7.01.104	Subtalar Arthroereisis		
Original Policy Date:	December 1, 2025	**Effective Date:**	June 1, 2026
Section:	7.0 Surgery	**Page:**	Page 1 of 13

State Guidelines

As of the publication of this policy, there are no applicable Medi-Cal guidelines (Provider Manual or All Plan Letter). Please refer to the Policy Statement section below.

Policy Statement

In the absence of any State Guidelines, please refer to the criteria below.

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

Policy Guidelines

Coding

See the Codes table for details.

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.

Summary of Evidence

For individuals who have flatfoot who receive subtalar arthroereisis, the evidence includes single-arm observational studies, systematic reviews of observational data, 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 observational 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.

Additional Information
Not applicable.

Related Policies

- N/A

Benefit Application

Blue Shield of California Promise Health Plan is contracted with L.A. Care Health Plan for Los Angeles County and the Department of Health Care Services for San Diego County to provide Medi-Cal health benefits to its Medi-Cal recipients. In order to provide the best health care services and practices, Blue Shield of California Promise Health Plan has an extensive network of Medi-Cal primary care providers and specialists. Recognizing the rich diversity of its membership, our providers are given training and educational materials to assist in understanding the health needs of their patients as it could be affected by a member's cultural heritage.

The benefit designs associated with the Blue Shield of California Promise Medi-Cal plans are described in the Member Handbook (also called Evidence of Coverage).

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
Incore Subtalar System	Nextremity Solutions, Inc.	12/21	K213301
Bioplan subtalar implant	BRM Extremities	12/22	K222820

[a] FDA 510(k) database search product code HWC

Health Equity Statement

Blue Shield of California Promise Health Plan's mission is to transform its health care delivery system into one that is worthy of families and friends. Blue Shield of California Promise Health Plan seeks to advance health equity in support of achieving Blue Shield of California Promise Health Plan's mission.

Blue Shield of California Promise Health Plan ensures all Covered Services are available and accessible to all members regardless of sex, race, color, religion, ancestry, national origin, ethnic group identification, age, mental disability, physical disability, medical condition, genetic information, marital status, gender, gender identity, or sexual orientation, or identification with any other persons or groups defined in Penal Code section 422.56, and that all Covered Services are provided in a culturally and linguistically appropriate manner.

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.

Flatfoot

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 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.

Systematic Review
Galan-Olleros et al (2024) conducted a systematic review and meta-analysis of children who received subtalar arthroereisis (the Calcaneo-stop procedure) for symptomatic flexible flatfoot.[1] Twenty studies were included (N=1415 patients, N=2394 feet). Mean patient age at the time of the procedure was 11.2 years. Improved pain was observed in 93.5% of patients (95% confidence interval [CI], 89 to 97.99; I^2=79%). Heel valgus correction was observed in 95.21% of patients (95% CI, 91.14 to 99.28; I^2=88%). Almost all patients (94.83%) reported high satisfaction following the procedure (I^2=2%). The overall rate of complications was 7.8%.

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.

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.[3] 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 ($p<.01$). 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 ($p=.01$). 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

Silva et al (2025) reported the results of a single-center retrospective study of 336 pediatric patients (N=644 feet) with idiopathic flexible flatfoot who received subtalar arthroereisis.[4] Mean age at implantation was 11.7 years. Implants were removed after at least 2 years or after the foot had grown by 2 sizes (mean duration, 26.8 months). Mean follow-up after the implant removal was 41.3 months. A successful outcome was achieved in 94% of patients (defined as lack of pain, corrected foot, and patient satisfaction). Failure was observed in 35 feet (20 patients), most commonly ongoing pain (in 27 feet). Activity levels after implant removal returned to baseline but did not increase beyond baseline levels. Application of these results is limited by lack of a control group.

Graham et al (2012) published a case series that was not confounded by adjunctive procedures and had a relatively long follow-up.[5] 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.

Moraca et al (2025) was another case series of subtalar arthroereisis in 37 children (74 feet) with symptomatic flexible flatfeet with extended follow-up (mean follow-up, 10 years).[6] Numeric pain rating scale decreased from a mean of 2.5 to a mean of 0.9 at last follow-up (p<.01). Radiographic outcomes all significantly improved after the procedure compared to baseline. Implant intolerance was reported in 11 feet, which resulted in 7 devices being removed. Failure of the implant to correct the flat foot was reported in 3 feet.

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.[7] 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.[8] 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.[9] 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.[10] 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.[11] 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.[12] The patients' average age at the time of surgery was 12 years (range, 6 to 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 to 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 to 48 months) in 35 patients (60 feet) after use of the Maxwell-Brancheau Arthroereisis implant with adjunct procedures.[13] The patients' mean age was 14.3 years (range, 5 to 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 of single-arm observational studies, systematic reviews of observational data, 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 observational 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, or lack of a control group. 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 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.[14] 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.[15] 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.[16] 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.[17] 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 U.S. professional society, an international society with U.S. 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.[18]

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]."[19]

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 February 2025 did not identify any ongoing or unpublished trials that would likely influence this review.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical findings (i.e., pertinent symptoms and duration)
  - Comorbidities
  - Activity and functional limitations
  - Family history, if applicable
  - Reason for procedure/test/device, when applicable
  - Pertinent past procedural and surgical history

  - Past and present diagnostic testing and results
  - Prior conservative treatments, duration, and response
  - Treatment plan (i.e., surgical intervention)
- Consultation and medical clearance report(s), when applicable
- Radiology report(s) and interpretation (i.e., MRI, CT, discogram)
- Laboratory results
- Other pertinent multidisciplinary notes/reports: (i.e., psychological or psychiatric evaluation, physical therapy, multidisciplinary pain management), when applicable

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

NOTE: 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

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	Code	Description
CPT®	0335T	Insertion of sinus tarsi implant
	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
12/01/2025	New policy.
06/01/2026	Administrative update. Definitions of Decision Determinations section updated.

Definitions of Decision Determinations

Healthcare Services: For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

Medically Necessary or **Medical Necessity** means reasonable and necessary services to protect life, to prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, as required under W&I section 14059.5(a) and 22 CCR section

51303(a). Medically Necessary services must include services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity.

For Members less than 21 years of age, a service is Medically Necessary if it meets the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) standard of Medical Necessity set forth in 42 USC section 1396d(r)(5), as required by W&I sections 14059.5(b) and 14132(v). Without limitation, Medically Necessary services for Members less than 21 years of age include all services necessary to achieve or maintain age-appropriate growth and development, attain, regain or maintain functional capacity, or improve, support, or maintain the Member's current health condition. Contractor must determine Medical Necessity on a case-by-case basis, taking into account the individual needs of the Child.

Criteria Determining Experimental/Investigational Status

Below is an excerpt of the language taken from California Children's Services Numbered Letter 05-1020.*

*Department of Healthcare Services Numbered Letter 05-1020. Accessed April 21, 2026, from https://www.dhcs.ca.gov/services/ccs/Documents/CCS-NL-05-1020-Experimental-and-Investigational-Services.pdf

Policy

A. The California Children's Services (CCS) Program and the Genetically Handicapped Persons Program (GHPP) will not provide coverage for experimental services unless specifically authorized by law.
B. The CCS Program and GHPP may provide coverage for an investigational service if:
    1. It is approved by the FDA under any Investigational New Drug (IND) Application; or
    2. It is authorized for use under the State of California's Right to Try Act; and
    3. Its use is consistent with its FDA-approved IND Application or the State of California's Right to Try Act;
C. Additional criteria that will be considered in the adjudication process include:
    1. Conventional therapy will not adequately treat the intended patient's condition;
    2. Conventional therapy will not prevent progressive disability or premature death;
    3. The provider of the proposed service has a record of safety and success with it or equivalent to that of other providers of the investigational services;
    4. Other criteria (e.g., cost and availability) may be considered in the adjudication of a given request in cases in which more than one investigational service is available;
    5. There is reasonable expectation that the investigational service will significantly prolong the patient's life or will maintain or restore a range of physical and social function suited to activities of daily living; and
    6. The service is not being performed as part of a research study protocol. For a beneficiary with cancer who participates in a clinical trial for cancer, California Health and Safety Code (HSC) § 1370.6 requires that all routine patient care costs related to the clinical trial be covered if the beneficiary's CCS-paneled treating physician recommends participation in the clinical trial after determining that participation in the clinical trial has a meaningful potential to benefit the enrollee. The coverage does not include investigational services that have not been approved by the FDA and that are associated with the clinical trial.

Feedback

Blue Shield of California Promise Health Plan is 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 Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into

consideration. Our medical policies are available to view or download at www.blueshieldca.com/en/bsp/providers.

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

Questions regarding the applicability of this policy should be directed to the Blue Shield of California Promise Health Plan Prior Authorization Department at (800) 468-9935, or the Complex Case Management Department at (855) 699-5557 (TTY 711) for San Diego County and (800) 605-2556 (TTY 711) for Los Angeles County or visit the provider portal at www.blueshieldca.com/en/bsp/providers.

Disclaimer: Blue Shield of California Promise Health Plan 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 member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield of California Promise Health Plan reserves the right to review and update policies as appropriate.