Cohere Medicare Advantage Policy - Tarsometatarsal Arthrodesis

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: June 10, 2024

Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Disorders of the Musculoskeletal System
Guideline Name: Cohere Medicare Advantage Policy - Tarsometatarsal Arthrodesis

Date of last literature review: 6/10/2024
Document last updated: 6/10/2024
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Tarsometatarsal Arthrodesis

Benefit Category
Not applicable.

Recommended Clinical Approach
Tarsometatarsal (TMT) joint arthrodesis may be used to treat traumatic or degenerative diseases of the midfoot and advanced hallux valgus deformities involving first TMT joint instability or arthritis.[1-3]

Evaluation of Clinical Benefits and Potential Harms
Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of tarsometatarsal arthrodesis procedures. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

The potential clinical harms of using these criteria may include:

- Inadequate management of midfoot or bunion pain due to inappropriate denials. Untreated bunions can lead to osteoarthritis and chronic pain.[8] This can also result in worsening deformity which can make you unsteady on your feet resulting in increased risk of falls.
- Risks with inappropriate surgical procedures include infection, bleeding, injury to neurovascular structures, anesthetic risk, recurrent deformity, persistent pain, secondary metatarsalgia, delayed union or nonunion, hallux varus deformity, and the need for secondary or additional procedures due to implant failure. Barg et al also describe high patient dissatisfaction rates up to 47%.[9]
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Improved patient outcomes by ensuring timely and appropriate access to tarsometatarsal arthrodesis. Stoedle et al noted favorable outcomes

for tarsometatarsal arthrodesis in patients with Lisfranc injuries with decreased foot pain.[6]

- Surgical management of bunions with tarsometatarsal arthrodesis has been shown to improve pain and deformity in patients who have failed conservative management. It is important to consider imaging findings, especially the hallux valgus angle (HVA) and intermetatarsal angle (IMA). Shi et al proposed a classification system to help determine the recommended surgical procedure for bunion treatment.[3] They report that non operative treatment can alleviate most patients' pain and therefore should be attempted before surgery. This includes shoes with a wider toe box, metatarsal pads, orthotics, toe spacers or sleeves. They state that no single procedure can universally be applied to all patients with bunions and that patient factors as well as surgeons training and experience should be considered.
- Reduction in complications and adverse effects from unnecessary procedures. Barg et at reviewed published studies for treatment of first metatarsophalangeal pain and found patient dissatisfaction rates of 10.6% with recurrent deformities occuring 4.9% of the time.[9] They also report the complications from surgical treatment of a bunion to include recurrence of the deformity, persistent pain, secondary metatarsalgia, nerve injury, infection, delayed union or nonunion, hallux varus deformity, and the need for secondary procedures. Dissatisfaction and need for hardware removal are frequently noted in many clinical series with rates as high as 47% dissatisfaction, and hardware removal occurring in 25% of patients. Due to the relatively high patient dissatisfaction rates and complications, it is important to use criteria to carefully select patients expected to have a good outcome.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

➔ **Tarsometatarsal Arthrodesis** is considered appropriate if **ALL** of the following are **TRUE**[1-7]:

- The patient has **ANY** of the following positive findings:
  - Bunion deformity with persistent pain and difficulty walking; **OR**
  - Documented hypermobility of the 1st TMT joint; **OR**
  - Painful TMT joint with tenderness on exam; **AND**
- Failure of conservative management (e.g., shoe modification, splinting, padding, rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 3 months. Documentation should include detailed evidence of the measures taken, rather than solely a physician's statement[2-3]; **AND**
- Radiographic confirmation (must be weight-bearing radiographs of the foot) of **ANY** of the following:
  - Intermetatarsal (IM) angle greater than 16 degrees[3]; **OR**
  - Advanced osteoarthritis of the tarsometatarsal (TMT) joint (e.g., joint space narrowing, osteophyte formation, subchondral cysts); **OR**
  - Traumatic disruption of the TMT articulation.

Non-Indications

➔ **Tarsometatarsal Arthrodesis** is not considered appropriate if **ANY** of the following is **TRUE**:

- 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 (may be necessary for deformity correction for a DM ulcer).

Level of Care Criteria

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
28735	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (eg, flatfoot correction)
28740	Arthrodesis, midtarsal or tarsometatarsal, single joint

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. When administered through a sciatic nerve block in the popliteal fossa following a bunionectomy, LB 133 mg exhibited superior and enduring pain management compared to BUPI. The results are clinically significant as they were accompanied by simultaneous decreases in pain levels and opioid usage for up to 4 days post-surgery, with a notably higher proportion of participants abstaining from opioids. (ClinicalTrials.gov Identifier: NCT05157841).[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 usage of opioids. 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 requirements after ambulatory orthopedic surgery without systemic side effects.[5]

Stødle et al. (2020) conducted a RCT to evaluate primary arthrodesis of the first tarsometatarsal (TMT) joint in comparison to temporary bridge plating for managing unstable Lisfranc injuries. The study compared primary arthrodesis (PA) and temporary bridge plate (BP) treatments for Lisfranc injuries, 48 patients were followed for 2 years. 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 better alignment of the first metatarsal was noted in the BP group. Overall, favorable outcomes were noted for both treatments.[6]

References

1. 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.
2. Clinical Practice Guideline Forefoot Disorders Panel, 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.
4. 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.
5. Ilfeld BM, Plunkett A, Vijjeswarapu AM, et al. Percutaneous peripheral nerve stimulation (neuromodulation) for postoperative pain: A randomized, sham-controlled pilot study. *Anesthesiology*. 2021 July 1;135(1):95-110. doi: 10.1097/ALN.0000000000003776. PMID: 33856424; PMCID: PMC8249357.
6. Stødle AH, Hvaal KH, Brøgger HM, 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 NAC, Stollenwerck GANL, Lodewijks L, Bransen J, Evers SMAA, Poeze M. Lisfranc injuries: fix or fuse?. Bone Jt Open. 2021;2(10):842-849. doi:10.1302/2633-1462.210.BJO-2021-0127.R1
8. InformedHealth.org [Internet]. Cologne, Germany: Institute for Quality and Efficiency in Health Care (IQWiG); 2006-. Overview: Bunions. [Updated 2022 Jan 31]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK513134
9. Barg A, Harmer JR, Presson AP, Zhang C, Lackey M, Saltzman CL. Unfavorable Outcomes Following Surgical Treatment of Hallux Valgus Deformity: A Systematic Literature Review. J Bone Joint Surg Am. 2018 Sep 19;100(18):1563-1573. doi: 10.2106/JBJS.17.00975. PMID: 30234626; PMCID: PMC6636801.

Clinical Guideline Revision History/Information

Original Date: May 27, 2024		
Review History		
Version 2	6/10/2024	422.101 Disclaimer added