Molina Clinical Policy
Foot Surgery Guidelines for Deformities of the Toes (Bunion, Hammertoe, Hallux Rigidus): Policy No. 401

Last Approval: 4/13/2022
Next Review Due By: April 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

This policy addresses miscellaneous foot surgery done to correct certain foot deformities such as hammertoe, hallux rigidus, and poor alignment of the big toe caused by a Tailors bunion or bunionette.

Hallux rigidus is a painful arthritis of the first metatarsophalangeal joint (big toe), which can cause stiffness and progressive loss of motion. It is the most common arthritic condition of the foot. The first metatarsophalangeal joint develops progressive degenerative changes resulting in pain, inflammation, and limited motion. The condition is more prevalent in females than males and has an average age of onset of about 50 years. Over 95% of patients have it bilaterally and two thirds have a positive family history. Arthrodesis is the most common treatment for patients with advanced hallux rigidus but carries additional risks including the potential for loss of foot function and joint motion, diminished gait efficiency, failure of fixation, nonunion, and transfer metatarsalgia. Hallux limitus is the earlier stage of hallux rigidus and movement of the big toe is only somewhat affected. Generally conservative measures can often relieve pain and improve function. (Fields, 2022).

Hallux valgus is a common deformity of the big toe characterized by a lateral deviation of the proximal phalanx at the level of the metatarsal joint. It is frequently associated with a concomitant medial (varus) deviation of the first metatarsal. The result is a bony prominence or “bump” on the medial side of the first metarsophalangeal joint. This is often referred to as a “bunion” and may be associated with soft tissue swelling and pain. In addition, the articular surface of the first metatarsal may have a valgus (lateral) inclination also contributing to the deformity. As the deformity progresses the sesamoid complex will shift laterally aided by the deforming force of the adductor tendon and the lateral capsule tightens while the medial side attenuates. When conservative management fails, the surgical correction of bony and/or soft tissue hallux valgus is often performed, and over 100 different surgical techniques have been described in the literature. Surgical procedures include simple bunionectomy, various soft tissue procedures, metatarsal and phalangeal osteotomies, resection arthroplasty and metatarsophalangeal arthrodesis. (Ferrari, 2021).

Bunionette deformity (or Tailor’s bunion) involves the fifth metatarsal head with a painful lateral bony prominence. It is often associated with constrictive footwear causing pain, inflammation, keratosis, and ulceration. When conservative management fails, surgical methods include condylar excision, proximal or distal osteotomies. (Fields, 2022).

Hammer toe is characterized by flexion deformity of the proximal interphalangeal joint of one or more of the lesser four toes. In severe or chronic conditions, it may be associated with either flexion or extension of the distal interphalangeal or hyperextension of the metatarsophalangeal joint. The most commonly affected toe is the second, although multiple toes can be involved. Hammer toes are considered flexible if passively correctable or rigid if not correctable to the neutral position. (Fields, 2022).

Several procedures are typically done to correct these deformities in an ambulatory or out-patient setting by an orthopedist foot/ankle surgeon or podiatrist.

COVERAGE POLICY

This policy addresses foot surgery performed to correct certain foot deformities such as hammertoe, hallux rigidus, hallux limitus, and poor alignment of the big toe caused by a Tailors bunion or bunionette (AIM, 2021; AMR, 2021).

1. **Hammertoe.** Hammertoe deformity surgery **may be considered medically necessary** in skeletally mature individuals when **ALL** of the following criteria are met:

   a. Age 18 or older; **AND**

   b. Diagnosis of hammertoe with clinical evidence of **ONE** of the following conditions:
   - Adventitious bursitis on the dorsal surface of the hammertoe; **OR**
   - Ankylosis of the distal interphalangeal (DIP) joint or proximal interphalangeal (PIP) joint; **OR**
   - Inter-digital neuroma caused by the deformity; **OR**
   - Lateral metatarsophalangeal (MTP) capsular tear caused by the deformity; **OR**
   - Painful nail conditions secondary to persistent trauma; **OR**
   - Presence of co-existing or causative conditions (e.g., tendon contracture) that need repair; **OR**
   - Subluxation or dislocation of the MTP joint; **OR**
   - Synovitis/capsulitis of the MTP joint; **OR**
   - Ulceration of the apices.

   AND

   c. Documentation of adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses); **AND**

   d. Radiographic confirmation of a hammer toe, claw toe, or mallet toe; **AND**

   e. Significant pain and functional impairment that persists after at least 3 months of conservative therapy or non-healing ulcer attributed to the lesser toe deformity that includes at least **TWO** of the following:
   - Corticosteroid injections; **OR**
   - Debridement of associated hyperkeratotic lesions (e.g., corns, calluses); **OR**
   - Foot orthotics (e.g., adaptive footwear such as shoe inserts, footgear; **OR**
   - modifications, corrective splinting)/orthopedic shoes (i.e., wide/deep toe box); **OR**
   - Oral analgesics and/or nonsteroidal anti-inflammatory drugs (NSAIDs); **OR**
   - Protective padding; **OR**
   - Taping or adhesive devices

   AND

   f. Fixation implants are considered experimental, investigational or unproven due to insufficient evidence in the peer reviewed literature of efficacy and safety.

2. **Hallux Rigidus-Limitus.** Hallux Rigidus-Limitus deformity surgery **may be considered medically necessary** in skeletally mature patients when **ALL** of the following requirements are met:

   a. Age 18 years or older; **AND**

   b. Diagnosis of Hallux rigidus-limitus; **AND**

   c. Presence of **ONE** of the following:
   - Severe hallux rigidus confirmed by radiography includes **BOTH** of the following findings:
     i. Marked osteophyte formation and loss of the joint space, cystic changes with or without subchondral sclerosis; **AND**
     ii. Nearly constant pain, pain throughout the range of motion including midrange.

   OR

- Moderate hallux rigidus confirmed by radiography with excessive (hyper) mobility of the first metatarsophalangeal joint includes **BOTH** of the following findings:
  i. Moderate osteophyte formation and joint space narrowing; subchondral sclerosis
  ii. Moderate-to-severe pain constant at the extremes of motion, moderate-to-severe stiffness.

OR

- Failed prior hallux valgus/rigidus surgery (applicable to first metatarsophalangeal joint arthrodesis procedure only, not applicable to cheilectomy or osteotomy).

AND

d. Limited and/or painful range of motion first metarsophalangeal joint with findings that include **ONE** of the following:
   - Extension or dorsiflexion < 25 degrees; **OR**
   - Palpable dorsal osteophytes.

AND

e. Significant pain and functional impairment of the first metatarsophalangeal joint that persists after failed prior first metatarsophalangeal surgery or after at least 3 months of conservative management that includes **TWO** of the following:

   - Alternative or modified footwear; **OR**
   - Corticosteroid injections; **OR**
   - Debridement of associated hyperkeratotic lesions (e.g., corns, calluses); **OR**
   - Foot orthotics (e.g., adaptive footwear such as shoe inserts, footgear; **OR**
   - modifications, corrective splinting); **OR**
   - Oral analgesics or nonsteroidal anti-inflammatory drugs (NSAIDS); **OR**
   - Protective cushions/pads; **OR**
   - Taping or adhesive devices.

AND

f. Documentation of adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses)

3. **Tailors Bunion or Bunionette.** Hallux valgus or bunionette deformity surgery **may be considered medically necessary** skeletally mature patients when **ALL** of the following are met:

   a. Age 18 years or older; **AND**

   b. Diagnosis of **ANY** of the following:
      - Ulceration at metatarsophalangeal joint; **OR**
      - Nonhealing ulcer at the sole of the foot or the second toe; **OR**
      - Inability to accommodate or modify footwear to control pain; **OR**
      - Avulsion fracture of proximal phalanx; **OR**
      - Malunion or nonunion of prior surgery

   AND

   c. Significant pain and functional limitation of the first or fifth metatarsophalangeal joint that persists after at least 3 months of conservative management; that includes **TWO** of the following:
      - Alternative or modified footwear; **OR**
      - Corticosteroid injections; **OR**
      - Debridement of associated hyperkeratotic lesions (e.g., corns, calluses); **OR**
      - Foot orthotics (e.g., adaptive footwear such as shoe inserts, footgear modifications, corrective splinting); **OR**
      - Oral analgesics or nonsteroidal anti-inflammatory drugs (NSAIDS); **OR**

- Protective cushions/pads; **OR**
- Taping or adhesive devices

AND

d. Radiographic confirmation of a hallux valgus angle (HVA) or metatarsophalangeal angle greater than 15 degrees or an intermetatarsal angle greater than 9 degrees; **AND**

e. Documentation of adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses).

Limitations and Exclusions

(AIM, 2021; AMR, 2021)

The following clinical conditions and treatments are considered not medically necessary that include but are not limited to **ALL** of the following:

1. Asymptomatic hallux valgus, hallux rigidus-limitus or bunionette deformity
2. Surgical intervention solely for cosmetic purposes
3. Implant arthroplasty

Contraindications to any of the above surgery include but are not limited to **ALL** of the following:

1. Active infection of the joint
2. Active systemic bacteremia
3. Active skin infection
4. Inadequate bone stock for osteotomy or arthrodesis
5. Poor wound healing
6. Peripheral vascular disease with non-healing ulcerative wounds

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

The peer reviewed literature describes many different procedures for the correction of hammertoe, hallux rigidus, and Tailor's bunionette deformities. Randomized controlled trials comparing the various techniques to correct the deformities are lacking. Relevant meta-analysis, systematic reviews and case series are outlined below.

Hallux Rigidus

Patel et al. (2019) performed a systematic review to investigate clinical outcomes and complications following interposition arthroplasty for moderate to severe hallux rigidus, for patients who would prefer to maintain range of motion in the MTP joint. The search was conducted using MEDLINE, EMBASE and Cochrane library database in February 2018; data were included from 15 articles (demographics, surgical techniques, clinical outcomes, radiological outcomes and complications and analysis) and analysis was performed using a linear regression model. Mean scores of the American Orthopaedic Foot and Ankle Society (AOFAS) improved preoperatively (41%) to postoperatively (83%). In addition, pain, function, and alignment score also improved postoperatively. Range of motion (ROM) also improved (21.06° to 46.43°); joint space increased from 0.8mm to 2.5mm. Common complications following surgery included metatarsalgia, loss of ground contact, osteonecrosis, great toe weakness, hypoesthesia, decreased push off power, and callous formation. The authors also note that interposition arthroplasty may also be effective for patient with moderate-severe hallux rigidus and want to maintain ROM; patients should be educated on the risk of future complications. Arthrodesis of MTP joint is the gold standard treatment.

Maffulli et al. (2011) performed a systematic review to assess whether benefits from surgery, validated and standardized measures should be used to compare the outcomes of patients undergoing standard surgical procedures. Surgical techniques include cheilectomy, Keller resection arthroplasty, arthrodesis, Silastic implantation, phalangeal or metatarsal osteotomy, capsular arthroplasty, partial or total joint replacement, interposition arthroplasty. To perform the comprehensive systematic review, data were found in CINAHL, Embase, Medline and the Cochrane Central Registry of Controlled Trials; a total of 69 peer reviewed articles were included. Cheilectomy and first metatarsal or phalangeal corrective osteotomy were found to provide better outcomes for those with early and intermediate hallux rigidus (Stages I-II). Arthrodesis or arthroplasty are recommended for the management of more severe conditions. Definitive conclusions were not made on the use of techniques for routine management due to limitations of the published literature (specifically extensive clinical heterogeneity). Additional research is needed specifically randomized clinical trials using standard diagnostic assessment, common and validated scoring system comparing reported outcomes and duration of follow-up >2 years.

Hallux Valgus

Ferrari et al. (2004) performed a Cochrane review to identify and evaluate the evidence from randomized trials of surgical treatments used to correct hallux valgus. A total of 21 trials were included; the quality of trials was largely poor and had small trial sizes. A summary of the trials is below:

- Three trials (332 participants) analyzed conservative treatments against no treatment; evidence did not show a difference in outcomes between the two groups.
- A trial of 140 participants analyzed surgery to conservative treatment. Evidence indicates improvement in all patient outcomes among patients who received chevron osteotomy versus those who received orthoses. The same analyzed surgery to no treatment – evidence indicated an improvement in all patient outcomes in patients who received chevron osteotomy versus those who received no treatment.
- Two trials (133 participants) analyzed those with hallux valgus and compared Keller's arthroplasty with other surgical techniques. There was no advantage or disadvantage in the use of Keller's versus other techniques. Distal osteotomy indicated more benefit when compared to Keller's arthroplasty, especially regarding the intermetatarsal angle and preserving joint range of motion. Data show that arthroplasty had less impact on walking ability versus the arthrodesis.
- Six trials (309 participants) analyzed chevron (and chevron-type) osteotomy with other techniques. No advantage was found with chevron osteotomy.
- Two trials (94 participants) analyzed a type of proximal osteotomy to a proximal chevron osteotomy. No evidence was found regarding outcome differences between techniques.
- Three trials (157 participants) examined outcomes between a patient's original operation and surgical adaptations. No advantage was indicated for any of the adaptations.
- Three trials (71 participants) focused on those with hallux valgus and compared new methods of fixation to traditional methods. No evidence was indicated that fixation methods were harmful to patient outcomes.
- Four trials (162 participants) analyzed post-operative rehabilitation methods. Continuous passive motion use indicated an improved range of motion and faster recovery from surgery. Early weightbearing or crepe bandaging were not harmful to the final outcome.
- A few studies analyzed conservative treatments. Evidence indicates that orthoses and night splints were no more beneficial than no treatment in improving outcomes. Chevron osteotomy was found to be beneficial versus orthoses or no treatment – when compared to other osteotomies, no technique was superior.
- One trial examined an osteotomy to an arthroplasty; limited evidence indicates better outcomes with the osteotomy gat the osteotomy.

The authors noted that high dissatisfaction at follow-up was reported among some trial participants (25 to 33%), despite improvement with pain and hallux valgus angle. A few of the more recent trials used assessment scores that combine several aspects of patient outcomes. Most final outcomes were measured at one year; a few trials maintained follow-up for three years. The ranges of time are minimal as most patients will be on their feet 20-30 years following treatment. Additional research is needed that include patient-focused outcomes, standardized assessment criteria and longer surveillance periods (5-10 years). (Ferrari et al., 2004).

Hammertoe

A systematic review conducted by Wei et al. (2020) compared the surgical outcomes of K-wires versus novel internal fixation devices in Proximal Interphalangeal Joint (PIPJ) arthrodesis in claw/hammer toe surgery. Five studies, including one randomized controlled trial and four case-controlled studies, were included in the systematic review. Studies showed potential results in union rates using the novel internal devices compared to K-wires. The authors note that the novel internal devices are unlikely to present advantages in clinical parameters (e.g., pain levels, patient satisfaction, foot-related function, or surgical complication rates).

Lehman and Smith (1995) analyzed a single case series that included 76 patients (100 feet) that were treated by a one surgeon. This included flexible and rigid hammertoes with a PIP arthrodesis using custom-machined drills, a peg cutter, and hole cutter, combined with an extensor tenotomy and dorsal capsulotomy. Almost half of the patients reported that they were satisfied without reservation; over one-third were satisfied with reservations; and 15% were dissatisfied. Incidence of radiographic fusion was 95%. Common explanations for reservation or dissatisfaction included: incomplete pain relief, residual toe angulation, and prolonged shoe wear restriction post-operative. In conclusion, using a peg and socket arthrodesis for hammertoe correction a 95% rate of radiographic fusion was found. In addition, patients over age 65 should be educated about a diminished rate of satisfaction. Distal flexor tenotomy is recommended for patients with a preoperative DIP flexion contracture.

Tailors Bunion

Martijin et al. (2018) performed a systematic review and meta-analysis to assess the appropriate type of osteotomy for correcting an increased fourth to fifth intermetatarsal angle (IMA) and metatarsophalangeal angle (MPA). Main outcome measures included the IMA, MPA, and American Orthopaedic Foot and Ankle Society Lesser Metatarsophalangeal-Interphalangeal scale and satisfaction scores. A systematic search was performed in Medline, Embase, Cochrane, SPORTdiscus, and CINAHL (through September 2016). In addition, prospective and retrospective studies were included that evaluated outcomes of fifth metatarsal osteotomies to correct a bunionette deformity; all patient ages were included. A total of 28 studies were included in the meta-analysis. Overall, the effect of osteotomies on the MPA saw a significant reduction. Proximal and diaphyseal osteotomies resulted in significant differences in MPA correction versus distal osteotomies. Major complications were least in the distal osteotomy group. The overall success rate of bunionette surgery was 93%; patients reported most satisfaction with proximal osteotomies, followed by distal and diaphyseal osteotomies. While all types of osteotomy have the ability to significantly reduce the fourth to fifth IMA and MPA, the fewest complications were found with distal osteotomies – the greatest satisfaction score was found among proximal osteotomies but this only included one study Distal osteotomies resulted in a high satisfaction rate and accounted for the majority of represented osteotomies in the meta-analysis. Distal osteotomy could be the choice when major IMA and MPA reduction is not required due to a low complication rate.

Additional studies reviewed include: Baumhauer, Singh, and Glazebrook (2016); Caravelli et al. (2018); Mao et al. (2020); Mueller et al. (2018); Morawe and Schmieschek (2018); Park et al. (2019); Saxena et al. (2019); Scott, Hendry, and Locke (2016); Shi et al. (2018); Siddiqui and LaPorta (2018); and Stibolt et al. (2019).

National and Specialty Organizations

The Clinical Practice Guideline Forefoot Disorders Panel of the **American College of Foot and Ankle Surgeons (ACFAS)** (2009) published a guideline that focused on clinical practice and a review of peer reviewed literature. Initial treatment is typically nonsurgical for symptomatic digital deformity including, but not limited to the padding techniques; orthotic devices/shoe insole modifications; debridement; corticosteroid injection; taping; and footwear changes.

Surgical treatment options for digital deformities include:

- For manually reducible deformities, tenotomy or tendon lengthening at the level of the MPJ, PIPJ, or DIPJ. (May require a combination with capsular and/or ligamentous release [reefing]).
- For manually *semi-reducible or rigid* deformities, osseous and soft tissue procedures (in combination).
- Exostectomy, particularly for hyperkeratotic lesions along the medial or lateral aspects of the toe.
- Partial amputation, especially in when the condition impacts the fifth toe. Complete amputation of a lesser toe may be considered to allow shoe fitting (e.g., coexistence of a deformity of a second toe, hallux valgus

deformity in elderly patients).

- Correction of associated conditions may be indicated in the surgical care of some digital deformities.
- Surgical repair of tears associated with the plantar plate.
- Correction of forefoot, midfoot, or hindfoot conditions that contribute to the formation of a digital deformity.

The **ACFAS** (2020) also published a *Position Statement on Cosmetic Surgery.* Currently there are a lack of training programs specializing in cosmetic surgery for the foot, ankle or leg.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
28110	Ostectomy, partial excision, fifth metatarsal head (bunionette) (separate procedure)
28112	Ostectomy, complete excision; other metatarsal head (second, third or fourth)
28232	Tenotomy, open, tendon flexor; toe, single tendon (separate procedure)
28285	Correction hammertoe
28286	Correction, cock-up fifth toe, with plastic skin closure (eg, Ruiz-Mora type procedure)
28288	Ostectomy, partial, exostectomy or condylectomy, metatarsal head, each metatarsal head
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
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
28307	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal with autograft (other than first toe)
28308	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; other than first metatarsal, each
28310	Osteotomy, shortening, angular or rotational correction; proximal phalanx, first toe (separate procedure)
28312	Osteotomy, shortening, angular or rotational correction; other phalanges, any toe
28750	Arthrodesis, great toe; metatarsophalangeal joint

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

4/13/2022	Policy reviewed; no changes to criteria; updated Summary of Medical Evidence and Reference sections.
4/5/2021	New policy.

REFERENCES

Government Agency

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Evidence Based Reviews and Publications

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Peer Reviewed Publications

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*