Cohere Medicare Advantage Policy - Great Toe Surgical Treatments

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Disorders of the Musculoskeletal System
Guideline Name: Cohere Medicare Advantage Policy - Great Toe Surgical Treatments

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Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Great Toe Surgical Treatments

Benefit Category

Not applicable.

Recommended Clinical Approach[1-9]

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.[1] 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).[9] 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]

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 Great Toe Surgical Treatments. This process helps to prevent both incorrect denials and inappropriate approvals of medically unnecessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inadequate management of great toe conditions, leading to complications like progression of the condition, worsening pain, and reduced mobility. Untreated bunions can lead to osteoarthritis and

chronic pain.[13] 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 and need for repeat or additional procedures due to hardware failure, malunion or nonunion. According to Shi et al, preoperative selection is important, a physical examination determining if additional toe deformities are present, standing radiographic images with measurements of deformities, especially the hallux valgus angle (HVA) and intermetatarsal angle (IMA); they have proposed a classification system to help determine the recommended surgical procedure for bunion treatment.[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 necessary surgical treatments for managing great toe conditions. With appropriate surgical treatment, patients can remain active with decreased pain and improved quality of life.
- Reduction in complications and adverse effects from unnecessary procedures. 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.[14] 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

- ➔ **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**
      - Difficulty walking due to pain in the MTP joints; **OR**
      - Lateral deviation of the great toe; **OR**
      - Non-healing ulceration caused by the bunion; **OR**
      - Malunion or non-union of previous surgery; **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; **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**
        - Difficulty walking due to pain in the MTP joints; **OR**
        - Lateral deviation of the great toe; **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; **AND**
    - Radiographic confirmation (must be weight-bearing radiographs of the foot) of **ANY** of the following:
        - Intermetatarsal angle (IMA) greater than 9°; **OR**
        - 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:
        - 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**
    - 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; **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 metatarsophalangeal (MTP) joint; **OR**
  - Limited motion in the sagittal plane of the first MTP joint; **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; **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 metatarsophalangeal (MTP) joint; **OR**
  - Limited motion in the sagittal plane of the first MTP joint; **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; **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 diabetic 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).[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.[11]

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.[12]

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