Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/24**
(See policy history boxes for previous effective dates)

Title: IN-OFFICE NEEDLE ARTHROSCOPY (E.G., MI-EYE 2™, MI-EYE 3 NEEDLESCOPE™ WITH CANNULA, AND VISIONSCOPE®)

Description/Background

Most treatment decisions for knee joint pathology are based on history, physical examination, plain radiographs, and MRI. When results of these tests are not clearly diagnostic, the clinician may wish to pursue arthroscopy for further diagnosis.[1]

A complete diagnostic arthroscopy includes visualization of all internal structures of the knee: the suprapatellar pouch, medial and lateral gutters, medial and lateral compartments, intercondylar notch, and the posterior medial and posterior lateral compartments. Standard arthroscopy is a surgical procedure that exposes the patient to general anesthesia and the risks associated with operative intervention.

The mi-eye 2™ technology is a small-bore 14-gauge needle and camera unit intended for in-office arthroscopy. The handheld arthroscope interfaces with a digital display via a USB port. With respect to preparation of the patient, the knee is prepared with a topical antiseptic solution and local anesthetic. The patient is awake for the procedure.

The mi-eye 2™ system provides illumination and visualization of an interior cavity of the body through either a natural or surgical opening and is designed to be used for diagnostic and therapeutic arthroscopic and endoscopic procedures.[2]

The mi-eye 3 needlescope™ with cannula, mi-tablet 3™ is a portable visualization device that uses a probe with integrated camera and separate LCD monitor attached via a cable and is substantially equivalent to the previously cleared mi-eye 2™, mi-eye 2 monitor (K162475). The sterile, single-use needlescope probe includes the camera and image capture features with LED light source. The mi-eye 3 probe connects to, and is powered by, the reusable mi-tablet 3™. The mi-tablet 3™ includes an internal battery and power supply, along with a cable for

external charging. The mi-tablet 3™ LCD Monitor displays a real-time image from the probe. The Monitor is also capable of connecting to separate ultrasound transducer, linear and convex, imaging probes and displaying their visual output. The mi-eye 3 needlescope™ with cannula has a rigid shaft that extends from the handle. The distal tip of the probe contains the camera, illumination, and imaging optics. Irrigation may be provided through the distal end of the probe from user supplied solution attached to the handle.[3]

Although less invasive than standard arthroscopy, needle arthroscopy is still a surgical procedure. Both MRI and standard arthroscopy provide more information, and needle arthroscopy has not been shown to replace or reduce the need for either of these procedures.

Regulatory Status

Table 1. Food and Drug Administration Clearances

Device	K Number	Notification Date	Indication
Mi-Eye 2™, Mi-Eye 2 Monitor Camera Enabled Probe	K162475 K141119	Sept 16, 2016 July 29, 2014	The mi-eye 2™ is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening.
VisionScope	K101734	Jun 15, 2010	The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening.
mi-eye 3 needlescope™ with cannula, mi-tablet 3™	K212556	Sept 15, 2021	The mi-eye 3 needlescope ™ with cannula, is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening.

Medical Policy Statement

In-office needle arthroscopy using the mi-eye 2™, mi-eye 3 needlescope™ with cannula, and VisionScope® is experimental/investigational. Its use has not been scientifically demonstrated to improve patient clinical outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

29800	29805	29830	29840	29860	29870
29900	29999				

The above codes are experimental/investigational when conducted in the physician office.

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Safety Feasibility Studies

In an 2017 article, McMillan et al, offers a standardized diagnostic approach to needle arthroscopy of the knee.[1] Needle arthroscopy is an office-based technique allowing direct visualization of the knee cavity and selective sampling of the synovial membrane. In 150 patients with synovitis of the knee, in office needle arthroscopy was performed (1) to evaluate the diagnostic potential in early arthritis, (2) to perform therapeutic lavage in persistent inflammatory synovitis and (3) to assess the balance between technical feasibility, safety and patient comfort on the one hand, and the relevance of the obtained macro- and microscopic information for diagnosis and research purposes on the other. After disinfection of the leg and local anesthesia of the skin and joint, a 1.8-2.7 mm needle arthroscope was introduced into the knee. Synovial fluid was aspirated and lavage of the joint cavity was performed to allow macroscopic evaluation of hyperemia and hypertrophy of the synovial membrane. Biopsies were taken at inflamed sites, followed by another lavage to remove blood and debris. Needle arthroscopy of the knee is a simple and easy to perform technique made particularly attractive by the local anesthesia and the ambulatory setting. It allows good macroscopic evaluation of synovial inflammation and selective sampling of the synovial membrane. Biopsies are suitable for RNA and DNA extraction, bacterial or lymphocyte culture, and cell isolation. Because samples were sometimes too small for representative histology, a switch was made from a 1.8 mm to a 2.7 mm biopsy forceps with good results. In nearly all cases the arthroscopy was well tolerated. Moreover, some patients reported relief of symptoms and even improvement of mobility after lavage of the inflamed joint. No major complications were noted. It was concluded that needle arthroscopy of the knee is a simple, safe and well-tolerated technique, with promising perspectives as a diagnostic, scientific and possibly therapeutic tool in rheumatic diseases.

According to Patel et al (2018), arthroscopy is currently the gold standard for diagnosing intra-articular knee pathology.[4] Magnetic resonance imaging (MRI) can be a clinical adjunct for diagnosis; however, it is not without its shortcomings. Although highly accurate, even advanced imaging misdiagnoses the condition in 1 in 14 patients with regard to anterior cruciate ligament pathology. Previous studies have indicated that MRI fails to identify meniscal pathology when one exists in 1 of every 10 cases, and diagnoses pathology when pathology truly does not exist in 1 of every 5 patients. In-office arthroscopy could offer an alternative to formal diagnostic arthroscopy, with reduced cost and risk of complications.

Deirmengian et al (2018) described the use of a small bore needle arthroscope and MRI to diagnose intra-articular knee pathology.[5] The use of arthroscopy for purely diagnostic purposes has been largely supplanted by noninvasive technologies, such as magnetic resonance imaging (MRI). The mi-eye™ (Trice Medical) technology is a small-bore needle unit for in-office arthroscopy. The authors conducted a pilot study comparing the mi-eye™ unit with MRI, using surgical arthroscopy as a gold-standard reference. This prospective, multicenter, observational study was approved by the Institutional Review Board. There were 106 patients (53 males, 53 females) in the study. MRIs were interpreted by musculoskeletally trained radiologists. The study was conducted in the operating room using the mi-eye™ device. The mi-eye™ device findings were compared with the MRI findings within individual pathologies, and a “per-patient” analysis was performed to compare the arthroscopic findings with those of the mi-eye™ and the MRI. In addition to all mi-eye™ findings and MRI findings all arthroscopy findings were identified. The mi-eye™ demonstrated complete accuracy of all pathologies for 97 (91.5%) of the 106 patients included in the study, whereas MRI demonstrated complete accuracy for 65 patients (61.3%) ($P < .0001$). All discrepancies between mi-eye™ and arthroscopy were false-negative mi-eye™ results, as the mi-eye™ did not reveal some aspect of the knee’s pathology for 9 patients. The mi-eye™ was more sensitive than MRI in identifying meniscal tears (92.6% vs. 77.8%; $P = .0035$) and more specific in diagnosing these tears 100% vs. 41.7%; $P < .0001$). The mi-eye™ device proved to be more sensitive and specific than MRI for intra-articular findings at time of knee arthroscopy. There are contraindications to using the mi-eye™, and these results do not obviate the need for MRI, but this study did demonstrate that the mi-eye™ needle arthroscope can safely provide excellent visualization of intra-articular knee pathology.

In a 2019 review, Zhang et al, explored the current literature regarding both the clinical indications and utility of minimally invasive in-office needle arthroscopy (IONA) relative to conventional imaging modalities.[6] Among 932 conference abstracts and 369 studies identified, 11 publications involving 404 patients (395 knees and 9 shoulders) were included, with 9 clinical studies and 2 cost analyses. The median Methodological Index for Non-Randomized Studies (MINORS) score was 9 for noncomparative and 23 for comparative studies. Among the 9 clinical studies, IONA had a superior sensitivity, specificity, positive predictive value, and negative predictive value to magnetic resonance imaging (MRI) in the evaluation of knee osteoarthritis, anterior cruciate ligament insufficiency, and meniscal tears. IONA was comparable or inferior to MRI in the same parameters for the diagnosis of osteochondral defects and rotator cuff tears. In the 2 cost analyses, IONA had lower costs when used in place of MRI for treatment algorithms involving medial meniscal tears and rotator cuff tears but not lateral meniscal tears. The authors concluded that IONA holds potential for cost savings and improved diagnostic accuracy relative to MRI, primarily for intra-articular meniscal,

ligamentous, and chondral defects of the knee. However, its current indications for use in other joints are limited to rotator cuff tears in the shoulder, making its diagnostic value in other joints much more limited. The current quality and amount of evidence are significantly lacking, with numerous practical shortcomings. To improve acceptance of IONA, priority should be placed on establishing defined protocols, indications, contraindications, and patient perspectives for the procedure.

Case Reports

Chapman and Amin (2018) reports on a case of a patient who developed persistent knee pain with mechanical symptoms after an uncomplicated patellofemoral arthroplasty.[7] The etiology of his knee pain remained inconclusive following magnetic resonance imaging due to metallic artifact image distortion. With the use of an in-office needle arthroscopy, an immediate and definitive diagnosis was obtained, preventing an unnecessary surgery for a diagnostic arthroscopy. The authors discovered a lateral meniscus tear, an anterior cruciate ligament tear, and a medial femoral condyle chondral defect for which the patient underwent arthroscopic partial meniscectomy, ligament reconstruction, and osteochondral allograft transplantation, with resolution of his knee pain.

In another case report, West and Amin (2017) detailed the use of IONA in a patient with chronic knee pain and inconclusive MRI findings.[8] The patient is a 40-year-old male who presented to clinic after an extended history of right knee pain along the medial aspect with previous failed treatments. Magnetic resonance imaging without contrast had demonstrated full-thickness chondral fissuring of the lateral patellar facet, mild abnormal signals of the proximal patellar tendon and Hoffa's fat pad, and intact anterior cruciate ligament and posterior cruciate ligament. The patient was previously treated with an ultrasound-guided injection of 2 cm^3 of 1% lidocaine without epinephrine and 1 cm^3 of Kenalog-40 and scheduled for follow-up. At follow-up, clinical examination showed antalgic gait, minimal tenderness along medial joint line, medial pain in deep flexion, and no pain when in varus or valgus. Due to continued discomfort with a negative magnetic resonance imaging, IONA was performed using mi-eye 2 revealing a tear of the mid-body of the medial meniscus. The patient subsequently underwent arthroscopic repair with complete resolution of medial joint pain. This report highlights the clinical utility of IONA in the management of patients with persistent knee pain and negative or equivocal findings on magnetic resonance imaging.

Cost Analysis

Amin et al (2019) set out to determine whether IONA compared with MRI in the diagnosis and treatment of meniscal tears is cost-effective when evaluated over a 2-year period via patient reported outcomes.[9] The hypothesis is that improved diagnostic accuracy with needle arthroscopy would lead to less costly care and similar outcomes.

A Markov model/decision tree analysis was performed using TreeAge Pro 2017 software. Patients were evaluated for degenerative and traumatic damage to the lateral/medial meniscus. Assumed sensitivities and specificities were derived from the medical literature. The direct costs for care were derived from the 2017 Medicare fee schedule and from private payer reimbursement rates. Costs for care included procedures performed for false-positive findings and for care for false-negative findings. Effectiveness was examined using the global knee injury and osteoarthritis outcome score (KOOS). Patients were evaluated over 2 years for costs and outcomes, including complications. Dominance and incremental cost-effectiveness were evaluated, and 1- to 2-way sensitivity analysis was performed to

determine those variables that had the greatest effect. The consolidated economics evaluation and reporting standards checklist for reporting economic evaluations was used. IONA was found to be less costly and had similar KOOS versus MRI for both the medial/lateral meniscus with private pay. Costs were less for both Medicare and private pay for medial meniscus, $780 to $1,862, and lateral meniscus, $314 to $1,256, respectively. Based on the reported MRI incidence of false positives with the medial meniscus and false negatives with the lateral meniscus and based on assumed standards of care, more costly care is provided when using MRI compared with IONA.

McMillan et al (2017) in a 200 patient retrospective review, examined IONA as a cost effective and reproducible procedure with potential cost and quality-of-life benefits for commercial payers and patients.[1] According to the authors, minimum savings of $418 and $554.62 were realized for noncontrast knee and shoulder magnetic resonance imaging (MRI) scans, respectively, in independent MRI facilities. Those savings more than doubled in hospital-based facilities: $961.08 and $1097.62, respectively, for knee and shoulder noncontrast MRI scans.

Summary of Evidence
For individuals who have indeterminate knee pain and receive in-office diagnostic arthroscopy, the published evidence includes eight abstracts (one prospective study comparing traditional arthroscopy with MRI and mi-eye needle arthroscopy results, two case reports, one systematic review, two cost studies and two articles describing the mi-eye technique). Among the clinical studies, IONA holds potential for cost savings and improved diagnostic accuracy relative to MRI, primarily for intra-articular meniscal, ligamentous, and chondral defects of the knee. However, its current indications for use in other joints are limited to rotator cuff tears in the shoulder, making its diagnostic value in other joints much more limited. The current quality and quantity of evidence are significantly lacking, with numerous practical shortcomings. To improve acceptance of IONA, priority should be placed on establishing defined protocols, indications, contraindications, and patient perspectives for the procedure. At this time there is inadequate data regarding the use of in-office needle arthroscopy for the identification of abnormalities and the impact on the management of the individual with knee pain.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

National Institute for Health and Care Excellence (NICE)
No guidance or position statements found for in-office diagnostic arthroscopy.

Arthroscopy Association of Canada (AAC)
In the AAC 2018 position statement “Arthroscopic debridement and/or lavage of the knee joint has not been shown to have any beneficial effect on the natural history of OA, nor are these procedures indicated as a primary treatment in the management of OA of the knee.[10] However, this does not preclude the judicious use of arthroscopic surgery when indicated to manage symptomatic coexisting disease or abnormality in the presence of OA or degeneration”. They do not address in-office diagnostic arthroscopy.

Arthroscopy Association of North America (AANA)
No guidelines or position statements found for in-office diagnostic arthroscopy.

American Academy of Orthopedic Surgeons (AAOS)
No guidelines or position statements found for in-office diagnostic arthroscopy.

Ongoing and Unpublished Clinical Trials
There are currently no clinical trials located on ClinicalTrials.gov evaluating in-office diagnostic arthroscopy using mi-eye 2™, mi-eye 3 needlescope™ with cannula, or VisionScope®.

Government Regulations

National:

NCD: Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee (publication number 100-3; manual section number 150.9). Effective date 6/11/2004.[11]

This NCD does not address in-office diagnostic arthroscopies.

Local:

N/A

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

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2. Trice Medical. Trice Medical receives FDA 510k clearance for mi-eye 2. October 2016. PR Newswire. Available at: https://tricemedical.com/trice-medical-receives-fda-510k-clearance-mi-eye-2/#:~:text=6%2C%202016%20%2FPRNewswire%2F%20%E2%80%94,joint%20injuries%20in%20their%20clinic. Accessed July 2023.
3. Trice Medical. Trice Medical receives FDA 510k clearance for mi-eye 3. October 21. PR Newswire. Available at: https://tricemedical.com/trice-medical-breaks-surgical-boundaries-with-the-worlds-first-fda-cleared-single-use-25-needle-arthroscope-giving-surgeons-the-tools-they-need-to-see-more-pathology/#:~:text=Malvern%2C%20PA%20(October%2026%2C,use%2C%20single%2Dhand%20device.
4. Patel K, Makovicka JK, Dulle DL, et al. Diagnostic evaluation of the knee in the office setting using small-bore needle arthroscopy. Arthroscopy Techniques. 2018;7(1):17-21.
5. Deirmengian CA, Dines JS, Vernace JV, et al. Use of a small-bore needle arthroscope to diagnose intra-articular knee pathology: comparison with MRI. Am J Orthop. 2018;47(2): PMID: 29494711.

6. Zhang K, Crum RJ, Samuelsson K, et al. In-office needle arthroscopy: a systematic review of indications and clinical utility. Arthroscopy. 2019;35(9):2709-2721.
7. Chapman GL, and Amin NH. The benefits of an in-office arthroscopy in the diagnosis of unresolved knee pain. Case Rep Orthop. 2018;2018:6125676.
8. West JA, and Amin NH. In-office arthroscopy for the evaluation of chronic knee pain: a case report. SAGE Open Med Case Rep. 2017;5:2050313X17740992.
9. Amin NH, McIntyre L, Carter T, et al. Cost-effectiveness analysis of needle arthroscopy versus MRI in the diagnosis and treatment of meniscal tears of the knee. Arthroscopy. 2019;35(2):554-562.
10. Arthroscopic Association of Canada (AAC). Position statement of the AAC concerning arthroscopy of the knee joint—September 2017. Orthop J Sports Med. 2017;6(2):2325967118756597.
11. Centers for Medicare and Medicaid Services. National Coverage Determination for Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee. (150.9). Effective 6/11/2004. Available at: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=285&ncdver=1&bc=0. Accessed July 2023.
12. HAYES Evidence Analysis Research Brief. Mi-eye 2 (Trice Medical) Camera-Enabled Probe for Evaluation of Knee Pain. Lansdale, PA: HAYES, Inc., published August 22, 2019. This analysis is no longer available on Hayes 7/25/23.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through July 25, 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/20	10/15/19		Joint policy established
1/1/21	10/20/20		Routine policy maintenance. No change in policy status.
1/1/22	10/19/21		Routine policy maintenance. No change in policy status.
1/1/23	10/18/22		Routine policy maintenance. No change in policy status. (ky)
1/1/24	10/17/23		Routine policy maintenance. No change in policy status. Added mi-eye 3 needlescope™ with cannula to title, MPS, description/background, and regulatory status section. Vendor: NA (ky)

Next Review Date: 4th Qtr. 2024

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: IN-OFFICE NEEDLE ARTHROSCOPY (E.G., MI-EYE 2™, MI-EYE 3 NEEDLESCOPE ™ WITH CANNULA , AND VISIONSCOPE®)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.