

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, 2021). Conservative (nonsurgical) therapy is usually attempted before symptoms are deemed refractory (Ferrari, 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 and Alvi, 2022).

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 is greater than 40 degrees on imaging.

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- 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 (Chohan, 2ND edition). 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

Simple Bunionectomy (removal of soft tissue only without bony correction) may be considered medically necessary for members who meet **ALL** the following criteria:

- A. Diagnosis of HV with radiographic confirmation and interpretation of the affected foot, indicating the following:
1. Mild or moderate HVA (15 degrees or more) in the weight-bearing anteroposterior and lateral views; **and**
 2. No degenerative changes at the MTP joint (no arthritis or mild arthritis).

AND

- B. Member meets **ONE** of the following (**1 OR 2**):

1. Member has diabetes **AND** has an ulcer and/or infection at the first MTP joint stemming solely from the bunion that has not responded to local wound care.

OR

2. Clinical symptoms of the first MTP and a history of conservative management with **ALL** the following documentation:
 - a. ANY of the following signs/symptoms directly attributable to an HV deformity:
 - Significant and persistent pain at first MTP joint; **OR**
 - Ulceration or skin breakdown at first MTP joint; **OR**
 - Clinically significant functional limitation resulting in impaired ambulation.

AND

- b. Persistent pain and functional limitation despite at least 6 months of conservative treatment under the supervision of a healthcare practitioner, including but not limited to the following:
 - Alternative or modified footwear (e.g., an accommodative shoe with wide toe box and low heel); **AND**
 - Protective cushions, bunion pad or foot orthotics; **OR**
 - Oral medication (e.g., acetaminophen, NSAID) or corticosteroid injections; **OR**
 - Debridement of hyperkeratotic lesions.

AND

3. Adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses).

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Bony Correction Bunionectomy may be considered medically necessary for members who meet **ALL** the following criteria:

- A. Diagnosis of HV and radiographic confirmation and interpretation of the affected foot, indicating the following findings:
1. Moderate (between 20 and 40 degrees) or severe HVA (greater than 40 degrees); **AND**
 2. Moderate (14 and 20 degrees) or severe IMA (greater than 20 degrees); **AND**
 3. No degenerative changes at the MTP joint (no arthritis or mild arthritis).

AND

- B. Clinical symptoms of the first MTP and a history of conservative management with **ALL** following documentation:
1. ANY of the following signs/symptoms directly attributable to an HV deformity:
 - a. Significant and persistent pain at first MTP joint; **OR**
 - b. Ulceration or skin breakdown at first MTP joint; **OR**
 - c. Clinically significant functional limitation resulting in impaired ambulation.

AND

2. Persistent pain and functional limitation despite at least 6 months of conservative treatment under the supervision of a healthcare practitioner, including but not limited to the following:
 - a. Alternative or modified footwear: accommodative shoe with wide toe box and low heels; **AND**
 - b. Protective cushions, bunion pad, foot orthotics; **OR**
 - c. Oral medication (e.g., acetaminophen, NSAID) or corticosteroid injections; **OR**
 - d. Debridement of hyperkeratotic lesions.

AND

3. Adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses)

Bunionette deformity (tailor's bunion) (e.g., osteotomy or resection procedures) may be considered medically necessary for members who meet **ALL** the following criteria:

- A. Diagnosis of Bunionette deformity and radiographic confirmation and interpretation of the affected foot, indicating IMA greater than 9 degrees or the MTP angle is greater than 15 degrees

AND

- B. Clinical symptoms of the fifth MTP and a history of conservative management with **ALL** the following documentation:
1. ANY of the following signs/symptoms directly attributable to a bunionette deformity:
 - a. Significant and persistent pain at first MTP joint; **OR**
 - b. Ulceration or skin breakdown at first MTP joint; **OR**
 - c. Clinically significant functional limitation resulting in impaired ambulation.
 2. Persistent pain and functional limitation despite at least 6 months of conservative treatment under the supervision of a healthcare practitioner, including but not limited to the following:
 - a. Alternative or modified footwear: accommodative shoe with wide toe box and low heels; **AND**
 - b. Protective cushions, bunion pad, foot orthotics; **OR**
 - c. Oral medication (e.g., acetaminophen, NSAID) or corticosteroid injections; **OR**
 - d. Debridement of hyperkeratotic lesions.

AND

3. Adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses).

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LIMITATIONS AND EXCLUSIONS

The following are considered **experimental, investigational, and unproven** based on insufficient evidence:

1. Any indications other than those listed above.
2. Asymptomatic hallux valgus or bunionette deformity (no pain or limitations in daily activities).
3. Surgical intervention solely for the improvement of appearance or for cosmetic purposes.

The following are considered **contraindications/exclusions** based on insufficient evidence:

1. 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).
2. Severe vascular insufficiency.
3. Poor wound healing.
4. Poor/inadequate bone stock for osteotomy or arthrodesis.

AGE RESTRICTION: 18 years of age or documentation of skeletal maturity (for bony procedures only)

ADMINISTRATION: Outpatient

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. (2019) performed a systematic review that reported the outcomes of a spectrum of surgical procedures for HV deformity. The systematic review included 229 studies of 16,273 surgical corrective procedures in 12,866 patients with HV deformity. The pooled outcomes for simple bunionectomy in analysis of 4-11 studies with 199-615 patients over mean follow-up of 6 years concluded that simple bunionectomy was associated with patient dissatisfaction in 23%, postoperative infection in 8.4%, recurrence of hallux valgus in 5.9%, and reoperation in 5.5% in patients with hallux valgus deformity. 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. This systematic review found that arthrodesis and arthroplasty procedures had greater percentages of unfavorable outcomes.

Fields (2023), in an evidence-based peer review, noted that "Most bunionettes are readily detected by visual inspection of the foot and rarely cause significant symptoms. When symptoms do occur, they typically include pain directly over the fifth MTP joint or over the lateral aspect of the fifth MTP with pressure from the shoe. Examination may reveal abnormal callusing and sometimes mild MTP joint swelling. Radiographs have no routine role except in patients considering surgery." It is noted that shoes with a wider toe box or an orthotic that incorporates a lateral fifth ray post often relieves the pain for those who have mild to moderate symptoms, while patients with an extremely supinated gait or foot strike may require a more extensive orthotic correction. Most symptomatic patients respond adequately to conservative care; however, athletes who are unable to compete or patients whose ability to walk is impaired due to severe pain may require surgery. Distal osteotomies and other treatments can help alleviate pain and restore foot function, and recurrence rates appear to be low, despite the paucity of controlled trials.

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.*" Thirteen statements for evaluations considerations, perioperative considerations, and postoperative considerations were addressed and rated on an appropriateness scale* and includes the following:

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- 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

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 Codes

CPT	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 (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)
28312	Osteotomy, shortening, angular or rotational correction; other phalanges, any toe

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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

4/13/2023 New policy, replaces MCP-401: Foot Surgery. IRO Peer Review March 31, 2023 by a practicing, board-certified physician in Orthopedic Surgery.

REFERENCES

Government Agency

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (no National Coverage Determination identified). Accessed March 2023. <https://www.cms.gov/medicare-coverage-database/search.aspx>.

Peer Reviewed Publications

1. Barg A, Harmer JR, Presson AP, et al. Unfavorable outcomes following surgical treatment of hallux valgus deformity: A systematic literature review. *J Bone Joint Surg Am*. 2018 Sep 19;100(18):1563-1573. doi: 10.2106/JBJS.17.00975.
2. [DEFINITION] Chohan, S. Waldman SD ed. Pain management (2nd ed.). Chapter 118: Hallux Valgus, Bunion, Bunionette, and Other Painful Conditions of the Toe. 2011: 869-871. ISBN 9781437707212. <https://doi.org/10.1016/B978-1-4377-0721-2.00118-5>.
3. Shi GG, Humayun A, Whalen JL, Kitaoka HB. Management of bunionette deformity. *J Am Acad Orthop Surg*. 2018 Oct 1. 26 (19):e396-e404. doi: 10.5435/JAAOS-D-17-00345.

National and Specialty Organizations

1. American College of Foot and Ankle Surgeons (ACFAS). Meyr AJ, Doyle MD, King CM, et al. The American College of Foot and Ankle Surgeons® clinical consensus statement: Hallux valgus. *J Foot Ankle Surg*. 2022 Mar;61(2):369-383. doi: 10.1053/j.jfas.2021.08.011.
2. American Orthopaedic Foot & Ankle Society (AOFAS). Evidence-Based Medicine Committee. Choosing Wisely. Accessed March 14, 2023. <https://www.choosingwisely.org/wp-content/uploads/2015/02/AOFAS-Choosing-Wisely-List.pdf>.

Other Authoritative Publications (used in the development of this policy)

1. DynaMed. EBSCO Information Services. Hallux valgus (bunion). Accessed March 10, 2023. <https://www.dynamed.com>.
2. DynaMed. EBSCO Information Services. Management of hallux valgus (bunion). Accessed March 14, 2023. <http://www.dynamed.com>.
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5. Ray JJ, Friedmann AJ, Hanselman AE, et al. Hallux valgus. *Foot Ankle Orthop*. 2019 May 7;4(2):2473011419838500. doi: 10.1177/2473011419838500.

APPENDIX

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