DRAFT Medical Coverage Policy | Implantable Shock Absorbers for Treatment of Knee Osteoarthritis

EFFECTIVE DATE: 12|01|2026
POLICY LAST REVIEWED: 08|05|2026

OVERVIEW

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.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

The use of implantable shock absorbers as a treatment for knee osteoarthritis is not covered as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Commercial Products

The use of implantable shock absorbers as a treatment for knee osteoarthritis is not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable not medically necessary benefits/coverage.

BACKGROUND

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.

Regulatory Status
On April 10, 2023, the U.S. Food and Drug Administration (FDA) granted marketing authorization (De Novo classification, DEN220033)[5] for the MISHA Knee System (Moximed, Inc., Fremont, CA). 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 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.

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 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. Long-term durability and device safety data specific to the MISHA Knee System beyond 24 months are not yet available from peer-reviewed publications; the FDA-required post-market study (NCT06118892) is ongoing and will provide 5-year follow-up data. The ongoing MOTION RCT (NCT06843980), with an estimated completion of June 2030, is expected to provide evidence on the MISHA Knee System compared to nonsurgical management. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products
The following CPT/HCPCS code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

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)

RELATED POLICIES

None

PUBLISHED

Provider Update, October 2026

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