



Louisiana

Automated Percutaneous and Percutaneous Endoscopic Discectomy

Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 09/26/2020

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 patients 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 patients 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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This medical policy 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. 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

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 instruments through an endoscope, and aspiration of disc material.

The following conclusions are based on a review of the evidence, including, but not limited to, published evidence and clinical expert opinion, via BCBSA's Clinical Input Process.

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For individuals who have herniated intervertebral disc(s) who receive automated percutaneous discectomy, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. 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. Clinical input suggests this intervention 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. However, the clinical input is not generally supportive of a clinically meaningful improvement in net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have herniated intervertebral disc(s) who receive percutaneous endoscopic discectomy, the evidence includes a number of RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Many of the RCTs were conducted at a single center in Europe. Some trials have reported outcomes at least as good as traditional approaches with an open incision, while 1 RCT from a different center in Europe reported a trend toward increased complications and reherniations using an endoscopic approach. There are few reports from the United States. Clinical input suggests this intervention may be an appropriate treatment option for the highly selected patient who has a small focal disc herniation causing lumbar radiculopathy according to clinical input expert opinion. However, respondents were mixed in the level of support of this indication, and overall there was not a preponderance of clinical input support in general cases. The evidence is insufficient to determine the effects of the technology on health outcomes.

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.

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2018 Input

In response to requests, clinical input on automated percutaneous discectomy and percutaneous endoscopic discectomy for herniated intervertebral disc(s) was received from 3 respondents, including 2 specialty society-level responses and including physicians with academic medical center affiliation, while this policy was under review in 2018.

Evidence from clinical input is integrated within the Rationale section summaries and the Summary of Evidence.

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

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (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 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

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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 Dekompessor was limited. There were no recommended indications for the Dekompessor.

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
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,



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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.

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 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02602093	(Cost) Effectiveness of Percutaneous Transforaminal Endoscopic Discectomy vs. Open Microdiscectomy for Patients With Symptomatic Lumbar Disc Herniation	682	Dec 2019
<i>Unpublished</i>			
NCT02742311	EuroPainClinics [®] ‡ Study V Prospective Observational Study (EPCSV)	500	Jan 2019

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			(unknown)
NCT02441959	Full-Endoscopic vs Open Discectomy for the Treatment of Symptomatic Lumbar Herniated Disc: A Prospective Multi-Center Randomized Study	200	Jul 2018 (terminated)
NCT01622413 ^a	Transforaminal Endoscopic Surgery Cost Outcome Research Trial (TESCORT)	0	Sep 2017 (withdrawn)
NCT02358291	Microendoscopic Discectomy Vs Transforaminal Endoscopic Lumbar Discectomy Vs Open Discectomy for the Treatment of Lumbar Disc Herniation	240	Mar 2017 (unknown)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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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.
- 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.

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- 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 to track BCBSA. 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.
- Next Scheduled Review Date: 07/2021

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Current Effective Date: 09/26/2020

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ICD-10 Diagnosis	M51.06, M51.36, M51.37

*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

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Automated Percutaneous and Percutaneous Endoscopic Discectomy

Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 09/26/2020

3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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