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## **Subtalar Implant**

**Policy Number: HS-034**

**Original Effective Date: 7/17/2008**

**Revised Date(s): 7/23/2009; 7/28/2010;  
8/2/2011**

### **DISCLAIMER**

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

### **APPLICATION STATEMENT**

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

## BACKGROUND

The Food and Drug Administration (FDA) issued initial 510(k) approval (K960692) for KMI's Subtalar MBA Orthopedic Foot Implant on July 23, 1996. This device is indicated 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 while blocking excessive pronation and the resulting sequelae.

A second version of the MBA Implant, the MBA Resorb Implant, received 510(k) approval (K051611) on September 6, 2005. The indications for this device are slightly different from the original as it is made from a different material. It is approved as an internal support for primary surgical interventions in the treatment of flatfoot, providing structural support during the first 3 months of healing.

The subtalar MBA Implant is an "internal orthotic" designed for correction of pediatric pes valgus and adult posterior tibial dysfunction deformity. It is made of titanium and is available in five different sizes: 6, 8, 9, 10 and 12 mm. The implant is surgically placed into the sinus tarsi. It aims to restore the arch of the foot by blocking the anterior and inferior displacement of the talus and by preventing the foot from pronating. The implant permits normal subtalar joint motion while stimulating tissue to grow around the implant, which aids in holding the implant in place.

The MBA Resorb Implant is a soft-threaded (poly L-lactide) device designed to be inserted between the posterior and middle facets of the subtalar joint. The design differs from the predicate subtalar MBA device only in that the material is reabsorbed into the body (Hayes, 2006).

Also, the American College of Foot and Ankle Surgeons published clinical practice guidelines which include subtalar arthroereisis in a list of surgical options for flexible flatfeet. These guidelines note the controversial nature of this surgical technique.

Data in the published literature is inadequate to permit scientific conclusions. One limitation of the published data is the lack of long term outcomes, particularly important since the procedure is often performed in growing children. Well-designed studies are needed to ascertain the effectiveness and durability of the subtalar arthroereisis implant for the treatment of pathologic flatfoot.

## POSITION STATEMENT

Subtalar implants (arthroereisis) for the treatment of pediatric and adult flexible flatfoot **is considered experimental and investigational.**

## CODING

### Non Covered CPT\* Codes

**28899†** Unlisted procedure, foot or toes  
†Note Experimental/Investigational/Unproven/Not Covered when used to report subtalar arthroereisis.

### Non Covered ICD-9 Procedure

**81.18** Subtalar joint arthroereisis

### Non Covered HCPCS Codes

**S2117\*** Arthroereisis, subtalar

**\*S- Codes are NON COVERED FOR MEDICARE – Refer to HCPCS Level II Temporary National Codes**

**Non Covered ICD-9-CM Diagnosis Codes**

- 734** Flat foot
- 736.79** Other acquired deformities of ankle and foot
- 754.61** Congenital pes planus
- 754.69** Other valgus deformities of feet

**\*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

**REFERENCES**

**Peer Reviewed**

1. Canale and Beaty: Campbell's Operative Orthopaedics, 11 Edition. 2007.
2. Harris et al. Diagnosis and treatment of pediatric flatfoot. Journal of Foot and Ankle Surgery. 2004.
3. Hayes Search and Summary. Maxwell-Bracheau Arthroereisis (MBA®) (Kinetikos Medical Inc.) Implant for Treatment of Flexible Flatfoot. ARCHIVED. 2006.
4. Lee et al. Diagnosis and treatment of adult flatfoot. Journal of Foot and Ankle Surgery. 2005.
5. Marx et al. What's New in Foot and Ankle Surgery. Journal of Bone and Joint Surgery. 2008.

**Government Agencies, Professional and Medical Organizations**

1. Centers for Medicare and Medicaid Services. Coordination and Maintenance Committee. Subtalar Joint Arthroereisis. 2005.

**HISTORY AND REVISIONS**

<b>Date</b>	<b>Action</b>
12/1/2011	<ul style="list-style-type: none"><li>• New template design approved by MPC.</li></ul>
8/2/2011	<ul style="list-style-type: none"><li>• Approved by MPC. No changes.</li></ul>