

# Great Toe Surgical Treatments - Single Service

Clinical Guidelines for Medical Necessity Review

Version:

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#### **Guideline Information:**

**Specialty Area:** Diseases & Disorders of the Musculoskeletal System **Guideline Name:** Great Toe Surgical Treatments (Single Service)

Literature review current through: 4/19/2024

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

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# **Medical Necessity Criteria**

### Service: Great Toe Surgical Treatments

#### **General Guidelines**

- Units, Frequency, & Duration: None.
- Criteria for Subsequent Requests: None
- Recommended Clinical Approach<sup>1-9</sup>: Great toe surgical procedures are commonly performed and typically relate either to bunion deformity correction or to address 1st metatarsophalangeal joint osteoarthritis. Arthritis of the 1st 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 metatarsophalangeal joint and is more common in females. It involves valgus deviation of the proximal phalanx in combination with varus position of the first metatarsal. Initial treatment for these conditions is non-operative (shoewear modifications, orthotics, splints, cushions/pads, corticosteroid injections, NSAIDs). In cases that progress and remain symptomatic, surgical treatment is indicated. Surgical treatment can involve soft tissue procedures, osteotomies, cheilectomy, fusion, or joint replacement.2-3,5-9
- 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:
      - o 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
      - o Difficulty walking due to pain in the MTP joints; OR

- Lateral deviation of the great toe; OR
- Non-healing ulceration caused by the bunion; AND
- The patient has failed to show significant improvement in pain or disability due to symptoms despite treatment for at least 3 months with ANY of the following:
  - o Shoe modifications; OR
  - Protective cushions/pads; OR
  - Toe spacers; OR
  - Splinting; OR
  - o Orthotics; OR
  - 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°; OR
    - Intermetatarsal (IM) angle greater than 9°; 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 metatarsophalangeal (MTP) joint; OR
    - May have limited range of motion (ROM) at the first MTP joint; OR
    - Swelling of the first MTP joint; OR
    - o Difficulty walking due to pain in the MTP joints; OR
    - o Lateral deviation of the great toe; **AND**
  - The patient has failed to show significant improvement in pain or disability due to symptoms despite treatment for at least 3 months with ANY of the following:
    - Shoe modifications; OR
    - Protective cushions/pads; OR
    - o Toe spacers; **OR**
    - o Splinting; OR
    - o Orthotics; OR
    - 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:
  - Intermetatarsal angle (IMA) greater than 9°; OR
  - o A hallux valgus angle (HVA) greater than 20°; 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:
    - o Pain on the top of the first MTP joint; OR
    - Swelling and stiffness around the first toe metatarsophalangeal (MTP) joint; OR
    - Limited motion in the sagittal plane of the first MTP joint; AND
  - The patient fails to show significant improvement in pain or disability due to symptoms despite treatment for at least 3 months with **ANY** of the following:
    - o Shoe modifications; OR
    - Splinting; OR
    - Orthotics (i.e., Morton's extension orthosis); OR
    - Oral steroids, topical or oral anti-inflammatory medications, or oral analgesics; OR
    - o **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:
    - o Pain on the top of the first MTP joint; OR
    - Swelling and stiffness around the first toe metatarsophalangeal (MTP) joint; OR
    - Limited motion in the sagittal plane of the first MTP joint; AND
  - The patient has failed to show significant improvement in pain or disability due to symptoms despite treatment for at least 3 months with ANY of the following:
    - Shoe modifications; OR

- Splinting; OR
- Orthotics (i.e., Morton's extension orthosis); OR
- Oral steroids, topical or oral anti-inflammatory medications, or oral analgesics; OR
- 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:
    - o Pain on the top of the first MTP joint; OR
    - Swelling and stiffness around the first toe metatarsophalangeal (MTP) joint; OR
    - Limited motion in the sagittal plane of the first MTP joint; AND
  - The patient has failed to show significant improvement in pain or disability due to symptoms despite treatment for at least 3 months with ANY of the following:
    - Shoe modifications; OR
    - o Splinting; OR
    - o Orthotics (i.e., Morton's extension orthosis); OR
    - Oral steroids, topical or oral anti-inflammatory medications, or oral analgesics OR
    - o 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 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 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).

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.<sup>11</sup>

Daniels et al. (2019) conducted a prospective, randomized, double-blind, multicenter, placebo-controlled factorial clinical trial (ClinicalTrials.gov Identifier: NCT02689063). 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 (FDCs) 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.<sup>12</sup>

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# Clinical Guideline Revision History/Information

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