

Cohere Medicare Advantage Policy - Tarsometatarsal Arthrodesis

Clinical Policy for Medical Necessity Review

Version: 3

Revision Date: May 22, 2025

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

Cohere Health, Inc. ("Cohere") has published these clinical guidelines to determine the medical necessity of services (the "Guidelines") for informational purposes only, and solely for use by Cohere's authorized "End Users". These Guidelines (and any attachments or linked third-party content) are not intended to be a substitute for medical advice, diagnosis, or treatment directed by an appropriately licensed healthcare professional. These Guidelines are not in any way intended to support clinical decision-making of any kind; their sole purpose and intended use is to summarize certain criteria Cohere may use when reviewing the medical necessity of any service requests submitted to Cohere by End Users. Always seek the advice of a qualified healthcare professional regarding any medical questions, treatment decisions, or other clinical guidance. The Guidelines, including any attachments or linked content, are subject to change at any time without notice. This policy may be superseded by existing and applicable Centers for Medicare & Medicaid Services (CMS) statutes.

© 2025 Cohere Health, Inc. All Rights Reserved.

Other Notices:

HCPCS® and CPT® copyright 2025 American Medical Association. All rights reserved.

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

HCPCS and CPT are registered trademarks of the American Medical Association.

Policy Information:

Specialty Area: Disorders of the Musculoskeletal System

Policy Name: Cohere Medicare Advantage Policy - Tarsometatarsal Arthrodesis

Type: $[\underline{X}]$ Adult (18+ yo) | $[\underline{X}]$ Pediatric (0-17 yo)

Table of Contents

Important Notices	2
Medical Necessity Criteria	4
Service: Tarsometatarsal Arthrodesis	4
Related CMS Documents	4
Description	4
Medical Necessity Criteria	4
Indications	4
Non-Indications	5
Definitions	5
Level of Care Criteria	5
Procedure Codes (CPT/HCPCS)	6
Evaluation of Clinical Harms and Benefits	7
Medical Evidence	9
References	11
Clinical Guideline Revision History/Information	13

Medical Necessity Criteria

Service: Tarsometatarsal Arthrodesis

Related CMS Documents

Please refer to the <u>CMS Medicare Coverage Database</u> for the most current applicable CMS National Coverage.

There are no applicable NCDs or LCDs for tarsometatarsal arthrodesis.

Description

Tarsometatarsal (TMT) arthrodesis is a minimally invasive procedure that involves the surgical fusion of the tarsal bones (calcaneus, talus, cuboid, navicular, and cuneiform bones) with the metatarsal bones (the long bones that connect the toes to the rest of the foot). The goal of the procedure is to eliminate movement and pain in the affected joints by fusing the bones together. This is typically achieved through the use of internal fixation devices such as screws, plates, or rods.¹⁻²

Medical Necessity Criteria

Indications

Tarsometatarsal arthrodesis is considered appropriate if **ALL** of the following are **TRUE**^{1-Z}:

- The patient has ANY of the following positive findings:
 - o Bunion deformity and **ALL** of the following:
 - Persistent pain; AND
 - Difficulty walking; **OR**
 - Documented hypermobility of the first TMT joint suggested by greater than 10mm of total sagittal motion; OR
 - Painful TMT joint with tenderness on exam; OR
 - o Hindfoot deformity or arthrosis and triple arthrodesis indicated; AND

- Failure of conservative management for greater than 3 months, including
 ALL of the following:
 - Anti-inflammatory medications, non-opioid analgesics, or prescription medications (e.g., oral steroids, neuropathic pain medications) if not contraindicated; AND
 - Physical therapy, including a physician-directed home exercise program; AND
 - ANY of the following:
 - Corticosteroid injection if medically appropriate; OR
 - Documentation that corticosteroid injection is contraindicated; OR
 - Shoe modification; OR
 - Splinting or padding; OR
 - Orthotics; AND
- Radiographic confirmation with report (must be weight-bearing radiographs of the foot) of ANY of the following⁸:
 - o Intermetatarsal (IM) angle greater than 15 degrees³; **OR**
 - o Advanced osteoarthritis of the tarsometatarsal (TMT) joint (e.g., joint space narrowing, osteophyte formation, subchondral cysts)⁹; **OR**
 - o Traumatic disruption of the TMT articulation.

Non-Indications

Tarsometatarsal arthrodesis is not considered appropriate if **ANY** of the following is **TRUE**^{2,10}:

- The patient has not reached skeletal maturity; OR
- Inadequate blood supply that could prevent healing; OR
- The presence of active, untreated infection at the surgical site; OR
- Significant bone loss with shortening of the foot rays that requires bone block fusion.

Definitions

None applicable

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description	
28297	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method	
28730	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse	
28735	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (e.g., flatfoot correction)	
28740	Arthrodesis, midtarsal or tarsometatarsal, single joint	

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS' required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for tarsometatarsal arthrodesis may include:

- Adverse effects from delayed or denied treatment, which include nerve damage, osteoarthritis, worsening of chronic pain, worsening deformity, and increased fall risk.¹¹
- Inherent surgical complications include but are not limited to standard risks of anesthesia, infection, and iatrogenic injury.
- Surgical complications specific to this procedure include but are not limited to nonunion, malunion, hardware issues, compensatory joint arthrosis, peripheral nerve damage, and recurrent or malaligned deformities.¹²

The clinical benefits of using these criteria include:

- Improved patient selection for tarsometatarsal arthrodesis resulting in better long-term outcomes including pain relief, improved stability, and increased quality of life for individuals with painful or unstable tarsometatarsal joints. The procedure effectively stabilizes the joint, reducing pain and allowing for greater weight-bearing and activity.
- Maintenance of rigorous patient safety standards aligned to best available evidence.
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Schwartz et al. (2024) conducted a two-part, randomized, double-blind, active-controlled trial. The study examined the efficacy, safety, and how liposomal bupivacaine (LB) works in the body when given through ultrasound-guided sciatic nerve block in the popliteal fossa during bunionectomy surgery. In part A, patients were randomized 1:1:1 into 3 groups: LB 266 mg, LB 133 mg, or bupivacaine hydrochloride 50 mg (BUPI). Part B participants were randomized 1:1 to LB (at the dose established by part A) or to the BUPI group. When administered via sciatic nerve block in the popliteal fossa following a bunionectomy, LB 133 mg demonstrated superior pain management compared to BUPI. Patients experienced a decrease in pain levels and opioid usage for up to 4 days post-surgery, with a notably higher proportion of participants abstaining from opioids.⁴

Ilfeld et al. (2021) performed a randomized controlled trial (RCT) to determine the impact of percutaneous peripheral nerve stimulation on postoperative pain levels and opioid usage. Study participants included patients undergoing foot, ankle, knee, or shoulder surgeries. Each patient received percutaneous peripheral nerve stimulation preoperatively, followed by a single injection of long-acting local anesthetic along the same nerve. Postoperatively, patients were randomized into groups receiving active or sham stimulation for 14 days. The primary outcome measures were opioid consumption and pain scores within the first 7 postoperative days. Results showed that participants receiving active stimulation had significantly lower opioid consumption and pain scores compared to those receiving sham treatment. The authors concluded that percutaneous peripheral nerve stimulation effectively reduced pain and opioid usage after ambulatory orthopedic surgery without systemic side effects.⁵

Stødle et al. (2020) conducted an RCT to evaluate primary arthrodesis of the first tarsometatarsal (TMT) joint compared to temporary bridge plating for managing unstable Lisfranc injuries. This study compared primary arthrodesis (PA) and temporary bridge plate (BP) treatments for Lisfranc injuries. A total

of 48 patients were followed for 2 years. 24 patients were randomized to primary arthrodesis (PA) of the medial 3 TMT joints, whereas 24 patients were randomized to temporary bridge plate (BP) over the first TMT joint and primary arthrodesis of the second and third TMT joints. PA involved fusing the medial 3 TMT joints, while BP involved placing a plate over the first TMT joint and fusing the second and third TMT joints. The main outcome measured was the American Orthopaedic Foot & Ankle Society (AOFAS) midfoot scale, with secondary measures including SF-36, VAS pain scores, and radiographic assessments. Results showed no significant difference in AOFAS scores between groups, but authors noted better alignment of the first metatarsal in the BP group. Overall, favorable outcomes were observed for both treatments.⁶

References

- Coetzee JC, Wickum D. The Lapidus procedure: A prospective cohort outcome study. Foot Ankle Int. 2004 Aug;25(8):526-31. doi: 10.1177/107110070402500803. PMID: 15363372
- Thomas JL, Blitch EL, et al. Diagnosis and treatment of forefoot disorders. Section 1: Digital deformities. *J Foot Ankle Surg*. 2009 Mar-Apr;48(2):230-8. doi: 10.1053/j.jfas.2008.12.003. PMID: 19232978
- 3. Shi GG, Whalen JL, Turner NS, et al. Operative approach to adult hallux valgus deformity: Principles and techniques. *J Foot Ankle Surg.* 2009 Mar-Apr;48(2):230-8. doi: 10.1053/j.jfas.2008.12.003. PMID: 19232978
- Schwartz G, Gadsden JC, Gonzales J, et al. A phase 3 active-controlled trial of liposomal bupivacaine via sciatic nerve block in the popliteal fossa after bunionectomy. *J Clin Anesth*. 2024 Jun:94:111402. doi: 10.1016/j.jclinane.2024.111402. PMID: 38340677
- Ilfeld BM, Plunkett A, Vijjeswarapu AM, et al. Percutaneous peripheral nerve stimulation (neuromodulation) for postoperative pain: A randomized, sham-controlled pilot study. *J Anesth*. 2021 July 1;135(1):95-110. doi: 10.1097/ALN.000000000003776. PMID: 33856424; PMCID: PMC8249357
- Stødle A, Hvaal K, Brøgger H, et al. Temporary bridge plating vs primary arthrodesis of the first tarsometatarsal joint in Lisfranc injuries: Randomized controlled trial. *Foot Ankle Int*. 2020 Aug;41(8):901-910. doi: 10.1177/1071100720925815. PMID: 32501109; PMCID: PMC7406968

- 7. Van den Boom N, Stollenwerck G, Lodewijks L, Bransen J, et al. Lisfranc injuries: fix or fuse? *Bone Jt Open*. 2021;2(10):842-849. doi:10.1302/2633-1462.210.BJO-2021-0127.R1
- 8. Langan T, Brandão R, Goss D, Hyer C. Arthrodesis of the first tarsometatarsal joint for correction of hallux abductovalgus: Technique guide and tips, *J Foot Ankle Surg.* 2021, 100008, ISSN 2667-3967, https://doi.org/10.1016/j.fastrc.2021.100008.
- Vacketta V, Perkins J, et al. Surgical planning for staple fixation of the first tarsometatarsal joint: An anatomic study. J Foot Ankle Surg, Volume 4, Issue 1, 2024, 100358, ISSN 2667-3967 https://doi.org/10.1016 /j.fastrc.2023.100358
- 10. Lui TH. Arthroscopic tarsometatarsal arthrodesis. *Arthrosc Tech*. 2016;5(6):e1311-e1316. Published 2016 Nov 14. doi:10.1016/j.eats.2016.07.023
- InformedHealth.org. Cologne, Germany: Institute for Quality and Efficiency in Health Care (IQWiG); 2006. Overview: Bunions. [Updated 2024 Oct 9]. Available from: https://www.ncbi.nlm.nih.gov/ books/NBK513134/
- 12. Masuda RY, Pereira VF, Lemos AVKC, et al. Complications of first tarsometatarsal joint arthrodesis. *J Foot Ankle*. 2021;15(3):213-6. https://doi.org/10.30795/footankle.2021.v15.1554
- Rao S, Nawoczenski DA, Baumhauer JF, et al. Midfoot arthritis:
 Nonoperative options and decision-making for fusion. *Tech Foot Ankle Surg.* 2008;7(3):188-195

Clinical Guideline Revision History/Information

Original Date: May 27, 2024			
Review History			
Version 2	06/10/2024	422.101 Disclaimer added	
Version 3	05/22/2025	Annual Review.	
		References added	
		Harms and Benefits section revised	
		Clarified conservative care language	
		Removed nonindication regarding deformity related to Lisfranc arthritis	