MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Automated Percutaneous Discectomy and Image-Guided, Minimally Invasive Decompression**
Policy Number	**7.01.16**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our review and assessment of the peer-reviewed literature, automated percutaneous discectomy has not been medically proven to be effective and, therefore, is considered **investigational** as a technique of intervertebral disc decompression in patients with disc herniation of the cervical, thoracic or lumbar spine.

II. Based upon our review and assessment of the peer-reviewed literature, image-guided, minimally invasive, lumbar decompression (mild) or spinal decompression has not been medically proven to be effective and, therefore, is considered **investigational** as a technique of spinal canal decompression in patients with spinal stenosis.

Refer to Corporate Medical Policy #7.01.6 Intervertebral Disc Decompression Laser (Laser Discectomy) and Radiofrequency Coblation (Disc Nucleoplasty) Techniques

Refer to Corporate Medical Policy #7.01.97 Lumbar Decompression.

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

DESCRIPTION

Back pain and sciatica related to herniated discs is an extremely common condition and a frequent cause of chronic disability. Although many cases of acute back pain will resolve with conservative care, a surgical decompression is often considered when the pain is unimproved and is clearly neuropathic in origin. The primary surgical procedure for disc herniation/prolapse has been open discectomy for the relief of nerve root compression by removing the herniated nuclear material. However, minimally invasive options have also been proposed to relieve nerve root compression without damaging surrounding tissues, allowing for a quicker recovery and minimizing post-operative complications.

Originally, percutaneous discectomy was performed manually, using cutting forceps to remove nuclear material from within the disc annulus. This technique has been replaced with automated percutaneous discectomy (APD). APD is performed using local anesthetic, with or without conscious sedation. Under fluoroscopic guidance, a cannula is placed centrally within the disc using a posterolateral approach on the symptomatic side. A probe, connected to an automated cutting and aspiration device, is then introduced through the cannula. The disc is aspirated until no more nuclear material can be obtained. The Stryker DeKompressor Percutaneous Discectomy Probe (Stryker), the Nucleotome (Clarus Medical), and the SpineJet Hydrodiscectomy System (HydroCision) are examples of devices utilized in ADP.

Endoscopic techniques have also been developed to perform discectomy under local anesthesia. The procedure involves the percutaneous placement of a working channel under image guidance, followed by visualization of the working space and instruments through an endoscope. 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.

Image-guided, minimally invasive, lumbar decompression is a percutaneous procedure for decompression of the central spinal canal in individuals with lumbar spinal stenosis (LSS), using a specially designed tool kit, has been proposed as an ultra-minimally invasive treatment of central LSS. In this procedure, the epidural space is filled with contrast medium under fluoroscopic guidance. Using a six-gauge cannula clamped in place with a back plate, single-use tools (portal cannula, surgical guide, bone rongeur, tissue sculpter, trocar) are used to resect thickened ligamentum flavum and small pieces of lamina. The tissue and bone sculpting is conducted entirely under fluoroscopic guidance, with contrast media added throughout the procedure to aid visualization of the decompression. The process is repeated on the opposite side for bilateral decompression of the central canal. The devices are not intended for use near the lateral neural elements and are contraindicated for disc procedures.

RATIONALE

Automated percutaneous discectomy

Th(Stryker), and the Nucleotome (Clarus Medical) have received clearance from the FDA through the Section 510(k) process. Both have the same intended use label, e.g., “for use in aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine.” In 2003, HydroCision announced that the FDA had granted Section 510(k) clearance to market the SpineJet Hydrodiscectomy System for the cutting, resection, and removal of soft tissue in minimally invasive percutaneous spinal surgery.

The vast majority of the published literature addresses the use of ADP in lumbar disc herniation. Overall, based on conflicting evidence, the literature remains insufficient to determine the efficacy of ADP as a technique for disc decompression.

A Cochrane systematic review (Gibson et al. 2007) concluded that “trials of percutaneous discectomy provided moderate evidence that it produces poorer clinical outcomes than standard discectomy or chymopapain.” For example, Chatterjee et al. reported on the results of a study that randomized 71 patients with lumbar disc herniation to undergo either percutaneous discectomy or lumbar microdiscectomy. A successful outcome was reported in only 29% of those undergoing percutaneous discectomy, compared to 80% in the microdiscectomy group. The trial was halted early due to this inferior outcome. In a 1993 randomized study, Revel and colleagues compared the outcomes of percutaneous discectomy to chymopapain injection in 141 patients with disk herniation and sciatica. Treatment was considered successful in 61% of patients in the chymopapain group, compared to 44% in the percutaneous discectomy group. Another trial cited in the Cochrane review, Mayer et al., is not applicable, as the technique used modified forceps in addition to a suction probe. Finally, the last trial cited in the Cochrane review, Hermantin, et al., provided insufficient data to allow detailed analysis of results.

In the Lumbar Automated Percutaneous Discectomy Group (LAPDOG) study (Haines et al. 2002), a randomized trial was designed to compare percutaneous and open discectomy in patients with lumbar disc herniation. This trial was designed to recruit 330 patients, but was able to recruit only 36 patients. Of the evaluable 27 patients, 41% of the percutaneous discectomy patients and 40% of the conventional discectomy patients were assessed as having successful

outcomes at six months. The authors acknowledged that this trial was unable to enroll sufficient numbers of patients to reach a definitive conclusion and stated, "It is difficult to understand the remarkable persistence of percutaneous discectomy in the face of a virtually complete lack of scientific support for its effectiveness in treated lumbar disc herniation."

A task force of the American Society of Interventional Pain Physicians (Boswell et al. 2007) reported that percutaneous disc decompression remains controversial; although all observational studies were positive, the evidence from all four of the randomized published studies was negative. Questions also remain about the appropriate patient selection criteria (particularly related to the size and migration of the disc herniation) for this procedure.

The 2005 National Institute for Health and Excellence guidance for automated percutaneous mechanical lumbar discectomy concluded, "There is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, but evidence from small randomized controlled trials shows conflicting results. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and for audit or research."

Minimally invasive lumbar decompression (mild)
The largest RCT (Staats et al. 2016 and Benyamin et al. 2016) compared mild with ESIs (control) in 302 patients who had ligamentum flavum hypertrophy and who failed conservative therapy. Early results have suggested reductions in pain and improvements in function scores in the mild group versus the control group. The trial was unblinded, and there is evidence of differing expectations and follow-up in the two groups, suggesting a high risk of bias. The available evidence is insufficient to determine the efficacy of mild compared with placebo, or to determine the efficacy of mild compared with open decompression. Trials with relevant control groups could provide greater certainty on the risks and benefits of this procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
62287 **(E/I)**	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 (e.g. manual or automated percutaneous discectomy, percutaneous laser discectomy)
0274T **(E/I)**	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), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic

Code	Description
0275T **(E/I)**	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), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar

HCPCS Codes

Code	Description
C2614 **(E/I)**	Probe, percutaneous lumbar discectomy
G0276	Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial

ICD10 Codes

Code	Description
M43.12-M43.17	Spondylolisthesis (code range)
M48.02 – M48.07	Spinal stenosis (code range)
M50.20-M50.23	Other cervical disc displacement (code range)
M50.30-M50.33	Other cervical disc degeneration (code range)
M51.06	Intervertebral disc disorders with myelopathy, lumbar region
M51.24-M51.27	Other intervertebral disc displacement (code range)
M51.34-M51.37	Other intervertebral disc degeneration (code range)
M51.9	Unspecified thoracic, thoracolumbar and lumbosacral intervertebral disc disorder

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*Key Article

KEY WORDS

Automated percutaneous discectomy, DeKompressor, hydrodiscectomy, Nucelotome, Percutaneous discectomy, Percutaneous Image-guided Lumbar Decompression, minimally invasive lumbar decompression.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for percutaneous image-guided lumbar decompression for lumbar spinal stenosis. Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=358&ncdver=2&DocID=150.13&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&kq=true&SearchType=Advanced&bc=IAAAABAAAAAA&

CMS approved studies for percutaneous image-guided lumbar decompression for lumbar spinal stenosis under Coverage with Evidence Development (CED) are located here: https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/PILD

CMS issued a decision memo related to Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (CAG-00433N) that includes 0275T and G0276. It is located at: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=269