Molina Clinical Policy
Foot Surgery: Hallux Rigidus
Policy No. 701

Last Approval: 4/13/2023
Next Review Due By: April 2024

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 the surgical correction of the first metatarsophalangeal (MTP) joint, or hallux rigidus.

Hallux rigidus is characterized by mild to severe degenerative arthritis of the first MTP joint of the foot, resulting in progressive stiffness, pain, inflammation, and loss of range of motion restricted motion (mainly dorsiflexion) of the MTP joint of the great toe. Hallux rigidus is the second most common condition affecting the first MTP joint, after hallux valgus (Patel and Swords, 2022). The condition is more prevalent in females than males and has an average age of onset of about 50 years. In 80% of cases, it occurs bilaterally and 80% of patients with bilateral hallux rigidus have a positive family history (Heybeli and Günaydın; 2020). Additionally, bone spurs, or overgrowth, may develop with hallux rigidus and act as a mechanical block to motion and cause pain. Hallux rigidus is often assessed using the Coughlin and Shurnas classification system dividing this disease into four stages, including clinical symptoms as well as radiological findings (Refer to Supplemental section of policy; Table 1; Coughlin and Shurnas, 2003). Severe hallux rigidus is characterized by dorsiflexion of 10 degrees or less, considerable joint space narrowing, cystic alterations, sesamoid enlargement, and persistent and significant discomfort with limited to no range of motion. Typically, weight-bearing anteroposterior, lateral, and oblique radiographs are adequate to diagnose this condition.

Conservative treatment options for hallux rigidus may include nonsteroidal anti-inflammatory drugs, intra-articular injections, shoe modification, activity modification and physical therapy. Several surgical techniques, including but not limited to arthrodesis, cheilectomy, and the Keller resection arthroplasty, have been indicated for hallux rigidus. Advanced stages of hallux rigidus with moderate to severe joint damage can be treated with arthrodesis and/or arthroplasty (Park et al. 2019).

- **Cheilectomy** (trimming of the joint) is a surgical treatment that involves the removal of a bony lump or irregular bony spurs that form above the main joint of the big toe and limit motion. Early cases of hallux rigidus may benefit from this procedure.
- **Arthrodesis** (fusion of the joint), the most common treatment for patients with advanced hallux rigidus, is the current standard of care for managing more severe (grade 3 to 4) hallux rigidus. The procedure carries additional risks including the potential for loss of foot function and joint motion, diminished gait efficiency, failure of fixation, nonunion, and transfer metatarsalgia (Patel and Swords, 2022).
- **Keller resection arthroplasty** (simple excision of the joint) involves the removal of the base of the proximal phalanx (Stevens et al. 2017) Complications associated with Keller resection arthroplasty include hallux cock-up deformity, toe-off weakness, and transfer metatarsalgia.
- **Joint implant arthroplasty** of the first MTP joint has been proposed as an alternative to arthrodesis for more advanced hallux rigidus as a way of restoring joint motion.

RELATED POLICIES

- *MCP-700: Foot Surgery: Bunionectomy*
- *MCP-702: Lesser Toe Deformities (Hammer, Mallet, and Claw Toe)*

COVERAGE POLICY

Surgical correction of the first MTP joint for hallux rigidus may be considered medically necessary for members who meet **ALL** the following criteria:

A. Radiographic confirmation and interpretation of the affected foot, indicating hallux rigidus of the first MTP joint.

AND

B. Member has clinical symptoms and a history of conservative management AND meets **ALL** following criteria:

1. Documentation of ANY of the following signs/symptoms directly attributable to an HV deformity:
    a. Significant and persistent pain at the first MTP joint; **OR**
    b. Ulceration or skin breakdown at the 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; taping or adhesive devices; foot orthotics; **OR**
    c. Oral medication (e.g., acetaminophen, NSAID) or corticosteroid injections; **OR**
    d. Debridement or trimming of hyperkeratotic lesions (e.g., calluses).

AND

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

AND

<u>For First MTP Joint Arthrodesis or First MTP Joint Arthroplasty ONLY</u> (D OR E)

D. Member meets **ONE** of the following with documentation:
1. Moderate hallux rigidus with excessive (hyper) mobility of the first MTP joint confirmed by radiography; **OR**
2. Severe hallux rigidus confirmed by radiography; **OR**
3. For Arthrodesis only: Failed prior hallux rigidus surgery.

OR

E. **For joint arthroplasty only:**
*ONE of the following implant types will be used:
1. Total prosthetic replacement arthroplasty with silastic implants; **OR**
2. Hemiarthroplasty (metatarsal or phalangeal based).

* Refer to #6 in Limitations and Exclusions section for implant arthroplasty.

LIMITATIONS AND EXCLUSIONS

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

1. Any indications other than those listed above
2. MTP joint replacement for joints other than the first MTP joint
3. Asymptomatic hallux rigidus (no pain or limitations in daily activities)
4. Surgical intervention solely for the improvement of appearance or for cosmetic purposes
5. Peripheral neuropathy/Charcot joint
6. Implant arthroplasty with **ANY** of the following for the treatment of hallux rigidus are considered experimental and investigational for replacement of the first MTP joint because their long-term efficacy has not been established:

a. Bioabsorbable implants including, but not limited to, bioabsorbable poly-L-D-lactic acid RegJoint® inter-positional implant
b. Ceramic implant (e.g., Moje implant--not FDA approved)
c. Modular implants (e.g., the Arthrex metatarsal phalangeal joint implant, the METIS prosthesis, the OsteoMed ReFlexion 1st MTP Implant System, ToeMotion with/without HemiCAP® Implant, and Toefit-Plus™ prosthesis)
d. Molded cylindrical implants (e.g., Cartiva® Implant)
   – *Fragmentation, infection, joint pain and stiffness, radiographic loss of MTP joint space, and arthritis progression have all been reported as postoperative complications. High surgical revision rates have also been reported (Metikala et al., 2022; An et al., 2020; Harmer and Maher, 2020).*
e. Personalized (i.e., customized, patient-specific 3D printed) implants
   – *Manufacturing and sterilization methods and standards, approval pathways, and regulation of patient-specific 3D-printed implants are not well-defined.*

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

1. Active infection of the foot or joint
2. Severe vascular insufficiency
3. Poor wound healing
4. Poor/inadequate bone stock for osteotomy or arthrodesis

AGE RESTRICTION: 18 years of age or skeletally mature confirmed with documentation of epiphyseal closure.

CONTINUATION OF THERAPY: N/A

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

Implants for the replacement of the hallux MTP joint were developed in the 1970s, when the hip and knee were successfully replaced. Initially, metals and acrylics were investigated, but early failures led to the invention of single-stem and double-stem hinged silastic implants. In the 1980s, many complications associated with silastic implants appeared, including as reactive synovitis, late failures owing to wear, osteolysis, foreign body immune reaction, fracture, and component displacement. Bone liners and titanium grommets were created to safeguard implants against sharp edges and high shearing pressures. Implants are also made from metal-on-polyethylene and metal alloys, such as cobalt chrome and titanium. Double stem silastic implants are the most used and studied implants, with reported good implant survival and patient satisfaction rates. Metallic implants in hemiarthroplasty have been utilized for decades with favorable clinical outcomes.

According to Clough and Ring (2020), arthroplasty for end-stage HR is debatable. Arthrodesis remains the gold standard for surgical treatment, but it is not without complications, with rates of nonunion as high as 10%, re-operation as high as 14%, and metatarsalgia as high as 10%. The results of a double-stemmed silastic implant (Wright-Medical, Memphis, TN) for patients with end-stage HR were studied between January 2005 and December 2016 in a retrospective review of 108 consecutive implants in 76 patients, with a minimum follow-up of two years. At the time of surgery, the average age of the patients was 61.6 years (42 to 84). Data on clinical, radiological, and patient-reported outcome measures, as well as a pain VAS and satisfaction scores, were collected. At a mean follow-up of 5.3 years (2.1 to 14.1), the survivorship rate was 97.2%. The mean Manchester Oxford Foot and Ankle Questionnaire score increased from 78.1 to 11.0, and the VAS pain score decreased from 7/10 to 1.3/10. The satisfaction rate was 90.6%; three implants (2.8%) required revision, one for infection one month after surgery and two for stem breakage 10.4 and 13.3 years later. On radiological review, there was a 1.9% re-operation rate other than revision, 23.1% of patients developed a minor complication, and 21.1% of patients had non-progressive and asymptomatic cysts. This implant had a 97.2% survival rate at a mean follow-up of 5.3 years, and no evidence of progressive osteolysis as has been

previously reported was found. These findings suggested that this double-stemmed silastic implant offered a predictable and reliable alternative to arthrodesis for the treatment of end-stage HR.

Systematic Review and Meta-Analysis

Park et al. (2019) performed a meta-analysis of comparative studies comparing implant arthroplasty and arthrodesis for the treatment of advanced hallux rigidus. Clinical scores and patient satisfaction defined the primary outcomes. In addition, the rate of reoperation and complications were studied. There were seven comparative studies (2 prospective and 5 retrospective studies) included. The American Orthopaedic Foot and Ankle Society-Hallux Metatarsophalangeal Interphalangeal score, patient satisfaction rate, reoperation rate, and complication rate did not differ significantly between the two groups. The pain rating on the visual analog scale was lower in the arthrodesis group compared to the implant arthroplasty group. This meta-analysis found that implant arthroplasty and arthrodesis of the first metatarsophalangeal joint produced comparable clinical outcomes, patient satisfaction, reoperation rates, and complication rates, but arthrodesis resulted in much less discomfort. Additional high-quality methodological studies are required to validate these findings.

Stevens et al. (2017) in a systematic review of 33 studies (741 arthrodesis and 555 total joint replacements) arthrodesis was found to be superior for improving clinical outcome and reducing pain, and is less often accompanied by intervention-related complications and revisions, compared with total joint replacement in patients with symptomatic hallux rigidus. Studies assessing outcome with the American Orthopaedic Foot & Ankle Society-Hallux Metatarsophalangeal Interphalangeal score, Foot Function Index, visual analog scale for pain, or Short Form-36 in patients who underwent an arthrodesis or total joint replacement for the treatment of symptomatic hallux rigidus were included. Secondary outcomes were complications and revision rates. Prospective, randomized controlled trials, according to the authors, are needed to validate this conclusion.

National and Specialty Organizations

The **National Institute for Health and Care Excellence (NICE)** issued recommendations on the use of a synthetic cartilage implant for the treatment of osteoarthritis of the first metatarsophalangeal joint in 2022. NICE stated that patients with advanced joint disease who are indicated for arthrodesis should only undergo the procedure under special arrangements for clinical governance, consent, audit, and research. For all other patients with hallux rigidus (i.e., those with less severe disease), NICE recommended that the procedure be used only for research purposes. Evidence regarding the safety of synthetic cartilage implant insertion for first MTP joint osteoarthritis (hallux rigidus) has shown no major safety concerns in the short term, but evidence on efficacy is limited in quantity and quality, according to the guideline. Concerning patient selection, NICE noted that the procedure should not be performed on individuals with inflammatory arthritis or diabetic peripheral neuropathy, and that there is limited evidence regarding the patients for whom the procedure is most appropriate, including at what stage of osteoarthritis it should be performed.

SUPPLEMENTAL INFORMATION

Table 1. Grading Scales for Hallux Rigidus

Radiographic	Clinical	Qualitative	Coughlin and Shurnes
No radiographic evidence for osteoarthritis	No pain +/- mild stiffness		0
Mild-to-moderate osteophyte formation with no joint space involvement	Mild pain maximal with flexion, mild stiffness	Mild	1
Moderate osteophyte formation and joint space narrowing; subchondral sclerosis	Moderate-to-severe pain constant at the extremes of motion, moderate-to-severe stiffness	Moderate	2
Marked osteophyte formation and loss of the joint space, cystic changes with or without subchondral sclerosis	Nearly constant pain (3), pain throughout the range of motion (including midrange) (4)	Severe	3 or 4

Reference: Coughlin MJ, Shurnas PS. Hallux rigidus. Grading and long-term results of operative treatment. J Bone Joint Surg Am.2003;85(11):2072-88.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
28750	Arthrodesis, great toe; metatarsophalangeal joint
28289	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint
28291	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant

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 April 1, 2023 by a practicing, board-certified physician in Orthopedic Surgery.

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Government Agency

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National and Specialty Organization

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Other Authoritative Publications (used in the development of this policy; not cited)

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