and heel cord tightness (Evans and Rome, 2011; Metcalfe et al., 2011).

Debate is ongoing regarding the necessity of treatment and treatment options; however, it is generally accepted that symptomatic FF, RFF, progressive FF, or withdrawal from physical activity due to FF renders a need for detailed evaluation and accurate diagnosis. Untreated FF may lead to aberration of gait function and increased risk of injury. In untreated PTTD, the end result is rigid ankle valgus deformity and degenerative arthrosis of the midfoot and hindfoot requiring more invasive treatment options. Treatment options for FF consist of conservative measures and surgical correction. Conservative treatment options for children primarily include in-shoe foot orthoses and foot exercises, such as barefoot time, and prescribed activities (e.g., picking up marbles). When conservative measures fail at producing symptomatic relief, surgical management is indicated. There are no well-accepted objective parameters for surgical indications.
exist (Adelman, et al. 2008; Jerosch et al., 2009; Evans and Rome, 2011; Metcalfe et al., 2011).

The purpose of surgical intervention is to improve overall foot alignment and to reduce or eliminate pain. Surgical options include arthrodesis (joint fusion), osteotomy, and subtalar arthroereisis (SA). Standard operative treatment in children is subtalar arthrodesis. However, joint fusion may be associated with operative morbidity and longer-term sequelae with eventual transfer of energy to non-fused joints. Tarsal joint fusion and osteotomy have a potential for nonunion and growth plate disturbance. Soft tissue and bony reconstruction procedures such as hindfoot, midfoot, and forefoot osteotomies may be associated with questionable long-term correction. SA avoids distortion of the normal anatomy of the foot and is the least invasive operative intervention for FFF. SA has been associated with rapid recovery and potential for “reversibility” in case of failure. A distinct advantage of the arthroereisis procedure in the pediatric population is that the implant provides structural realignment of the rearfoot complex during skeletal growth, which may lead to permanent correction as the skeletal system matures (Adelman, et al. 2008; Jerosch et al., 2009; Evans and Rome, 2011; Metcalfe et al., 2011).

Subtalar arthroereisis (SA) involves limitation of subtalar joint pronation by placement of an “implant” or “stent” into the sinus tarsi. The purpose of the stent is to prevent abnormal rotation of the tarsus by producing a supinatory effect on the tarsus. It rotates the talus dorsally and externally, inverts the calcaneus and cuboid, and inverts and dorsiflexes the navicular relative to the cuboid during closed kinetic chain loading. It shifts loads from the medial to lateral column and decreases the movement about the talonavicular joint compared with a flattened foot without the implant. Correction is achieved by stimulation of proprioceptive foot receptors, allowing active inversion of the foot and normal subtalar joint motion while blocking excessive pronation (Jerosch et al., 2009; Cook et al., 2011; Metcalfe et al., 2011). The procedure may be performed under local, regional, or general anesthesia (Needleman, 2006; Koning et al., 2009). Various devices, including silicone, bio-resorbable, seated, and free-floating devices, have been used to serve as an “implant” into the sinus tarsi, and complications may vary depending on the device used (Jerosch et al., 2009; Metcalfe et al., 2011). While current arthroereisis devices are implanted using near-identical technique, details of the surgical approach may contribute to SA failure (Cook et al., 2011; Metcalfe et al., 2011). Procedures performed in association with SA may contribute to radiographic correction (Cicchinelli et al., 2008).

**Associated Procedures:** The following procedures may be performed when indicated based on flat foot etiology and associated/coexistent pathology: Achilles tendon lengthening, Broström lateral ankle ligament reconstruction, dorsal opening wedge medial cuneiform (Cotton) osteotomy with iliac crest allograft bone, flexor digitorum longus (FDL) tendon transfer, interosseous release, gastrocnemius lengthening, gastrocnemius resection, Lapidus first metatarsotarsal joint arthrodesis with modified McBride bunionectomy, medial column reconstruction, sinus tarsi evacuation, spring ligament reconstruction.

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**REGULATORY STATUS:**

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):**

   Subtalar arthroereisis (SA) is a procedure and therefore not subject to FDA regulation. However, SA implant devices are subject to FDA regulation. Several devices have been evaluated and cleared for marketing by the FDA.

   In May 2010, the FDA evaluated the SubFix Arthroereisis Implant (Memometal Technologies) (K093820;
approved May 19, 2010), which was found to be substantially equivalent to several previously evaluated devices, including (CDRH, 2010):

- Smith Subtalar Peg (Dow Corning Wright) (K792670): Approved February 22, 1980 (CDRH, 1980)
- Subtalar MBA System (Kinetkos Medical; now owned by Integra) (K960692): Approved July 23, 1996 (CDRH, 1996)
- Nexa Orthopedics Subtalar (Nexa Orthopedics) (K032902): Approved August 22, 2003 (CDRH, 2003b)
- Subtalar Peg Implant (Nexa Orthopedics) (K033046): Approved December 23, 2003 (CDRH, 2003c)
- Talus of Vilex (TOV) (Vilex Inc.) (K041289): Approved August 5, 2004 (CDRH, 2004)
- MBAResorb Implant (Kinetikos Medical; now owned by Integra) (K051611): Approved September 6, 2005 (CDRH, 2005)
- Arthrex ProStop Plus Arthroereisis Implant (Arthrex Inc.) (K071456): Approved January 17, 2008 (CDRH, 2008a)
- Sub-Talar Lok (Instratek Inc.) (K080280): Approved March 14, 2008 (CDRH, 2008b)

In summary, the FDA states that the SubFix Arthroereisis Implant and the predicate devices have similar design characteristics and intended use. The new device is substantially equivalent to the predicate devices and should not introduce new concerns in terms of safety or effectiveness.

According to the FDA statement on intended use, the SubFix Arthroereisis Implant is intended to treat the hyperpronated foot and stabilize the subtalar joint. It is intended to block forward, downward, and medial displacement of the talus, thus blocking excessive pronation and the resulting sequela. The SubFix Arthroereisis Implants are intended for single use only (CDRH, 2010).

According to the FDA Summary of Safety and Effectiveness, use of the MBAResorb Implant is contraindicated in patients with the following conditions (CDRH, 2005):

- Active local infection and/or any evidence of infection.
- Allergic reaction to foreign bodies.
- Poor or insufficient bone stock.
- The presence of any clinical or functional abnormalities that would preclude the potential of achieving a good result for the patient.
- Other conditions that may place the patient at risk (physiologically).

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):

According to the “Medicare Benefit Policy Manual” (MBPM), Chapter 15, Section 290, Medicare-covered foot care services only include medically necessary and reasonable foot care.

Certain foot care related services are not generally covered by Medicare. In general, the following services, whether performed by a podiatrist, osteopath, or doctor of medicine, and without regard to the difficulty or complexity of the procedure, are not covered by Medicare:

1. **Treatment of Flat Foot.** The term “flat foot” is defined as a condition in which one or more arches of the foot have flattened out. Services or devices directed toward the care or correction of such conditions, including the prescription of supportive devices, are not covered.
2. **Routine Foot Care.**
   Except as discussed below in the section entitled “Conditions that Might Justify Coverage”, routine foot care is excluded from coverage. Services that normally are considered routine and not covered by Medicare include the following:
   - The cutting or removal of corns and calluses;
   - The trimming, cutting, clipping, or debriding of nails; and
   - Other hygienic and preventive maintenance care, such as cleaning and soaking the feet, the use of skin creams to maintain skin tone of either ambulatory or bedfast patients, and any other service performed in the absence of localized illness, injury, or symptoms involving the foot.

3. **Supportive Devices for Feet.** Orthopedic shoes and other supportive devices for the feet generally are not covered, except Medicare does cover such a shoe if it is an integral part of a leg brace, and its expense is included as part of the cost of the brace. Also, a narrow exception permits coverage of special shoes and inserts for certain patients with diabetes.

### MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):

#### Non-Covered Services
The following list includes, but is not limited to, podiatry services which are not covered by MHCP:
- Subluxation of the foot
- Treatment of flat feet
- Routine foot care
- Services not covered by Medicare, or services denied by Medicare

**CLINICAL EVIDENCE:**

**SUMMARY:**

The evidence in the published medical literature from the past 10 years consists of retrospective case series with small sample sizes, variable specific indications and heterogeneity in surgical approaches, implant devices, and concomitant procedures. There is significant variability in outcome measures. The limitations common across many of the studies include small sample sizes and no power analysis, subjective outcome measures, inconsistent statistical analysis (one study did not report any statistical analysis), potential operator bias, and use of concomitant procedures potentially affecting outcome. Only four studies used validated tools for subjective outcome measures such as pain and quality of life. Assessors of clinical and radiographic outcomes often were the same persons performing the procedure. The quality of the body of evidence for all outcome measures and safety is low due to lack of high-quality prospective studies. No recent studies with randomization of treatment arms and comparison with other procedures commonly used for flatfoot (FF) were identified. Other limitations of the published data is the lack of long-term outcomes, particularly important since the procedure is often performed in growing children, and the difficulty in separating the effect of this procedure from that of other adjunctive treatments. In addition, some publications report high rates of complications and implant removal. Therefore, subtalar arthroereisis is considered investigational. Thus, it is difficult to draw a more definitive conclusion regarding the safety or efficacy of subtalar arthroereisis (SA) and the associated procedures for each particular outcome measure.
for each particular combination of pathological conditions.

APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<td>S2117</td>
<td>Arthroereisis, subtalar</td>
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<tr>
<td>727.9</td>
<td>Unspecified disorder of synovium, tendon and bursa (including posterior tibial tendon dysfunction)</td>
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<td>734</td>
<td>Flat foot</td>
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<tr>
<td>754.61</td>
<td>Congenital pes planus</td>
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<td>81.18</td>
<td>Subtalar joint arthroereisis</td>
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<tr>
<td>28899</td>
<td>Unlisted procedure, foot or toes [when specified as subtalar arthroereisis]</td>
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<tr>
<td>0335T</td>
<td>Extra-osseous subtalar joint implant for talotarsal stabilization</td>
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REFERENCES:


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