Clinical Policy Title: Subtalar arthroereisis (implant)

Clinical Policy Number: 14.03.05

Effective Date: April 1, 2017
Initial Review Date: August 17, 2016
Most Recent Review Date: September 21, 2017
Next Review Date: September 2018

Related policies:

CP# 14.03.04 Total ankle replacement

ABOUT THIS POLICY: AmeriHealth Caritas Louisiana has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Louisiana’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas Louisiana when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Louisiana’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Louisiana’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Louisiana will update its clinical policies as necessary. AmeriHealth Caritas Louisiana’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas Louisiana considers the use of subtalar arthroereisis to be investigational, and therefore, not medically necessary.

Limitations:

All other uses of subtalar arthroereisis are not medically necessary.

Alternative covered services:

- Orthotics.
- Physical therapy.
- Prescription drug therapy.
- Short leg walking cast or brace.
- Surgical procedures including, but not be limited to, the following:
- Arthrodesis.
- Osteotomy.
- Tendon transfer.

**Background**

Flatfoot (also called pes planus, pes planovalgus, or “fallen arch”) occurs when the tendons that form the medial arch of the foot fail to pull together properly, allowing the entire sole of the foot to touch the floor while standing. Flatfoot is characterized as flexible (the medial arch flattens upon standing but normalizes during non-weight bearing) and rigid (unaltered by weight bearing). It may result in alteration of foot biomechanics, subsequent foot misalignment, lower extremity pain, and limited physical activity.

The etiology can be congenital or acquired through wear-and-tear stresses, injury to the tendon or bone, arthritis, and neuropathy. Most children are born with very little arch in the feet. As they grow and walk, the soft tissues along the bottom of the feet tighten, which gradually shapes the medial arches (American Academy of Orthopaedic Surgeons [AAOS], 2013). If flexible flatfoot continues into adolescence, a child may experience symptoms requiring treatment (AAOS, 2013; Dare, 2014). Other factors that can increase the risk for flatfoot include obesity, diabetes (e.g., Charcot foot), aging, and pregnancy (AAOS, 2013; Stolzman, 2015). Pain may be located in the medial, plantar, or lateral parts of the foot and extend into the lower extremities depending on etiology (Toullec, 2015).

Most persons with flatfoot are asymptomatic and require no intervention. In general, treatment is indicated when a patient becomes symptomatic or withdraws from physical activity, but there is some debate regarding treatment necessity and best options. Treatment options typically begin with conservative medical management such as foot exercises, orthoses, and physical therapy. Acute painful flatfoot may require strict cast immobilization. Surgical options comprise arthrodesis, osteotomies, and numerous combinations of procedures to correct the underlying pathology (Toullec, 2014; Dare, 2014). Surgery is associated with operative morbidity and longer-term sequelae, with eventual transfer of energy to non-fused joints, nonunion, and growth plate disturbances.

**Subtalar arthroereisis:**

Subtalar arthroereisis (also called sinus tarsi implant or extra-osseous talotarsal stabilization) involves extra-articular placement of an implant that looks like a threaded cylinder within the sinus tarsi, with the goal of limiting excessive abnormal rotations of the tarsus. First described in congenital childhood flatfoot more than 60 years ago, subtalar arthroereisis is typically performed in conjunction with other tendon or bone procedures. As the least invasive surgical approach for flatfoot, it offers technical simplicity and rapid recovery but may not fully correct flatfoot. The main drawback is regular sinus tarsi pain, requiring removal of material while avoiding secondary correction loss (Toullec, 2015).

The U.S. Food and Drug Administration (FDA) does not regulate surgical procedures such as subtalar arthroereisis. However, FDA has cleared several implants used in the procedure for commercial use as Class II devices (FDA, 2016; product code HWC).
AmeriHealth Caritas Louisiana searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on August 1, 2016. Search terms were: "Subtalar Joint" (Mesh), "Joint Prosthesis"(Mesh), "Subtalar Joint/surgery"(Mesh), "Subtalar Joint/therapy" (Mesh), "Flatfoot" (Mesh) and free text terms “arthroereisis” and “arthroerisis.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Two systematic reviews (Hayes, 2012 [updated 2015]; Metcalfe, 2011), one overview (National Institute for Health and Clinical Excellence [NICE], 2008) and three clinical practice guidelines (NICE, 2009; Lee, 2005; Harris, 2004) provided the basis for this policy. The reviews concur that evidence supporting the use of subtalar arthroereisis consists of small case series and case reports lacking long-term follow-up. The largest body of literature evaluated subtalar arthroereisis in pediatric populations. The most common indication for surgery was treatment of persistent, symptomatic flexible flatfoot, and most patients underwent concomitant procedures such as Achilles tendon lengthening. Studies varied in instrumentation, procedure, outcome measurement, and etiology, particularly between adult and pediatric patients. Two recent case series (116 total patients, 130 total feet) not included in the reviews confirm these findings (Ozan, 2015; Saxena, 2016).

Subtalar arthroereisis for children has been used for decades and is a relatively simple intervention. The evidence suggests it has a lower risk of morbidity, shorter recovery time and favorable safety profile compared with other established surgical approaches. As no controlled studies have been published, it is not possible to determine definitive patient selection criteria or relative safety or efficacy of various implant devices. To note, other surgical options for symptomatic flatfoot, such as osteotomies and/or fusions, lack similar evidence from high quality comparative studies.
Evidence-based guidelines reflect the uncertainty in the evidence base and the clinical controversy surrounding the utility of subtalar arthroereisis in pediatric and, to an even greater extent, adult populations. NICE (2009) recommended using the procedure in selected children with persistent mobile flatfoot due to neuromuscular disorder, skeletal dysplasia or systemic ligamentous laxity, whose treatment is supervised by a multidisciplinary team; the procedure may be indicated rarely in highly selected adult patients. Two guidelines by the American Orthopaedic Foot and Ankle Society (AOFAS) stated long-term results of arthroereisis in adults have not been established, and the procedure in children remains controversial among surgeons (Lee, 2005; Harris, 2004). There appears to be greater acceptance of the procedure among podiatrists than orthopedists.

Shah (2015) conducted a web-based survey of AOFAS members for current practices regarding subtalar arthroereisis. A total of 572 respondents completed the survey (32 percent response rate), of whom 401 (70 percent) practice in the United States. Among U.S. practitioners, 40 percent have performed subtalar arthroereisis, and 60 percent of those still perform the procedure. Common indications were painful congenital flatfoot, posterior tibial tendon dysfunction, and flatfoot associated with accessory navicular. These results suggest while many doctors have performed subtalar arthroereisis, a significant number no longer do. Most doctors who still perform this procedure have removed the implants, commonly for pain.

Policy updates:

In 2017, we added an updated version of the Hayes systematic review (Hayes, 2012; updated 2016) with no change to its conclusions. No policy changes are warranted at this time.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hayes (2012, updated 2016)</td>
<td>Key points:</td>
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<tr>
<td>Subtalar arthroereisis for</td>
<td>• Systematic review of six</td>
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<td>treatment of flatfoot</td>
<td>retrospective small case series of</td>
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<td>children and three case series of</td>
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<td>adults (10 – 37 patients per study).</td>
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<td></td>
<td>• Update included one prospective</td>
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<td>comparison study, one prospective</td>
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<td>data analysis, two retrospective</td>
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<td>case series, one retrospective</td>
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<td>cohort study and one retrospective</td>
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<td>analysis.</td>
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<td></td>
<td>• Most common indication = flexible</td>
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<td>flatfoot.</td>
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<td></td>
<td>• Subtalar arthroereisis consistently improved pain, functionality, and radiographic findings not responsive to conservative treatment; effects observed for up to 12 years following the procedure.</td>
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<tr>
<td></td>
<td>• Favorable safety profile; pain and sinus tarsi tenderness being the most frequent complications. Infrequent explantation due to pain, implant dislocations or fractures.</td>
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<td></td>
<td>• Large-scale randomized clinical trials (RCTs) comparing long-term outcomes of subtalar arthroereisis with other surgical interventions are needed to establish the efficacy and safety.</td>
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Metcalfe (2011) | Key points:
Subtalar arthroereisis for pediatric flexible flatfoot

- Systematic review of 76 case series and case reports.
- Eight of nine radiographic parameters showed significant improvement in increased static arch height and joint congruency; calcaneal inclination angle demonstrated the least change.
- Complications including sinus tarsi pain, device extrusion and under-correction: overall complication rates (4.8% to 18.6%); unplanned removal rate (7.1% to 19.3%) across all device types.
- Interplay between osseous alignment and dynamic stability within the foot may contribute to procedure effectiveness. Qualitative outcome data based on disease specific, validated outcome tools may improve current evidence and permit comparison of future study data.

NICE (2008)
Sinus tarsi implant insertion for mobile flatfoot

Key points:

- Review of eight case series and four case reports (643 total feet), including only one case series of 23 adults (28 implants).
- Overall quality: Low. Variation in procedures (design, size, instrumentation/insertion), unclear patient selection criteria.
- Many patients also had concomitant Achilles tendon procedures or other procedures.
- Can be done bilaterally or unilaterally but no evidence available about efficacy of bilateral implantation or laterality (left/right implantation).
- Indications for this procedure are different in pediatric and adult populations.
- Lack of consensus from experts on efficacy and safety, clinical utility, need for additional research, and the use of biodegradable and non-biodegradable implants.

References

Professional society guidelines/other:


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**


**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tr>
<td>28899</td>
<td>Unlisted procedure, foot or toes</td>
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<tr>
<td>0335T</td>
<td>Extra-osseous subtalar joint implant for talotarsal stabilization</td>
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<thead>
<tr>
<th>ICD-10 Code</th>
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<td>Q66.50-Q66.52</td>
<td>Congenital pes planus</td>
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