Cohere Medicare Advantage Policy - Great Toe Surgical Treatments

Clinical Policy for Medical Necessity Review

Version: 3
Revision Date: May 29, 2025

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Policy Information:

Specialty Area: Musculoskeletal Care
Policy Name: Great Toe Surgical Treatments
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Great Toe Surgical Treatments

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.

- There are no applicable NCDs and/or LCDs for great toe surgical treatments

Description

Great toe surgical procedures are common and typically involve correcting a bunion deformity or first metatarsophalangeal (MTP) joint osteoarthritis. Great toe surgical procedures encompass several surgical treatments, including soft tissue procedures, osteotomies, cheilectomy, fusion, or joint replacement.[1-7] In bunionectomy and cheilectomy procedures, excess bony growth is surgically removed; in some cases, the bunionectomy may be combined with osteotomy to realign adjoining bones. In arthrodesis and arthroplasty procedures, the great toe joints are fused or replaced to relieve pain and restore function.

Medical Necessity Criteria

Indications

Great toe surgical treatments - hallux valgus are considered appropriate if **ALL** of the following are **TRUE**:

- Failure of conservative management for greater than 3 months, including **ALL** of the following[8-11]:
  - Trial of **ANY** of the following:
    - Taping; **OR**
    - Splinting; **OR**
    - Toe spacer; **OR**

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        - Toe sleeve; **OR**
        - Padding; **AND**
    - Shoe modifications; **AND**
    - Oral steroids, topical or oral anti-inflammatory medications, or oral analgesics; **AND**
- **ANY** of the following:
    - Documentation of skeletal maturity as indicated by first metatarsal physeal closure or near closure[17]; **OR**
    - Certain connective tissue or neuromuscular disorders that may affect etiology or severity of the condition (e.g., Cerebral Palsy, Ehlers-Danlos Syndrome, Marfan Syndrome, Osteogenesis Imperfecta, Fibrodysplasia Ossificans Progressiva)[16,18,19]; **AND**
- **ANY** of the following:
    - The procedure is a simple bunionectomy, and **ALL** of the following[12]:
        - The patient has **ANY** of the following positive findings[13]:
            - Pain at the first metatarsophalangeal (MTP) joint; **OR**
            - 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[14]; **OR**
            - Malunion or non-union of previous surgery[15]; **AND**
        - Radiographic confirmation (must be weight-bearing radiographs of the foot) of **ALL** of the following[13,16]:
            - **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:
        - The patient has **ANY** of the following positive findings[13]:
            - Pain at the first metatarsophalangeal (MTP) joint; **OR**
            - 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**

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            - Malunion or non-union of previous surgery[15]; **AND**
        - Radiographic confirmation (must be weight-bearing radiographs of the foot) of **ANY** of the following[16]:
            - A hallux valgus angle (HVA) greater than 15°; **OR**
            - Intermetatarsal angle (IMA) greater than 9°; **OR**
    - The procedure is a bunionectomy and medial cuneiform joint arthrodesis, and **ALL** of the following:
        - **ANY** of the following[1,13,16]:
            - Recurrent bunions; **OR**
            - Unstable/hypermobile first metatarsal; **OR**
            - Subluxation of the hallux joint; **OR**
            - Tarsometatarsal joint arthritis; **OR**
            - Malunion or non-union of previous surgery[15]; **AND**
        - Radiographic confirmation (must be weight-bearing radiographs of the foot) of **ANY** of the following[1,13]:
            - A hallux valgus angle (HVA) greater than 40°; **OR**
            - Intermetatarsal angle (IMA) greater than 15°.

Great toe surgical treatments - hallux rigidus are considered appropriate if **ALL** of the following are **TRUE**:

- Failure of conservative management for greater than 3 months, including **ALL** of the following[8-11]:
    - Trial of **ANY** of the following:
        - Taping; **OR**
        - Splinting; **OR**
        - Toe sleeve; **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**
- Documentation of skeletal maturity as indicated by first metatarsal physeal closure or near closure[17]; **AND**
- **ANY** of the following:

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- The procedure is a cheilectomy of the great toe MTP joint, and **ALL** of the following[3,20]:
  - The patient has **ANY** of the following positive findings[21]:
    - Pain on the top of the first MTP joint[22]; **OR**
    - Swelling and stiffness around the first toe metatarsophalangeal (MTP) joint[21]; **OR**
    - Limited motion in the sagittal plane of the first MTP joint[20,22]; **AND**
  - Radiographic findings of osteoarthritis of the first MTP joint (e.g., dorsal osteophyte, joint space narrowing, subchondral cysts)[22]; **OR**
- The procedure is an arthrodesis of the great toe MTP joint, and **ALL** of the following[20]:
  - The patient has **ANY** of the following positive findings[13]:
    - 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**
  - Radiographic findings of advanced stages of osteoarthritis (e.g., dorsal osteophyte, joint space narrowing, subchondral cysts)[21]; **OR**
- The procedure is a great toe MTP joint arthroplasty, and **ALL** of the following are **TRUE**[20]:
  - The patient has **ANY** of the following positive findings[21]:
    - Pain on the top of the first MTP joint[22]; **OR**
    - Swelling and stiffness around the first toe metatarsophalangeal (MTP) joint[3,21]; **OR**
    - Limited motion in the sagittal plane of the first MTP joint[20,22]; **AND**
  - Radiographic findings of advanced stages of osteoarthritis (e.g., dorsal osteophyte, joint space narrowing, subchondral cysts).[22]

Non-Indications

Great toe surgical treatments are not considered appropriate if **ANY** of the following is **TRUE**:

- Inadequate blood supply that would prevent healing[23]; **OR**
- Presence of active, untreated infection at the surgical site (may be necessary for a diabetic ulcer correction).[24]

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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
28297	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed, with first metatarsal and medial cuneiform joint arthrodesis, any method
28298	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal

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	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

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

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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 great toe surgical treatments may include:

- Adverse effects from delayed or denied treatment, such as disease progression, worsening pain, reduced mobility, development of osteoarthritis, chronic pain, reduced stability, and increased fall risk.[8,25]
- Risks with inappropriate surgical procedures include infection, bleeding, injury to neurovascular structures, anesthetic risk, and the need for repeat or additional procedures due to hardware failure, malunion, or nonunion.[1]

The clinical benefits of using these criteria for great toe surgical treatments may include:

- Improved patient selection for great toe surgical treatments, resulting in better long-term outcomes. With appropriate surgical treatment, patients can remain active with decreased pain and improved quality of life.[26]
- Reduction in complications and adverse effects from unnecessary procedures. Barg et al. reviewed published studies for treatment of first metatarsophalangeal pain and found patient dissatisfaction rates of 10.6% and a recurrent deformity rate of 4.9%.[27] Reported complications of surgical bunion treatment include deformity recurrence, 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, with dissatisfaction rates as high as 47% and hardware removal occurring in 25% of patients.

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- Maintenance of rigorous patient safety standards aligned to best available evidence. Patients with inadequate blood supply that would prevent healing who undergo great toe surgical treatments are at risk for wound hypoxia and possible limb loss due to limited blood flow.[23]
- Patients with active, untreated infection at the surgical site who undergo great toe surgical treatments are at risk for deep infection resulting in nonunion, limb loss, and increased mortality.[24,28]

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Medical Evidence

A 2024 Cochrane review of 25 studies with a total of 1597 participants evaluating surgical interventions for hallux valgus and bunions reported decreased pain and increased function after surgery compared to non-surgical treatments.[8] This meta-analysis also found no benefit in pain reduction or functional improvement, along with a higher complication rate, after complex versus simple osteotomy. In a 2016 review, Fraisler and colleagues reported that, while nonoperative management does not correct hallux valgus deformities, it can relieve symptoms and should be considered first-line treatment.[13] Particular care is advised in recommending surgical treatment to patients with hypermobility, ligamentous laxity, or neuromuscular disorders, for whom post-surgery recurrence rates are reported to be particularly high.

In a 2017 clinical trial, Goldberg et al. compared a novel hydrogel implant with traditional arthrodesis in the treatment of moderate to severe hallux rigidus and reported that both procedures similarly decreased pain scores.[29] This was not modulated by any of the patient characteristics assessed, including severity of deformity, body mass index, or age. The authors noted that great toe implants are often associated with high rates of long-term failure due to loosening, malalignment, dislocation, subsidence, implant fragmentation, and bone loss, while arthrodesis is considered reliable.

In 2022 the American College of Foot and Ankle Surgeons (ACFAS) published a clinical consensus statement on the diagnosis, clinical course, and treatment of hallux valgus, agreeing to the following statements: that hallux vagus is a chronic, progressive, and degenerative disorder; that evaluation and management of juvenile hallux valgus deformities should differ from adult deformities; that effective assessment requires radiographic evaluation; that the outcome of hallux valgus surgical correction is independent of procedure selection (i.e., there is no single surgical procedure able to address all deformities); and that physical medicine and rehabilitation interventions should accompany surgical procedures.[16] Two prospective controlled studies comparing surgical correction, custom orthotics, and no treatment were

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reviewed. Surgical patients reported less pain at final follow-up, with no differences between control and orthotic groups. Other nonsurgical interventions, including dynamic splinting, padding, and exercise programs, similarly led to minimal improvements in radiographic or functional outcomes compared with surgical interventions. The consensus statement also noted that rates of deformity recurrence vary widely across studies, perhaps partly due to differences in recurrence definition. Specific deformity characteristics, including more significant preoperative deformity, persistent first metatarsal head lateral cartilage malalignment, a relatively long first metatarsal, and postoperative sesamoid malalignment, may be associated with higher recurrence rates.

In their 2024 clinical consensus statement on hallux rigidus, the ACFAS defined hallux rigidus as a chronic and progressive degenerative condition affecting the first metatarsophalangeal joint with no single cause, diagnosed via any one of several possible weight-bearing radiographic findings and graded using physical examination and radiographic findings.[22] They went on to recommend that therapeutic management, starting with conservative care, be initiated when patients experience pain or reductions in quality of life. Joint-sparing procedures, including cheilectomy, were recommended for low-grade hallux rigidus, while these procedures lack long-term durability in later-stage disease. Joint destructive procedures, including arthrodesis and arthroplasty, should be reserved for high-grade disease.

While hallux valgus, hallux rigidus, and other conditions necessitating great toe surgical procedures are more prevalent in adults, they can present in pediatric patients, oftentimes comorbid with other conditions.[17-19] In juvenile populations, deformities are often characterized by reduced medial soft tissue hypertrophy, limited medial metatarsal head eminence, reduced valgus orientation of the hallux, hypermobility, relative plasticity of the immature bone, and the presence of open physis at the proximal first metatarsal.[16] Radiographic evaluation often suggests a more significant structural, as opposed to functional, component to the deformity. Authors have noted that the presence of an open physis should influence procedure selection and timing of surgical interventions, recommending that surgical procedures be avoided until physis closure, or at least near closure (around

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age 13.7 in females and 15.6 in males). However, some cases of juvenile deformity, notably in pediatric patients with connective tissue or neuromuscular conditions, may necessitate earlier surgical intervention to prevent further deformity.[19]

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Clinical Guideline Revision History/Information

Original Date: May 24, 2024		
Review History		
Version 2	6/10/2024	422.01 Disclaimer added
Version 3	5/29/2025	Annual review. Added indications for pediatric patients (at or near skeletally mature; connective tissue/neuromuscular disorders) and removed non-indication for skeletally immature. Added Code 28297 - Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed, with first metatarsal and medial cuneiform joint arthrodesis, any method Reorganized criteria (indications split into two sections: hallux valgus and hallux rigidus) Updated references Updated Medical Evidence

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