

## 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 to improve 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

### ***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  $\geq 40$  (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  $\geq 10$ -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,

# Molina Clinical Policy

## Implantable Shock Absorbers for Knee Osteoarthritis

### Policy No. 442

Last Approval: 06/11/2025

Next Review Due By: June 2026



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  $51 \pm 9$  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  $3.2 \pm 1.6$  years). In addition, WOMAC pain and function scores were taken before and after ISA implantation with a resulting pain score decrease of 71% ( $58 \pm 13$  to  $16 \pm 17$  points) from baseline to last follow up and an improvement in function score of 69% ( $56 \pm 18$  to  $17 \pm 17$  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 the 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 guideline is also endorsed by the Healthcare Improvement Scotland.

#### CODING & BILLING INFORMATION

##### CPT (Current Procedural Terminology)

Code	Description
<b>27599</b>	Unlisted procedure, femur or knee [when specified as placement of implantable shock absorbers for knee osteoarthritis]

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

Code	Description
<b>C1734</b>	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable) [when specified as implantable shock absorbers for knee osteoarthritis]
<b>C8003</b>	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

# Molina Clinical Policy

## Implantable Shock Absorbers for Knee Osteoarthritis

### Policy No. 442

Last Approval: 06/11/2025

Next Review Due By: June 2026



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

06/11/2025	Policy reviewed. No change to coverage policy.
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.

## REFERENCES

1. American Academy of Orthopaedic Surgeons. Surgical management of osteoarthritis of the knee. Evidence-based clinical practice guideline. Published December 02, 2022. Accessed April 21, 2025. <http://www.aaos.org/smoak2cpg>
2. ClinicalTrials.gov. Calypso Knee System Clinical Study [ID: NCT03671213]. National Library of Medicine. Updated April 10, 2025. Accessed April 21, 2025. <https://clinicaltrials.gov>
3. Deveza LA, Bennell K. Management of moderate to severe knee osteoarthritis. Updated February 11, 2025. Literature review current through March 2025. Accessed April 17, 2025. <https://www.uptodate.com>
4. Diduch DR, Crawford DC, Ranawat AS, Victor J, Flanigan DC. Implantable Shock Absorber Provides Superior Pain Relief and Functional Improvement Compared With High Tibial Osteotomy in Patients with Mild-to-Moderate Medial Knee Osteoarthritis: A 2-Year Report. *Cartilage*. 2023 Jun;14(2):152-163. doi: 10.1177/19476035231157335. Epub 2023 Feb 23. PMID: 36823955; PMCID: PMC10416201.
5. Gomoll AH, Diduch DR, Flanigan DC, et al. An implantable shock absorber yields an 85% survival-from-arthroplasty rate through 5 years in working-age patients with medial compartment knee osteoarthritis. *Knee Surg Sports Traumatol Arthrosc*. 2023 Mar 23. doi: 10.1007/s00167-023-07373-4.
6. Hayes. MISHA knee system (Moximed Inc.) for treatment of medial compartment knee osteoarthritis. Evolving Evidence Review. Published July 18, 2024. Accessed April 17, 2025. <https://evidence.hayesinc.com>
7. Mandl LA, Martin GM. Overview of surgical therapy of knee and hip osteoarthritis. Updated November 27, 2024. Literature review current through March 2025. Accessed April 17, 2025. <https://www.uptodate.com>
8. National Institute for Health and Care Excellence. Implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis. *Interventional procedures guidance [IPG512]*. Published: 23 January 2015. Accessed April 21, 2025. <https://www.nice.org.uk/guidance/ipg512>
9. Pareek A, Parkes CW, Gomoll AH, Krych AJ. Improved 2-Year Freedom from Arthroplasty in Patients with High-Risk SIFK Scores and Medial Knee Osteoarthritis Treated with an Implantable Shock Absorber versus Non-Operative Care. *Cartilage*. 2023 Jun;14(2):164-171. doi: 10.1177/19476035231154513.
10. United States Food and Drug Administration (FDA). De Novo: MISHA Knee System. Product code QVV. Denovo number: DEN220033. Updated April 14, 2025. Accessed April 17, 2025. <https://www.fda.gov>