

7.01.104 Subtalar Arthroereisis			
Original Policy Date:	April 3, 2009	Effective Date:	June 1, 2023
Section:	7.0 Surgery	Page:	Page 1 of 12

Policy Statement

- I. Subtalar arthroereisis is considered **investigational**.

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

There is no specific CPT code for this procedure. It is possible that providers may use any of the following codes to describe subtalar arthroereisis:

- **28725:** Arthrodesis; subtalar
- **28735:** Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (e.g., flatfoot correction)

Note: Arthrodesis describes joint fusion.

The following HCPCS S code is specific for this procedure:

- **S2117:** Arthroereisis, subtalar

The following category III code is for insertion of the HyProCure® device:

- **0335T:** Insertion of sinus tarsi implant

The following category III codes are specific to the removal and reinsertion of a sinus tarsi implant:

- **0510T:** Removal of sinus tarsi implant
- **0511T:** Removal and reinsertion of sinus tarsi implant

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.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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

Background

Subtalar arthroereisis has been performed for more than 50 years, with a variety of implant designs and compositions. The Maxwell-Brancheau Arthroereisis 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 Maxwell-Brancheau Arthroereisis 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 Maxwell-Brancheau Arthroereisis 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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant,

studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Clinical Context and Therapy Purpose

The purpose of subtalar arthroereisis in individuals who have flatfoot is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does subtalar arthroereisis improve the net health outcome in individuals with flatfoot?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with flatfoot.

Flexible flatfoot is a common disorder, anatomically described as excessive pronation during weight-bearing due to anterior and medial displacement of the talus. It may be congenital, or it may be acquired in adulthood due to posterior tibial tendon dysfunction, which in turn may be caused by trauma, overuse, inflammatory disorders, and other factors. Symptoms include dull, aching and throbbing, cramping pain, which in children may be described as growing pains. Additional symptoms include refusal to participate in athletics or walking long distances.

Interventions

The therapy being considered is subtalar arthroereisis.

Arthroereisis is a surgical procedure that limits movement across a joint. Subtalar arthroereisis (also called extraosseous talotarsal stabilization) is designed to correct excessive talar displacement and calcaneal eversion by reducing pronation across the subtalar joint. The stabilization procedure is performed by placing an implant in the sinus tarsi, which is a canal located between the talus and the calcaneus.

Comparators

Surgical approaches for painful flatfoot deformities include tendon transfers, osteotomy, and arthrodesis. Conservative treatments include orthotics or shoe modifications.

Outcomes

The outcomes of interest are symptoms, functional outcomes, and quality of life. The average length of follow-up was 18 to 24 months.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Literature searches on subtalar arthroereisis have identified few published studies, primarily consisting of single-institution case series and individual case reports, reporting on success rates following this procedure. There is a small controlled trial that has compared subtalar arthroereisis with alternative treatments.

Nonrandomized Clinical Trial

Chong et al (2015) reported on a small prospective nonrandomized trial that compared subtalar arthroereisis with lateral column calcaneal lengthening for the treatment of 24 painful flatfeet in children.¹ Seven children (13 feet) enrolled at a children's medical center were treated with arthroereisis and 8 children (11 feet) enrolled at another children's hospital were treated with lateral column lengthening. Children who underwent subtalar arthroereisis received a subdermal implant and were placed in below-knee walking casts for 3 weeks. Children treated with lateral column lengthening had an opening wedge osteotomy with the insertion of a wedge of cadaveric bone and were placed in non-weight-bearing casts for 1 month and "walker boots" for another month. Outcomes at a mean of 12.7 months after surgery included radiographs, foot pressure, kinematic analysis, and the Oxford Ankle-Foot Questionnaire for Children. The 2 groups showed similar improvements in the lateral talo-first metatarsal angle and talonavicular coverage and kinematics. Both groups showed statistically significant lateralization of the hindfoot and midfoot center of pressure ($p < 0.01$). There were no between-group differences for any clinical or functional outcomes. On within-group comparison, only the subtalar arthroereisis group had a statistically significant reduction in time on the hindfoot ($p = 0.01$). Both groups had improvements in the parental and child scores on the Oxford questionnaire, but only the subtalar arthroereisis group had a statistically significant improvement in this small sample. There were 2 complications in each group, with the removal of the hardware in 1 patient and removal of the implant in 2 patients. The improvement in pain and foot position was retained following implant removal.

Case Series and Reports

Metcalfe et al (2011) published a systematic review of the literature on subtalar arthroereisis for pediatric flexible flatfoot.² Seventy-six case series (none controlled) or case reports were identified. Ten of the studies (756 feet) provided a clinician-based assessment of the surgical result graded from "excellent to poor" with follow-up between 36 and 240 months. Six studies (212 feet) included estimates of overall patient satisfaction using nonvalidated outcome measures, while 1 study (16 feet) found significant improvement using a validated foot-specific patient outcome measure. Data from 15 studies that reported radiographic values were combined for analysis. Although 8 of 9 radiographic parameters showed statistically significant improvements following arthroereisis procedures, the relation between radiographic and clinical outcomes is uncertain. The procedure was associated with a number of complications including sinus tarsi pain, device extrusion, and undercorrection. Complication rates ranged from 4.8% to 18.6%, with unplanned removal rates between 7.1% and 19.3% across all device types. The influence of adjunctive procedures on outcomes was not addressed in this review.

Graham et al (2012) published a case series that was not confounded by adjunctive procedures and had a relatively long follow-up.³ This study reported mean 51-month follow-up of talotarsal

stabilization in 117 feet using the HyProCure device. Patients who received adjunctive procedures affecting the talotarsal joint were excluded from analysis. Adults who met the inclusion and exclusion criteria were invited to participate in the study. Eighty-three patients gave consent to participate, and 78 completed the Maryland Foot Score Questionnaire. Five patients did not complete the questionnaire because they had 7 (6%) implants removed. There were 16 revision surgeries with HyProCure. Nine of the surgeries called for the repositioning of a partially displaced device, or a change in the size of the device altogether. Of the patients who retained the device, 52% reported complete alleviation of foot pain, 69% had no limitations in their foot functional abilities, and 80% reported complete satisfaction with the appearance of their feet. This case series is notable for its assessment of functional outcomes at medium-term follow-up in patients who did not have adjunct procedures.

Other case series have generally not excluded the use of other adjunctive treatments. For example, Vedantam et al (1998) reported on a series of 78 children (140 feet) with neuromuscular disease who underwent subtalar arthroereisis with a subtalar arthroereisis-peg.⁴ The stem of this implant is placed into the calcaneus with the collar abutting the inferior surface of the lateral aspect of the talus, thus limiting motion. All but 5 of the children had additional procedures to balance the foot. Satisfactory results were reported in 96.4% of patients, although the contribution of the subtalar arthroereisis-peg cannot be isolated. Nelson et al (2004) reported on 37 patients (67 feet) who received a Maxwell-Brancheau Arthroereisis implant and had an average of 18.4 months of follow-up.⁵ While this study reported various improvements in anatomic measurements, there were no data on improvement in symptoms. In another series, Needleman (2006) reported significant improvements in pain and function in 78% of patients (23 patients, 28 feet) with use of a subtalar implant as a component of reconstructive foot and ankle surgery.⁶ However, because results were not compared with controls receiving reconstructive surgery without subtalar arthroereisis, the contribution of the implants to these outcomes is unclear. Also, Needleman (2006) reported an overall complication rate of 46%, with surgical removal of 39% of the implants due to sinus tarsi pain; and that postoperative sinus tarsi pain was unpredictable.

Cicchinelli et al (2008) reported on radiographic outcomes in a retrospective analysis of 28 feet in 20 pediatric patients treated with subtalar arthroereisis combined with gastrocnemius recession or with subtalar arthroereisis combined with gastrocnemius recession and medial column reconstruction.⁷ Lucaccini et al (2008) analyzed clinical and radiographic results of 14 patients (16 feet) with hallux valgus in abnormal pronation syndrome treated with distal osteotomy of the first metatarsal bone and subtalar arthroereisis performed in 1 stage.⁸ Scharer et al (2010) conducted a retrospective radiographic evaluation of 39 patients (68 feet) who received the Maxwell-Brancheau Arthroereisis implant to treat painful pediatric flatfoot deformities.⁹ The patients' average age at the time of surgery was 12 years (range, 6-16 years). Additional procedures included 12 (18%) gastrocnemius recessions, 6 (9%) Achilles tendon lengthening, and 4 (6%) Kidner procedures. At an average 24-month follow-up (range, 6-61 months), there were 10 (15%) complications requiring reoperation, including implant migration, undercorrection, overcorrection, and persistent pain. The implants were exchanged for a larger or a smaller implant. None of these case series permitted comparison with nonsurgical interventions or with other surgical interventions.

An example of a case series with longer follow-up is the retrospective study by Brancheau et al (2012), which reported on a mean 36-month follow-up (range, 18-48 months) in 35 patients (60 feet) after use of the Maxwell-Brancheau Arthroereisis implant with adjunct procedures.¹⁰ The patients' mean age was 14.3 years (range, 5-46 years). Significant changes were observed in radiographic measures (talocalcaneal angle, calcaneocuboid angle, first to second intermetatarsal angle, calcaneal inclination angle, talar declination angle). Seventeen percent of patients reported that 9 (15%) implants were removed after the initial surgery. Of the 24 (68.6%) patients who answered a subjective questionnaire (in person or by telephone at a mean of 33 months postoperatively), 95.8% reported resolution of the chief presenting complaint, and 79.2% said they were 100% satisfied with

their surgical outcome. The contribution of the Maxwell-Brancheau Arthroereisis implant to these results cannot be determined by this study design.

Section Summary: Flatfoot

The evidence evaluating the use of subtalar arthroereisis for treatment of flatfoot consists mainly of single-arm case series and a small nonrandomized controlled trial comparing subtalar arthroereisis with lateral column calcaneal lengthening. 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.

Talotarsal Joint Dislocation

Clinical Context and Therapy Purpose

The purpose of subtalar arthroereisis in individuals who have talotarsal joint dislocation is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does subtalar arthroereisis improve the net health outcome in individuals with talotarsal joint dislocation?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with talotarsal joint dislocation.

Talotarsal joint dislocation means that the joint surfaces of the talus are abnormally aligned on the heel and/or navicular bones

Interventions

The therapy being considered is subtalar arthroereisis.

Arthroereisis is a surgical procedure that limits movement across a joint. Subtalar arthroereisis (also called extraosseous talotarsal stabilization) is designed to correct excessive talar displacement and calcaneal eversion by reducing pronation across the subtalar joint. The stabilization procedure is performed by placing an implant in the sinus tarsi, which is a canal located between the talus and the calcaneus.

Comparators

Alternative surgical approaches for talotarsal joint dislocation.

Outcomes

The outcomes of interest are symptoms, functional outcomes, and quality of life. The follow-up was up to one year.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Bresnahan et al (2013) reported on a prospective study of talotarsal stabilization using HyProCure in 46 feet of 35 patients diagnosed with recurrent and/or partial talotarsal joint dislocation.¹¹ No procedures besides insertion of the HyProCure device were performed to address the talotarsal joint dislocation. At 1 year postoperatively, scores on the Maryland Foot Score (on a score out of 100) for 30 patients had improved from 69.53 preoperatively to 89.17 postoperatively. Foot pain decreased by 37.0%, foot functional activities improved by 14.4%, and foot appearance improved by 29.5%. Implants were removed from 2 feet with no unresolved complications.

Section Summary: Talotarsal Joint Dislocation

The evidence evaluating the use of subtalar arthroereisis for treatment of talotarsal joint dislocation consists of 1 prospective single-arm study of talotarsal stabilization using HyProCure. 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.

Adverse Events

Complications are frequently reported in the literature. Scher et al (2007) reported on 2 cases of extensive implant reaction in 2 children 2 years after a subtalar arthroereisis-peg procedure.¹² Due to the commonly seen complication of severe postoperative pain with failure to reconstitute the longitudinal arch on weight-bearing and a residual flatfoot deformity, the authors do not recommend subtalar arthroereisis in the treatment of painful flatfoot in children. In a radiographic study, Saxena and Nguyen (2007) evaluated a bioabsorbable subtalar arthroereisis and found poor outcomes in 3 of 6 patients who met the inclusion criteria and consented to additional imaging.¹³ Two patients requested implant removal; a third patient had persistent pain but refused explantation. Radiographic measurement (magnetic resonance imaging or computed tomography) found that these 3 patients had smaller tarsal canal widths than the diameter of the inserted interference screw. The authors noted that the implant length also had to be reduced before implantation.

Cook et al (2011) conducted a retrospective case-control study to identify factors that might contribute to failure (explantation) of titanium arthroereisis implants.¹⁴ All patients who required removal of a self-locking wedge-type subtalar arthroereisis (n=22) were compared in a 1:2 ratio (n=44) with patients with nonexplanted arthroereisis who were treated during the same period. Subjects were matched for preoperative radiographic measurements, age, sex, presenting diagnosis, and length of follow-up. Multivariate logistic regression showed no significant effect of age, sex, implant size, shape, length of follow-up, implant position, surgeon experience, or concomitant procedures. Patients who required explantation had slightly greater odds of radiographic undercorrection (odds ratio, 1.175) or residual transverse plane-dominant deformities (odds ratio, 1.096). The percentage of explantations in this retrospective analysis was not described.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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.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.

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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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
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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

Documentation for Clinical Review

Please provide the following documentation:

- CPT's 28725 & 28735 are subject to prior authorization. They are considered investigational if they represent arthroereisis. CPT's 28725 & 28735 may be allowable if they represent arthrodesis. The codes 0335T, 0510T, 0511T, and S2117 represent arthroereisis and are considered investigational. Post service reviews are also done to confirm the procedure performed. For CPT codes 28725 or 28735, please note if the request is for arthorereisis or arthrodesis.

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	0335T	Insertion of sinus tarsi implant

Type	Code	Description
	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)
HCPCS	S2117	Arthroereisis, subtalar

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
04/03/2009	BCBSA Medical Policy adoption
01/06/2012	Policy revision without position change
03/07/2014	Coding and Administrative Update
06/30/2015	Coding update
01/01/2017	Policy revision without position change
10/01/2017	Policy revision without position change
06/01/2018	Policy revision without position change
02/01/2019	Coding update
06/01/2019	Policy revision without position change
06/01/2020	Annual review. No change to policy statement. Literature review updated.
06/01/2021	Annual review. No change to policy statement. Policy guidelines and literature review updated.
06/01/2022	Annual review. No change to policy statement. Literature review updated.
09/01/2022	Administrative update.
06/01/2023	Annual review. No change to policy statement. Policy guidelines and literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and

effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p>Subtalar Arthroereisis 7.01.104</p> <p>Policy Statement:</p> <p>I. Subtalar arthroereisis is considered investigational.</p>	<p>Subtalar Arthroereisis 7.01.104</p> <p>Policy Statement:</p> <p>I. Subtalar arthroereisis is considered investigational.</p>