BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.104 Subtalar Arthroereisis

Effective Policy Date: July 1, 2023

Original Policy Date: December 2012

Related Policies:

None

Subtalar Arthroereisis

Description

Description

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.

OBJECTIVE

The objective of this evidence review is to determine whether subtalar arthroereisis improves the net health outcome in individuals who have flatfoot or talotarsal joint dislocation.

POLICY STATEMENT

Subtalar arthroereisis is considered **investigational**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

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.

Table 1. Representative Subtalar Implant Devices Cleared by U.S. Food and Drug Administration[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

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

RATIONALE

Summary of Evidence

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

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.[15,]

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]."[16,]

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.

REFERENCES

1. Chong DY, Macwilliams BA, Hennessey TA, et al. Prospective comparison of subtalar arthroereisis with lateral column lengthening for painful flatfeet. J Pediatr Orthop B. Jul 2015; 24(4): 345-53. PMID 25856275
2. Metcalfe SA, Bowling FL, Reeves ND. Subtalar joint arthroereisis in the management of pediatric flexible flatfoot: a critical review of the literature. Foot Ankle Int. Dec 2011; 32(12): 1127-39. PMID 22381197
3. Graham ME, Jawrani NT, Chikka A. Extraosseous talotarsal stabilization using HyProCure in adults: a 5-year retrospective follow-up. J Foot Ankle Surg. 2012; 51(1): 23-9. PMID 22196455
4. Vedantam R, Capelli AM, Schoenecker PL. Subtalar arthroereisis for the correction of planovalgus foot in children with neuromuscular disorders. J Pediatr Orthop. 1998; 18(3): 294-8. PMID 9600551
5. Nelson SC, Haycock DM, Little ER. Flexible flatfoot treatment with arthroereisis: radiographic improvement and child health survey analysis. J Foot Ankle Surg. 2004; 43(3): 144-55. PMID 15181430
6. Needleman RL. A surgical approach for flexible flatfeet in adults including a subtalar arthroereisis with the MBA sinus tarsi implant. Foot Ankle Int. Jan 2006; 27(1): 9-18. PMID 16442023
7. Cicchinelli LD, Pascual Huerta J, Garca Carmona FJ, et al. Analysis of gastrocnemius recession and medial column procedures as adjuncts in arthroereisis for the correction of pediatric pes planovalgus: a radiographic retrospective study. J Foot Ankle Surg. 2008; 47(5): 385-91. PMID 18725117
8. Lucaccini C, Zambianchi N, Zanotti G. Distal osteotomy of the first metatarsal bone in association with sub-talar arthroerisis, for hallux valgus correction in abnormal pronation syndrome. Chir Organi Mov. Dec 2008; 92(3): 145-8. PMID 19082522
9. Scharer BM, Black BE, Sockrider N. Treatment of painful pediatric flatfoot with Maxwell-Brancheau subtalar arthroereisis implant a retrospective radiographic review. Foot Ankle Spec. Apr 2010; 3(2): 67-72. PMID 20400415
10. Brancheau SP, Walker KM, Northcutt DR. An analysis of outcomes after use of the Maxwell-Brancheau Arthroereisis implant. J Foot Ankle Surg. 2012; 51(1): 3-8. PMID 22196453
11. Bresnahan PJ, Chariton JT, Vedpathak A. Extraosseous talotarsal stabilization using HyProCure: preliminary clinical outcomes of a prospective case series. J Foot Ankle Surg. 2013; 52(2): 195-202. PMID 23313499
12. Scher DM, Bansal M, Handler-Matasar S, et al. Extensive implant reaction in failed subtalar joint arthroereisis: report of two cases. HSS J. Sep 2007; 3(2): 177-81. PMID 18751791
13. Saxena A, Nguyen A. Preliminary radiographic findings and sizing implications on patients undergoing bioabsorbable subtalar arthroereisis. J Foot Ankle Surg. 2007; 46(3): 175-80. PMID 17466243
14. Cook EA, Cook JJ, Basile P. Identifying risk factors in subtalar arthroereisis explantation: a propensity-matched analysis. J Foot Ankle Surg. 2011; 50(4): 395-401. PMID 21708340
15. National Institute for Health and Care Excellence (NICE). Sinus Tarsi Implant Insertion for Mobile Flatfoot [IPG305]. 2009; https://www.nice.org.uk/guidance/IPG305. Accessed March 7, 2023.
16. Piraino JA, Theodoulou MH, Ortiz J, et al. American College of Foot and Ankle Surgeons Clinical Consensus Statement: Appropriate Clinical Management of Adult-Acquired Flatfoot Deformity. J Foot Ankle Surg. 2020; 59(2): 347-355. PMID 32131002

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2012	New policy	
December 2013	Replace policy	Policy update with literature review through August 2013. Policy statement and summary unchanged.
December 2017	Replace policy	Policy updated with literature review through June 22, 2017; no references added. Policy statement unchanged, but "not medically necessary, corrected to "investigational,.
June 2018	Replace policy	Policy updated with literature review through February 5, 2018; no references added. Policy statement unchanged.
June 2019	Replace policy	Policy updated with literature review through February 5, 2019; no references added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through January 31, 2020; no references added. Policy statement unchanged.
June 2021	Replace policy	Policy updated with literature review through January 11, 2021; reference added. Policy statement unchanged.
June 2022	Replace policy	Policy updated with literature review through January 17, 2022; no references added. Policy statement unchanged.
June 2023	Replace policy	Policy updated with literature review through January 16, 2023; no references added. Policy statement unchanged.