Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Subtalar Arthroereisis

Policy #: 357
Latest Review Date: April 2023
Category: Surgery
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after March 24, 2020:
Blue Advantage will treat **subtalar arthroereisis** as a **non-covered** benefit and as **investigational**.

Effective for dates of service February 26, 2018 through March 23, 2020, refer to LCD L34555.

Effective for dates of service prior to February 26, 2018:
Blue Advantage will treat **subtalar arthroereisis** as a **non-covered** benefit and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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

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.

KEY POINTS:

The most recent literature review was performed through January 16, 2023.

Summary of Evidence
For individuals who have flatfoot or talotarsal joint dislocation who receive STA, the evidence includes mainly single-arm case series and a small nonrandomized controlled trial comparing STA with lateral column calcaneal lengthening. The 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 STA, 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 the effects of the technology on health outcomes.

For individuals who have talotarsal joint dislocation who receive subtalar arthroereisis, the evidence consists of one 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.

Practice Guidelines and Position Statements
National Institute for Health and Care Excellence (NICE)
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: "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.

KEY WORDS:
Arthroereisis, Subtalar, MBA Implant, Subtalar Arthroereisis, HyProCure, peg, Kalix, Maxwell-Brancheau Arthroereisis (MBA)

APPROVED BY GOVERNING BODIES:
A number of implants have been cleared for marketing by the U.S. Food and Drug Administration (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.

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
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. [a] FDA 510(k) database search product code HWC (03/08/18).

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

For the insertion of the HyProCure® device use the following:

0335T	Insertion of sinus tarsi implant

There are no specific CPT codes for this procedure or any of the other implants. Physicians may use any of the following codes to file subtalar arthroereisis.

0510T	Removal of sinus tarsi implant
0511T	Removal and reinsertion of sinus tarsi implant
28725	Arthrodesis, subtalar
28735	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (e.g., flatfoot correction)
28740	Arthrodesis, midtarsal or tarsometatarsal, single joint
29907	Arthroscopy, subtalar joint, surgical; with subtalar arthrodesis
28899	Unlisted procedure, foot or toes

HCPCS:

S2117	Arthroereisis, subtalar

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POLICY HISTORY:

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Medical Policy Group, October 2015
Medical Policy Group, August 2017
Medical Policy Group, February 2018
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