Bunion and Bunionette Surgical Treatments

Humana®

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Medical Coverage Policy

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Related Medical/Pharmacy Coverage Policies

None

Description

A **bunion** or **hallux valgus deformity** consists of a lateral deviation from a straight line of the great toe toward the other toes of the foot with medial deviation of the 1st metatarsophalangeal (MTP) joint. The tissues surrounding the joint may become inflamed and painful. However, not all bunion deformities may cause symptoms. A bunion has many etiologies including, but not limited to, arthritic conditions, heredity or trauma while aggravation to the deformity may occur due to faulty foot mechanics or tight fitting shoe wear. This progressive deformity is not a single disorder but a complex deformity of the 1st ray or the column of bones that form the medial border of the fore foot.

Surgery may be recommended to correct the deformity and reconstruct the bones and joints, restoring normal pain-free function to individuals having difficulty walking and/or experiencing pain despite accepted conservative treatments.

Surgical repair of hallux valgus may include an osteotomy (cutting portions of bone on each side of the toe joint followed by realignment), shortening or lengthening tendons or ligaments, shaving tissue from the bunion, or arthrodesis (removing damaged portions of the joint and using screws, wires or a plate to hold

the joint together). Several operative procedures and osteotomies have been devised and modified over time. The precise intervention employed depends on careful clinical and radiological evaluation and planning, as all hallux valgus deformities are unique and no single osteotomy procedure can treat them all. [4]

Bunionette or tailor's bunion is a bony prominence on the lateral side of the 5th metatarsal head (toe). A painful callus or a localized keratosis may form beneath the 5th metatarsal head along with the bursa on the lateral side of the toe. [5] Surgical repair may be necessary when severe pain limits an individual's ability to walk.

Hallux limitus refers to a great toe that lacks normal motion but does not demonstrate degenerative arthritic changes at the MTP joint. This condition may originate from inflammation, thickening of the joint capsule or from an unknown cause. Uncontrolled studies suggest that surgery provides long term relief of pain and improved function. [11]

Hallux rigidus is a progressive disorder characterized by limitation of movement along with a dorsal bunion at the MTP joint of the great toe most often caused in an adult by degenerative arthritis. [5] An individual with hallux rigidus may have a history of pain and stiffness in the 1st MTP joint that increases with activity and is aggravated by shoes. [3] Many surgical procedures for hallux rigidus have been recommended including, but not limited to, arthrodesis (fusion) or resection arthroplasty.

A **1st MTP joint replacement,** also known as total prosthetic arthroplasty, is an alternative to an arthrodesis surgical procedure for those individuals with disabling pain and lack of motion in the 1st MTP joint not improved with conservative and/or surgical treatment due to degenerative or post traumatic arthritis (hallux rigidus). The US Food & Drug Administration (FDA) have approved both partial and full replacement implants made of acrylic, biocompatible hydrogel, metal, metal alloys and silastic.

Ceramic (eg, **Moje** implant) **and modular** (eg, **Metis** implant) **1st MTP joint total replacement implants** are currently not approved by the FDA. **(Refer to Coverage Limitations section)**

A **molded cylindrical 1st MTP joint implant**, created from a biocompatible hydrogel made of polyvinyl alcohol and saline, purportedly has elastic and compressive mechanical properties similar to articular cartilage and maintains range of motion in the joint. An example of an FDA-approved molded cylindrical implant includes, but may not be limited to, **Cartiva Synthetic Cartilage Implant** (SCI).[10] **(Refer to Coverage Limitations section)**

Coverage Determination

Bunion/Hallux Valgus Deformity
Humana members may be eligible under the Plan for **bony correction bunion or hallux valgus surgery** (eg, osteotomy or resection procedures) when the following criteria are met:

- Radiographic***** confirmation of an intermetatarsal (IM) angle greater than 9 degrees **and/or** hallux valgus (HV) angle greater than 20 degrees [4] ; **AND**

- Documentation of persistent pain and difficulty walking despite at least 3 months of conservative treatment under the direction of a healthcare professional with **ALL** of the following:
    - Alternative or modified footwear [2]; **AND**
    - Foot orthotics (shoe inserts) (generally certificate excluded) [2]; **AND**
    - Nonsteroidal anti-inflammatory drugs (NSAIDs) or oral analgesics if medically appropriate and not contraindicated [2]; **AND**
    - Protective cushions, pads or toe spacers [2];

AND any of the following:

- Development of a neuroma secondary to the bunion [2]; **OR**
- Limited or painful range of motion and pain upon palpation at the 1st toe MTP joint [2,14]; **OR**
- Painful prominence of the dorsiflexed 2nd toe due to pressure from the 1st toe;

*****Radiographic confirmation must include interpretation of weight bearing anterior/ posterior and lateral views of the affected foot.

Humana members may be eligible under the Plan for **bony correction bunion or hallux valgus surgery** (eg, osteotomy or resection procedures) **for a nonhealing ulceration** caused by a bunion (eg, diabetic ulcer) [14].

Humana members may be eligible under the Plan for **repeat bunion surgical treatment** (eg, arthrodesis) following failure of a previous surgical procedure.

Humana members may be eligible under the Plan for **simple bunionectomy or soft tissue correction of the hallux valgus** when the following criteria are met:

- Radiographic***** confirmation of an HV angle of 15 degrees or greater **and** no degenerative changes to the MTP joint [4]; **AND**
- Documentation of persistent pain and difficulty walking despite at least 3 months of conservative treatment under the direction of a healthcare professional with **ALL** of the following:
    - Alternative or modified footwear [2]; **AND**
    - Foot orthotics (shoe inserts) [2]; **AND**
    - NSAIDs or oral analgesics if medically appropriate and not contraindicated [2]; **AND**

- Protective cushions, pads or toe spacers [2];

***Radiographic confirmation must include interpretation of weight-bearing anterior/posterior and lateral views of the affected foot.

Hallux Limitus/Rigidus

Humana members may be eligible under the Plan for **surgical correction of the MTP joint** (eg, hallux limitus or rigidus) when the following criteria are met:

- Radiographic* confirmation of osteoarthritis within the 1st MTP joint, when performing surgical procedures for **hallux rigidus**, as evidenced, by any of the following [4]:
  - Cysts in the metatarsal head; **OR**
  - Loss of the cartilage space between the bones; **OR**
  - Mild to moderate bony proliferative pathology; **AND**
- Documentation of persistent pain and difficulty walking despite at least 3 months of conservative treatment under the direction of a healthcare professional with **ALL** of the following:
  - Alternative or modified footwear [2]; **AND**
  - Corticosteroid injections for hallux rigidus grade 1 and 2 if medically appropriate and not contraindicated [13]; **AND**
  - Foot orthotics, shoe inserts [2] (eg, Morton's extension); **AND**
  - NSAIDs or oral analgesics if medically appropriate and not contraindicated [2]

Radiographic confirmation must include interpretation of weight-bearing anterior/ posterior and lateral views of the affected foot. **Radiographic confirmation is not required for *hallux limitus.

Bunionette

Humana members may be eligible under the Plan for **bunionette surgery** (eg, osteotomy or resection procedures) when the following criteria are met:

- Radiographic* confirmation of an IM angle 10 degrees or greater **and** a lateral deviation angle 14 degrees or greater of the 5th MTP joint when performing an osteotomy; **OR**
- Radiographic* confirmation of bony prominence when performing a simple resection; **AND**
- Documentation of persistent pain and difficulty walking despite at least 3 months of conservative treatment under the direction of a healthcare professional with **ALL** of the following:

- Alternative or modified footwear; **AND**
- Foot orthotics (shoe inserts) **AND**
- NSAIDS or oral analgesics if medically appropriate and not contraindicated

*****Radiographic confirmation must include interpretation of weight bearing anterior/posterior and lateral views of the affected foot.

Humana members may be eligible under the Plan for **repeat bunionette surgical treatment** following failure of a previous surgical procedure.

MTP Joint Replacement

Humana members may be eligible under the Plan for **a partial or total replacement of the 1st MTP joint** with an FDA-approved device when the following criteria are met:

- Absence of contraindications; **AND**
- Radiographic***** confirmation of disabling hallux valgus or disabling degenerative or post traumatic arthritis (hallux rigidus stage 3 or 4); **AND**
- Documentation of persistent pain and difficulty walking despite at least 3 months of conservative treatment under the direction of a healthcare professional with **ALL** of the following:
  - Alternative or modified footwear [2]; **AND**
  - Foot orthotics, shoe inserts [2] (eg, Morton's extension); **AND**
  - NSAIDs or oral analgesics if medically appropriate and not contraindicated [2]

*****Radiographic confirmation must include interpretation of weight-bearing anterior/posterior and lateral views of the affected foot.

Humana members may be eligible under the Plan for **total replacement of the 1st MTP joint** following failure of a previous proximal phalanx resection (implant) surgical procedure.

(Refer to the Coverage Limitations section for a **ceramic prosthesis, molded cylindrical and modular implants** for MTP joint replacement.)

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **bunion, bunionette or hallux valgus surgery** for any indications other than those listed above including, but may not be limited to, when performed for

cosmetic purposes (to improve or change your appearance or self-esteem). All other indications are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for specific definition.

Humana members may **NOT** be eligible under the Plan for a **MTP joint replacement** for any indications other than those listed above **including any joint other than the 1st MTP joint**. This is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Contraindications to 1st MTP joint replacement include, but may not be limited to:

- Active infection of the foot; **OR**
- Allergy to polyvinyl alcohol; **OR**
- Inadequate bone stock due to:
    - Avascular necrosis
    - Congenital dislocation
    - Large osteochondral cyst (greater than 1 cm)
    - Malignancy
    - Osteoporosis; **OR**
- Lesions of the 1st MTP joint greater than 10 mm; **OR**
- Systemic and metabolic disorders leading to progressive deterioration of bone and/or tumors of the supporting bone structures

This is considered experimental/investigational as it is not identified as widely used and generally accepted for any other proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **replacement of the 1st MTP joint** with the following implants/prosthesis:

- Ceramic prosthesis (eg, Moje); **OR**
- Modular implant (eg, Metis); **OR**
- Molded cylindrical implant (eg, Cartiva SCI)

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
26535	Arthroplasty, interphalangeal joint; each joint	
26536	Arthroplasty, interphalangeal joint; with prosthetic implant, each joint	
28110	Ostectomy, partial excision, fifth metatarsal head (bunionette) (separate procedure)	
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	
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)	
28740	Arthrodesis, midtarsal or tarsometatarsal, single joint	
28750	Arthrodesis, great toe; metatarsophalangeal joint	
28899	Unlisted procedure, foot or toes	**Not Covered if used to report any treatment outlined in Coverage Limitations section**
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
L8641	Metatarsal joint implant	**Not Covered if used to report any implant outlined in Coverage Limitations section**
L8642	Hallux implant	**Not Covered if used to report any implant outlined in Coverage Limitations section**
L8658	Interphalangeal joint spacer, silicone or equal, each	
L8699	Prosthetic implant, not otherwise specified	**Not Covered if used to report any implant outlined in Coverage Limitations section**

References

1. American College of Foot and Ankle Surgeons (ACFAS). ACFAS position statement on cosmetic surgery. https://www.acfas.org. Published February 2020.

2. American College of Foot and Ankle Surgeons (ACFAS). Clinical Practice Guideline (ARCHIVED). Diagnosis and treatment of forefoot disorders. https://www.acfas.org. Published March/April 2009.

3. American Orthopaedic Foot and Ankle Society (AOFAS). Position Statement. Cosmetic foot and ankle surgery. https://www.aofas.org. Published May 5, 2015. Updated October 12, 2021.

4. ClinicalKey. Murphy GA. Disorders of the hallux. In: Azar FM, Beaty JH. *Campbell's Operative Orthopaedics,* 14th ed. Elsevier; 2021:4041-4153.e7. https://www.clinicalkey.com.

5. ClinicalKey. Murphy GA. Lesser toe abnormalities. In: Azar FM, Beaty JH. *Campbell's Operative Orthopaedics,* 14th ed. Elsevier; 2021:4227-4283.e3. https://www.clinicalkey.com.

6. ECRI Institute. Clinical Evidence Assessment. Cartiva synthetic cartilage (Cartiva, Inc.) for treating arthritis of the first metatarsophalangeal joint. https://www.ecri.org. Published July 19, 2017. Updated January 15, 2020.

7. ECRI Institute. Clinical Evidence Assessment. Lapiplasty (Treace Medical Concepts, Inc.) for treating hallux valgus deformity (bunions). https://www.ecri.org. Published October 12, 2020.

8. ECRI Institute. Clinical Evidence Assessment. Lesser Hemi MPJ implant (BIOPRO) for treating metatarsophalangeal joint arthritis. https://www.ecri.org. Published March 11, 2021.

9. ECRI Institute. Product Brief. HemiCAP MTP resurfacing hemi-arthroplasty implant (Arthrosurface, Inc.) for treating arthritis of the first metatarsophalangeal joint. https://www.ecri.org. Published September 9, 2019.

10. ECRI Institute. Product Brief. Minimally invasive bunion (MIB) plating system (Trlliant Surgical) for treating hallux valgus deformity. https://www.ecri.org. Published July 31, 2019.

11. Hayes, Inc. Clinical Research Response. Lapiplasty (Treace Medical Concepts Inc.) for the correction of hallux valgus. https://evidence.hayesinc.com. Published January 23, 2023.

12. Hayes, Inc. Health Technology Brief. Cartiva synthetic cartilage implant (Wright Medical, Group) for treatment of first metatarsophalangeal joint arthritis. https://evidence.hayesinc.com. Published March 22, 2019. Updated May 17, 2021.

13. Lam A, Chan J, Surace M, Vulcano E. Hallux rigidus: how do I approach it? *World J Orthop*. 2017;8(5):364-371.

14. MCG Health. Bunionectomy. 27th edition. https://humana.access.mcg.com/index.

15. UpToDate, Inc. Forefoot pain: evaluation, diagnosis and select management of common causes of forefoot pain in adults. https://www.uptodate.com. Updated April 3, 2024.

16. UpToDate, Inc. Hallux valgus deformity (bunion). https://www.uptodate.com. Updated March 2024.

17. US Food & Drug Administration (FDA). 510(k) summary: Arthrosurface Toemotion. https://www.fda.gov. Published February 26, 2014.

18. US Food & Drug Administration (FDA). Summary of safety and effectiveness data: Cartiva Synthetic Cartilage Implant (SCI). https://www.fda.gov. Published April 20, 2016.

Appendix

APPENDIX A
Grading of Severity of Hallux Rigidus (Coughlin and Shurnas)[4]

Grade	Radiograph	Pain	MTP joint motion
0	Normal	None	Stiffness or slight loss
1	Minor narrowing of MTP joint space	Intermittent	Mild restriction
2	Moderate joint space narrowing, osteophyte formation	More consistent	Moderate restriction
3	Severe joint space narrowing, extensive osteophyte formation	Constant (no pain at midrange of MTP joint motion)	Moderately severe restriction (less the 20 degrees total motion)
4	Same as grade 3	Pain at midrange of passive MTP	Same as grade 3

Change Summary

- 04/25/2024 Annual Review, Coverage Change.