

**EVIDENCE-BASED CRITERIA
SECTION: MEDICINE**

**ORIGINAL EFFECTIVE DATE: 10/01/26
LAST REVIEW DATE: 07/29/26
CURRENT EFFECTIVE DATE: 10/01/26
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:**

NEXT ANNUAL REVIEW DATE: 3RD QTR 2027

IMPLANTABLE SHOCK ABSORBERS FOR TREATMENT OF KNEE OSTEOARTHRITIS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

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.

Knee Osteoarthritis

Knee osteoarthritis (OA) is the most common form of arthritis and a leading cause of chronic pain and disability. 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.

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.). 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 an 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. 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) 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.

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Criteria:

- The use of implantable shock absorbers as a treatment for knee osteoarthritis is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:
1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
 5. Insufficient evidence to support improvement outside the investigational setting

Resources:

Literature reviewed 07/29/26. We do not include marketing materials, poster boards and non-published literature in our review.

1. U.S. Centers for Disease Control and Prevention. Osteoarthritis (2024). Accessed April 13, 2026.
2. Nowell JA, Flanigan DC. Implantable Shock Absorber: Breakthrough or Hype?. Curr Rev Musculoskelet Med. Mar 25 2026; 19(1). PMID 41880036
3. Steinmetz JD, Culbreth GT, Haile LM, et al. Global, regional, and national burden of osteoarthritis, 1990-2020 and projections to 2050: a systematic analysis for the Global Burden of Disease Study 2021. Lancet Rheumatol. Sep 2023; 5(9): e508-e522. PMID 37675071
4. 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. Jun 2023; 14(2): 152-163. PMID 36823955
5. FDA. De Novo request for classification of the MISHA Knee System (April 10, 2023). Accessed April 14, 2026.
6. Pham T, Van Der Heijde D, Lassere M, et al. Outcome variables for osteoarthritis clinical trials: The OMERACT-OARSI set of responder criteria. J Rheumatol. Jul 2003; 30(7): 1648-54. PMID 12858473
7. Collins NJ, Prinsen CA, Christensen R, et al. Knee Injury and Osteoarthritis Outcome Score (KOOS): systematic review and meta-analysis of measurement properties. Osteoarthritis Cartilage. Aug 2016; 24(8): 1317-29. PMID 27012756

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8. Tubach F, Ravaud P, Baron G, et al. Evaluation of clinically relevant changes in patient reported outcomes in knee and hip osteoarthritis: the minimal clinically important improvement. Ann Rheum Dis. Jan 2005; 64(1): 29-33. PMID 15208174
9. Anzillotti G, Pavone S, Queirazza P, et al. Knee Joint Distraction and Implantable Shock Absorbers for Knee Osteoarthritis: A Systematic Review of Joint-Preserving Outcomes, Structural Changes, and Complications. Cartilage. Jan 30 2026: 19476035251409412. PMID 41618156
10. Pareek A, Parkes CW, Gomoll AH, et al. 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. Jun 2023; 14(2): 164-171. PMID 37198901
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). Accessed April 15, 2026.

Coding:

HCPCS: C1734

History:

Date:

Activity:

Medical Policy Panel	07/29/26	Approved guideline (effective 10/01/26)
Medical Director (Dr. Sutanto)	06/25/26	Development

Policy Revisions:

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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Dii kwe'é atah nilinigií Blue Cross Blue Shield of Arizona haada yit'éego bina'idilkidgo éi doodago Háida bį́į́ anilyeedigií t'áadoo le'é yina'idilkidgo beehaz'áanii hólo dii t'áa hazaadk'ehji háká a'doowołgo bee haz'a doo baqah ilinígóó. Ata' halne'ígíi kooj' bich'į́' hodiilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



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