Subtalar Arthroereisis

(701104)

Medical Benefit

Effective Date: 10/01/08  
Next Review Date: 11/18

Preauthorization

No  
Review Dates: 07/07, 07/08, 09/09, 03/10, 01/11, 01/12, 01/13, 01/14, 11/14, 11/15, 11/16, 11/17

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

### Populations

- **Individuals:** With flatfoot

### Interventions

- **Interventions of interest are:** Subtalar arthroereisis

### Comparators

- **Comparators of interest are:** Alternative surgical procedures

### Outcomes

- **Relevant outcomes include:**
  - Symptoms
  - Functional outcomes
  - Quality of life

### Description

Arthroereisis is a surgical procedure that purposely limits movement across a joint. Subtalar arthroereisis (STA) or extraosseous talotarsal stabilization is designed to correct excessive talar displacement and calcaneal eversion by reducing pronation across the subtalar joint. Extraosseous talotarsal stabilization is also being evaluated as a treatment of talotarsal joint dislocation. It is performed by placing an implant in the sinus tarsi, which is a canal located between the talus and the calcaneus.

### 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.
Policy
Subtalar arthroereisis is considered investigational.

Background

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 standalone 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.

Regulatory Status
A number of implants have been cleared for marketing by the U.S. Food and Drug Administration (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 the 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). The 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® device 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 MBA® Implant was cleared for marketing by FDA.
through the 510(k) process (K051611). This implant employs the same basic mechanical features as the predi-
cate 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.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are
considered investigational. For explanation of experimental and investigational, please refer to the Technology
Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to
conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced
procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to
products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references
below.

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