Subtalar Arthroereisis

Policy # 00592
Original Effective Date: 12/20/2017
Current Effective Date: 08/14/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers subtalar arthroereisis (STA) to be investigational.*

Background/Overview
Subtalar arthroereisis 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, subtalar arthroereisis 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 stand-alone procedure, although children and adults often require adjunctive surgical procedures on bone and soft tissue to correct additional deformities.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
A number of implants have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process, a sampling of which are summarized in Table 1. In general, these devices are indicated for insertion into the sinus tarsi of the foot, allowing normal subtalar joint motion while blocking excessive pronation. FDA Product Code: HWC.
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Table 1. Representative Subtalar Implant Devices Cleared by U.S. Food and Drug Administration

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subtalar MBA®‡</td>
<td>Integra LifeSciences</td>
<td>07/96</td>
<td>K960692</td>
</tr>
<tr>
<td>OsteoMed Subtalar Implant System</td>
<td>OsteoMed</td>
<td>08/03</td>
<td>K031155</td>
</tr>
<tr>
<td>BioPro Subtalar Implant</td>
<td>BioPro</td>
<td>09/04</td>
<td>K041936</td>
</tr>
<tr>
<td>HyProCure Subtalar Implant System</td>
<td>Graham Medical Technologies</td>
<td>09/04</td>
<td>K042030</td>
</tr>
<tr>
<td>MBA Resorb Implant</td>
<td>Kinetikos Medical</td>
<td>09/05</td>
<td>K051611</td>
</tr>
<tr>
<td>Metasurg Subtalar Implant</td>
<td>Metasurg</td>
<td>05/07</td>
<td>K070441</td>
</tr>
<tr>
<td>Subtalar Implant</td>
<td>Biomet Sports Medicine</td>
<td>07/07</td>
<td>K071498</td>
</tr>
<tr>
<td>Arthrex ProStop Plus Arthroereisis Subtalar Implant</td>
<td>Arthrex</td>
<td>01/08</td>
<td>K071456</td>
</tr>
<tr>
<td>Trilliant Surgical Subtalar Implant</td>
<td>Trilliant Surgical</td>
<td>02/11</td>
<td>K103183</td>
</tr>
<tr>
<td>Metasurg Subtalar Implant</td>
<td>Metasurg</td>
<td>08/11</td>
<td>K111265</td>
</tr>
<tr>
<td>NuGait™‡ Subtalar Implant System</td>
<td>Ascension Orthopedic</td>
<td>08/11</td>
<td>K111799</td>
</tr>
<tr>
<td>Disco Subtalar Implant</td>
<td>Trilliant Surgical</td>
<td>12/11</td>
<td>K111834</td>
</tr>
<tr>
<td>OsteoSpring FootJack Subtalar Implant System</td>
<td>OsteoSpring Medical</td>
<td>12/11</td>
<td>K112658</td>
</tr>
<tr>
<td>IFS Subtalar Implant</td>
<td>Internal Fixation Systems</td>
<td>12/11</td>
<td>K113399</td>
</tr>
<tr>
<td>The Life Spine Subtalar Implant System</td>
<td>Life Spine</td>
<td>06/16</td>
<td>K160169</td>
</tr>
</tbody>
</table>

* FDA 510(k) database search product code HWC (03/08/18)
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Rationale/Source
This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Arthroereisis is a surgical procedure that purposely limits movement across a joint. Subtalar arthroereisis 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.

For individuals who have flatfoot who receive subtalar arthroereisis, the evidence includes mainly single-arm case series and a small nonrandomized controlled trial comparing subtalar arthroereisis 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 subtalar arthroereisis, 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. Also, some studies have reported high rates of complications and implant removal. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have talotarsal joint dislocation who receive subtalar arthroereisis, the evidence consists of 1 prospective single-arm study of talotarsal stabilization using HyProCure. Relevant outcomes are symptoms, functional outcomes, and quality of life. Although improvements in pain and function were observed, the current evidence on the use of subtalar arthroereisis for treatment of talotarsal joint dislocation is insufficient to draw conclusions about treatment efficacy with certitude. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.
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**Supplemental Information**

**Clinical Input from Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

**2012 Input**

In response to requests, input was received through 2 physician specialty societies and 2 academic medical centers while this policy was under review in 2012. Input was mixed, with most reviewers considering this procedure to be investigational.

**2009 Input**

In response to requests, input was received through 1 physician specialty society (3 reviews) and 5 academic medical centers while this policy was under review in 2009. Input was mixed regarding the medical necessity of arthroereisis.

**Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

**National Institute for Health and Care Excellence**

Guidance from the National Institute for Health and Care Excellence (2009) concluded that current evidence on the safety and efficacy of sinus tarsi implant insertion for mobile flatfoot was inadequate in quality and quantity.

**American College of Foot and Ankle Surgeons**

Piraino et al (2020) published the following Clinical Consensus Statement on the appropriate clinical management of adult-acquired flatfoot deformity: "Subtal arthroereisis should not be considered as a single corrective procedure for stage IIB AAFD [adult flatfoot]."
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U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in March 2023 did not identify any ongoing or unpublished trials that would likely influence this review.

References
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Policy History
Original Effective Date:  12/20/2017
Current Effective Date:  08/14/2023

12/07/2017  Medical Policy Committee review
12/20/2017  Medical Policy Implementation Committee approval. New policy.
12/06/2018  Medical Policy Committee review
12/19/2018  Medical Policy Implementation Committee approval. No change to coverage.
01/01/2019  Coding update
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12/05/2019 Medical Policy Committee review
12/11/2019 Medical Policy Implementation Committee approval. No change to coverage.
Coding update
07/02/2020 Medical Policy Committee review
07/08/2020 Medical Policy Implementation Committee approval. No change to coverage.
07/01/2021 Medical Policy Committee review
07/14/2021 Medical Policy Implementation Committee approval. No change to coverage.
07/07/2022 Medical Policy Committee review
07/13/2022 Medical Policy Implementation Committee approval. No change to coverage.
07/06/2023 Medical Policy Committee review
07/12/2023 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 07/2024

**Coding**

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2022 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.
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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>0335T, 0510T, 0511T, 28899</td>
</tr>
<tr>
<td>HCPCS</td>
<td>S2117</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>All related Diagnoses</td>
</tr>
</tbody>
</table>

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.
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NOTICE:  Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.