cohere HEALTH

Cohere Medical Policy -Great Toe Surgical Treatments *Clinical Guidelines for Medical Necessity Review*

Version: 2 September 20, 2024 Effective Date:

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Guideline Information:

Specialty Area: Diseases & Disorders of the Musculoskeletal System **Guideline Name:** Cohere Medical Policy - Great Toe Surgical Treatments

Literature review current through: 7/18/2024 Document last updated: 9/20/2024 Type: [X] Adult (18+ yo) | [X] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Great Toe Surgical Treatments

<u>General Guidelines</u>

- Units, Frequency, & Duration: None.
- Criteria for Subsequent Requests: None.
- Recommended Clinical Approach: Great toe surgical procedures are commonly performed and typically relate either to bunion deformity correction or to address 1st metatarsophalangeal (MTP) joint osteoarthritis. Arthritis of the first MTP joint is often referred to as hallux rigidus and is the most common arthritic disease of the foot. Most patients complain of pain in the MTP joint of the great toe and associated loss of motion. Bone spurs can develop around the joint, mainly dorsally, in addition to a loss of the articular surface cartilage. A bunion deformity is a complex deformity of the first ray that develops on the inside of the foot at the great toe MTP joint. It is more common in females and involves valgus deviation of the proximal phalanx in combination with the varus position of the first metatarsal. Initial treatment for these conditions is non-operative (e.g., shoewear modifications, orthotics, splints, cushions/pads, corticosteroid injections, NSAIDs). In cases that progress and remain symptomatic, surgical treatment is indicated and may involve soft tissue procedures, osteotomies, cheilectomy, fusion, or joint replacement.¹⁻⁹
- Exclusions: None.

Medical Necessity Criteria

Indications

- → Great toe surgical treatments are considered appropriate if ANY of the following is TRUE:
 - The procedure is a simple bunionectomy, and ALL of the following are TRUE:
 - The patient has **ANY** of the following positive findings:
 - Pain at the first metatarsophalangeal (MTP) joint; **OR**

- May have limited range of motion (ROM) at the first MTP joint; OR
- Swelling of the first MTP joint; **OR**
- \circ $\;$ Difficulty walking due to pain in the MTP joints; OR
- Lateral deviation of the great toe; OR
- \circ $\,$ Non-healing ulceration caused by the bunion; AND
- Failure of conservative management for greater than 3 months, including **ALL** of the following:
 - Trial of **ANY** of the following:
 - ◆ Taping; **OR**
 - Splinting; **OR**
 - Toe spacer; OR
 - Toe sleeve; OR
 - Padding; AND
 - Shoe modifications; **AND**
 - Oral steroids, topical or oral anti-inflammatory medications, or oral analgesics; AND
- Radiographic confirmation (must be weight-bearing radiographs of the foot) of **ALL** of the following:
 - **ANY** of the following:
 - A hallux valgus angle (HVA) greater than 15 degrees; OR
 - Intermetatarsal (IM) angle greater than 9 degrees; AND
 - None to mild degenerative changes to the MTP joint;
 OR
- The procedure is a bunionectomy with osteotomy, and ALL of the following are TRUE:
 - The patient has **ANY** of the following positive findings:
 - Pain at the first MTP joint; **OR**
 - May have limited ROM at the first MTP joint; OR
 - Swelling of the first MTP joint; **OR**
 - Difficulty walking due to pain in the MTP joints; **OR**
 - Lateral deviation of the great toe; **AND**
 - Failure of conservative management for greater than 3 months, including **ALL** of the following:
 - Trial of **ANY** of the following:
 - ◆ Taping; **OR**
 - ♦ Splinting; OR

- ◆ Toe spacer; **OR**
- ♦ Toe sleeve; OR
- Padding; AND
- Shoe modifications; AND
- Oral steroids, topical or oral anti-inflammatory medications, or oral analgesics; AND
- Radiographic confirmation (must be weight-bearing radiographs of the foot) of **ANY** of the following:
 - IM angle greater than 9 degrees; OR
 - A HVA greater than 20 degrees; OR
- The procedure is a cheilectomy of the great toe MTP joint, and ALL of the following are TRUE:
 - The patient has **ANY** of the following positive findings:
 - Pain on the top of the first MTP joint; **OR**
 - Swelling and stiffness around the first toe MTP joint;
 OR
 - Limited motion in the sagittal plane of the first MTP joint; **AND**
 - Failure of conservative management for greater than 3 months, including **ALL** of the following:
 - Trial of **ANY** of the following:
 - ◆ Taping; OR
 - ♦ Splinting; OR
 - Toe spacer; OR
 - ◆ Toe sleeve; OR
 - Padding; AND
 - Shoe modifications; **AND**
 - Oral steroids, topical or oral anti-inflammatory medications, or oral analgesics; AND
 - **ANY** of the following:
 - Corticosteroid injection if medically appropriate; OR
 - Corticosteroid injection is contraindicated; AND
 - Radiographic findings of osteoarthritis of the first MTP joint (e.g., dorsal osteophyte, joint space narrowing, subchondral cysts); **OR**
- The procedure is an arthrodesis of the great toe MTP joint, and ALL of the following are TRUE:
 - The patient has **ANY** of the following positive findings:

- Pain on the top of the first MTP joint; OR
- Swelling and stiffness around the first toe MTP joint;
 OR
- Limited motion in the sagittal plane of the first MTP joint; **AND**
- Failure of conservative management for greater than 3 months, including **ALL** of the following:
 - Trial of **ANY** of the following:
 - ◆ Taping; **OR**
 - ♦ Splinting; **OR**
 - ◆ Toe spacer; OR
 - ♦ Toe sleeve; OR
 - Padding; AND
 - Shoe modifications; **AND**
 - Oral steroids, topical or oral anti-inflammatory medications, or oral analgesics; AND
 - **ANY** of the following:
 - Corticosteroid injection if medically appropriate; OR
 - Corticosteroid injection is contraindicated; AND
- Radiographic findings of advanced stages of osteoarthritis (e.g., dorsal osteophyte, joint space narrowing, subchondral cysts); OR
- The procedure is a great toe MTP joint arthroplasty, and ALL of the following are TRUE:
 - The patient has **ANY** of the following positive findings:
 - Pain on the top of the first MTP joint; OR
 - Swelling and stiffness around the first toe MTP joint;
 OR
 - Limited motion in the sagittal plane of the first MTP joint; AND
 - Failure of conservative management for greater than 3 months, including **ALL** of the following:
 - Trial of **ANY** of the following:
 - ◆ Taping; **OR**
 - Splinting; OR
 - ◆ Toe spacer; OR
 - ♦ Toe sleeve; OR
 - Padding; AND

- Shoe modifications; **AND**
- Oral steroids, topical or oral anti-inflammatory medications, or oral analgesics; AND
- **ANY** of the following:
 - Corticosteroid injection if medically appropriate; OR
 - Corticosteroid injection is contraindicated; AND
- Radiographic findings of advanced stages of osteoarthritis (e.g., dorsal osteophyte, joint space narrowing, subchondral cysts).

Non-Indications

- → Great toe surgical treatments are not considered appropriate if ANY of the following is TRUE:
 - The patient has not reached skeletal maturity; OR
 - Inadequate blood supply that would prevent healing; OR
 - Presence of an active, untreated infection at the surgical site (may be necessary for a DM ulcer correction).

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description	
28240	Tenotomy, lengthening, or release, abductor hallucis muscle	
28289	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; without implant	
28291	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant	
28292	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with resection of proximal phalanx base, when performed, any	

	method	
28295	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal metatarsal osteotomy, any method	
28296	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with distal metatarsal osteotomy, any method	
28298	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal phalanx osteotomy, any method	
28299	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with double osteotomy, any method	
28306	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal	
28310	Osteotomy, shortening, angular or rotational correction; proximal phalanx, first toe (separate procedure)	
28750	Arthrodesis, great toe; metatarsophalangeal joint	
L8641	Metatarsal joint implant	

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 bupivacaine hydrochloride. 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).¹⁰

Ilfeld et al. (2021) performed a randomized controlled trial 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.¹

Daniels et al. (2019) conducted a prospective, randomized, double-blind, multicenter, placebo-controlled factorial clinical trial. The study aimed to assess the effectiveness and safety of a combination of ibuprofen and acetaminophen (multimodal analgesia) administered intravenously for managing postoperative pain following bunionectomy. While oral fixed-dose combinations are available, the study focused on the IV route, which may be necessary in certain clinical situations. The study demonstrated that a combination of ibuprofen and acetaminophen given intravenously provided superior pain relief compared to either medication alone, as evidenced by reduced opioid usage rates. The safety profile of the combination was similar to that of ibuprofen or acetaminophen alone. The study suggests that this combination therapy could effectively manage pain with fewer adverse events. (ClinicalTrials.gov Identifier: NCT02689063).¹²

References

- 1. Nix S, Smith M, Vicenzino B. Prevalence of hallux valgus in the general population: A systematic review and meta-analysis. *J Foot Ankle Res.* 2010;3(1). doi: 10.1186/1757-1146-3-21.
- 2. Coughlin MJ, Shurnas PS. Hallux rigidus: Grading and long-term results of operative treatment. *J Bone Joint Surg*. 2003; 85(11):2072-2088.
- 3. Hamid K, Parekh S. Clinical presentation and management of hallux rigidus. *Foot Ankle Clin*. 2015;20(3):391-399. doi: 10.1016/j.fcl.2015.04.002.
- American Academy of Orthopaedic Surgeons (AAOS). Hallux rigidus (stiff big toe). Updated October 2022. Accessed July 1, 2024. https://orthoinfo.aaos.org/en/diseases--conditions/stiff-big-toe-hallux -rigidus.
- 5. O'Malley M, Basran H, Gu Y, et al. Treatment of advanced stages of hallux rigidus with cheilectomy and phalangeal osteotomy. *J Bone Joint Surg*. 2013;95(7):606-610. doi: 10.2106/jbjs.k.00904.
- 6. Ellington JK, Jones CP, Cohen BE, et al. Review of 107 hallux MTP joint arthrodesis using dome-shaped reamers and a stainless-steel dorsal plate. *Foot Ankle Int*. 2010;31(5):385-390. doi: 10.3113/FAI.2010.0385.
- Johnson JE, Clanton TO, Baxter DE, et al. Comparison of Chevron osteotomy and modified McBride bunionectomy for correction of mild to moderate hallux valgus deformity. *Foot Ankle*. 1991;12(2):61-68. doi: 10.1177/107110079101200201.
- Aminian A, Kelikian A, Moen T. Scarf osteotomy for hallux valgus deformity: An intermediate followup of clinical and radiographic outcomes. *Foot Ankle Int*. 2006;27(11):883–886. doi: 10.1177/107110070602701103.
- Shi GG, Whalen JL, Turner NS, et al. Operative approach to adult hallux valgus deformity: Principles and techniques. J Am Acad Orthop Surg. 2020 May 15;28(10):410-418. doi: 10.5435/JAAOS-D-19-00324.
- 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.
- 11. Ilfeld BM, Plunkett A, Vijjeswarapu AM, et al. Percutaneous peripheral nerve stimulation (neuromodulation) for postoperative pain: A

randomized, sham-controlled pilot study. *Anesthesiology*. 2021 Jul 1;135(1):95-110. doi: 10.1097/ALN.000000000003776. PMID: 33856424.

 Daniels SE, Playne R, Stanescu I, et al. Efficacy and safety of an intravenous acetaminophen/ibuprofen fixed-dose combination after bunionectomy: A randomized, double-blind, factorial, placebo-controlled trial. *Clin Ther*. 2019 Oct;41(10):1982-1995.e8. doi: 10.1016/j.clinthera.2019.07.008. PMID: 31447129.

Clinical Guideline Revision History/Information

Original Date: April 19, 2024			
Review History			
Version 2	9/20/2024	Updated language regarding conservative treatment.	