



Automated Percutaneous and Percutaneous Endoscopic Discectomy

Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 12/30/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers automated percutaneous discectomy 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 to be **investigational**.*

Based on review of available data, the Company considers percutaneous endoscopic discectomy 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 to be **investigational**.*

Background/Overview

Back pain or radiculopathy related to herniated discs is an extremely common condition and a frequent cause of chronic disability. Although many cases of acute low back pain and radiculopathy will resolve with conservative care, surgical decompression is often considered when the pain is unimproved after several months and is clearly neuropathic in origin, resulting from irritation of the nerve roots. Open surgical treatment typically consists of discectomy in which the extruding disc material is excised. When performed with an operating microscope, the procedure is known as a microdiscectomy.

Minimally invasive options have also been researched, in which some portion of the disc is removed or ablated, although these techniques are not precisely targeted at the offending extruding disc material. Ablative techniques include laser discectomy and radiofrequency decompression. Intradiscal electrothermal annuloplasty is another minimally invasive approach to low back pain. In this technique, radiofrequency energy is used to treat the surrounding disc annulus.

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Herein, BCBSA addresses automated percutaneous and endoscopic discectomy, in which the disc decompression is accomplished by the physical removal of disc material rather than its ablation. Traditionally, discectomy was performed manually through an open incision, using cutting forceps to remove nuclear material from within the disc annulus. This technique was modified by automated devices that involve placement of a probe within the intervertebral disc and aspiration of disc material using a suction cutting device. Endoscopic techniques may be intradiscal or may involve extraction of noncontained and sequestered disc fragments from inside the spinal canal using an interlaminar or transforaminal approach. Following insertion of the endoscope, decompression is performed under visual control.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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

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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.

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

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2018 Input

Clinical input was sought to help determine whether the use of automated percutaneous discectomy or endoscopic percutaneous discectomy for individuals with herniated intervertebral discs would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from

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Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 12/30/2023

3 respondents, including 2 specialty society-level response(s); no physician-level responses identified through a specialty society; 1 physician-level response identified through an academic medical center.

For individuals who have herniated intervertebral discs who receive automated percutaneous discectomy or percutaneous endoscopic discectomy, clinical input does not support a clinically meaningful improvement in net health outcome and does not indicate this use is consistent with generally accepted medical practice. Clinical input suggests that automated percutaneous discectomy may be an appropriate treatment option for the highly selected patient who has a small focal disc fragment compressing a lumbar nerve causing radiculopathy in the absence of lumbar stenosis or severe bony foraminal stenosis. Similarly, clinical input suggests that endoscopic percutaneous discectomy may be an appropriate treatment option for the highly selected patient who has a small focal disc herniation causing lumbar radiculopathy. However, respondents were mixed in the level of support for this indication, and overall the clinical input is not generally supportive of a clinically meaningful improvement in net health outcome.

2013 Input

In response to requests, input was received from 4 physician specialty societies and 3 academic medical centers while this policy was under review in 2013. Overall, input agreed that percutaneous and endoscopic discectomy are investigational. Most reviewers considered discectomy with tubular retractors to be a variant of open discectomy, with the only difference being the type of retraction used.

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. The guidance

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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. 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. 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. 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 herniation 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



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Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 12/30/2023

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.

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.

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Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 12/30/2023

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.

Ongoing and Unpublished Clinical Trials

Currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT01997086	Percutaneous Transforaminal Endoscopic Discectomy (PTED) vs. Microendoscopic Discectomy (MED) for the treatment of Lumbar Disc Herniation: A Prospective Randomized Controlled Study	125	Aug 2023

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Page 8 of 21



Automated Percutaneous and Percutaneous Endoscopic Discectomy

Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 12/30/2023

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Policy # 00208

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Current Effective Date: 12/30/2023

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Current Effective Date: 12/30/2023

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Automated Percutaneous and Percutaneous Endoscopic Discectomy

Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 12/30/2023

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Automated Percutaneous and Percutaneous Endoscopic Discectomy

Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 12/30/2023

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Automated Percutaneous and Percutaneous Endoscopic Discectomy

Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 12/30/2023

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Automated Percutaneous and Percutaneous Endoscopic Discectomy

Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 12/30/2023

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03/09/2006	Medical Director review
03/15/2006	Medical Policy Committee approval
04/04/2007	Medical Director review
04/18/2007	Medical Policy Committee approval. Coverage eligibility unchanged.
03/04/2009	Medical Director review
03/18/2009	Medical Policy Committee approval. No change to coverage.
03/05/2010	Medical Policy Committee approval
03/19/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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Automated Percutaneous and Percutaneous Endoscopic Discectomy

Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 12/30/2023

03/03/2011	Medical Policy Committee review
03/16/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/12/2012	Medical Policy Committee review
04/25/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Rationale updated.
04/04/2013	Medical Policy Committee review
04/24/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/03/2014	Medical Policy Committee review
04/23/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/08/2016	Medical Policy Committee review
09/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
07/06/2017	Medical Policy Committee review
07/19/2017	Medical Policy Implementation Committee approval. Coding update.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Changed investigational statements. Title changed to "Automated Percutaneous and Percutaneous Endoscopic Discectomy."
10/01/2018	Coding update
07/03/2019	Medical Policy Committee review
07/18/2019	Medical Policy Implementation Committee approval. No change to coverage.
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. No change to coverage.
07/01/2021	Medical Policy Committee review
07/14/2021	Medical Policy Implementation Committee approval. No change to coverage.

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Automated Percutaneous and Percutaneous Endoscopic Discectomy

Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 12/30/2023

09/01/2022 Medical Policy Committee review

09/14/2022 Medical Policy Implementation Committee approval. No change to coverage.

09/07/2023 Medical Policy Committee review

09/13/2023 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 09/2024

Coding

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Automated Percutaneous and Percutaneous Endoscopic Discectomy

Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 12/30/2023

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0274T, 0275T, 62287, 62380
HCPCS	C2614
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

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Automated Percutaneous and Percutaneous Endoscopic Discectomy

Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 12/30/2023

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