Anthem

Medical Policy

Subject: Implantable Shock Absorber for Treatment of Knee Osteoarthritis
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Description/Scope

This document addresses the use of an implantable shock absorber device (for example, MISHA™ Knee System [Moximed, Inc., Fremont, CA]) for the treatment of osteoarthritis of the knee.

Position Statement

Investigational and Not Medically Necessary:

Use of an implantable shock absorber device for treatment of osteoarthritis of the knee is considered **investigational and not medically necessary**.

Rationale

Osteoarthritis is caused by damage or breakdown of joint cartilage between bones. Treatment may be non-surgical or surgical. Surgical treatment can include high tibial osteotomy or total knee arthroplasty. Individuals may not be eligible for, or do not want to have, knee arthroplasty, particularly younger individuals. An implantable shock absorber device, the MISHA Knee System, has been developed and is being studied as an alternative to knee arthroplasty. The device is placed subcutaneously alongside the knee joint to help reduce the amount of load carried by part of the joint.

The shock absorber was compared to high tibial osteotomy in a non-randomized study, with results reported by Diduch and colleagues (Diduch, 2023). In this prospective, open-label cohort study, 81 participants with osteoarthritis of the medial compartment of the knee and a failure of ≥ 6 months of nonsurgical treatments received implantation of the shock absorber and were compared to 81 participants in a historical control arm who received high tibial osteotomy surgery. Participants were followed for 24 months. The primary endpoint was the proportion of individuals in each arm that met five criteria at 24 months: responder for Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain score, responder for WOMAC function score, no deep infection requiring surgical intervention, maintained integrity of the implant or hardware, and no requirement of conversion to arthroplasty or other joint-modifying surgery. At the 24-month follow-up, there were 85.6% of participants in the implantable shock absorber arm and 65.5% of participants in the high tibial osteotomy group who achieved the primary endpoint. Time to full weightbearing in the implantable shock absorber group was 13.4 days (± 10.12 [SD]) and 58.0 days (± 39.91) in the high tibial osteotomy group. Baseline mean WOMAC pain rating was 60.4 (± 12.37 [SD]) in the implantable shock absorber group and 52.9 (± 13.1) in the high tibial osteotomy group. At 24 months, the mean pain rating was 14.2 in the implantable shock absorber arm and 19.9 in the high tibial osteotomy arm. Baseline mean functional WOMAC score at baseline was 59.9 in the implantable shock absorber arm and 48.4 in the high tibial osteotomy arm. The 24-month scores were 15.4 in the implantable shock absorber arm and 20.1 in the high tibial osteotomy arm. There were no mechanical device malfunctions in either arm. There were 11/81 implant removals in the implantable shock absorber arm and 61/81 removals in the high tibial osteotomy arm. Reasons for removal of the shock absorber included infection, catching/pulling sensation, pain, scar formation, and dissatisfaction. In the high tibial osteotomy group, reasons for implant removals included bone consolidation, pain, swelling, and nerve injury/neuropathy. Limitations of the study include the open-label, non-randomized design and use of historical controls which could have biased outcomes.

Subchondral insufficiency fracture of the knee (SIFK) is associated with high rates of knee osteoarthritis and arthroplasty. A 2023 study by Pareek and colleagues (Pareek, 2023a) compared freedom-from-arthroplasty in those with medial compartment knee osteoarthritis and SIFK who received an implantable shock absorber to a matched cohort of individuals treated non-surgically. The authors also reported on the ability of SIFK scores to predict the 2-year rate of arthroplasty in both groups. The participant population in the implantable shock absorber arm were selected from the enrollees in the Diduch 2023 study discussed above. The control group of participants were taken from a retrospective review of charts and were matched with a 1:1 ratio. SIFK scoring uses radiographic findings of individuals with SIFK to predict the likelihood of progression to arthroplasty. An SIFK score is calculated based on 5 clinical parameters: (1) lateral meniscus extrusion, (2) lateral meniscus root tear, (3) Kellgren-Lawrence (K-L) Grade 4, (4) SIFK on the medial femoral condyle, and (5) medial meniscus extrusion. The maximum possible SIFK score (highest risk) is 11 points. This study was comprised of 21 individuals in each arm. At the 2-year follow-up, 19% (8/21) of participants progressed to knee arthroplasty, all from the control group. For those in the control group, the median 2-year arthroplasty-free survival probability was 55% vs. 100% in the implantable shock absorber group. This study is limited by the lack of a prospective control group, blinding, and other methodological factors.

Another study by Pareek and colleagues (Pareek, 2023b) evaluated whether the use of an implantable shock absorber altered likelihood that an individual with SIFK will progress to knee arthroplasty. This was a retrospective case-control (2:1) study comparing those with SIFK who received the implanted shock absorber (n=19) compared to those who did not receive surgery (n=38). In the control group, there were 34% of participants who progressed to knee arthroplasty, with 16% of participants progressing by 2 years. In the implantable shock absorber group, none of the participants progressed to knee arthroplasty. Overall survival rates were 77% at 2 years and 52% at 5 years. In this study, the majority of the participants had received prior surgical procedures including partial meniscectomy and chondroplasty. This previous surgical management may have had an effect on the natural history of progression to arthroplasty.

Gomoll and colleagues (2023) report the 5-year outcomes of three single-arm studies of 171 individuals who had insertion of an implantable shock absorber for treatment of medial knee osteoarthritis after a failure of ≥ 6 months of conservative treatment. Primary outcome was treatment survival rate without a conversion to knee arthroplasty or high tibial osteotomy. Secondary outcomes included changes in WOMAC pain and function scores after implantable shock absorber insertion. Overall treatment survivorship (freedom from conversion to arthroplasty) was 90.6% (155/171). The mean time to conversion was 2.1 years. Mean baseline WOMAC pain score was 57.6 with the latest follow-up score of 16.0. Mean baseline WOMAC function score was 55.7 with the latest follow-up score of 16.9. Limitations include the single-arm study design.

The implantable shock absorber device is implanted outside the knee capsule and extends from the distal femur to the proximal tibia.

It employs a shock absorbing mechanical system and is stabilized by plates and screws. The use of screws may lead to failure over time. Also, since the device is anchored on one side of the knee joint it may lead to asymmetric wear and tear on the knee. The currently available literature addressing the safety, efficacy and clinical utility of implantable shock absorbers for knee osteoarthritis consists predominantly of retrospective matched control studies and a lack of head-to-head comparisons between treatment modalities. Further study is necessary to assess improvement in net health outcomes of this type of device.

Background/Overview

Osteoarthritis is the most common type of arthritis. It occurs most frequently in the hands, hips, and knees. It is estimated that osteoarthritis affects over 32.5 million adults in the United States (Centers for Disease Control and Prevention [CDC], 2023). Symptoms of osteoarthritis include pain, stiffness, and swelling of the joint. Treatment can include physical therapy, medications, and surgery.

On April 10, 2023, the United States Food and Drug Administration (FDA) authorized marketing of the MISHA™ Knee System (Moximed, Inc., Fremont, CA) as a medial knee implanted shock absorber for treatment of knee osteoarthritis for those who have failed surgical or non-surgical treatment modalities. The FDA clearance was based on a determination of substantial equivalence to previously classified devices. This device is implanted under she skin alongside the knee joint and is intended to provide physical support, decrease joint load and pain, and slow or stop progression of osteoarthritis.

Definitions

Osteoarthritis: The breakdown of cartilage within a joint.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
27599	Unlisted procedure, femur or knee [when specified as implantation of a medial knee implanted shock absorber]
HCPCS	
	For the following HCPCS codes **when specified as supply of a medial knee implanted shock absorber**:
A4649	Surgical supply, miscellaneous
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to-bone (implantable)
ICD-10 Diagnosis	
	All diagnoses, including but not limited to
M17.0-M17.9	Osteoarthritis of knee

References

Peer Reviewed Publications:

1. Diduch DR, Crawford DC, Ranawat AS, et al. 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; 14(2):152-163.
2. 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; 31(8):3307-3315.
3. 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. 2023a; 14(2):164-171.
4. Pareek A, Parkes CW, Slynarski K, et al. Risk of arthroplasty in patients with subchondral insufficiency fractures of the knee: a matched study of the implantable shock absorber using a validated predictive model. J Knee Surg. 2023b Feb 23. Online ahead of print.

Government Agency, Medical Society, and Other Authoritative Publications:

1. U.S. Food and Drug Administration (FDA) De Novo classification. MISHA Knee System. DEN220033. April 10, 2023. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf22/DEN220033.pdf. Accessed on December 11, 2023.

Websites for Additional Information

1. Centers for Disease Control and Prevention. Osteoarthritis (OA). Available at: https://www.cdc.gov/arthritis/basics/osteoarthritis.htm. Accessed on December 11, 2023.

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MISHA knee system
Osteoarthritis

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
New	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

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. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.