Implantable Shock Absorbers for Treatment of Knee Osteoarthritis

Medicare Advantage Medical Policy #MA-237
Original Effective Date: 12/01/2026
Current Effective Date: 12/01/2026

Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Blue Advantage does not cover investigational or experimental services, including any drug, device, procedure, or service provided under the investigational arm of a clinical trial or study unless mandated by the Centers for Medicare and Medicaid Services. Coverage is limited to routine services for Category A IDE studies and to devices and related services for Category B IDE studies when not supplied by the trial sponsor. Approved IDE studies are posted on www.cms.gov/medicare/coverage/evidence.

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 Health Plan 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.

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.

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 federal 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™‡ 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 81patients 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 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
Ongoing			
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	100	Jun 2030

	Comparison of Therapies for Medial Knee Osteoarthritis.		
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.

References

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5. FDA. De Novo request for classification of the MISHA Knee System (April 10, 2023).
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11. Slynarski K, Walawski J, Smigielski R, et al. Two-Year Results of the PHANTOM High Flex Trial: A Single-Arm Study on the Atlas Unicompartmental Knee System Load Absorber in Patients With Medial Compartment Osteoarthritis of the Knee. Clin Med Insights Arthritis Musculoskelet Disord. 2019; 12: 1179544119877170. PMID 31579106

12. Hayes DA, Waller CS, Li CS, et al. Safety and Feasibility of a KineSpring Knee System for the Treatment of Osteoarthritis: A Case Series. Clin Med Insights Arthritis Musculoskelet Disord. 2015; 8: 47-54. PMID 26279631
13. American Academy of Orthopaedic Surgeons. Management of Osteoarthritis of the Knee (Non-Arthroplasty). Evidence-Based Clinical Practice Guideline (August 31, 2021).

Policy History

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Current Effective Date: 12/01/2026
09/15/2026 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 09/2027

Coding

The five character codes included in the Health Plan 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 the Health Plan Medical Policy Coverage Guidelines is with the Health Plan 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 the Health Plan 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 the Health Plan 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, 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.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's 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 Health Plan

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: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

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 Blue Advantage), Blue Advantage 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 Blue Advantage health plan.

Medicare Advantage Members
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening.

If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.