Effective November 1, 2023, refer to <u>CMS</u> <u>Manual 100-02, Chapter</u> <u>16-General Exclusions</u> <u>from Coverage</u> for services included in this policy.



Name of Blue Advantage Policy:

Automated Percutaneous and Percutaneous Endoscopic Discectomy

Policy #: 137

Latest Review Date: July 2023

Category: Surgery

ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

- 1. Safe and effective;
- 2. Not experimental or investigational*;
- 3. Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient's medical needs and condition;
 - Ordered and furnished by qualified personnel;
 - One that meets, but does not exceed, the patient's medical need; and
 - At least as beneficial as an existing and available medically appropriate alternative.

*Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare** for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).

POLICY:

Blue Advantage will treat automated percutaneous discectomy as a non-covered benefit and as investigational 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.

Blue Advantage will treat percutaneous endoscopic discectomy as a non-covered benefit and as investigational 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.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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. Removal of disc herniations under endoscopic visualization is also being investigated. 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.

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 microdiscectomy.

Minimally invasive options have also been researched, in which some portion of the disc material is removed or ablated, although these techniques are not precisely targeted at the offending extruding disc material. Ablative techniques include laser discectomy and radiofrequency (RF) decompression. In addition, intradiscal electrothermal annuloplasty (also known as intradiscal electrothermal therapy [IDET]) is another minimally invasive approach to low back pain. In this technique, RF energy is used to treat the surrounding disc annulus. (See Medical Policy #090: Decompression of the Intervertebral Disc Using Laser Energy [Laser Discectomy] or Radiofrequency Coblation [Nucleoplasty] and Medical Policy #041: Percutaneous Intradiscal Electrothermal Annuloplasty (IDET), Radiofrequency Annuloplasty and Biacuplasty).

This 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 is performed manually through an open incision, using cutting forceps to remove nuclear material from within the disc annulus. This technique has been 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 the extraction of non-contained and sequestered disc fragments from inside the spinal canal using an interlaminar or transforaminal approach. Following insertion of the endoscope, the decompression is performed under visual control.

KEY POINTS:

The most recent literature search was performed through May 5, 2023. Following is a summary of the key literature to date.

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 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment related morbidity. The published evidence is insufficient to evaluate the impact of automated percutaneous discectomy on the net health outcome. Evidence from small RCTs does not support the use of this procedure. Well-designed and executed RCTs are needed to determine the benefits and risks of this procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have herniated intervertebral disc(s) who receive endoscopic percutaneous 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 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 the effects of the technology on health outcomes.

Practice Guidelines and Position Statements National Institute for Health and Care Excellence

The National Institute for Health and Clinical Excellence (NICE) published guidance in 2005 on automated percutaneous mechanical lumber discectomy, indicating that there is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, and evidence from small randomized controlled trials shows conflicting results. The guidance states 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 review in 2009, but did not meet the review criteria; the 2005 guidance is therefore considered current.

A NICE guideline on percutaneous transforaminal endoscopic lumbar discectomy for sciatica was published in 2016. The guidance has 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, and location and size of prolapsed disc.

A NICE guidance on percutaneous interlaminar endoscopic lumbar discectomy for sciatica was published in 2016. 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, and location and size of prolapsed disc.

American Society of Interventional Pain Physicians

The 2013 guideline update from the American Society of Interventional Pain Physicians states that the evidence for percutaneous disc decompression with Dekompressor is limited. There were no recommended indications for Dekompressor.

North American Spine Society

In 2014, the North American Spine Society published clinical guidelines on the diagnosis and treatment of lumbar disc herniation. Table 1 summarizes recommendations specific to endoscopic percutaneous discectomy and automated percutaneous discectomy.

Table 1. NASS Recommendations for Lumbar Disc Herniation with Radiculopathy

Table 1. NASS Recommendations for Lumbar Disc Hermation 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.	В
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.	С
Automated percutaneous discectomy may be considered for treatment.	С
Patients undergoing percutaneous endoscopic discectomy experience better outcomes if <40 years and symptom duration <3 months.	II

LOE: level of evidence; NASS: North American Spine Society

^a Grade B: fair evidence (level II or III studies with consistent findings; grade C: poor quality evidence (level IV or V studies).

^b Level of evidence II: lesser quality randomized controlled trial (e.g., <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 2009 clinical practice guidelines from the American Pain Society 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. 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 the table below.

Table 2. Recommendations for Percutaneous and Endoscopic Procedures

Recommendation	Grade ^a	Level of Evidence ^b	Level of Certainty [Net Benefit] ^c
Percutaneous Endoscopic Discectomy	В	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.

U.S. Preventive Services Task Force Recommendations

Not Applicable.

KEY WORDS:

Percutaneous endoscopic discectomy, herniated disc, LDH, lumbar disc herniation, Yess procedure, Yeung procedure, Yeung endoscopic spinal surgery, SED, selective endoscopic discectomy, PLD, percutaneous lumbar discectomy, IDET, intradiscal electrothermal therapy, IEA, intradiscal electrothermal annuloplasty, MED, microendoscopic discectomy, percutaneous radiofrequency thermo-modulation, percutaneous intradiscal radiofrequency thermocoagulation, Nucleoplasty, microdiscectomy, laser-assisted discectomy, LADD, open microdiscectomy, METRxTM, Dekompressor, Stryker, Laurimed

APPROVED BY GOVERNING BODIES:

The Stryker DeKompressor® Percutaneous Discectomy Probe (Stryker), Herniatome Percutaneous Discectomy Device (Gallini Medical Devices), and the Nucleotome® (Clarus Medical) are examples of percutaneous discectomy devices that received clearance from the U.S. Food and Drug Administration (FDA) through the 510(k) process. Both have the same labeled intended use, i.e., "for use in aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine."

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

A variety of endoscopes and associated surgical instruments have received marketing clearance through the FDA's 510(k) process.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT codes:

62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar.
0274T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (e.g., fluoroscopic, CT), single or multiple levels, unilateral or bilateral; cervical or thoracic
0275T	; lumbar

HCPCS Codes:

C2614	Probe, percutaneous lumbar discectomy
	71

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POLICY HISTORY:

Adopted for Blue Advantage, March 2005 Available for comment May 1-June 14, 2005 Medical Policy Group, August 2005 Medical Policy Group, March 2006 Available for comment March 25-May 8, 2006 Medical Policy Group, January 2007

Medical Policy Group, January 2009

Medical Policy Group, January 2010

Medical Policy Group, December 2011

Medical Policy Group, January 2012

Medical Policy Group, September 2013

Available for comments September 19 through November 2, 2013

Medical Policy Group, March 2014

Medical Policy Group, May 2015

Medical Policy Group, April 2016

Medical Policy Group, April 2017

Medical Policy Group, February 2018

Medical Policy Group, April 2020: Reinstated policy effective March 24, 2020.

Medical Policy Group, August 2020

Medical Policy Group, July 2021

Medical Policy Group, August 2022

Medical Policy Group, July 2023

Medical Policy Group, November 2023: Archived effective 11/1/2023.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plans contracts.