MEDICAL POLICY

SUBJECT: AUTOMATED PERCUTANEOUS AND ENDOSCOPIC DISCECTOMY	EFFECTIVE DATE: 05/28/09 REVISED DATE: 04/22/10, 03/17/11, 05/24/12, 04/18/13, 03/20/14, 02/19/15, 01/21/16, 01/19/17, 01/18/18
POLICY NUMBER: 7.01.16 CATEGORY: Technology Assessment	PAGE: 1 OF: 8

- ***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 product, covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare 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.***

POLICY STATEMENT:

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

Refer to Corporate Medical Policy #7.01.17 regarding Percutaneous Intradiscal Electrothermal Annuloplasty (IDET/IDTA, PIRFT, biacuplasty).

Refer to Corporate Medical Policy #7.01.62 regarding Intervertebral Disc Decompression: Laser and Radiofrequency Coblation Techniques.

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

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

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 SpineJet Hydrodiscectomy System (HydroCision) are examples of devices utilized in automated percutaneous discectomy.

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.

RATIONALE:

Automated percutaneous discectomy

The Stryker DeKompressor Percutaneous Discectomy Probe (Stryker), and the Nucleotome (Clarus Medical) have received clearance from the U.S. Food and Drug Administration (FDA) through the 510(k) process. Both have the same labeled intended use, 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 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 automated percutaneous discectomy in lumbar disc herniation. Overall, based on conflicting evidence, the literature remains insufficient to determine the efficacy of automated percutaneous discectomy as a technique for disc decompression.

A Cochrane systematic review (Gibson , et al. 2000, 2003 and 2007) concluded ... "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 since 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.

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 only was able to recruit 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 6 months. The authors concluded that this trial was unable to enroll sufficient numbers of patients to reach a definitive conclusion. The authors state, "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) reports that percutaneous disc decompression remains controversial; although all observational studies were positive, the evidence from 4 of 4 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".

Endoscopic discectomy

A variety of endoscopes and associated surgical instruments have received marketing clearance through the FDA's 510(k) process. There is insufficient evidence from clinical studies proving additional benefits from using an endoscope for performing disc decompression. Currently, there are no reliable clinical studies of endoscopic spinal surgery that have included an adequate comparison group of patients receiving open procedures. In addition, there is limited evidence on the long-term outcomes resulting from these endoscopic procedures. The current evidence is insufficient to evaluate the overall health outcomes of endoscopic discectomy in the treatment of disc herniation.

In 2010, Nellensteijn and colleagues published a systematic review of the literature on transforaminal endoscopic surgery for symptomatic lumbar disc herniations that included English, German, and Dutch language articles published through May 2008. One randomized controlled trial, 7 non-randomized controlled trials, and 31 observational studies were identified. Analysis of the 8 controlled trials found no significant differences between the endoscopic and open microdiscectomy groups for leg pain reduction (89% vs. 87%), overall improvement (84% vs. 78%), re-operation rate (6.8% vs. 4.7%) or complication rate (1.5% vs. 1%, all respectively). The methodologic quality of these studies was described as poor, providing insufficient evidence to support or refute this procedure.

In 2010, Teli et al. reported a randomized controlled trial of micro-endoscopic interlaminar lumbar discectomy compared to microdiscectomy or open discectomy in 240 patients with posterior lumbar disc herniation. The majority of herniations (60%) were extrusions. Group assignment was randomized but was revealed to the patients before the surgery due to a requirement of the local ethics committee. Laminotomy, medial facetectomy when needed, and nerve root retraction followed by discectomy were performed identically in the 3 groups. Surgeons had at least 5 years' experience in all of the operative techniques. The average surgical time was longer in the endoscopic group (56 minutes) compared to micro or open discectomy (43 and 36 minutes, respectively). Follow-up assessments were performed at 6, 12, and 24 months by an independent investigator; 212 patients (91%) completed the 24-month evaluation. Intent-to-treat analysis showed no significant difference in the outcome variables (VAS, ODI, Short Form-36 [SF-36]). The endoscopic procedure resulted in an increase in dural tears (8.7% vs. 2.7 or 3%), root injuries (3% vs. 0% or 0%), and recurrent herniations (11.4% vs. 4.2% or 3%) compared with the microdiscectomy or open approach, although these were not statistically different.

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 Disc Decompressor.

CODES: Number Description

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:

62287	**(E/I)**	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method, single or multiple levels, lumbar (e.g. manual or automated percutaneous discectomy, percutaneous laser discectomy)
62380	**(E/I)**	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar

Percutaneous discectomy is also a component of the following category III CPT codes:

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 (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic

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 (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar

HCPCS:	C2614 **(E/I)**	Probe, percutaneous lumber discectomy
ICD10:	M50.20-M50.23	Other cervical disc displacement (code range)
	M50.30-M50.33	Other cervical disc degeneration (code range)
	M51.24-M51.27	Other intervertebral disc displacement, thoracic, thoracolumbar, lumbar and lumbosacral intervertebral disc disorder (code range)
	M51.34-M51.37	Other intervertebral disc degeneration, thoracic, thoracolumbar, lumbar and lumbosacral intervertebral disc disorder (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.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, neither automated percutaneous discectomy nor endoscopic discectomy is not addressed in National or Regional Medicare coverage determinations. There is currently a Local Coverage Determination (LCD) for Category III codes (L33392). Please refer to the following LCD website for Medicare Members:
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33392&ContrId=298&ver=74&ContrVer=1&CntrctrSelected=298*1&Cntrctr=298&name=National+Government+Services%2c+Inc.+(13201%2c+A+and+B+and+HHH+MAC%2c+J+-+K)&s=All&DocType=Active&bc=AggAAAQAAAAAAA%3d%3d&
CMS issued a decision memo related to Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (CAG-00433N) that includes 0275T. It is located at:
https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=269