WELLPOINT

Medical Policy

Subject:	Percutaneous and Endoscopic Spinal Surgery		
Document #:	SURG.00071	**Current Effective Date:**	
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Description/Scope

Percutaneous and endoscopic spinal surgery has been investigated as an alternative to open (traditional and micro) spinal procedures. In percutaneous and endoscopic spinal procedures, the surgeon does not have direct visualization of the operative site.

Percutaneous spinal surgery techniques are those where a probe is introduced through the skin via cannula using remote imaging (e.g. fluoroscopy) for visual guidance to access the operative site and perform the surgery.

Endoscopic spinal surgery requires a small incision or puncture through which a small scope equipped with a camera that magnifies and illuminates the operative site. The surgeon then performs the surgery viewing the operative site not directly, but on a monitor.

Open spinal procedures are performed with direct visualization through a skin incision. In micro procedures, the surgeon performs the surgery through a much smaller incision and views the operative site using a surgical microscope or glasses with magnifying capabilities. In traditional spinal procedures, the surgeon performs the surgery though a larger incision.

Note: Please see the following related documents for additional information:

- SURG.00052 Intradiscal Decompression Procedures (Percutaneous Intradiscal Electrothermal Therapy Coagulation [IDET], and Percutaneous Intradiscal Radiofrequency Thermocoagulation [PIRFT]) and Intradiscal Biacuplasty
- SURG.00073 Epiduroscopy
- SURG.00111 Axial Lumbar Interbody Fusion

Position Statement

Investigational and Not Medically Necessary:

Percutaneous or endoscopic spinal surgical techniques are considered **investigational and not medically necessary.**

Rationale

Percutaneous techniques

Automated percutaneous lumbar discectomy (APLD) was introduced in the 1980s using a suction curettage device. Initial case series focusing on lumbar disc disease reported encouraging results and the technique was widely adopted. However, controlled trials reported less impressive results. For example, Revel and colleagues reported on a controlled randomized study comparing chemonucleolysis and APLD (Revel, 1993). A total of 61% of those

treated with chemonucleolysis reported favorable results compared to 44% in those treated with APLD. Chaterjee reported on the results of a randomized study that compared APLD with open surgical microdiscectomy (Chaterjee, 1995). A total of 29% of individuals in the APLD group reported satisfactory results compared to 80% in the microdiscectomy group.

The LAPDOG study was a randomized trial to compare APLD and open discectomy in individuals with lumbar disc herniation (Haines, 2002). This trial was designed to recruit 330 participants, but was only able to enroll 36. Of 27 evaluable participants, 41% of percutaneous discectomy group and 40% of conventional discectomy group were judged to have a successful outcome at 6 months. However, the authors concluded the trial was unable to enroll sufficient numbers to reach a definitive conclusion.

Amoretti and colleagues (2006) reported an uncontrolled case series of 50 individuals presenting with lumbar disc disease that were treated with a percutaneous discectomy probe, the DeKompressor® (Stryker, Inc., Kalamazoo, Michigan). This device, which received clearance from the U.S. Food and Drug Administration (FDA) through the 510(k) process in 2003, is used to aspirate disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine. When activated, the probe rotates to create suction and removes the nucleus pulposus. The clinical outcome measured in the Amoretti study was a visual analog scale (VAS) assessment of pain at 2, 7, 30 and 180 days following treatment. A decrease of baseline pain of more than 70% was observed in 39 of 50 individuals treated. Of the 39 individuals with a successful pain reduction outcome, 31 required no further medication therapies and the remaining 8 individuals were able to reduce medication therapies. The limitations of this study include a lack of randomization for comparison of surgical versus non-surgical therapies and its small size.

The body of literature for lumbar laser discectomy is limited to case series and review articles that describe different techniques using different types of lasers. The literature regarding cervical laser discectomy is less extensive and no controlled trials were identified for lumbar or cervical applications. Ahn and colleagues (2004) reported on a case series of 111 consecutive individuals undergoing cervical laser discectomy. With a mean follow-up of 49.4 months, the outcomes were considered either excellent or fair in 80% of individuals. Hellinger and colleagues reported on a case series of 42 individuals with thoracic discogenic pain who were treated with laser discectomy (Hellinger, 2003). At 6 weeks, 41 of the 42 individuals were considered to have a successful outcome. However, the lack of a control group and randomization limits scientific interpretation of either of these trials.

Nucleoplasty-based percutaneous discectomy is a relatively new technology and the available published literature consists of small non randomized studies and case series for lumbar and cervical disc treatment. Gerszten and colleagues (2006) reported a prospective nonrandomized longitudinal cohort study of sixty-seven participants with a contained lumbar disc herniation who underwent nucleoplasty in an outpatient setting. In this study the authors evaluated pain, functioning, and quality of life (QOL) pre and post operatively. The authors found that compared with preoperative QOL, there was a statistically significant improvement in QOL at 3 and 6 months. In another small, prospective study (n=69), Al-Zain et al (2008) reported one year outcomes for lumbar nucleoplasty showed a statistically significant reduction in analgesic consumption, disability and occupational incapacitation. However, both of these studies were small with limited follow-up and not randomized or controlled.

Calisaneller and colleagues (2007) studied 29 individuals who underwent lumbar nucleoplasty and found that there were statistically significant reductions ($p < 0.001$) in Visual Analogue Scale (VAS) scores post-operatively as compared to pre-operative values. The authors concluded that although nucleoplasty appeared to be a safe

minimally invasive procedure, the value of this new technique for the treatment of discogenic low-back pain remains unproven. Further randomized placebo-controlled studies with longer follow-up are needed.

Nardi and colleagues (2005) studied fifty consecutive individuals who underwent a cervical disc nucleoplasty and reported that 80% had pain resolution. Although the results were encouraging, they acknowledged the small size and limited follow-up in this study.

Complications following percutaneous disc procedures include reherniation, disc instability, and device malfunction.

The Vertos Minimally Invasive Lumbar Decompression (MILD®) device (Vertos Medical, Inc., Aliso Viejo, CA) received 510K clearance from the FDA in 2010 and is used for image-guided minimally invasive lumbar decompression to treat lumbar spinal stenosis. This percutaneous procedure is performed via a small incision for a dorsal approach to the spine. Under fluoroscopic image guidance, a metal tube or cannula is inserted through the incision. The device is passed through the cannula to increase the diameter of the stenosed spinal canal by removal of tissue and bone. Clinical trials are in progress to determine the clinical efficacy of this device.

Endoscopic Techniques
Righesso and colleagues (2007), in a small randomized controlled trial, studied 40 participants with sciatica caused by lumbar disc herniations unresponsive to conservative treatment. The participants underwent either an open discectomy (OD) or microendoscopic discectomy (MED). The only statistically significant differences found were for size of the incision, length of hospital stay, and operative time. The former two were greater in the OD group ($P < 0.01$ and $P = 0.05$, respectively), and the latter was greater in the MED group ($P < 0.01$). In this study, the few parameters that were found to be statistically significant between the groups did not affect the overall clinical outcome.

Haufe and Mork (2007), in a case series, studied 10 individuals who underwent unilateral endoscopic facetectomy for the treatment of severe foraminal stenosis to determine whether endoscopic facetectomies result in instability. In this small study, pre and post operative specialized computer based imaging evaluated altered mobility between the 2 sets of x-rays. Compared with controls, the imaging showed no statistically significant change in sagittal rotational or translational motion. Larger controlled studies with longer follow up are needed to validate the efficacy of this procedure.

Newer spinal endoscopic devices have become available allowing endoscopic surgeries to be performed through one incision by full endoscopy with instrumentation. The difference between basic endoscopic techniques and full endoscopic techniques is that basic endoscopy involves an incision for the endoscope and additional incisions for passage of the instruments. In full endoscopic techniques, only one incision is needed for the endoscope and instrumentation is performed through additional ports in the endoscopic device.

Rutten and colleagues studied full endoscopic modalities and reported outcomes in 2 preliminary studies. The first study was a prospective randomized, controlled trial comparing full-endoscopic posterior cervical foraminotomy (FPCF) and anterior cervical decompression and fusion (ACDF) for lateral disc herniation (Rutten, 2007). Two hundred individuals requiring cervical decompression were divided into 2 groups. One hundred participants underwent traditional ACDF and one hundred participants underwent FPCF. Randomization assignment was accomplished by alternation in the order of presentation. The operative levels varied from C4 to T1. Post operatively, the groups were evaluated at 3, 6, 12 and 24 months. One hundred seventy-five participants (88%)

were included in the 24 month follow-up (84 in the ACDF group; 91 in the FPCF group) and were evaluated by the visual analogue score (VAS), North American Spine Society Instrument Score (NASS) and Hilibrand criteria. In both groups, the measuring instruments showed an improvement ($p<0.001$) in arm pain and activities of daily living (ADL). Clinical outcome measures did not differ significantly between the two treatment groups and there were no significant differences between the groups in revision and complication rate. Regarding the procedure, the authors identified FPCF disadvantages as limited possibility to expand the operation in the event of unforeseen hindrances, the technique is limited to lateral localization of the pathology, and there is no reconstruction of the intervertebral space and no direct decompression in ventrally caused stenosis.

In the second study, Rutten and colleagues (2008) conducted a prospective randomized, controlled trial comparing full-endoscopic lumbar discectomy from a transforaminal (TF) or an interlaminar (IL) approach with conventional lumbar microdiscectomy. Two hundred individuals requiring lumbar decompression were divided into 2 groups. One hundred individuals underwent conventional microsurgical (MI) discectomy and one hundred underwent full endoscopic (FE) discectomy (41 in the TF and 59 in the IL groups). Randomization was accomplished by alternate selection to either the MI or the FE groups. Two operating surgeons selected operative access within the MI and the FE groups. The operative levels varied from L1-S1. Post operatively, participants were evaluated at 3, 6, 12 and 24 months. One hundred seventy-eight participants (89%) were included in the 24 month follow-up evaluations [87 in the MI; 91 (38 TF, 53 IL) in the FE groups]. They were assessed using the VAS, NASS and Oswestry Low-Back Pain Disability Questionnaire (ODI). Both groups showed improvement ($p<0.001$) in leg pain and ADLs according to the measuring instruments. There were no significant differences in clinical outcomes or recurrent symptoms between the two treatment groups at two years. The authors also identified the disadvantage of FE is limited possibility to expand the operation in the event of unforeseen hindrances.

Although the early results in both of these full-endoscopic spinal surgical studies are promising, the authors cautioned that there is a steep learning curve for using full endoscopic techniques. Demonstrated surgeon proficiency and larger studies with longer follow up are necessary before the clinical efficacy, safety and durable outcome advantages of full endoscopic spinal procedures can be determined.

Nellensteijn and colleagues (2010a) conducted a systematic literature review to evaluate the efficacy of transforaminal endoscopic surgery compared to open microdiscectomy for symptomatic disc herniation. Thirty one observational studies and 8 clinical trials (1 randomized controlled; 7 non randomized controlled) were found. In the 8 trials, no statistically significant differences were found for leg pain reduction between the transforaminal endoscopic surgery group (89%) and the open microdiscectomy group (87%). The 31 studies differed in participant selection, indications, operative technique and follow-up. The methodological quality of these studies was poor.

In another review, Nellensteijn and colleagues (2010b) evaluated transforaminal endoscopic surgery for lumbar stenosis. No randomized controlled trials were found. The authors found 7 observational studies differing in participant selection, indications, technique and outcome measures, with poor methodological quality.

Both of the reviews found that the available literature did not support endoscopic surgery for disc herniation or lumbar stenosis and that well designed randomized clinical studies are needed.

A 2007 Cochrane review for surgical interventions treating spinal disc disease, Gibson and Waddell found that microdiscectomy gives broadly comparable results to standard open discectomy. There was insufficient evidence for percutaneous or endoscopic discectomy techniques to draw firm conclusions

In an evidence-based clinical practice guideline addressing surgery for low back pain, Cohen and colleagues stated:

> In addition, insufficient evidence exists to evaluate alternative surgical methods including laser- or endoscopic-assisted techniques, various percutaneous techniques, Coblation® nucleoplasty or the Disc Decompressor [American Pain Society (APS), 2009].

Background/Overview

Spinal surgery is generally performed in the cervical and lumbar regions of the spine because the degree of mobility in these areas is greater and can cause misalignment and instability of the vertebral structures.

Disc disease is most common and usually due to a protrusion (herniation) of a vertebral disc. The disc may tear through surrounding tissue (annulus fibrosus), resulting in an extruded disc, or may remain intact but stretched resulting in a contained disc prolapse, compressing one or more nerve roots and resulting in pain, numbness or weakness.

Percutaneous and endoscopic instrumented techniques have been investigated over the years as a treatment of back pain related to disc disease and bone structure.

Percutaneous techniques include automated percutaneous lumbar discectomy (APLD), laser discectomy and nucleoplasty. APLD involves the percutaneous insertion of a probe into the disc space with fluoroscopic guidance and then physical removal of the disc material using a suction curettage device. For laser discectomy, a variety of different lasers have been investigated, including the YAG, KTP, holmium, argon and carbon dioxide lasers. Regardless of the type of laser, the procedure involves placement of the laser within the nucleus under fluoroscopic guidance. Due to differences in absorption, the energy requirements and the rate of application differ among the lasers. Additionally, it is unknown how much disc material must be removed to achieve decompression. Therefore, protocols vary according to the length of treatment, but typically the laser is activated for brief periods. The nucleoplasty procedure is similar to the laser procedure but uses bipolar radiofrequency energy in a process referred to as Coblation technology. The technique consists of small, multiple electrodes that emit a fraction of the energy required by traditional radiofrequency energy systems. The result is that a portion of nucleus tissue is ablated not with heat, but with a low-temperature plasma field of ionized particles. These particles have sufficient energy to break organic molecular bonds within tissue, creating small channels in the disc. The proposed advantage of this Coblation technology is that the procedure provides for a controlled and highly localized ablation, resulting in minimal therapy damage to surrounding tissue.

Endoscopic spinal surgery has been studied for lumbar, thoracic and cervical disc herniations, foraminal stenoses and degenerative facet joint conditions when there are radicular symptoms. One technique separates, instead of cutting, the tissue (muscle, fascia) by passing tubes that increase in size through a small incision. The endoscope, equipped with a camera, is introduced through this opening. The camera transmits a 2 dimensional view of the operative area on a monitor. Depending on the equipment used, surgical instruments can be passed through additional ports adjacent to the endoscope or through access within the endoscope itself to perform discectomy and bone restructure.

The spinal region may need stabilization when large amounts of bony structures and tissue are removed during these procedures. The vertebrae in the region can be stabilized by fusion or by the insertion of screws or spacers. Endoscopic applications for these procedures have been proposed and are currently being studied.

Definitions

Disc degeneration: The normal aging process of intervertebral discs that begins soon after puberty. The degenerative process begins with loss of water content of the nucleus (the center of the disc) and progresses to include decreased height of the disc, the development of annular fissures (cracks in the outer fibers) and circumferential enlargement of the disc.

Discectomy: A surgical procedure in which the central portion of an intervertebral disc, the nucleus pulposus, is removed. This surgery is performed via an open incision (considered the gold standard) allowing the surgeon the greatest ability to see and explore the surgical site.

Discogenic pain: Pain generated by the disc itself which is externally intact, as opposed to disc prolapse or herniation which put pressure on nearby nerve roots.

Herniated disc: A condition in which a portion of the nucleus pulposus extends through the annulus (the outer disc layers). Herniated discs may additionally be classified as: contained (there is still a retained thin outer layer of annulus or ligament), extruded (the nuclear material extends into the spinal canal) or sequestrated (when a herniated fragment migrates away from the disc).

Laminectomy: A spine operation to remove all or a portion of the roof of the spinal canal; frequently performed to decompress the neural elements.

Lamina: The part of the vertebra that forms the roof of the spinal canal.

Microdisectomy: This surgery is performed through an incision much smaller than the incision used in a standard open discectomy. The operative site is viewed with a surgical microscope or magnifying eyeglasses. The magnified view makes it possible for the surgeon to remove herniated disc material through the smaller incision, thus causing less damage to surrounding tissue.

Microendoscopic Discectomy: In this technique, a guide wire is passed through the skin and tissue to the operative site under fluoroscopic guidance. A small tube is passed over the guide wire to the operative site. Progressively larger tubes are passed over one another until the tissue is opened by separation, not cutting. Ultimately, an endoscope with a camera and illumination is passed and the smaller tubes are removed through the endoscope. A thin retractor is passed through the endoscope to move the compressed nerve away from the disc. The disc material is removed by an additional instrument(s). The nerve retractor is removed and finally the endoscope.

Percutaneous: through the skin (puncture as opposed to "open" surgical incision)

Radicular pain: A type of pain that radiates to the upper or lower extremity directly along the course of a spinal nerve root. Radicular pain is caused by compression, inflammation and/or injury to a spinal nerve root.

Spine anatomy: the spine is divided into three major sections: the cervical (neck), the thoracic (mid-back) and lumbar spine (lower back). These sections are made up of individual bones called vertebrae, which are the primary weight bearing structures of the torso alternating with intervertebral discs

Spinal fusion: An operative procedure whose goal is to stop movement at one or more levels (a level is two vertebrae with a disc between) of the spine. It is frequently accomplished by removing disc or joint tissue and then placing bone graft materials

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

62287	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)
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, including open and endoscopically-assisted approaches; 1 interspace, cervical [when specified as endoscopic]
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, including open and endoscopically-assisted approaches; 1 interspace, lumbar [when specified as endoscopic]
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, including open and endoscopically-assisted approaches; each additional interspace, cervical or lumbar (add-on) [when specified as endoscopic]
64999	Unlisted procedure, nervous system [when specified as percutaneous decompression or laser procedures of cervical or thoracic spine]

HCPCS

S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar [DISC nucleoplasty]

ICD-9 Procedure

80.59	Other destruction of intervertebral disc [when specified as percutaneous lumbar disc decompression, laser discectomy, coblation nucleoplasty]

ICD-9 Diagnosis

All diagnoses

Future ICD-10 coding (effective 10/01/2013)

A draft of ICD-10 Coding related to this document, as it might look today, is available for reference and comments at: Appendix 1: Future ICD-10 coding

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Web Sites for Additional Information

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	02/17/2011	Medical Policy & Technology Assessment Committee (MPTAC) review. Description clarified. Additional information added to Rationale and Definitions. References updated.
	04/29/2010	Information regarding the Vertos Minimally Invasive Lumbar Decompression (MILD®) device added to the Rationale. References updated.
Reviewed	02/25/2010	MPTAC review. Coding and references updated.
Revised	02/26/2009	MPTAC review. Position statement revised, title changed, rationale, background, coding and references updated.
Reviewed	11/20/2008	MPTAC review. Updated review date, references and history sections. Updated coding section with 01/01/2009 CPT changes.
Reviewed	11/29/2007	MPTAC review. Updated review date, rationale, background/overview, references and history sections. The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary".
Reviewed	12/07/2006	MPTAC review. Rationale and references sections updated.
Reviewed	03/23/2006	MPTAC review.
	11/18/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title

Anthem, Inc.	07/27/2004	SURG.00052	Chronic Spine Pain Treatments/Procedures (Minimally Invasive)
WellPoint Health Networks, Inc.	09/23/2004	3.07.04	Percutaneous Techniques for Disc Decompression