



Louisiana

Subtalar Arthroereisis

Policy # 00592

Original Effective Date: 12/20/2017

Current Effective Date: 08/09/2021

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. FDA through the 510(k) process, and 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.

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Table 1. Representative Subtalar Implant Devices Cleared by FDA^a

Device	Manufacturer	Date Cleared	510(k) No.
Subtalar MBA ^{®‡}	Integra LifeSciences	07/96	K960692
OsteoMed Subtalar Implant System	OsteoMed	08/03	K031155
BioPro Subtalar Implant	BioPro	09/04	K041936
HyProCure Subtalar Implant System	Graham Medical Technologies	09/04	K042030
MBA Resorb Implant	Kinetikos Medical	09/05	K051611
Metasurg Subtalar Implant	Metasurg	05/07	K070441
Subtalar Implant	Biomet Sports Medicine	07/07	K071498
Arthrex ProStop Plus Arthroereisis Subtalar Implant	Arthrex	01/08	K071456
Trilliant Surgical Subtalar Implant	Trilliant Surgical	02/11	K103183

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Device	Manufacturer	Date Cleared	510(k) No.
Metasurg Subtalar Implant	Metasurg	08/11	K111265
NuGait™ [‡] Subtalar Implant System	Ascension Orthopedic	08/11	K111799
Disco Subtalar Implant	Trilliant Surgical	12/11	K111834
OsteoSpring FootJack Subtalar Implant System	OsteoSpring Medical	12/11	K112658
IFS Subtalar Implant	Internal Fixation Systems	12/11	K113399
The Life Spine Subtalar Implant System	Life Spine	06/16	K160169

FDA: Food and Drug Administration.

^aFDA 510(k) database search product code HWC (03/08/18).

Rationale/Source

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

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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.

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.

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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

In 2004, the American College of Foot and Ankle Surgeons (ACFAS) published practice guidelines for the diagnosis and treatment of pediatric and adult flatfoot (neither is included in the ACFAS library of current clinical practice guidelines).

The ACFAS guidelines on adult flatfoot have stated:

“In the adult, arthroereisis is seldom implemented as an isolated procedure. Because of the long-term compensation and adaptation of the foot and adjunctive structures for flatfoot function, other ancillary procedures are usually used for appropriate stabilization. Long-term results of arthroereisis in the adult flexible flatfoot patient have not been established. Some surgeons advise against the subtalar arthroereisis procedure because of the risks associated with implantation of a foreign

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material, the potential need for further surgery to remove the implant, and the limited capacity of the implant to stabilize the medial column sag directly.”

The ACFAS guidelines on pediatric flatfoot have stated: “proponents of this procedure (arthroereisis) argue that it is a minimally invasive technique that does not distort the normal anatomy of the foot. Others have expressed concern about placing a permanent foreign body into a mobile segment of a child’s foot. The indication for this procedure remains controversial in the surgical community.”

Piraino et al (2020) published the following Clinical Consensus Statement on the appropriate clinical management of adult-acquired flatfoot deformity: "Subtalar arthroereisis should not be considered as a single corrective procedure for stage IIB AAFD [adult flatfoot]."

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](https://clinicaltrials.gov) in March 2021 did not identify any ongoing or unpublished trials that would likely influence this review.

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Policy History

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|-------------------------------------|---|
| 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 |
| 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. |
| Next Scheduled Review Date: 07/2022 | |

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Coding

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

Code Type	Code
CPT	0335T, 0510T, 0511T, 28899
HCPCS	S2117
ICD-10 Diagnosis	M21.40-M21.42, Q66.50-Q66.52, Q66.00-Q66.92

*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

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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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
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