

## 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 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 & 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 & Günaydın 2020). Additionally, bone spurs, or overgrowth, may develop with hallux rigidus and function 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 (Coughlin & 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 metatarsophalangeal (MTP) joint for hallux rigidus (HR) may be **considered medically necessary** for members who meet ALL the following criteria:

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 an HR deformity:
  - a. Significant and persistent pain at the first metatarsophalangeal (MTP) joint
  - b. Ulceration or skin breakdown at the first MTP joint
  - 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., accommodative shoe with wide toe box and low heel)
  - b. Protective cushions, taping or adhesive devices or foot orthotics
  - c. Oral medication (e.g., acetaminophen, NSAID) or corticosteroid injections
  - d. Debridement or trimming of hyperkeratotic lesions (e.g., calluses)
4. Documentation of adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses)
5. Member meets ONE of the following with documentation
  - a. Moderate hallux rigidus with excessive (hyper) mobility of the first MTP joint confirmed by radiography
  - b. Severe hallux rigidus confirmed by radiography
6. For **First MTP Joint Arthroplasty**: Either total prosthetic replacement arthroplasty with silastic implants OR hemiarthroplasty (metatarsal or phalangeal based) implants will be utilized in the procedure
7. Absence of ALL the following contraindications:
  - a. Active infection of the foot or joint
  - b. Severe vascular insufficiency
  - c. Poor wound healing
  - d. Poor/inadequate bone stock for osteotomy or arthrodesis

**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 metatarsophalangeal (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

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as high as 14%, and metatarsalgia as high as 10%. The results of a double-stemmed silastic implant 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 Reviews and Meta-Analyses**

Esser et al. (2024) performed a systematic review to assess the effectiveness of minimally invasive dorsal cheilectomy (MIDC) in treating hallux rigidus. The review included six studies with a total of 348 patients (370 feet) and a mean follow-up of 37.9 months. Key outcome measures included the American Orthopedic Foot and Ankle Society (AOFAS) score, visual analog scale (VAS) pain scores, and postoperative range of motion (ROM) of the first metatarsophalangeal joint (MTPJ). Preoperative AOFAS scores averaged 68.9 with a postoperative mean of 87.1. Pain scores improved significantly, with the mean VAS score decreasing from 7.8 preoperatively to 2.6 postoperatively. ROM also showed improvement, with the average 1st MTPJ ROM increasing from 21.5° preoperatively to 42.8° postoperatively. Dorsiflexion improved from a mean of 26.8° to 57.2°, while plantarflexion increased from 11° to 14°. The complication rate associated with MIDC was 8.4%, with persistent joint pain and stiffness being the most reported issues. Failure occurred in 32 cases (8.7%), and 33 secondary procedures (8.9%) were performed. This review suggests that MIDC can improve pain, range of motion, and overall clinical outcomes in the short term for patients with hallux rigidus.

Sánchez Guzmán et al. (2024) conducted a systematic review comparing the outcomes and complications of arthrodesis and interposition arthroplasty for moderate to severe hallux rigidus. Based on 26 studies involving 1,348 feet, treatments were divided into four groups: Cartiva hemiarthroplasty, double-stem silicone arthroplasty, total metallic arthroplasty, and arthrodesis. The primary outcomes assessed were The American Orthopedic Foot and Ankle Society-Hallux Metatarsophalangeal Interphalangeal (AOFAS-HMI) scores, Visual Analog Scale (VAS) pain scores, Foot and ankle ability measure of activities of daily living (FAAM ADL), Foot and ankle ability measure of sport (FAAM SPORT), and Manchester Oxford Foot Questionnaire (MOXFQ). In the arthrodesis group, postoperative AOFAS-HMI scores improved significantly compared to preoperative scores. VAS scores dropped from 86 to 4. Arthrodesis achieved a high fusion rate (98.6%), though some patients experienced discomfort due to materials. Total metallic arthroplasty outcomes varied, with the ROTO-GLIDE system demonstrating excellent results (AOFAS score of 95) and low complications, while the TOEFIT-PLUS and BIOMED-MERCK systems had revision rates of 37% and 15% due to aseptic loosening. Cartiva hemiarthroplasty improved FAAM ADL and FAAM SPORT scores significantly but required implant removal and conversion to arthrodesis in 20.5% of cases. Double-stem silicone arthroplasty improved MOXFQ scores (from 78.1 to 11.0) and preserved an average motion range of 22.3 degrees, although 10% of cases developed lysis. Overall, arthrodesis is the most reliable option for advanced hallux rigidus, offering superior and long-lasting outcomes. Arthroplasty remains a viable alternative for patients seeking to maintain joint mobility but carries higher risks of complications and revision.

de Bot et al. (2022) conducted a systematic review and meta-analysis comparing patient-reported outcomes, pain reduction, complications, and revision rates for two treatments of symptomatic hallux rigidus: metallic first metatarsophalangeal joint (MTP1) hemiarthroplasty and MTP1 arthrodesis. The study included 13 publications that focused exclusively on these interventions and excluded studies involving hallux valgus, inflammatory arthropathy, or alternative surgical treatments such as silicone or non-metallic implants, total joint replacements, and procedures like Keller's arthroplasty or cheilectomy. The outcomes measured included functional and quality-of-life scores (e.g., American Orthopaedic Foot & Ankle Society Hallux Metatarsophalangeal-Interphalangeal [AOFAS-HMI], Visual Analogue Scale [VAS] for pain) complications, revisions, radiological findings, and range of motion (ROM). All studies reported significant improvements in AOFAS-HMI scores after surgery, with arthrodesis showing a slightly higher, though non-significant, improvement compared to hemiarthroplasty (P = 0.69). Both procedures significantly reduced pain, but arthrodesis resulted in a significantly lower postoperative VAS pain score than metallic hemiarthroplasty (P

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< 0.00001). Complications differed by procedure. Hemiarthroplasty complications included metatarsalgia, infections, persistent pain, and implant-related issues like hyperextension, clawing toe, stiffness, and migration. Arthrodesis complications involved hardware-related pain requiring removal, delayed or nonunion, superficial infections, and metatarsalgia. The study concluded that both procedures are effective for treating hallux rigidus. Arthrodesis offers better pain relief, while metallic hemiarthroplasty preserves MTP1 motion.

Butler et al. (2021) conducted a systematic reviewed that analyzed the outcomes of Interpositional Arthroplasty (IPA) in the treatment of hallux rigidus. Sixteen studies were included in the review with a total of 428 patients. Outcomes measured pre- and post-operative included the American Orthopaedic Foot and Ankle Society hallux metatarsophalangeal-interphalangeal (AOFAS-HMI) score, visual analogue scale score, short-form 36 score, and range of motion (ROM). The mean preoperative AOFAS-HMI score was 51.6 and 88.0 postoperative ( $p \leq .001$ ) The ROM improved from  $39.3^\circ$  during preoperative evaluation to  $61.5^\circ$  at the postoperative follow-up ( $p \leq .001$ ). Metatarsalgia was the most reported complication with an overall surgical complication rate of 21.5%. The low quality of evidence in literature and inconsistent data reporting were limitations of this review. Overall, the IPA procedure does demonstrate improvement in functional and ROM outcomes.

Emmons & Carreira (2019) conducted a systematic review to examine outcomes following interposition arthroplasty of the first metatarsophalangeal joint (MTP) joint. Twenty studies were included in the review with 498 patients and 539 feet. Studies were included if they were published in English, treatment involved interposition of soft-tissue or a synthetic “spacer,” reported clinical outcomes using a standardized outcome scoring measure and had a mean follow-up time of  $\geq 1$  year and with  $\geq 6$  patients. Outcomes were measured by American Orthopaedic Foot & Ankle Society Hallux Metatarsophalangeal-Interphalangeal Scoring System (AOFAS-HMI), Foot Function Index (FFI), Foot and Ankle Ability Measure (FAAM), the Visual Analog Scale for Pain (Pain VAS), and the Short Form–36 Health Survey (SF-36). Eight studies reported pre- and post-operative scores using AOFAS-HMI and 6 of the studies reported a mean improvement  $\geq 30.2$  points. Four studies reported pre- and post-operative scores using FAAM-ADL, FAAM-Sports, Pain VAS, and FFI. All four studies reported mean improvements exceeding each minimal clinically important difference (MCID) for the respective scoring system. Nine of the ten studies that measured range of motion reported statistically significant improvements in dorsiflexion from pre-operative to post-operative measures. The study is limited by the quality of current literature that is available and the small treatment population in the included studies. The review suggests interposition arthroplasty is a viable treatment option for moderate to severe hallux rigidus.

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 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



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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**

**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

**CODING & BILLING INFORMATION**

**CPT (Current Procedural Terminology)**

Code	Description
28750	Arthrodesis, great toe; metatarsophalangeal joint
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

**HCPCS (Healthcare Common Procedure Coding System)**

Code	Description
L8642	Hallux implant
L8658	Interphalangeal joint spacer, silicone or equal, each
L8659	Interphalangeal finger joint replacement, two or more pieces, metal (e.g., stainless steel or cobalt chrome), ceramic-like material (e.g., pyrocarbon) for surgical implantation, any size
L8699	Prosthetic implant, not otherwise specified

**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**

- 02/12/2025** Policy reviewed. Clarified clinical indications by reorganizing criteria and removing E/I/U indications. Updated Summary of Medical Evidence and References. IRO Peer Review on December 27, 2024, by a practicing physician board-certified in Orthopedic Surgery.
- 04/10/2024** Policy reviewed, no changes to criteria. Updated Summary of Medical Evidence and References.

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04/13/2023 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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## APPENDIX

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

### Washington

For Medicaid, there is a language around foot care in the following Washington Administrative Codes: WAC 182-531-0150: Noncovered physician-related and health care professional services—General and administrative; and WAC 182-531-1300: Foot care services for clients twenty-one years of age and older. Per the WACs, routine foot care is considered a non-covered healthcare service unless the client meets conditions and criteria outlined in WAC 182-531-1300. If criteria are needed for medical necessity review in the case that the member has a qualifying condition, this MCP can be applied as a medical necessity tool.