Molina Clinical Policy
MISHA™ Knee Implant System: Policy No. 442

Last Approval: 08/09/2023
Next Review Due By: August 2024

Ohio Medicaid: All requests are reviewed on a case-by-case basis for medical necessity.

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, caused by the breakdown of joint cartilage, is the most common chronic joint condition. Affecting over 32.5 million American adults, osteoarthritis is a leading cause of disability as it results in pain, decreased range of motion, swelling, and stiffness of the affected joints. For mild to moderate knee osteoarthritis the first line of treatment is lifestyle modification, followed by pharmacological treatment, and if those fail, surgery is considered. The current surgical avenue for mild to moderate osteoarthritis is high tibial osteotomy, as a total knee replacement is reserved for severe osteoarthritis typically in patients 60 years and older.

The **MISHA™ Knee System** is an implantable shock absorber (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 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. This ISA is intended for patients with painful mild to moderate medial knee osteoarthritis that interferes with their activities of daily living and are unwilling/ineligible for total knee replacement.

Regulatory Status
The MISHA™ Knee System is FDA approved for marketing as of April 10, 2023. The FDA identified this system as a regulatory Class II medical device under the generic name ‘medial knee implanted shock absorber.’ The FDA approved The MISHA™ Knee System with the following indications 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 are also unwilling to undergo or ineligible for total knee replacement due to age or absence of advanced osteoarthritis”.

COVERAGE POLICY

The MISHA™ Knee System as a treatment for osteoarthritis is considered **experimental, investigational, or unproven** due to insufficient evidence in peer reviewed medical literature that have not established 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.

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SUMMARY OF MEDICAL EVIDENCE

Moximed conducted a clinical trial to evaluate the MISHA™ (aka Calypso, as named in the clinical study documentation) Knee System (ClinicalTrials.Gov 2023). The clinical trial began in September 2018 and completed its primary objective in January 2022. Eighty-one participants age 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. 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 compared to 39 in the HTO arm.

Gomoll et al (2023) conducted a multicenter prospective single arm trial to evaluate the efficacy of an ISA in treating symptomatic medial knee osteoarthritis 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. At two years 100% of the ISA participants remained free from arthroplasty compared to 55% of the control group.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Code

CPT	Description
27599	Unlisted procedure, femur or knee [when specified as placement of MISHA Knee System]

HCPCS (Healthcare Common Procedure Coding System) Code

HCPCS	Description
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable) [when specified as MISHA Knee System 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

08/09/2023 New policy. IRO Peer Review July 2023.

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REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Accessed July 13, 2023. https://www.cms.gov/medicare-coverage-database/search.aspx.
2. ClinicalTrials.gov. Calypso Knee System Clinical Study [ID: NCT03671213]. National Library of Medicine. Accessed July 14, 2023. http://clinicaltrials.gov.
3. 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.
4. MISHA™ Knee System [Internet]. 2023. https://moximed.com/misha
5. Osteoarthritis (OA) (2020) Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/arthritis/basics/osteoarthritis.htm Accessed July 17,2023.
6. 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.
7. United States Food and Drug Administration (FDA). MISHA™ Knee System (DEN220033). Notice of Approval April 10, 2023. Accessed July 14, 2023. https://www.accessdata.fda.gov/cdrh_docs/pdf22/DEN220033.
8. United States Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). Device Classification Under Section 513(f)(2)(De Novo). Search code QVV. Fda.gov. Accessed July 2023.

APPENDIX

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

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