Foot Surgical Procedures

INDEPENDENT CARE HEALTH PLAN

Effective Date: 10/08/2024
Revision Date: 10/08/2024
Review Date: 09/24/2024
Policy Number: WI.PA-1032
Line of Business: Medicare

Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA). Refer to CMS website for the most current applicable CMS Online Manual System (IOMs) and Transmittals.

Type	Title	Document ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
Internet-Only	Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15	§290- Foot Care		

Manuals (IOMs)				

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.

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. 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.

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. 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. Many surgical procedures for hallux rigidus have been recommended including, but not limited to, arthrodesis (fusion) or resection arthroplasty.

Deformities of the lesser (2 through 5) toes are generally known as **hammer toe, claw toe and mallet toe**. Hammer toe refers to an abnormal flexion posture at the proximal interphalangeal (PIP) joint of one or more of the lesser four toes. The most affected toe is the second, although multiple toes can be involved. If the flexion contracture is severe and of long duration, associated hyperextension of the

metatarsophalangeal (MTP) joint and extension of the distal interphalangeal (DIP) joint may occur. Hammer toes are classified as either flexible (passively correctable) or rigid (not passively correctable to the neutral position).[4] In claw toe, there is hyperextension of the proximal phalanx on the MTP joint and plantar flexion of the PIP and DIP joints. Mallet toes demonstrate a flexion contracture of the DIP joint only.[7] As all of these are similar in their etiology and treatment, this policy pertains to all three deformities.

Surgical procedures utilized for the correction of hammer toe include, but may not be limited to, amputation for severe deformity, arthrodesis, arthroplasty, flexor to extensor tendon transfer, partial or total phalangectomy or tenotomy. Kirschner wires may be used as fixation devices for arthrodesis and arthroplasty.

Implants have been developed to stabilize the PIP joint, purportedly to promote fusion. Such implants are not universally accepted and are exceedingly difficult to remove should the surgery fail. Their removal could lead to substantial bone loss, making subsequent revision procedures challenging.

The **midtarsal/tarsometatarsal joint (TMT)**, referred to as the **Lisfranc joint**, is comprised of the five metatarsal bones M1-M5, cuneiforms C1-C3 and the cuboid bone. Lisfranc injuries encompass a wide spectrum of injuries from frank fracture dislocations to subtle ligamentous injuries only revealed with stress tests. Injuries that create joint instability warrant surgical intervention. **Arthrodesis** or fusion is one surgical treatment option to correct TMT instability.

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.

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).

Coverage Determination

ICare follows the Medicare requirements that only allow coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, ICare may consider the criteria contained in the following:

Bunion/Hallux Valgus Deformity

Bunion surgical treatment will be considered medically reasonable and necessary when the following requirements are met:

- Radiographic evidence with weight bearing anterior/ posterior (A/P) and lateral views, of an intermetatarsal (IM) angle greater than 9 degrees **and/or** hallux valgus (HV) angle greater than 20 degrees for **bony correction bunionectomy** (eg, Akin, Chevron, Keller, Lapidus, proximal metatarsal osteotomy etc.); **OR**

- Radiographic evidence, with weight bearing anterior/posterior and lateral views, of an HV angle of 15 degrees or greater **and** no degenerative changes to the MTP joint for **simple bunionectomy or soft tissue correction of the hallux valgus (removal of soft tissue bump only without bony correction)**; **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:~~

- Documentation of failure of pre-procedure conservative treatment, when appropriate. **(If conservative treatment is not appropriate, documentation must be contained in the medical record of why the treatment is not reasonable.)** Conservative treatment, as clinically appropriate, may include one or more of the following:

  - Alternative or modified footwear; ~~**AND**~~ **OR**

  - Foot orthotics (shoe inserts); ~~**AND**~~ **OR**

  - Nonsteroidal anti-inflammatory drugs (NSAIDs) or oral analgesics if medically appropriate and not contraindicated; ~~**AND**~~ **OR**

  - Protective cushions, pads or toe spacers;

AND one of the following:

- Development of a neuroma secondary to the bunion; **OR**

- Limited or painful range of motion and pain upon palpation at the 1st toe MTP joint; **OR**

- Painful prominence of the dorsiflexed 2nd toe due to pressure from the 1st toe

Bunion surgical treatment will be considered medically reasonable and necessary for a nonhealing ulceration caused by a bunion (eg, diabetic ulcer).

Repeat bunion surgical treatment (eg, arthrodesis) will be considered medically reasonable and necessary following failure of a previous surgical procedure.

Hallux Limitus/Rigidus

Surgical correction of the MTP joint (eg, hallux limitus or rigidus) will be considered medically reasonable and necessary when the following requirements are met:

- Radiographic evidence *, with weight bearing A/P and lateral views, of osteoarthritis within the 1st MTP joint, when performing surgical procedures for **hallux rigidus**, as evidenced, by any of the following:
  - 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:~~
- Documentation of failure of pre-procedure conservative treatment, when appropriate. **(If conservative treatment is not appropriate, documentation must be contained in the medical record of why the treatment is not reasonable.)** Conservative treatment, as clinically appropriate, may include one or more of the following:
  - Alternative or modified footwear; ~~**AND**~~ **OR**
  - Corticosteroid injections for hallux rigidus grade 1 and 2 if medically appropriate and not contraindicated; ~~**AND**~~ **OR**
  - Foot orthotics (shoe inserts e.g. Morton's extension); ~~**AND**~~ **OR**
  - NSAIDs or oral analgesics if medically appropriate and not contraindicated

Radiographic evidence is not required for *hallux limitus.

Bunionette

Bunionette surgery will be considered medically reasonable and necessary when the following requirements are met:

- Radiographic evidence, with weight bearing A/P and lateral views, 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 evidence, with weight bearing anterior/posterior and lateral views, 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:~~

- Documentation of failure of pre-procedure conservative treatment, when appropriate. **(If conservative treatment is not appropriate, documentation must be contained in the medical record of why the treatment is not reasonable.)** Conservative treatment, as clinically appropriate, may include one or more of the following:

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

Repeat bunionette surgical treatment (eg, arthrodesis) will be considered medically reasonable and necessary following failure of a previous surgical procedure.

Hammertoe

Hammer toe surgical treatment will be considered medically reasonable and necessary when the following requirements are met:

- Radiographic confirmation of hammer toe deformity with interpretation of A/P and lateral views; **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:~~
- Documentation of failure of pre-procedure conservative treatment, when appropriate. **(If conservative treatment is not appropriate, documentation must be contained in the medical record of why the treatment is not reasonable.)** Conservative treatment, as clinically appropriate, may include one or more of the following:

  - Alternative or modified footwear with adequate toe box[Error! Reference source not found.,6]; ~~**AND**~~ **OR**
  - Corticosteroid injections if medically appropriate and not contraindicated. Steroid injections should be avoided 3 months prior to planned hammer toe surgery[Error! Reference source not found.,6]; ~~**AND**~~ **OR**
  - Foot orthotics, one of the following[Error! Reference source not found.,6]:
    - Protective cushions/pads
    - Shoe inserts
    - Splints
    - Toe spacers; ~~**AND**~~ **OR**
  - Nonsteroidal anti-inflammatory drugs (NSAIDS) or oral analgesics if medically appropriate and not contraindicated [Error! Reference source not found.,6]; ~~**AND**~~ **OR**
  - Taping[Error! Reference source not found.,6];

AND ONE of the following**:**

- Adventitious bursa on the hammertoe; **OR**
- Ankyloses of the PIP and/or DIP joints; **OR**
- Interdigital neuroma caused by the deformity; **OR**
- Lateral MTP capsular tear caused by the deformity; **OR**
- Subluxation or dislocation of the MTP joint caused by the deformity; **OR**
- Synovitis/capsulitis of the MTP joint; **OR**
- Ulceration caused by the deformity

Repeat hammer toe surgical treatment will be considered medically reasonable and necessary following failure of a previous surgical procedure.

MTP Joint Replacement
Partial or total replacement of the 1st MTP joint with an FDA-approved device will be considered medically reasonable and necessary when the following requirements are met:

- Radiographic confirmation, with weight bearing A/P and lateral views, of disabling hallux valgus or disabling degenerative or post traumatic arthritis (hallux rigidus stage 3 or 4); **AND**
- Absence of all of the following:
  - Active infection of the foot
  - Allergy to implant material
  - Inadequate bone stock due to:
    - Avascular necrosis
    - Congenital dislocation
    - Large osteochondral cyst (greater than 1 cm)
    - Malignancy
    - Osteoporosis;
  - Lesions of the 1st MTP joint greater than 10 mm

- Systemic and metabolic disorders leading to progressive deterioration of bone and/or tumors of the supporting bone structures; **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:~~
- Documentation of failure of pre-procedure conservative treatment, when appropriate. **(If conservative treatment is not appropriate, documentation must be contained in the medical record of why the treatment is not reasonable.)** Conservative treatment, as clinically appropriate, may include one or more of the following:

  - Alternative or modified footwear; ~~**AND**~~ **OR**
  - Foot orthotics, shoe inserts (eg, Morton's extension); ~~**AND**~~ **OR**
  - NSAIDs or oral analgesics if medically appropriate and not contraindicated

Total replacement of the 1st MTP joint will be considered medically reasonable and necessary following failure of a previous proximal phalanx resection (implant) surgical procedure.

Midtarsal/Tarsometatarsal (Lisfranc) injury imaging:

Midtarsal/tarsometatarsal (Lisfranc) injury imaging will be considered medically reasonable and necessary with the following:

- Initial X-rays (eg, A/P, lateral, oblique, [weightbearing when possible][3, 24, 25]); **OR**
- Advanced imaging (eg, computed tomography [CT]), magnetic resonance imaging [MRI]) when initial X-rays are equivocal or when helpful for definitive treatment planning[3, 24, 25]

Midtarsal/Tarsometatarsal Fusion
Midtarsal/tarsometatarsal fusion (Lisfranc joint) will be considered medically reasonable and necessary when the following requirements are met:

- No evidence of the following:
  - Active infection[16]
  - Inflammatory arthritis[24]
  - Non-ambulatory status[24]
  - Severe medical comorbidity[24]
  - Soft tissue compromise (eg, sprain, strain, tendonitis)[16]

AND one of the following:

- Radiographic evidence, with weight bearing (if possible) A/P, lateral and oblique views of joint instability (eg, arch collapse[25], complete ligamentous disruption[21], extraarticular fractures with joint instability[25] or greater than 2 millimeters diastasis[25]) ; **OR**

- Inability to bear weight[25] and no instability[25] detected on initial radiographic imaging[25] with **ALL** of the following:

  - X-rays repeated on two-week follow-up with no instability detected[25]
  - Persistent edema, tenderness of tarsometarsal joint or plantar ecchymosis [25]
  - Stress X-rays with findings of instability[24]; **OR**

- Chronic injury that has led to post-traumatic osteoarthritis[24]

The use of the criteria above provides clinical benefits highly likely to outweigh any clinical harms (eg, adverse effects including, but not limited to, recurrence of the deformity, development of opposite deformity, malunion, transfer of keratotic lesions[6]). Services that do not meet the criteria above are not medically reasonable and necessary and may result in unnecessary exposure to potential complications. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

Services that are not medically reasonable and necessary may result in unnecessary exposure to potential complications. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Joint fixation implant or replacement (eg, InterPhlex hammertoe system, OSSIOfiber hammertoe fixation implant, Smart Toe II device, StayFuse device, ToeGrip device) will not be considered medically reasonable and necessary.

A review of the current medical literature shows that there is **no evidence** to determine that this service is standard medical treatment. There is an absence of current, widely used treatment guidelines or acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

Replacement of the 1st MTP joint will not be considered medically reasonable and necessary with the following implant devices:

- Ceramic prosthesis (eg, Moje); **OR**

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

A review of the current medical literature shows that the **evidence is insufficient** to determine that these devices are standard medical treatment for this indication. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of these devices in clinical management for these indications.

Summary of Evidence

MTP Joint Implants
Ceramic and modular implants are not FDA approved. Regarding the Cartiva implant, the body of evidence is limited by the publication of only one study within which results were conflicting and did not demonstrate a clear benefit of the Cartiva SCI over the standard, arthrodesis.[15]

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	
28285	Correction, hammertoe (eg, interphalangeal fusion, partial or total phalangectomy)	
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	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
L8641	Metatarsal joint implant	
L8642	Hallux implant	
L8658	Interphalangeal joint spacer, silicone or equal, each	
L8699	Prosthetic implant, not otherwise specified	

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Appendix

APPENDIX A
Grading of Severity of Hallux Rigidus (Coughlin and Shurnas)[6]

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

01/01/2024 New Policy.

03/26/2024 Annual Review, Coverage Change.
04/23/2024 Update, No Coverage Change.
09/24/2024 Update, Coverage Change. Updated Coding Information