

# Cohere Medical Policy Great Toe Surgical Treatments

**Clinical Policy for Medical Necessity Review** 

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#### **Policy Information:**

**Specialty Area:** Musculoskeletal Care

**Policy Name:** Cohere Medical Policy - Great Toe Surgical Treatments

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

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## **Medical Necessity Criteria**

#### Service: Great Toe Surgical Treatments

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere
  Health medical policy, medical necessity will be determined based on
  established clinical best practices, as supported by evidence-based
  literature, peer-reviewed sources, professional society guidelines, and
  state or national recommendations, unless otherwise directed by the
  health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
  - The medical necessity of each individual request
  - Why prior imaging or procedures were inconclusive, or why additional/follow-up studies are needed
  - o How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

#### **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. 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<sup>8-14</sup>:
  - Trial of ANY of the following:
    - Taping or splinting; **OR**
    - Toe spacer; OR
    - Toe sleeve; OR
    - Padding; **AND**
  - o Shoe modifications; AND
  - Oral steroids, topical or oral anti-inflammatory medications, or oral analgesics; AND
- ANY of the following:
  - Documentation of near or full skeletal maturity as indicated by first metatarsal physeal closure or near closure<sup>12</sup>; OR
  - Documentation of 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)<sup>13-15</sup>; AND
- ANY of the following:
  - The procedure is a simple bunionectomy, and **ALL** of the following<sup>16</sup>:
    - The patient has **ANY** of the following positive findings:::
      - Pain, swelling, or limited range of motion (ROM) at the first metatarsophalangeal (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<sup>18</sup>; OR
- Malunion or non-union of previous surgery<sup>19</sup>; AND
- Radiographic confirmation with radiologic report (must be weight-bearing radiographs of the foot) of **ALL** of the following 13.17:
  - ANY of the following:
    - Hallux valgus (HV) angle greater than 15°; OR
    - Intermetatarsal (IM) angle greater than 9°; AND
  - Minimal degenerative changes to the MTP joint; OR
- The procedure is a bunionectomy with osteotomy, and ALL of the following<sup>16</sup>:
  - ANY of the following:
    - Current nicotine user with no product use for 6 weeks; and ANY of the following<sup>20,21</sup>:
      - Negative urine (cotinine) lab test within 30 days<sup>22</sup>; OR
      - Surgery is urgently required due to documented reason; OR
    - No history of nicotine product use within the last 12 months; OR
    - No lifetime history of nicotine product use, AND
  - The patient has ANY of the following positive findings:
    - Pain, swelling, or limited range of motion (ROM) at the first metatarsophalangeal (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<sup>18</sup>; OR
    - Malunion or non-union of previous surgery<sup>19</sup>; AND
  - Radiographic confirmation with radiologic report (must be weight-bearing radiographs of the foot) of ALL of the following 13.17:
    - ANY of the following:
      - HV angle greater than 15°; OR
      - o IM angle greater than 9°; **OR**
- The procedure is a bunionectomy with medial cuneiform joint arthrodesis, and ALL of the following:
  - ANY of the following:
    - Current nicotine user with no product use for 6 weeks; and ANY of the following<sup>20,21</sup>:
      - Negative urine (cotinine) lab test within 30 days<sup>22</sup>; OR
      - o Surgery is urgently required due to documented reason; OR

- No history of nicotine product use within the last 12 months; OR
- No lifetime history of nicotine product use, AND
- **ANY** of the following<sup>1,13,17</sup>:
  - 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<sup>19</sup>; AND
- Radiographic confirmation with radiologic report (must be weight-bearing radiographs of the foot) of ANY of the following<sup>1,17</sup>:
  - HV angle greater than 40°; OR
  - IM angle 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<sup>8-14</sup>:
  - 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
- Documentation of near or full skeletal maturity as indicated by first metatarsal physeal closure or near closure<sup>12</sup>; AND
- ANY of the following:
  - The procedure is a chellectomy of the great toe MTP joint, and ALL of the following<sup>3,23</sup>:
    - The patient has ANY of the following positive findings<sup>24</sup>:
      - Pain on the top of the first MTP joint<sup>25</sup>; **OR**
      - Swelling and stiffness around the first toe MTP joint<sup>24</sup>; OR
      - Limited motion in the sagittal plane of the first MTP joint<sup>23,25</sup>; AND

- Radiographic findings with radiologic report of osteoarthritis of the first MTP joint (e.g., dorsal osteophyte, joint space narrowing, subchondral cysts)<sup>25</sup>; OR
- The procedure is an arthrodesis of the great toe MTP joint, and ALL of the following<sup>23</sup>:
  - **ANY** of the following:
    - Current nicotine user with no product use for 6 weeks; and ANY of the following<sup>20,21</sup>:
      - Negative urine (cotinine) lab test within 30 days<sup>22</sup>; OR
      - Surgery is urgently required due to documented reason; OR
    - No history of nicotine product use within the last 12 months; OR
    - No lifetime history of nicotine product use, AND
  - The patient has **ANY** of the following positive findings $^{\text{IZ}}$ :
    - 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
  - Radiographic findings with radiologic report of advanced stages of osteoarthritis (e.g., dorsal osteophyte, joint space narrowing, subchondral cysts)<sup>24</sup>; OR
- The procedure is a great toe MTP joint arthroplasty, and ALL of the following<sup>23</sup>:
  - The patient has ANY of the following positive findings<sup>24</sup>:
    - Pain on the top of the first MTP joint<sup>25</sup>; OR
    - Swelling and stiffness around the first toe MTP joint 3.24; OR
    - Limited motion in the sagittal plane of the first MTP joint<sup>23,25</sup>; AND
  - Radiographic findings with radiologic report of advanced stages of osteoarthritis (e.g., dorsal osteophyte, joint space narrowing, subchondral cysts).<sup>25</sup>

#### **Non-Indications**

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

- Inadequate blood supply that would prevent healing<sup>26</sup>; OR
- Presence of an active, untreated infection at the surgical site (may be necessary for a diabetic ulcer correction).<sup>27</sup>

#### **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 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**

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. 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. 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 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. 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. <sup>25</sup>

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. 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. 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 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.<sup>15</sup>

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 valgus 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. Two prospective controlled studies comparing surgical correction, custom orthotics, and no treatment were 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.<sup>13</sup>

Pediatric patients may have more severe structural deformities compared with adult patients, who tend to have more functional ailments. Early intervention with lateral hemiepiphysiodesis prior to skeletal maturity may be beneficial in pediatric patients. Although a systematic literature review (Al-Mohrej et al., 2023) showed that hemiepiphysiodesis improves clinical and radiological outcomes in patients with juvenile hallux valgus (JHV) deformities, more rigorous studies are needed to confirm efficacy, as studies in this review were mostly retrospective case series (with only one prospective

cohort study).<sup>28</sup> Another systematic literature review (AlZeedi et al., 2023) analyzed growth modulation for JHV, which included hemiepiphysiodesis procedures. This review had promising results but recognized that prospective and comparative studies are needed to validate the efficacy of this surgical approach as a standard treatment for pediatric populations with certain bunion deformities.<sup>29</sup>

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.<sup>30</sup> 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.<sup>30</sup>

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## Policy Revision History/Information

Original Date: April 19, 2024			
Review History			
Version 2	09/20/2024	Updated language regarding conservative treatment.	
Version 3	07/31/2025	Annual review.  Added CPT code 28297.  Reorganized criteria (indications split into two sections: hallux valgus and hallux rigidus) and placed conservative care indications outside of individual procedure sections.  Added indications for pediatric populations (near or full skeletal maturity; connective tissue/neuromuscular disorders) and removed non-indication for skeletal immaturity.	
		Added nicotine cessation indications to osteotomy/arthrodesis sections.  Literature review - Description and Medical Evidence sections updated (including references).	