

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 surgical treatment of bunions by exostectomy and osteotomy.

Hallux valgus (HV), also referred to as a bunion, is the most common foot deformity, with an estimated prevalence of 23% in people aged 18 to 65 and 35.7% in individuals over 65 (Ray et al. 2019). It is a deformity of the forefoot affecting the first ray and characterized by a medial bony protrusion of the first metatarsal head that frequently results in altered joint mechanics, functional impairment, and progressive foot discomfort (Dynamed 2022). The precise etiology is unknown but is thought to be multifaceted, involving genetics, joint hypermobility, aberrant foot anatomy/biomechanics, and footwear. A physical examination is generally sufficient to diagnose HV, and most patients do not require radiographs to be diagnosed or managed by imaging. Radiographs are recommended when surgery is being considered as a treatment option for severe or refractory symptoms to assess the severity of the deformity and the determine the appropriate surgical approach. HV deformity is treated with both nonsurgical and surgical procedures, with initial non-surgical management, although there is limited published evidence that conservative, non-surgical management is effective (Ray et al. 2019). However, clinical experience has demonstrated that patients with mild symptoms may achieve sufficient symptomatic relief with interventions such as footwear modifications, orthoses, splinting, stretching, activity modifications, and/or manipulation, as well as the use of ice, analgesics, and bunion pads (Ferrari & Monson 2021). Conservative (nonsurgical) therapy is usually attempted before symptoms are deemed refractory (Ferrari & Monson 2021). Surgical management is reserved for patients who have not responded to nonsurgical treatment with the goals of pain relief, correction of the deformity, improved first-ray stability, and improved quality of life.

There are several surgical options for treating HV, with the primary goal of realigning and balancing the first metatarsophalangeal (MTP) joint to relieve pain and improve quality of life. Generally, surgical treatment techniques are determined by the patient's condition, degree of deformity, symptoms, and radiological data with consideration of aspects of the deformity. Several scales and classifications are used in the classification of HV severity (e.g., mild, moderate, and severe). Radiological images visually quantify deformity severity using angles, such as the hallux valgus angle (HVA), the intermetatarsal angle (IMA), and, for certain patients, the distal metatarsal articular angle measurements. The HVA is defined as the angle formed by the longitudinal central lines that transect the proximal phalanx and the first metatarsal. The HVA is normally less than 15 degrees. Mild HV is defined as HVA less than or equal to 19 degrees, moderate HV as HVA between 20 and 40 degrees, and severe HV as HVA greater than 40 degrees (Kuhn & Alvi 2023).

HV, or simple bunions, may be sufficiently treated with exostectomy (e.g., surgical excision of bony growths), whereas more severe presentations may require osteotomy (e.g., bone repositioning) or arthrodesis (e.g., fusing bones together). Surgical operative management typically involves a combination of osseous and soft tissue procedures, common bunion surgical procedures include:

- Exostectomy (bunionectomy), is the surgical excision of bony growths. It may be sufficient for treating simple bunions; however, it is usually performed with osteotomy and soft tissue repair since removing the bunion does not realign the joint. Procedures other than exostectomy should be considered for bunion treatment if the HVA

Molina Clinical Policy
Foot Surgery: Bunionectomy
Policy No. 700

Last Approval: 12/11/2024
Next Review Due By: April 2025



- is greater than 40 degrees on imaging.
- Osteotomy involves cutting the first metatarsal and realigning the bone in a less adducted position. The procedure repositions it to transfer load or weight-bearing from the pathologic to the normal joint alignment and is usually accompanied by soft tissue repair.
 - Arthrodesis (e.g., bones fusion) is reserved for patients with severe arthritis or bunions, or those whose previous bunion surgery failed to solve the issue.

Bunionette deformity, also known as Taylor'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. The fourth to fifth intermetatarsal angle varies between 3 and 11 degrees, with a mean of 6.5 to 8.0 degrees. The angle is often more than 10 degrees in patients with symptomatic bunionette deformity. The fifth metatarsophalangeal angle is normally less than 14 degrees and is more than 16 degrees in those with bunionette (Shi et al. 2018). When conservative management fails, surgical methods include condylar excision, proximal or distal osteotomies. Nonsurgical therapy of symptomatic bunionettes is frequently effective. When nonsurgical treatment fails, surgical treatments are available based on the underlying bone abnormality.

RELATED POLICIES

MCP-702: Lesser Toe Deformities (Hammer, Mallet, and Claw Toe)

COVERAGE POLICY

Bunionectomy surgery may be **considered medically necessary** when ALL the following criteria are met:

1. Member is \geq 18 years old, or has documented evidence of skeletal maturity
2. Documentation of ANY of the following signs/symptoms directly attributable to a hallux valgus (HV) deformity:
 - a. Significant and persistent pain at first metatarsophalangeal (MTP) joint [Simple Bunionectomy, Bony Correction Bunionectomy] or fifth MTP joint [Bunionette Deformity]
 - b. Ulceration or skin breakdown at first MTP joint [Simple Bunionectomy, Bony Correction Bunionectomy] or fifth MTP joint [Bunionette Deformity]
 - c. Clinically significant functional limitation resulting in impaired ambulation
3. Documentation of clinically significant symptoms resulting in persistent pain and functional limitation despite at least 6 months of conservative treatment, including but not limited to the following:
 - a. Alternative or modified footwear (e.g., an accommodative shoe with wide toe box and low heel)
 - b. Protective cushions, bunion pad or foot orthotics
 - c. Oral medication (e.g., acetaminophen, NSAID) or corticosteroid injections
 - d. Debridement of hyperkeratotic lesions
4. Documentation of adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses)
5. Absence of ALL the following contraindications:
 - a. Active infection of the foot or joint, unless correction of hallux valgus deformity is necessary for wound management (e.g., nonhealing ulcer over the medial prominence)
 - b. Severe vascular insufficiency
 - c. Poor wound healing
 - d. Poor/inadequate bone stock for osteotomy or arthrodesis
6. Diagnosis of HV with radiographic confirmation and interpretation of the affected foot indicating ONE of the following:
 - a. For **Simple Bunionectomy** (removal of soft tissue without bony correction):

Molina Clinical Policy
Foot Surgery: Bunionectomy
Policy No. 700

Last Approval: 12/11/2024
Next Review Due By: April 2025



- i. Mild (> 15 degrees) hallux valgus angle (HVA) in the weight-bearing anteroposterior and lateral views
- ii. No degenerative changes, absent or mild arthritis, at the MTP joint
- b. For **Bony Correction Bunionectomy**:
 - i. Moderate (between 20 and 40 degrees) or severe HVA (greater than 40 degrees)
 - ii. Moderate (14 and 20 degrees) or severe (greater than 20 degrees) intermetatarsal angle (IMA)
 - iii. No degenerative changes, absent or mild arthritis, at the MTP joint
- c. For **Bunionette Deformity** (tailor's bunion) (e.g., osteotomy or resection procedures):
 - i. Mild to severe (> 9 degrees) IMA OR mild to severe (> 15 degrees) MTP angle

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

Barg et al. (2018) conducted a systematic review to analyze the outcomes of surgical correction for hallux valgus deformity. A total of 229 studies were included in the review with 16,273 procedures on 12,866 patients. Nine different surgery types were reviewed including distal osteotomy, proximal osteotomy, shaft osteotomy, joint hemiresection, simple bunionectomy, shaft and akin osteotomies, proximal and akin osteotomies, and first TMT arthrodesis. Outcomes measured included postoperative patient satisfaction, postoperative pain, recurrence of HV deformity, intraoperative nerve injury, rate of infection, osseous nonunion, rate of reoperation, and postoperative hallux varus deformity. A significant difference was reported in patient satisfaction across the nine different surgery types ($p = 0.004$). Dissatisfaction was highest in patient who underwent a simple bunionectomy or joint hemiresection. A significant difference was reported in the prevalence of postoperative metatarsalgia ($p < 0.001$) with the highest rates in patients who underwent joint hemiresection. Postoperative pain was comparable between the surgery types ($p = 0.026$). The rate of recurrent HV deformity ($p = 0.43$) and intraoperative nerve injury ($p = 0.38$) was comparable across surgery types. There was a significant difference in postoperative infection rates across the surgeries ($p = 0.02$). A significant difference in postoperative rates of osseous nonunion was reported across the different surgery types ($p = 0.012$). Patients who underwent a first tarsometatarsal arthrodesis had the highest rates of postoperative infection and osseous nonunion. Rate of reoperation was comparable across all surgery types ($p = 0.005$) as was the need for hardware removal ($p < 0.001$). Rates of postoperative hallux deformity was highest in patients who underwent a proximal osteotomy. It should be noted that the quality of the source literature, which is dominated by single-surgeon retrospective case series, as well as the extended period covered, with varied data-quality standards, limited the scope of this review. The systematic review found that arthrodesis and arthroplasty procedures had greater percentages of unfavorable outcomes.

A systematic review was conducted to evaluate open and minimally invasive surgical (MIS) techniques used for treating recurrent hallux valgus (HV). Ten articles including 273 patients and 301 feet were included in the review. Articles included were published in the English language, included patient who had undergone revision surgery following primary HV correction surgery, and reported data points for primary and revision surgery. Review articles, expert opinion cases, and single case reports were excluded. Eighty-six (28.6%) patients underwent revision with MIS techniques with distal first metatarsal osteotomy (32) and modified subcapital metatarsal osteotomy (54). Open revision techniques included 80 scarf osteotomies (26.6%), 51 Lapidus procedures (16.9%), and 84 first MTP joint arthrodesis (27.9%). The American Orthopaedic Foot and Ankle Society (AOFAS) score, pain scoring, patient satisfaction, HV angle (HVA), and intermetatarsal angle (IMA) measurements were used. AOFAS score was an average of 38.3 for MIS revisions and 26.8 for traditional open techniques. MIS techniques had median postoperative reduction of 5.6 degrees IMA and 18.4 degrees HVA. Open revision techniques had a median of 4.4 degrees IMA and 18.4 degrees HVA. Pain scoring and patient satisfaction varied between studies which prevented the pooling of outcomes. Complications were reported in 74 surgeries and included nonunion, painful or broken metalwork requiring correction/removal, infection requiring antibiotics, transfer metatarsalgia, recurrent HV after revision, delayed union, malunion, and stiffness. While MIS techniques did not show worse outcomes or safety concerns compared to open techniques, due to inability to pool outcomes and directly compare studies this review was unable to make firm

Molina Clinical Policy

Foot Surgery: Bunionectomy

Policy No. 700

Last Approval: 12/11/2024

Next Review Due By: April 2025



recommendation for MIS over open techniques (Nair et al. 2022).

Dragosloveanu et al. (2022) conducted a randomized controlled trial to evaluate open and minimally invasive surgical (MIS) technique approaches for chevron osteotomy. Forty patients were included in the study with 26 (24 female and 2 male) in the open chevron (OC) osteotomy (group and 24 (24 female and 0 male) in the MIS group. Patient were eligible for the study if they were older than 20 years, previously failed conservative treatment, and had a moderate valgus deformity. Exclusion criteria included patients with previous first metatarsal osteotomy, instability of the first metatarsocuneiform, metatarsophalangeal joint osteoarthritis, and systemic disease affecting the musculoskeletal system. Outcomes included pain measured by the Visual Analog Scale (VAS), function measured with The American Orthopaedic Foot and Ankle Surgery score (AOFAS), hallux angle (HVA), and intramedullary angle (IMA). VAS scores were significantly better for the MIS group at discharge ($p < 0.001$), 3 weeks ($p < 0.001$), 6 weeks ($p < 0.001$), and 6 months ($p = 0.004$) post-surgery. At 6-months postoperative the VAS score was comparable between both groups ($p = 0.285$). There was no significant difference in AOFAS scores reported between groups pre- or post-operative ($p = 0.882$). While both groups demonstrated improvements in IMA and HVA at the last post-operative follow-up there was no significant differences reported between the groups. Complications reported included the screw prominence (3 MIS and 1 OS patient) and one metatarsalgia in the OC group. The study was limited by the small sample and short-term follow-up. The results demonstrate that minimally invasive and open techniques for chevron osteotomy have comparable results although more studies are needed to further evaluate the procedures.

A systematic review and analysis by Hernández-Castillejo et al. (2020) conducted review of 12 articles to assess the effectiveness of hallux valgus surgery on patient quality of life (QoL). Inclusion criteria included patients > 16 years old, open or minimally invasive surgery procedures, QoL reports on physical, mental and social domains, included randomized controlled trials (RCTs), non-randomized experimental studies, and single-arm pre-post studies, and written in English or Spanish. Studies were excluded if they reported on foot or ankle pathologies other than hallux valgus (HV) and patients who had undergone HV revision surgery. Pooled effect size (ES) for QoL physical domain scores were 1.01 for body pain and 0.43 for physical function. Mental domain ES was 0.24 and 0.42 for social domain. The pooled difference in means for Vas score was -4.1. This study was limited by selection bias and limited availability of complete information from study reports. It was also noted that several clinician- and patient-related factors including surgical approach, surgeon skills, and comorbidities may have influenced outcomes. This review concluded that HV surgery results is decreased body pain, improved physical function, and improved social QoL, but did not affect mental QoL.

National and Specialty Organizations

American College of Foot and Ankle Surgeons (ACFAS)

The ACFAS issued a clinical consensus statement “*on a broad range of topics relevant to the clinical practice of foot and ankle surgeons as it relates to the hallux valgus deformity utilizing not only the best available evidence but also a degree of our clinical experience and common sense*” (ACFAS 2022). Thirteen statements for evaluations considerations, perioperative considerations, and postoperative considerations were addressed and rated on an appropriateness scale* and includes the following:

- Radiographic evaluation is required for effective assessment of hallux valgus deformity (ACFAS Appropriate)
- The outcome of surgical correction is independent of procedure selection (ACFAS Appropriate)
 - No consensus reached on the concept of basing procedure selection on severity of deformity (ACFAS Neither appropriate nor inappropriate)
 - There may be multiple procedures that can achieve the goals of operative management in a single patient
- Use of biologic augmentation, such as bone marrow aspirate concentrate, may be considered in the surgical correction of hallux valgus (ACFAS Neither appropriate nor inappropriate)

* ACFAS appropriateness scale to attain consensus on clinical questions by members of the panel: Rating: 1, 2, 3, 4, 5, 6, 7, 8, 9. Inappropriate: 1, 2, or 3; Neither inappropriate or appropriate: 4, 5, or 6; Appropriate: 7, 8, or 9

Molina Clinical Policy
Foot Surgery: Bunionectomy
Policy No. 700

Last Approval: 12/11/2024
 Next Review Due By: April 2025



SUPPLEMENTAL INFORMATION

Traditional Radiographic Classification of Hallux Valgus Deformity (Severity Based)

Severity of Deformity	Hallux Valgus Angle (HVA)	First-Second Intermetatarsal Angle (IMA)	Treatment
Normal	<15°	<9°	None
Mild	<20°	9-11°	Distal osteotomy ± soft tissue procedure
Moderate	20-40°	11-16°	Proximal osteotomy ± soft tissue procedure
Severe	>40°	>16°	Proximal osteotomy or first tarsometatarsal arthrodesis ± soft tissue procedure

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
Bunionette	
28110	Ostectomy, partial excision, fifth metatarsal head (bunionette) (separate procedure)
28113	Ostectomy, complete excision; fifth metatarsal head
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
Bunionectomy	
28292	Correction, hallux valgus with bunionectomy, with sesamoidectomy, when performed; with resection of proximal phalanx base, when performed, any method
28295	Correction, hallux valgus with bunionectomy, with sesamoidectomy, when performed; with proximal metatarsal osteotomy, any method
28296	Correction, hallux valgus with bunionectomy, with sesamoidectomy, when performed; with distal metatarsal osteotomy, any method
28297	Correction, hallux valgus with bunionectomy, with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method
28298	Correction, hallux valgus with bunionectomy, with sesamoidectomy, when performed; with proximal phalanx osteotomy, any method
28299	Correction, hallux valgus with 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)
28312	Osteotomy, shortening, angular or rotational correction; other phalanges, any toe

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

12/11/2024 Clarified clinical indications by reorganizing criteria into one coverage section for all surgeries and removing E//U indications.

Molina Clinical Policy
Foot Surgery: Bunionectomy
Policy No. 700

Last Approval: 12/11/2024

Next Review Due By: April 2025



Annual review will be completed as scheduled in 2025.

04/10/2024 Policy reviewed, no changes to criteria. Updated Summary of Medical Evidence and References.

04/13/2023 New policy, replaces MCP-401: Foot Surgery. IRO Peer Review March 31, 2023, by a practicing, board-certified physician in Orthopedic Surgery.

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