Molina Clinical Policy
Implantable Shock Absorbers for Knee Osteoarthritis
Policy No. 442

Last Approval: 06/10/2026
Next Review Due By: June 2027

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

Osteoarthritis (OA) is a degenerative condition characterized by the progressive breakdown of joint cartilage, subchondral bone changes, and synovial inflammation, and is the most common chronic joint condition that affects over 32.5 million American adults. OA results in pain, decreased range of motion, swelling, and stiffness of the affected joints, making it a leading cause of disability. OA can range from mild to severe, as judged by its impact on daily living, and the treatments range accordingly. For mild to moderate knee OA, the first line of treatment is lifestyle modification, including nonpharmacologic measures such as exercise, knee braces, and psychologic interventions. Pharmacological treatment may also be used, such as topical or oral nonsteroidal anti-inflammatory drugs (NSAIDs), or duloxetine when NSAIDs are ineffective or contraindicated. If conservative treatments fail, surgery may be considered. The current surgical avenue for mild to moderate OA is high tibial osteotomy. Benefits of this procedure include preservation of knee anatomy, less restriction on function, and possible delay of a need for arthroplasty. Disadvantages include long healing times, incomplete pain relief, requirement of further surgery, and increased complexity if arthroplasty is later needed. Total joint arthroplasty is the gold standard treatment for patients with severe end-stage symptomatic OA who have failed to respond to nonpharmacologic and pharmacology treatment and who have significant impairment in quality of life (Mandl & Martin 2024; Deveza & Bennell 2025).

A medial knee **implantable shock absorber (ISA)** is a device implanted outside of the knee capsule extending from the distal femur to the proximal tibia for the purpose of reducing load on the intra-articular medial joint surface and improving symptoms of OA. The MISHA Knee System is an ISA intended to reduce load on the knee while allowing for natural joint motion. It is placed under the skin and fixed to the bases of the medial cortices of the distal femur and proximal tibia via locking screws. The device insertion is typically performed as an outpatient procedure utilizing a single incision and standard orthopedic tools. Implantation should not require resection of muscle, bone, or ligaments, or disruption of the medial knee joint capsule. The MISHA Knee System is intended for patients with painful, mild to moderate medial knee OA that interferes with their activities of daily living and who are unwilling or ineligible for total knee replacement (Hayes 2024; FDA 2025).

Regulatory Status

The MISHA Knee System was FDA approved via the De Novo classification pathway on April 10, 2023, under the product code QVV. The FDA identified this system as a regulatory Class II medical device under the generic name ‘medial knee implanted shock absorber.’ The MISHA Knee System is indicated for use in patients with medial compartment knee osteoarthritis that have failed to find relief in surgical and/or non-surgical treatment modalities and are still experiencing pain that interferes with activities of daily living and who are also unwilling to undergo or ineligible for total knee replacement due to age or absence of advanced OA.

COVERAGE POLICY

Implantable shock absorbers, including the MISHA Knee System, for the treatment of knee osteoarthritis are considered **experimental, investigational, and unproven** due to insufficient evidence in the peer reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes

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

Systematic Reviews and Meta-Analyses

Anzillotti et al. (2025) published a systematic review of published clinical studies examining knee joint distraction (KJD) and implantable shock absorbers (ISA) as joint-preserving interventions for tibiofemoral knee osteoarthritis. The review included studies with at least 12 months of follow-up reporting patient-reported outcomes, imaging findings, biomarkers, or adverse events, while excluding preclinical studies, case reports, reviews, and non-clinical literature. Seventeen studies (13 evaluating KJD and 4 evaluating ISA), representing approximately 400 patient-level observations across heterogeneous and partially overlapping cohorts, were included and assessed using risk-of-bias tools. Across studies, KJD was associated with clinically meaningful short- to mid-term improvements in validated pain and function measures and demonstrated signals of structural response on radiography and MRI in a subset of patients, though it was consistently accompanied by a high incidence of pin-tract infections and device-related complications. ISA studies similarly showed consistent improvements in pain and function and higher short-term arthroplasty-free survival compared with high tibial osteotomy or non-operative comparators but provided limited data on structural joint modification and were largely derived from nonrandomized or industry-sponsored cohorts. The authors highlighted substantial limitations across the evidence base, including small sample sizes, clinical and methodological heterogeneity, overlapping study populations, short- to mid-term follow-up, absence of pooled quantitative synthesis, and moderate-to-serious risk of bias, resulting in an overall low-to-moderate certainty of evidence. The review concluded that while KJD and ISA may offer short- to mid-term symptomatic benefit and potential delay of arthroplasty in carefully selected patients, the current evidence is insufficient to support widespread adoption, and larger, independently replicated randomized trials with standardized clinical and structural endpoints are needed to establish long-term safety, durability, and net health benefit.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Moximed conducted a clinical trial to evaluate the MISHA (referred to as Calypso in the clinical study documentation) Knee System (ClinicalTrials.Gov 2025). The clinical trial began in September 2018 and completed its primary objective in January 2022. Eighty-one participants aged 25- 65 years old with a Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain score of ≥ 40 (scale 0-100) were enrolled in the study to evaluate the safety and efficacy of the Calypso (MISHA) Knee System when used to treat symptomatic medial knee osteoarthritis (OA). The 81 participants were compared to a historical control arm of 81 participants who underwent a high tibial osteotomy (HTO). In the ISA arm the average time to full weight bearing post-surgery was 13 days compared to 58 days in the HTO arm. From baseline to 24 months post-surgery the ISA arm had a decrease in WOMAC pain score of -76 compared to a decrease of -64.7 in the HTO arm; and an improvement in the WOMAC function score of -73.9 and -58.8, respectively. Eighteen of the 81 ISA participants had reported serious adverse events (SAEs) compared to 39 in the HTO arm.

Diduch et al. (2023) reported 2-year findings of a prospective, open-label cohort study evaluating the safety and effectiveness of a subcutaneous ISA for unloading the medial knee joint in patients with symptomatic medial knee OA aged 25-65 years. The ISA was compared against HTO, a standard surgical unloading procedure, using a historical, propensity matched control group. The study enrolled 81 participants in each arm, with subjects in the ISA group undergoing implantation between 2018 and 2020 across 10 centers in the United States and Europe. The study was

conducted under FDA Investigational Device Exemptions (NCT03671213 and NCT03838978), with all subjects meeting radiographic inclusion criteria (Kellgren and Lawrence grade 1-4) after failing at least six months of non-surgical treatment. The primary endpoint was a composite measure evaluated at 24 months that included pain and function improvement (measured using WOMAC scores), absence of SAEs, maintenance of implant/hardware integrity, and avoidance of further joint-modifying surgery. The composite endpoint was met by 85.6% of ISA recipients, compared with 65.5% of HTO patients, demonstrating both inferiority and statistical superiority for ISA. Secondary endpoints also favored ISA, including significantly faster time to full weightbearing (13.4 days vs. 58.7 days, $p < 0.001$), greater pain and function improvement at both 3 and 24 months, and higher responder rates. At 24 months, 95.8% of ISA subjects and 87.9% of HTO subjects were pain responders. 91.7% of ISA subjects and 81.3% of HTO subjects were function responders. Improvements were assessed using WOMAC pain and function subscales, where a responder was defined as at least 20% improvement from baseline and a ≥ 10-point reduction. Adverse events occurred significantly less frequently in the ISA group, with 16% experiencing device or procedure related SAEs compared to 45.7% in the HTO group ($p < 0.001$). Pain was the most frequent SAE, affecting 4.9 of ISA patients versus 35.8% in the HTO group. Infections were reported in four ISA participants. Device integrity was maintained in both groups, though secondary hardware removal was substantially more common in the HTO group (75.3%) compared to the ISA group (13.6%). One subject in each group progressed to further joint-modifying surgery. Operative time and intraoperative complications were comparable between groups, though ISA resulted in significantly less blood loss. Hospital stay duration varied by region, but 90.5% of procedures were in the U.S. and performed on an outpatient basis. Subjects treated with the ISA showed sustained clinical benefit through 24 months, even among those who later had the device removed. The authors note this may be due to durable changes in joint loading and symptom improvement that persist beyond device removal. The authors concluded that ISA provides a clinically meaningful, well-tolerated, and durable treatment option for younger patients with medial knee OA who are not yet candidates for arthroplasty and who have not responded to conservative treatments.

Gomoll et al (2023) conducted a multicenter prospective single arm trial to evaluate the efficacy of an ISA in treating symptomatic medial knee OA without conversion to arthroplasty or high tibial osteotomy within five years of implantation. One hundred and seventy-one subjects (age 51 ± 9 years) were enrolled in the study and followed for a minimum of 2 and up to 5 years following shock absorber implantation. Of the 171 subjects enrolled, 151 did not require arthroplasty or high tibial osteotomy at the last follow up (mean 3.2 ± 1.6 years). In addition, WOMAC pain and function scores were taken before and after ISA implantation with a resulting pain score decrease of 71% (58 ± 13 to 16 ± 17 points) from baseline to last follow up and an improvement in function score of 69% (56 ± 18 to 17 ± 17 points).

Pareek et al (2023) conducted a retrospective case-control study that compared the two-year freedom from arthroplasty rate of subjects treated with an ISA versus non-surgical interventions. Controlling for subchondral insufficiency fracture of the knee (SIFK) scores, age, and body mass index, forty-two subjects were enrolled, all of which had no prior surgical history. Twenty-one subjects were in the control group versus twenty-one participants had a shock absorber implanted. MRI and radiographs were taken at baseline and two years to evaluate for meniscus or ligament injuries, insufficiency fractures, and subchondral edema. In ISA patients the 1- and 2-year freedom-from-arthroplasty rates were both 100%, and for the control group patients the rates were 76% and 55% respectively ($P = 0.001$ for cross-group comparison). The control group knees with low, medium, and high-risk SIFK scores had respective 1- and 2-year survival rates of 100% and 100%, 90% and 68% ($P = 0.07$ vs. ISA), and 33% and 0% ($P = 0.002$ vs. ISA).

National/Specialty Organizations

The **American Academy of Orthopaedic Surgeons (AAOS)** (2022), in an evidenced-based clinical practice guideline for surgical management of osteoarthritis of the knee, recommend unicompartmental knee arthroplasty or tibial osteotomy for the treatment of knee osteoarthritis, which is supported by a moderate quality of evidence. The guideline is also endorsed by the Arthroscopy Association of North America and the American Association of Hip and Knee Surgeons.

The **National Institute for Health and Care Excellence (NICE)** (2015) conclude that the current evidence on the safety and efficacy of the implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis is inadequate in quantity and quality, and that the procedure should only be used in the context of research. NICE guidelines also note that treatment for osteoarthritis depends on the severity. Conservative treatments include analgesics and corticosteroid injections to relieve pain and inflammation, physiotherapy and exercise to

improve function and mobility, and weight loss for people who are overweight or obese. When symptoms are severe, surgery may be indicated, which includes high tibial osteotomy or unicompartmental or total knee arthroplasty. The guidelines are also endorsed by the Healthcare Improvement Scotland.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
27599	Unlisted procedure, femur or knee [when specified as placement of implantable shock absorber for knee osteoarthritis]

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
C8003	Implantation of medial knee extraarticular implantable shock absorber spanning the knee joint from distal femur to proximal tibia, open, includes measurements, positioning and adjustments, with imaging guidance (e.g., fluoroscopy)

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

06/10/2026 Policy reviewed. No changes to coverage criteria.
06/11/2025 Policy reviewed. No change to coverage policy. Title changed to “Implantable Shock Absorbers for Knee Osteoarthritis”.
08/14/2024 Policy reviewed. No changes to coverage criteria.
08/09/2023 New policy. IRO Peer Reviewed on July 24, 2023, by a practicing board certified Orthopedic Surgery physician.

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