

Implantable Shock Absorbers for Treatment of Knee Osteoarthritis

Policy # 00978

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of implantable shock absorbers (e.g., MISHA Knee System Implant) as a treatment for knee osteoarthritis to be **investigational**.*

Background/Overview

Knee Osteoarthritis

Knee osteoarthritis (OA) is the most common form of arthritis and a leading cause of chronic pain and disability. Approximately 33 million U.S. adults have OA, with the knee being the most commonly affected joint. The condition is characterized by progressive degradation of articular cartilage, subchondral bone changes, synovial inflammation, osteophyte formation, and joint space narrowing, resulting in chronic pain, stiffness, functional limitation, and reduced quality of life. The global burden of OA is projected to increase by 75% by 2050, driven by aging demographics and increasing rates of obesity. Risk factors include increasing age, obesity, prior joint injury, and repetitive joint stress.

Treatment

No curative therapy is currently available for knee OA, and overall management goals are to reduce pain, preserve function, and delay or avoid the need for joint replacement surgery. Nonsurgical first-line approaches include exercise, physical therapy, weight management, analgesics (NSAIDs, acetaminophen), intra-articular injections (corticosteroids, hyaluronic acid), and off-loader bracing. For individuals who fail nonsurgical management, surgical options include high tibial osteotomy (HTO) and knee arthroplasty. A clinical gap exists for younger, active individuals who have failed conservative care but are not yet appropriate candidates for arthroplasty.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

On April 10, 2023, the U.S. Food and Drug Administration (FDA) granted marketing authorization (De Novo classification, DEN220033) for the MISHA Knee System (Moximed, Inc., Fremont, CA), as summarized in Table 1. The MISHA Knee System is indicated to treat people with medial knee OA who have failed to find relief from non-surgical or surgical treatment, continue to experience pain that interferes with daily activities, and are ineligible for or unwilling to undergo joint replacement due to age or absence of advanced OA. The MISHA Knee System is the most recent and commercially available iteration of Moximed's implantable shock absorber technology; the earlier Atlas Knee System (developed in 2014) served as a developmental predecessor and was studied in early feasibility trials (eg, the PHANTOM High Flex Trial, Table 3) that informed the design of the current device. The Atlas system was not FDA-authorized for commercial distribution and should be considered a stepping stone in the development of the MISHA platform. An earlier ISA device, the KineSpring Knee Implant System (Biomet), was studied in early feasibility research but was never FDA-authorized and is no longer commercially available. See Table 1 for FDA authorization details.

Table 1. U.S. Food and Drug Administration-Approved Implantable Shock Absorbers for Knee Osteoarthritis

Device	Manufacturer	FDA Cleared Indication	Description	FDA Product Codes	Clearance	Date
MISHA Knee System	Moximed	Treatment of medial compartment knee OA in patients who failed nonsurgical or surgical treatment, continue to experience pain interfering with daily activities, and are ineligible for or unwilling to undergo joint replacement	Extracapsular implantable shock absorber; cylindrical polymer absorber fixed via titanium plates to distal femur and proximal tibia. It is intended to reduce loads on the intra-articular medial joint surface to improve symptoms of OA. The device is not intended to span the lateral knee.	QVV	DEN220033 (De Novo)	2023

OA: osteoarthritis.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Implantable shock absorbers for the knee are intended to relieve pain and improve function in individuals with knee osteoarthritis who have failed nonsurgical treatment and are not candidates for or are unwilling to undergo joint replacement surgery. The MISHA^{TM†} Knee System (Moximed, Inc.) is the first and currently only U.S. Food and Drug Administration (FDA)-authorized implantable shock absorber for this indication.

Summary of Evidence

For individuals with knee osteoarthritis (OA) who receive implantable shock absorbers (ISA), the evidence consists primarily of a single pivotal nonrandomized cohort and a supporting qualitative systematic review of low-to-moderate certainty evidence. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The MISHA Knee System received FDA De Novo authorization in April 2023. It is indicated to treat people with medial knee OA who have failed to find relief from non-surgical or surgical treatment, continue to experience pain that interferes with daily activities, and are ineligible for or unwilling to undergo joint replacement due to age or absence of advanced OA. The pivotal trial for the MISHA Knee System is the industry funded Calypso Study, a prospective, multicenter, open-label cohort study conducted at 10 centers across the United States and Europe. The Calypso Study demonstrated superiority of the MISHA Knee System (n=81) over high tibial osteotomy (HTO, n=81) on a prespecified FDA-agreed composite primary endpoint at 24 months, with clinically meaningful and statistically significant improvements in pain and function. Key methodological limitations include the nonrandomized open-label design with a historical (HTO) control arm. Five-year follow-up data of 81 patients from the single-arm pivotal MISHA IDE cohort became available in 2026 and reported 90.1% treatment survivorship, 95.7% clinically meaningful improvement in pain scores (WOMAC), and 11/81 (13.6%) implant removals for discomfort, infection, or dissatisfaction, with similar limitations including lack of randomization, no concurrent control, potential selection bias, and potential residual confounding. The FDA-required post-market study (NCT06118892) is ongoing and will provide 5-year follow-up data on long-term safety and effectiveness data in a post-approval population (estimated completion in July 2030). The ongoing MOTION RCT (NCT06843980), with an estimated completion of June 2030, is expected to provide evidence on the MISHA Knee System compared to guideline-based nonsurgical management. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US

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representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons (AAOS) Management of Osteoarthritis of the Knee (Non-Arthroplasty) Evidence-Based Clinical Practice Guideline (3rd Edition, August 2021) provides 27 evidence-based recommendations and 2 consensus statements covering nonsurgical and less-invasive surgical treatments for symptomatic knee OA, including exercise, weight management, pharmacologic therapies, injections, tibial osteotomy, and other procedures less invasive than arthroplasty. The guideline includes a consensus statement recommending against the use of free-floating (unfixed) interpositional devices for symptomatic medial compartment knee OA; the MISHA Knee System is an extracapsular fixed device and is not addressed by this recommendation. The guideline does not otherwise address ISAs specifically, as it predates FDA authorization of the MISHA Knee System (April 2023). No subsequent AAOS guideline update addressing ISA devices has been published as of April 2026.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT06843980 ^a	Evaluation of the MISHA ^{®†} Knee System for Symptom Relief in Subjects With Medial Knee Osteoarthritis Versus the Use of Non-surgical Treatment: Randomized Clinical Trial and Comparison of Therapies for Medial Knee Osteoarthritis.	100	Jun 2030
NCT06118892 ^a	Post-Market Evaluation of the MISHA ^{®†} Knee System for Symptom Relief in Subjects With Medial Knee Osteoarthritis.	120	Jul 2030

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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08/06/2026 Medical Policy Committee review

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08/12/2026 Medical Policy Implementation Committee review

08/20/2026 Medical Quality Management Committee approval. New policy.

Next Scheduled Review Date: 08/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	27599
HCPCS	C8003
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety,

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effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.