

Regence

Subtalar Arthroereisis

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Subtalar arthroereisis (also referred to as arthroisis) is a surgical procedure where an implant is placed below the talus (ankle bone), with the intention of blocking forward, downward, and medial displacement of the talus. This limits excessive eversion of the hindfoot. It has been performed for a number of years, with new implant designs and compositions being developed, primarily for treatment of flexible flatfoot (pes planus deformity); however, its use in other deformities such as club foot have been reported. It may be performed alone, or it may be combined with other procedures.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: This policy addresses subtalar *arthroereisis* only; it does not address subtalar *arthrodesis* which is a significantly different procedure and is considered a standard of care for some indications. However, **any procedure** is non-covered by Medicare when it is performed as a treatment of flat foot (see "CMS Coverage Manuals" below).

CMS Coverage Manuals*	For subtalar arthroereisis for the treatment of flat foot (<i>See Section 290 in the following link</i>): <ul style="list-style-type: none"> ✓ Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §290 - Foot Care, B. Exclusions from Coverage, 1. Treatment of Flat Foot
National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*	None
Medical Policy Manual	<p><i>Medicare coverage guidance is not available for subtalar arthroereisis for conditions other than flat foot. Therefore, the health plan's medical policy is applicable.</i></p> <p>For subtalar arthroereisis for indications OTHER THAN flat foot (e.g., club foot):</p> <ul style="list-style-type: none"> ✓ Subtalar Arthroereisis, Surgery, Policy No. 144 (<i>see "NOTE" below</i>)

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. ([Medicare IOM Pub. No. 100-04, Ch. 23, §30 A](#)). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an **objective, evidence-based process, based on authoritative evidence**. ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REGULATORY STATUS

Several arthroereisis implants have received FDA approval through either the PMA or 510(k) approval processes. Examples of FDA approved subtalar implants include, but are not limited to, the following:

- Arthrex ProStop Plus™ (Arthrex, Naples, FL)
- Arthroereisis Implant Talus of Vilex
- HyProCure® Subtalar Implant System (Graham Medical Technologies)
- Sub-Talar Lok™ (Instrateck™ Inc.)
- MBA® implant (now owned by Integra LifeSciences Corp., Plainsboro, NJ)

- MBAResorb Implant
- Osteomed Talar-Fit™
- Subtalar Peg Implant (Nexa Orthopedics, Inc.)
- SubFix™ arthroereisis implant (Memometal Technologies, Bruz, France)
- Wright Medical Smith Sta-Peg

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, CMS or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

[Investigational \(Experimental\) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services](#), Medicine, Policy No. M-149

REFERENCES

None

CODING

NOTE: Subtalar arthroereisis and subtalar arthrodesis are significantly different procedures for which the description and coding are not interchangeable. The appropriate CPT code for subtalar arthroereisis is 28899 as there is no specific CPT code for this procedure.

Codes	Number	Description
CPT	28899	Unlisted procedure, foot or toes
	0335T	Extra-osseous subtalar joint implant for talotarsal stabilization
	0510T	Removal of sinus tarsi implant
	0511T	Removal and reinsertion of sinus tarsi implant
HCPCS	S2117	Arthroereisis, subtalar <i>(Not recognized by Medicare for payment)</i>

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.