Clinical Review Criteria
Subtalar Arthroereisis for the Treatment of Pes Planus (Flat Feet)

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Criteria
For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
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<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>Medicare Benefit Policy Manual (MBPM) Chapter 15 section 290 – Foot Care, B. Exclusions from Coverage</td>
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<tr>
<td>National Coverage Determinations (NCD)</td>
<td>None</td>
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<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
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<tr>
<td>Local Coverage Article</td>
<td>None</td>
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</tbody>
</table>

For Non-Medicare Members
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
Flatfoot is a progressive developmental or acquired deformity characterized by plantar medial rotation of the talus, decrease in the medial arch height, and supination and abduction of the forefoot. The posterior tibial tendon may weaken and tear and the talo-navicular capsule, the tibio-navicular ligament, the spring ligament, the long and short plantar ligaments and the plantar aponeurosis may become stretched. There is a shift in the load from lateral column to the medial column, which may cause the medial arch to flatten further (Arangio 2007).

Flexible flatfoot is also referred to as “collapsing pes valgo planus” in which collapsing refers to the flexibility of the deformity, pes refers to the foot, planus refers to the flattened arch, and vulgus refers to the everted calcaneous (Forg 2001). It is one of the most common foot deformities in adults and can cause pain, fatigue, night cramps, and abnormal gait.

A vast majority of flexible flatfeet can be controlled with functional orthoses, but the worst deformities may require surgical intervention to reconstruct the foot deformity and reduce posterior tendon dysfunction. Many surgical procedures as tendon and muscle lengthening, osteotomies, arthrodesis, and arthroereisis have been described (Saxena 2007).

Arthroereisis was developed more than 30 years ago to be used in combination with other bone and soft tissue procedures. It involves placing various shaped implants beneath the talus to limit excessive eversion while preserving inversion. The implants are intended to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation. They do not replace reconstructive surgery, but are used in conjunction with other operative soft-tissue and bony procedures (Needleman 2006, Saxena 2007).
The operative procedure includes inserting the arthroereisis implant after correcting all parts of the flatfoot deformity and associated conditions in sequence; ankle, hindfoot, midfoot and forefoot. To date there are at least four cylindrical metallic implants (composed of titanium alloys) designed to be placed under the talus in the tarsal canal and sinus tarsi lesion. They range from 6 -14 mm in width, and 12-18 mm in length. The Futura Biomedical Subtalar Peg Implant, the Maxwell-Brancheau Arthroereisis (MBA) Sinus Tarsi Implant, the Kalix device, and the HyProCure Sinus Tarsi implant are all approved by the Food and Drug Administration for use as an internal support to primary surgical interventions in the treatment of flatfoot. The devices are contraindicated in cases of active local infection, allergic reactions to foreign bodies, poor or insufficient bone stock, the presence of clinical or functional abnormalities that would prevent the potential of achieving good results, or other conditions that may place the patient at risk.

**Medical Technology Assessment Committee (MTAC)**

**Subtalar Arthroereisis**

06/04/2007: MTAC REVIEW

**Evidence Conclusion:** There is insufficient published evidence to determine the efficacy and safety of Arthroereisis in the treatment of flexible flatfeet in adults. The published studies on the technology are only small case series with no comparison groups to compare the outcomes of the intervention to alternative therapies.

**Articles:** The search revealed around twenty articles on subtalar arthroereisis for the correction of flatfeet in adults. There were no randomized or non-randomized controlled trials that compared the procedure with an alternative therapy. The majority of the published articles reported on experimental studies performed on cadavers. The reports on human adult patients were either case reports or case series with less than 25 patients. The largest were two case series (Needleman 2006, and Viladot 2003) with 23 and 21 patients respectively, and each on a different arthroereisis implant. Both were critically appraised. Needleman RL. A surgical approach for flexible flatfeet in adults including a subtalar arthroereisis with MBA Sinus tarsi Implant.  Foot & Ankle International 2006;27:9-18. See Evidence Table. Viladot R, Pons M, Alvarez F, et al. Subtalar arthroereisis for posterior tibial tendon dysfunction. A preliminary report.  Foot & Ankle International 2003;24:600-606. See Evidence Table.

The use of Subtalar Arthroereisis in the treatment of Pes Planus does not meet the Kaiser Permanente Medical Technology Assessment Criteria.