



FEP Medical Policy Manual

FEP 7.01.18 Automated Percutaneous and Percutaneous Endoscopic Discectomy

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Related Policies:

7.01.72 - Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty and Intraosseous Basivertebral Nerve Ablation

7.01.93 - Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency-Coblation (Nucleoplasty)

Automated Percutaneous and Percutaneous Endoscopic Discectomy

Description

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Surgical management of herniated intervertebral discs most commonly involves discectomy or microdiscectomy, performed manually through an open incision. Automated percutaneous discectomy involves placement of a probe within the intervertebral disc under image guidance with aspiration of disc material using a suction cutting device. Endoscopic discectomy involves the percutaneous placement of a working channel under image guidance, followed by visualization of the working space and instrumentation through an endoscope, and aspiration of disc material.

OBJECTIVE

The objective of this evidence review is to evaluate whether the use of automated percutaneous discectomy or endoscopic percutaneous discectomy improves the net health outcome in individuals with herniated intervertebral discs.

POLICY STATEMENT

Automated percutaneous discectomy is considered **investigational** as a technique of intervertebral disc decompression in individuals with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine.

Percutaneous endoscopic discectomy is considered **investigational** as a technique of intervertebral disc decompression in individuals with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Percutaneous discectomy may be performed by surgeons, but anesthesiologists or other physicians whose practices focus on pain management may also perform this procedure.

FDA REGULATORY STATUS

The Dekompressor Percutaneous Discectomy Probe (Stryker), Herniatome Percutaneous Discectomy Device (Gallini Medical Devices), and the Nucleotome (Clarus Medical) are examples of percutaneous discectomy devices that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA indication for these products is for "aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine." FDA product code: HRX.

A variety of endoscopes and associated surgical instruments have also been cleared for marketing by FDA through the 510(k) process.

RATIONALE

Summary of Evidence

For individuals who have herniated intervertebral disc(s) who receive automated percutaneous discectomy, the evidence includes randomized controlled trials (RCTs) and systematic reviews of observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The published evidence from small RCTs is insufficient to evaluate the impact of automated percutaneous discectomy on the net health outcome. Well-designed and executed RCTs are needed to determine the benefits and risks of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have herniated intervertebral disc(s) who receive percutaneous endoscopic discectomy, the evidence includes a number of RCTs, systematic reviews, and observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Many of the more recent RCTs are conducted at institutions within China. There are few reports from the United States. Results do not reveal a consistently significant improvement in patient-reported outcomes and treatment-related morbidity with percutaneous endoscopic discectomy in comparison to other discectomy interventions. 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.

National Institute for Health and Care Excellence

The NICE (2005) published guidance on automated percutaneous mechanical lumbar discectomy, indicating there was limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, and evidence from small RCTs showed conflicting results.⁹⁶ The guidance indicated that, in view of uncertainty about the efficacy of the procedure, it should not be done without special arrangements for consent and for audit or research. The guidance was considered for an update in 2009, but failed review criteria; the 2005 guidance is therefore considered current.

A NICE (2016) guidance on percutaneous transforaminal endoscopic lumbar discectomy for sciatica was published.⁹⁷ The guidance stated that current evidence is adequate to support the use of percutaneous transforaminal endoscopic lumbar discectomy for sciatica. Choice of operative procedure (open discectomy, microdiscectomy, or percutaneous endoscopic approaches) may be influenced by symptoms, location, and size of the prolapsed disc.

A NICE (2016) guidance on percutaneous interlaminar endoscopic lumbar discectomy for sciatica was also published.⁹⁸ The guidance stated that current evidence is adequate to support the use of percutaneous interlaminar endoscopic lumbar discectomy for sciatica. Choice of operative procedure (open discectomy, microdiscectomy, or percutaneous endoscopic approaches) may be influenced by symptoms, location, and size of the prolapsed disc.

American Society of Interventional Pain Physicians

The guidelines from the American Society of Interventional Pain Physicians (2013) indicated that the evidence for percutaneous disc decompression with the Dekompressor was limited.³ There were no recommended indications for the Dekompressor.

North American Spine Society

The North American Spine Society (2014) published clinical guidelines on the diagnosis and treatment of lumbar disc herniation⁹⁹. Table 1 summarizes recommendations specific to percutaneous endoscopic discectomy and automated percutaneous discectomy.

Table 1. Recommendations for Lumbar Disc Herniation With Radiculopathy

Recommendations	Grade or LOE ^a
Endoscopic percutaneous discectomy is suggested for carefully selected patients to reduce early postoperative disability and reduce opioid use compared with open discectomy.	B
There is insufficient evidence to make a recommendation for or against the use of automated percutaneous discectomy compared with open discectomy.	I
Endoscopic percutaneous discectomy may be considered for treatment.	C
Automated percutaneous discectomy may be considered for treatment.	C
Patients undergoing percutaneous endoscopic discectomy experience better outcomes if <40 years and symptom duration <3 months.	II

LOE: level of evidence.

^a Grade B: fair evidence (level II or III studies with consistent findings; grade C: poor quality evidence (level IV or V studies). Level of evidence II: lesser quality randomized controlled trial (eg, <80% follow-up, no blinding, or improper randomization), prospective comparative study, systematic review of level II studies or level I studies with inconsistent results; level of evidence III: case control, retrospective, systematic review of level III studies; level of evidence IV: case series; level of evidence V: expert opinion.

American Pain Society

The clinical practice guidelines from the American Pain Society (2009) found insufficient evidence to evaluate alternative surgical methods to standard open discectomy and microdiscectomy, including laser or endoscopic-assisted techniques, various percutaneous techniques, coblation nucleoplasty, or the Dekompressor.¹⁰⁰

American Society of Pain and Neuroscience

The American Society of Pain and Neuroscience (ASPN; 2022) published clinical guidance for interventional treatments for low back pain. [Sayed D, Grider J, Strand N, et al. *The American S...*; 15: 3729-3832. PMID 36510616] The guideline states that discectomy procedures (such as percutaneous and endoscopic disc procedures) have favorable safety and efficacy profiles for the treatment of lumbar disc herniation with persistent radicular symptoms; however, it is stated that further research is needed to evaluate complications rates in order for these procedures to supplant classic open microdiscectomy. Recommendations specific to percutaneous endoscopic discectomy are summarized in Table 2.

Table 2. Recommendations for Percutaneous and Endoscopic Procedures

Recommendation	Grade ^a	Level of Evidence ^b	Level of Certainty [Net Benefit] ^c
Percutaneous Endoscopic Discectomy	B	I-a	High

^a Grade B: (The ASPN Back Group recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial..

^b Evidence Level: I-A: At least one controlled and randomized clinical trial, properly designed

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.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2012	New policy	Percutaneous and Endoscopic discectomy are considered investigational.
September 2013	Replace policy	Policy updated with literature review; references 1-4, 10, 22-23, 25, and 27-29 added; policy statement clarified to read "back pain and/or radiculopathy,
June 2014	Replace policy	Policy updated with literature review, references 13, 14, 18 added; policy statements unchanged.
June 2015	Replace policy	Policy updated with literature review, references 17-18, 27, and 34 added; policy statement changed to investigational from not medically necessary
June 2017	Replace policy	Policy updated with literature review through March 6, 2017; references 10, 15-16, 18 and 21 added. Policy statements unchanged. Policy title changed to "Automated Percutaneous and Percutaneous Endoscopic Discectomy,.
March 2019	Replace policy	Policy updated with literature review through June 4, 2018; reference 21 added. Policy statements unchanged.
September 2019	Replace policy	Policy updated with literature review through April 18, 2019; references added. Policy statements unchanged.
September 2020	Replace policy	Policy updated with literature review through May 7, 2020; references added. Policy statements unchanged.
September 2021	Replace policy	Policy updated with literature review through April 26, 2021; references added. Policy statements unchanged.
September 2022	Replace policy	Policy updated with literature review through April 22, 2022; references added. Minor editorial refinements to policy statements; intent unchanged.
September 2023	Replace policy	Policy updated with literature review through May 5, 2023; references added. Policy statements unchanged.

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