National Medical Policy

Subject: Disc Decompression Procedures – Percutaneous and Laser

Policy Number: NMP61

Effective Date*: October 2003

Updated: September 2015

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For Medicaid Plans: Please refer to the appropriate Medicaid Manuals for coverage guidelines prior to applying Health Net Medical Policies.

The Centers for Medicare & Medicaid Services (CMS)
For Medicare Advantage members please refer to the following for coverage guidelines first:

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Percutaneous Disc Decompression Procedures Sep 15


None

Use Health Net Policy

Instructions
- Medicare NCDs and National Coverage Manuals apply to ALL Medicare members in ALL regions.
- Medicare LCDs and Articles apply to members in specific regions. To access your specific region, select the link provided under “Reference/Website” and follow the search instructions. Enter the topic and your specific state to find the coverage determinations for your region. *Note: Health Net must follow local coverage determinations (LCDs) of Medicare Administration Contractors (MACs) located outside their service area when those MACs have exclusive coverage of an item or service. (CMS Manual Chapter 4 Section 90.2)
- If more than one source is checked, you need to access all sources as, on occasion, an LCD or article contains additional coverage information than contained in the NCD or National Coverage Manual.
- If there is no NCD, National Coverage Manual or region specific LCD/Article, follow the Health Net Hierarchy of Medical Resources for guidance.

Current Policy Statement
Health Net, Inc. considers the following types of percutaneous disc decompression procedures **not** medically necessary for treatment of herniated lumbar discs:

1. Percutaneous Lumbar Discectomy (manual or automated [APLD])
2. Percutaneous Laser Discectomy (PLD)
3. Laser-assisted Disc Decompression (LADD)
4. Percutaneous laser disc decompression (PLDD)
5. Percutaneous nucllectomy
6. Microdiscectomy
7. Percutaneous endoscopic diskectomy
8. Endoscopic laser percutaneous diskectomy or LASE
9. Endoscopic Spinal Surgery System
10. Endoscopic disc decompression

**Note:** Clinical studies have not established clinically significant benefit of use of a laser over use of a scalpel for percutaneous lumbar discectomy. There is a paucity of clinical studies proving additional benefits from using an endoscope for performing disc decompression (such as in percutaneous endoscopic diskectomy or endoscopic laser percutaneous diskectomy or LASE). At this time there are minimal published studies of endoscopic spinal surgery that have included an adequate comparison group of patients receiving open procedures. In addition, none of the published studies have reported on the long-term outcomes resulting from these endoscopic procedures.
Health Net, Inc. considers minimally invasive lumbar decompression (MILD; Vertos Medical Inc.) for Lumbar Spinal Stenosis investigational since there is a paucity of peer-reviewed literature to support the efficacy of this procedure. Additional randomized controlled or comparative studies are necessary to determine which surgical approach to lumbar spinal stenosis achieves the best outcomes.

**Codes Related To This Policy**

**NOTE:**
The codes listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit documents and medical necessity criteria. This list of codes may not be all inclusive.

On October 1, 2015, the ICD-9 code sets used to report medical diagnoses and inpatient procedures will be replaced by ICD-10 code sets. Health Net National Medical Policies will now include the preliminary ICD-10 codes in preparation for this transition. Please note that these may not be the final versions of the codes and that will not be accepted for billing or payment purposes until the October 1, 2015 implementation date.

**ICD-9 Codes**
- 724.2 Low back pain (lumbago)
- 724.3 Sciatica
- 722.10 Herniated lumbar intervertebral disc without myelopathy

**ICD-10 Codes**
- M51.26 Other intervertebral disc displacement, lumbar region
- M54.16 Radiculopathy, lumbar region
- M54.30-
- M54.32 Sciatica
- M54.40-
- M54.42 Lumbago with sciatica

**CPT Codes**
- 0275T Percutaneous laminotomy/laminectomy (intralaminar 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.
- 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 the use of an endoscope, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar (Code revised in 2012)

* **Important Note:** This code encompasses various disc procedures, not all of which are considered medically necessary by Health Net. To determine medical necessity, the actual procedure to be performed must be specified. Refer to related policies for additional information: IDET and Nucleoplasty.
HCPCS Codes
N/A

Scientific Rationale Update – September 2015
Techniques using imaging for guidance include automated percutaneous lumbar discectomy (APLD), laser discectomy and nucleoplasty. APLD, introduced in the 1980’s, 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. The goal of APLD is to remove herniated disc material that may be pressing on nerve roots and thereby causing pain and other symptoms. Initial case series focusing on lumbar disc disease reported encouraging results and the technique was widely adopted. However, controlled trials reported less impressive results.

There is a paucity of peer-reviewed evidence to support percutaneous lumbar laser disc decompression. Observational, nonrandomized, studies are insufficient to permit conclusions concerning the effect of this technology on health outcomes due to methodologic limitations such as the lack of randomized treatment allocation, small study size, short-term follow-up, generally one year or less, and the lack of a control group for comparison. There is insufficient evidence in the peer-reviewed medical literature to support the safety and efficacy of APLD. Results of published studies are inconsistent and do not demonstrate long-term improvement.

Studies and Position Statements
The North American Spine Society (NASS, 2012), published evidence-based clinical guidelines for the diagnosis and treatment of lumbar disc herniation with radiculopathy. Within these guidelines, NASS defines automated percutaneous discectomy as a procedure in which a cannula is inserted into the disc space and nuclear material is removed by use of a nucleotome, laser, or radiofrequency heat without direct visualization. Therefore, the NASS definition includes laser discectomy and nucleoplasty, which are not included in this report. NASS recommends that automated percutaneous discectomy may be considered for the treatment of lumbar disc herniation with radiculopathy. The grade of the recommendation is C, which reflects the poor quality of the evidence. NASS also concluded that there is insufficient evidence to recommend for or against automated percutaneous discectomy compared with open discectomy (grade I, insufficient evidence).

North American Spine Society (NASS, 2014) notes laser spine surgery in the cervical or lumbar spine is not indicated at this time. Due to lack of high quality trials it cannot be endorsed at this time. Coverage Policy Recommendations from the North American Spine Society (NASS) state that endoscopic discectomy should "be covered treatment of lumbar disc herniation with radiculopathy. The authors also state that the coverage recommendations are not representative of a "standard of care" and should not be viewed as "fixed treatment protocols" (NASS, 2014).

Singh et al. (2013) rated the current evidence for percutaneous lumbar laser disc decompression for short and long-term relief of pain as "limited” or poor when rated according to U.S. Preventive Services Task Force (USPSTF) criteria. There were 17 observational studies and no RCTs. Due to the lack of RCTs, meta-analysis could not be conducted. There was a lack of standardization of both selection and outcome criteria. In addition, the authors noted that the lack of a control group in observational studies limited the conclusions that could be made on efficacy.

Manchikanti et al. (2013) completed a systematic review of the literature to develop evidence-based clinical practice guidelines for the diagnosis and treatment of chronic spinal pain. A total of 19 observational studies of APLD met their inclusion criteria. However, none of the published randomized trials met their inclusion criteria. Reasons for exclusion of the randomized trials included poor patient selection, lack of a control group, poor patient accrual, inclusion of patients who were in litigation, underpowered, protocol violations, inclusion of patients with contraindications to APLD, inexperienced operators, high rate of rare technical problems, and short follow-up duration. Based upon the United States Preventive Services Task Force (USPSTF, 2013) criteria, the American Society of Interventional Pain Physicians (ASIPP) gave APLD a ‘limited’ level of evidence for short- and long-term relief of symptoms. This means that the evidence base is insufficient to assess the effects of the intervention on health outcomes. Despite this, ASIPP concluded that this technique may be performed when indicated, but did not provide patient selection criteria. Nor was the recommendation graded; the authors indicated only that this recommendation was based on “individual experience and the large amount of literature.” Therefore, this recommendation is not considered evidence-based.

Per UpToDate, Chou et al. (2015):

- Minimally invasive discectomy techniques have not been demonstrated to be superior to traditional discectomy methods and may not be applicable for many patients. For patients with lumbar radicular symptoms of at least 6 to 12 weeks who are good surgical candidates and desire surgery based on shared decision-making, we suggest either open discectomy or microdiscectomy (Grade 2B). Earlier surgery may be indicated for patients with severe and disabling pain related to lumbar disc prolapse that is unresponsive to medical therapy.
- In patients with lumbar disc prolapse and radiculopathy who do not have severe or progressive neurologic deficits, there is no evidence that early referral for surgery improves outcomes. Outcomes for patients who undergo discectomy, compared to nonsurgical therapy, favor surgery at short-term follow-up but are equivalent at one to two years.
- The authors suggest not performing surgery for most patients with chronic symptoms attributed to nonspecific low back pain (Grade 2B). Decisions regarding surgery should be based on shared decision-making. We suggest that surgery be limited to patients with nonspecific low back pain who meet the following criteria: persistent symptoms with associated disability for at least one year despite nonsurgical interventions; appropriate surgical candidate; and intensive rehabilitation with a cognitive behavioral therapy component is either not available or has not been effective (Grade 2B).
- Subacute low back pain is commonly defined as back pain lasting between 4 and 12 weeks, and chronic low back pain as pain that persists for 12 or more weeks. For those with chronic symptoms, few achieve the complete resolution they seek, but rather treatment focuses on controlling pain and improving activity.

Additional Studies
Lurie et al. (2014) completed concurrent prospective randomized and observational cohort studies to assess the 8-year outcomes of surgery versus nonoperative care.
Although randomized trials have demonstrated small short-term differences in favor of surgery, long-term outcomes comparing surgical with nonoperative treatment remain controversial. Surgical candidates with imaging-confirmed lumbar intervertebral disc herniation meeting Spine Patient Outcomes Research Trial eligibility criteria enrolled into prospective randomized (501 participants) and observational cohorts (743 participants) at 13 spine clinics in 11 US states. Interventions were standard open discectomy versus usual nonoperative care. Main outcome measures were changes from baseline in the SF-36 Bodily Pain and Physical Function scales and the modified Oswestry Disability Index-AAOS/Modems version assessed at 6 weeks, 3 months, and 6 months, and annually thereafter. Advantages were seen for surgery in intent-to-treat analyses for the randomized cohort for all primary and secondary outcomes other than work status; however, with extensive nonadherence to treatment assignment (49% patients assigned to nonoperative therapy receiving surgery versus 60% of patients assigned to surgery) these observed effects were relatively small and not statistically significant for primary outcomes (bodily pain, physical function, Oswestry Disability Index). Importantly, the overall comparison of secondary outcomes was significantly greater with surgery in the intent-to-treat analysis (sciatica bothersomeness [P > 0.005], satisfaction with symptoms [P > 0.013], and self-rated improvement [P > 0.013]) in long-term follow-up. An as-treated analysis showed significant surgical treatment effects for primary outcome measures (mean change, surgery vs. nonoperative care; treatment effect; 95% confidence interval): bodily pain (45.3 vs. 34.4; 10.9; 7.7 to 14); PF (42.2 vs. 31.5; 10.6; 7.7 to 13.5); and Oswestry Disability Index (-36.2 vs. -24.8; -11.3; -13.6 to -9.1). Carefully selected patients who underwent surgery for a lumbar disc herniation achieved greater improvement than nonoperatively treated patients; there was little to no degradation of outcomes in either group (operative and nonoperative) from 4 to 8 years. (Level of Evidence: 2).

Rasouli et al. (2014) selected randomised controlled trials (RCTs) and quasi-randomised controlled trials (QRCTs) that compared microdiscectomy (MD)/open discectomy (OD) with a minimally invasive discectomy (MID) (percutaneous endoscopic interlaminar or transforaminal lumbar discectomy, transmuscular tubular microdiscectomy and automated percutaneous lumbar discectomy) for treatment of adults with lumbar radiculopathy secondary to discopathy. The authors evaluated the following primary outcomes: pain related to sciatica or low back pain (LBP) as measured by a visual analogue scale, sciatic specific outcomes such as neurological deficit of lower extremity or bowel/urinary incontinence and functional outcomes (including daily activity or return to work). The following secondary outcomes were also evaluated: complications of surgery, duration of hospital stay, postoperative opioid use, quality of life and overall participant satisfaction. 11 studies with 1172 participants were identified. Seven out of 11 studies were noted to have high overall risk of bias. There was low-quality evidence that MID was associated with worse leg pain than MD/OD at follow-up ranging from six months to two years (e.g. at one year: MD 0.13, 95% CI 0.09 to 0.16), but differences were small (less than 0.5 points on a 0 to 10 scale) and did not meet standard thresholds for clinically meaningful differences. There was low-quality evidence that MID was associated with worse LBP than MD/OD at six-month follow-up (MD 0.35, 95% CI 0.19 to 0.51) and at two years (MD 0.54, 95% CI 0.29 to 0.79). There was no significant difference at one year (0 to 10 scale: MD 0.19, 95% CI -0.22 to 0.59). Statistical heterogeneity was small to high (I(2) statistic = 35% at six months, 90% at one year and 65% at two years). There were no clear differences between MID techniques and MD/OD on other primary outcomes related to functional disability (Oswestry Disability Index greater than six months postoperatively) and persistence of motor and sensory
neurological deficits, though evidence on neurological deficits was limited by the small numbers of participants in the trials with neurological deficits at baseline. There was just one study for each of the sciatica-specific outcomes including the Sciatica Bothersomeness Index and the Sciatica Frequency Index, which did not need further analysis. For secondary outcomes, MID was associated with lower risk of surgical site and other infections, but higher risk of re-hospitalisation due to recurrent disc herniation. In addition, MID was associated with slightly lower quality of life (less than 5 points on a 100-point scale) on some measures of quality of life, such as some physical subclasses of the 36-item Short Form. Some trials found MID to be associated with shorter duration of hospitalisation than MD/OD, but results were inconsistent. MID may be inferior in terms of relief of leg pain, LBP and re-hospitalisation; however, differences in pain relief appeared to be small and may not be clinically important. Potential advantages of MID are lower risk of surgical site and other infections. MID may be associated with shorter hospital stay but the evidence was inconsistent. Given these potential advantages, more research is needed to define appropriate indications for MID as an alternative to standard MD/OD.

Evaniew et al. (2014) completed a meta-analysis performed a meta-analysis to determine the effects of minimally invasive versus open surgery on functional outcomes, pain, complications and reoperations among patients undergoing cervical or lumbar discectomy. The authors searched MEDLINE, Embase and the Cochrane Library for reports of relevant randomized controlled trials published to Jan. 12, 2014. Two reviewers assessed the eligibility of potential reports and the risk of bias of included trials. We analyzed functional outcomes and pain using standardized mean differences (SMDs) that were weighted and pooled using a random-effects model. 4 trials were included in the cervical discectomy group (n = 431) and 10 in the lumbar discectomy group (n = 1159). Evidence overall was of low to moderate quality. The authors found that minimally invasive surgery did not improve long-term function (cervical: SMD 0.11, 95% confidence interval [CI]-0.09 to 0.31; lumbar: SMD 0.04, 95% CI -0.11 to 0.20) or reduce long-term extremity pain (cervical: SMD -0.21, 95% CI -0.52 to 0.10; lumbar: SMD 0.08, 95% CI -0.16 to 0.32) compared with open surgery. The evidence suggested overall higher rates of nerve-root injury (risk ratio [RR]1.62, 95% CI 0.45 to 5.84), incidental durotomy (RR 1.56, 95% CI 0.80 to 3.05) and reoperation (RR 1.48, 95% CI 0.97 to 2.26) with minimally invasive surgery than with open surgery. Infections were more common with open surgery than with minimally invasive surgery (RR 0.24, 95% CI 0.04 to 1.38), although the difference was not statistically significant. Current evidence does not support the routine use of minimally invasive surgery for cervical or lumbar discectomy. Well-designed trials are needed given the lack of high-quality evidence.

Per the manufacturer, HydroCision, ‘The SpineJet HydroSurgery System’ uses a power console along with the SpineJet instruments to simultaneously ablate, cut, and remove targeted tissue. HydroSurgery has the power density of laser and radiofrequency technologies, but does not cause thermal tissue damage, and is available with various handpieces designed for specific spinal procedures.

Additional well-designed studies comparing conventional (open approach) procedures to endoscopic spinal discectomy and disc decompression as well as image-guided minimally invasive lumbar decompression are needed. High quality randomized controlled trials with sufficiently large sample sizes and longer follow-up periods are needed to determine if percutaneous and endoscopic spinal surgery procedures are more effective than conventional (open approach) procedures.
Minimally invasive lumbar decompression (MILD) are considered not medically necessary since the clinical evidence is limited to small, uncontrolled studies. Additional randomized, controlled trials comparing these procedures to standard procedures are needed to determine impact on health outcomes and long-term efficacy.

**Scientific Rationale Update – November 2014**

Image guided minimally invasive lumbar decompression (MILD) is a percutaneous procedure for decompression of the central spinal canal that is proposed for pain relief in patients with lumbar spinal stenosis (LSS). This procedure consists of filling the epidural space with contrast medium under fluoroscopic guidance. Using a 6-gauge cannula that is clamped in place with a back plate, single use tools (i.e., portal cannula, surgical guide, bone rongeur, tissue sculpter and 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 additional 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 (i.e., mild tool kit) are not intended to be used near the lateral neural elements and are contraindicated for disc procedures.

The mild tool kit (Vertos Medical Inc., San Jose, CA) initially received 510(k) marketing clearance as the X-Sten MILD Tool Kit (X-Sten Corp.) from the U.S. Food and Drug Administration (FDA) on December 19, 2006, as a class II device with intended use as a set of specialized surgical instruments to be used to perform percutaneous lumbar decompressive procedures for the treatment of various spinal conditions. A subsequent approval for the Vertos Medical mild Device Kit (Vertos Medical Inc.) was given by the FDA on February 4, 2010. Vertos mild® instructions for use state that the devices are not intended for disc procedures but rather for tissue resection at the perilaminar space, within the interlaminar space, and at the ventral aspect of the lamina.

Based on peer reviewed literature the evidence is insufficient to determine the efficacy of ‘the MILD device’ compared to a placebo and is also insufficient to determine the comparative efficacy of image guided minimally invasive lumbar decompression in relation to alternative surgical approaches. Randomized controlled trials are necessary to determine which surgical approach to lumbar spinal stenosis achieves the best outcomes. Further trials with larger numbers of subjects, longer follow up and relevant control groups are needed to determine the effect on health outcomes with greater certainty. Therefore, image guided minimally invasive lumbar decompression (MILD) is considered investigational for all indications.

**Scientific Rationale Update – August 2013**

Per Canale & Beatty (2012) Lumbar decompression without fusion may be indicated in a select group of predominantly older patients with symptoms of radiculopathy or neurogenic claudication, minimal axial pain, and loss of disc space height at the level of the slip, which may be an indicator of increasing stability. Although decompression alone is not recommended in children because of the risk of progressive spondylolisthesis, the Gill laminectomy has provided satisfactory long-term results in 75% to 90% of patients, regardless of postoperative slipping. Progression of spondylolisthesis may occur less frequently after Gill laminectomy if there is antecedent stabilizing disc degeneration. This procedure simply is a resection of all bone and fibrous tissue from the pars defect distally, including the lower portion of the pars interarticularis, lamina, spinous process, inferior articular facet, and all
intervening ligamentous structures. Radiculopathy is relieved in most patients; however, significant back pain should be considered as an indication for fusion.

**Scientific Rationale Update – September 2011**

A variety of discectomy techniques are available:

- The traditional open discectomy is performed with a standard surgical incision, often with the aid of eyepiece (loupe) magnification. It frequently involves a laminectomy (removal of the vertebral lamina to relieve pressure on nerve roots).

- Microdiscectomy is a refinement of open discectomy and involves a smaller incision in the back, with visualization through an operating microscope; this is followed by a hemilaminectomy (removal of part of the lamina in order to adequately visualize the disc) and removal of the disc fragment compressing the affected nerve or nerves.

- Minimally invasive techniques include percutaneous manual nucleotomy, automated percutaneous lumbar discectomy, laser discectomy, endoscopic discectomy, microendoscopic discectomy, coblation nucleoplasty, and the disc DeKompressor. Tubular or trochar discectomy is a less invasive technique in which a tubular retractor is inserted over a guidewire, gaining access to the disc by muscle splitting rather than muscle incision and detachment.

Minimally invasive techniques involve smaller incisions and surgery with the aid of indirect visualization; some techniques employ lasers to vaporize parts of the disc or automated techniques for removing portions of the disc. They have the potential advantage of quicker recovery from surgery compared to standard open discectomy or microdiscectomy.

Chen et al. (2011) Open discectomy remains the standard method for treatment of lumbar disc herniation, but can traumatize spinal structure and leaves symptomatic epidural scarring in more than 10% of cases. The usual transfarominal approach may be associated with difficulty reaching the epidural space due to anatomical peculiarities at the L5-S1 level. The endoscopic interlaminar approach can provide a direct pathway for decompression of disc herniation at the L5-S1 level. This study aimed to evaluate the clinical results of endoscopic interlaminar lumbar discectomy at the L5-S1 level and compare the technique feasibility, safety, and efficacy under local and general anesthesia (LA and GA, respectively). One hundred twenty-three patients with L5-S1 disc herniation underwent endoscopic interlaminar lumbar discectomy from October 2006 to June 2009 by two spine surgeons using different anesthesia preferences in two medical centers. Visual analog scale (VAS) scores for back pain and leg pain and Oswestry Disability Index (ODI) sores were recorded preoperatively, and at 3, 6, and 12 months postoperatively. Results were compared to evaluate the technique feasibility, safety, and efficacy under LA and GA. VAS scores for back pain and leg pain and ODI revealed statistically significant improvement when they were compared with preoperative values. Mean hospital stay was statistically shorter in the LA group. Complications included one case of dural tear with rootlet injury and three cases of recurrence within 1 month who subsequently required open surgery or endoscopic interlaminar lumbar discectomy. There were no medical or infectious complications in either group. Disc herniation at the L5-S1 level can be adequately treated endoscopically with an interlaminar
approach. GA and LA are both effective for this procedure. However, LA is better than GA in the authors’ opinion.

Smith et al. (2010) completed a retrospective review of consecutive case series. Sixteen consecutive patients with recurrent lumbar disc herniation who failed conservative management underwent microendoscopic discectomy (MED). Before surgery and at follow-up, patients completed the Oswestry Disability Index, SF-36, and assessment of leg pain using the Visual Analog Scale. Outcome was also assessed using modified McNab criteria. No case required conversion to an open procedure. Mean operative time was 108 minutes, and mean estimated blood loss was 32 mL. The only surgical complications were 2 durotomies that were treated with dural sealant without sequelae. Mean hospital stay was 23 hours, and mean follow-up was 14.7 months. Approximately 80% of patients had good or excellent outcomes based on modified McNab criteria. The remaining 3 patients had fair outcomes, and no patient had a poor outcome. All standardized measures improved significantly, including mean Visual Analog Scale for leg pain (8.2 to 2.2, \( P<0.001 \)), mean Oswestry Disability Index (59.3 to 26.7, \( P<0.001 \)), SF-36 Physical Component Summary score (28.3 to 42.4, \( P<0.001 \)), and SF-36 Mental Component Summary score (38.2 to 48.3, \( P<0.001 \)). As of last follow-up no patient has showed recurrence of herniation or evidence of delayed instability. MED is a safe and effective surgical approach for the treatment of recurrent lumbar disc herniation. Standardized measures of outcome show that MED for recurrent herniation produces improvement in pain, disability, and functional health that is at least comparable with outcomes reported for conventional open microdiscectomy.

Ahn et al. (2009) completed a study in which the purpose was to assess the clinical outcome, prognostic factors and the technical pitfalls of percutaneous endoscopic lumbar discectomy (PELD) for upper lumbar disc herniation. Forty-five patients with a soft disc herniation at L1-L2 or L2-L3 underwent percutaneous endoscopic discectomy. Posterolateral transforaminal endoscopic laser-assisted disc removal was performed under local anesthesia. Clinical outcomes were assessed using the Prolo scale. The prognostic factors associated with outcome were then analyzed. The mean follow-up was 38.8 months (range, 25-52 months). The outcome of the 45 patients was excellent in 21 (46.7%), good in 14 patients (31.1%), fair in six patients (13.3%), and poor in four patients (8.9%). Four patients with a poor outcome underwent further open surgery. Mean scores on a visual analog scale decreased from 8.38 to 2.36 (\( P < 0.0001 \)). Age less than 45 years and a lateral disc herniation were independently associated with an excellent outcome (\( P < 0.05 \)). Patient selection and an anatomically modified surgical technique promote a more successful outcome after percutaneous endoscopic discectomy for upper lumbar disc herniation.

Brouwer et al. (2009) completed a randomized prospective multi-center trial, in which two treatment strategies are compared in a parallel group design. Patients (age 18-70 years) are considered for inclusion in the trial when sciatica due to lumbar disc herniation has lasted more than 8 weeks. Patients with disc herniation smaller than 1/3 of the spinal canal diameter, without concomitant lateral recess stenosis or sequestration, are eligible for participation, and are randomized into one of two treatment arms; either Percutaneous Laser Disc Decompression or conventional discectomy. The functional outcome of the patient, as assessed by the Roland Disability Questionnaire for Sciatica at 8 weeks and 1 year after treatment, is the primary outcome measure. The secondary outcome parameters are recovery as perceived by the patient, leg and back pain, incidence of re-intervention,
complications, quality of life, medical consumption, absence of work and secondary costs.

Rutten et al. (2008) completed a trial that compared endoscopic discectomy and microdiscectomy with two-year follow-up; 200 patients were entered into the study and 178 followed-up at two years. The endoscopic technique used either transforaminal or interlaminar approaches as indicated by patient anatomy; all procedures were performed by one of two experienced surgeons. Disability and pain outcomes were similar for the two procedures, though return-to-work was significantly faster in the endoscopic surgery group (25 versus 49 days). However, results are difficult to interpret because of several methodological shortcomings, including lack of intention-to-treat analysis and unclear presentation of randomization, blinding, and exclusion criteria.

Righesso et al. (2007) compared the intra and postoperative differences, as well as the final outcome of patients with herniated lumbar discs who underwent either open discectomy (OD) or microendoscopic discectomy (MED). The authors performed a prospective controlled randomized study of 40 patients with sciatica caused by lumbar disc herniations nonresponsive to conservative treatment who underwent OD or MED with a 24-month follow-up period. Pre- and postoperative neurological status, pain, and functional outcome were evaluated. Other studied variables were the duration of the procedure, blood loss, time of hospital stay, and time to return to work. Statistical analysis with a P value less than 0.005 was carried out. 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). The few parameters that were found to be statistically significant between the groups did not affect the overall outcome. In the current series, the final clinical and neurological results were similarly satisfactory in both the OD and the MED groups.

Mourelet et al. (2007) completed a study to assess the efficacy of percutaneous laser disc decompression for patients with radicular pain due to lumbar disc hernia and to identify factors that may predict outcome. It included all patients treated with percutaneous laser disc decompression from May 2003 through May 2005 at Reims University Hospital and the Courlancy Clinic of Reims. Each patient had previous undergone at least six weeks of conventional medical treatment. The same technique, with either a laser diode or Nd: YAG, was used under endoscopic control and with neuroleptanalgesia. They were seen at 1, 3, 6 and 12 months. The principal evaluation criteria were the course of radicular pain, return to work, and need for surgery. The authors reexamined 149 patients 1 month after the procedure, 135 after 3 months, 102 after 6 months and 59 a year after the procedure. At a month after surgery, radicular pain had decreased by at least half, and sometimes even completely disappeared in 63.1% of patients at 1 month, 66.6% at 3 months, 73.5% at 6 months, and 83.1% at 12 months, while 24%, 50, 4%, 61.2%, and 67.3%, respectively, had returned to work. No patient had serious complications. Finally, 45 of the 149 (30.2%) patients chose to have a traditional surgical procedure after percutaneous laser disc decompression. Percutaneous laser disc decompression is effective, noninvasive and well tolerated for patients with radicular pain due to lumbar disc hernia.

The usual surgical treatment of refractory sciatica caused by lumbar disc herniation, is open discectomy. Minimally invasive procedures, including percutaneous therapies
under local anesthesia, are increasingly gaining attention. One of these treatments is Percutaneous Laser Disc Decompression (PLDD). This treatment can be carried out in an outpatient setting and swift recovery and return to daily routine are suggested. Thus far, no randomized trial into cost-effectiveness of PLDD versus standard surgical procedure has been performed. We present the design of a randomized controlled trial, studying the cost-effectiveness of PLDD versus conventional open discectomy in patients with sciatica from lumbar disc herniation.

Scientific Rationale Initial
Herniation may occur anywhere along the spine but most commonly in the lumbar region, usually between the fifth lumbar and first sacral vertebrae (L5-S1). The usual cause is degeneration of the posterior longitudinal ligaments and the annulus fibrosis, frequently occurring in adults 35 years and older. A herniated disc is classified as a disc protrusion (annulus intact), extrusion (where the nucleus pulposus has violated the annulus fibrosis) or sequester (if the herniated material is separated from the disc through a perforated posterior longitudinal ligament). The MRI/CT scan can help to distinguish the different types of abnormalities. A differentiation is also made between a disc protrusion with a broad base or one with a narrow base.

Overall, only a small percentage of patients with back pain and sciatica should require surgery. Those who meet criteria for surgery generally do well, with 90% achieving at least partial relief from sciatica and back pain with conservative measures. Preoperative markers of a poor outcome include physical findings suggesting a behavioral disturbance; distribution and quality of pain that deviate from expected anatomic pain radiation; pending workers' compensation claims; and psychologic tests showing hysteria, hypochondriasis, and somatization.

In past years, nearly 200,000 standard open hemilaminectomies with discectomy have been performed annually in the United States to relieve sciatica. An estimated 5% to 15% of these procedures resulted in poor outcomes and reoperation, largely because of inappropriate patient selection. For the short-term, results of standard discectomy provides excellent relief from sciatica in appropriate patients. Three quarters of such patients are sciatica-free 1 year after surgery, compared with one third of patients treated conservatively. Approximately one half of patients are completely pain-free (i.e., without sciatica or back pain) 1 year after surgery. However, long-term outcomes of discectomy and conservative care are comparable after 4 to 10 years. Standard discectomy entails a posterior longitudinal incision, removal of laminar bone, incision of the ligamentum flavum, exploration for other abnormalities, and removal of herniated disc material. Complications include dural tears, discitis, nerve root damage, and spinal instability. Recuperation is often lengthy.

During the past decade, hemilaminectomy with discectomy has been largely replaced by minimally invasive procedures. A very high percentage of patients coming to surgery for large disk extrusions and sciatica do very well with minimally invasive discectomy. In most patients given relatively early surgical treatment, the primary predictor of outcome is the size of the disk herniation and the remaining competency of the anulus fibrosus. Surgical interventions to treat degenerative disc disease range from the widely accepted to those considered experimental. Accepted percutaneous techniques include manual or automated percutaneous lumbar discectomy (APLD, PLD, percutaneous nuclectomy), laser-assisted disc decompression (LADD) and percutaneous laser disc decompression (PLDD). Microdiscectomy has emerged as the
surgical standard with which all minimally invasive spine surgery techniques have been compared as they have been developed. Each has its own complications and requires a long learning curve to develop familiarity with the technique. Patient selection, and especially disc morphology, are the most important factors in choice of technique. The optimal candidate has a previously untreated single-level herniation with limited migration or sequestration of free fragments.

Procedures still considered to be investigational in nature include percutaneous endoscopic discectomy, percutaneous endoscopic laser discectomy, Yeung Endoscopic Spinal Surgery System (Y.E.S.S.), and microsurgical anterior foraminotomy for cervical spondylotic myelopathy. There are no clinical studies proving additional benefits from using an endoscope for performing disc decompression. At this time, there are no published studies of endoscopic spinal surgery that have included an adequate comparison group of patients receiving open procedures. In addition, no published study has yet reported on the long-term outcomes resulting from these endoscopic procedures.

A microdiscectomy is an open operation using a one to two inch midline incision through which the surgical field is visualized using an operating microscope. It is actually more effective for treating substantial radiculopathy pain than for lower back pain. A small portion of the bone over the nerve root and/or disc material from under the nerve root is removed to relieve neural impingement and provide more room for the nerve to heal. While it may take weeks or months for the nerve root to fully heal, and any numbness or weakness to get better, patients normally feel relief from leg pain almost immediately after a microdiscectomy surgery.

During a microdiscectomy, the back muscles (erector spinae) are lifted off the bony arch (lamina) of the spine. Since these back muscles run vertically, they can be moved out of the way rather than cut. The surgeon is then able to enter the spine by removing a membrane over the nerve roots (ligamentum flavum), and uses either operating glasses (loupes) or an operating microscope to visualize the nerve root. The nerve root is then gently moved to the side and the disc material is removed from under the nerve root. Importantly, since almost all of the joints, ligaments and muscles are left intact, a microdiscectomy procedure does not change the mechanical structure of the patient’s lumbar spine. Microdiscectomy and standard open discectomy have similar efficacy. Numerous studies in the medical literature have reported success rates for a microdiscectomy in the range of 90% to 95% with a low incidence of complications, reducing the duration of hospitalization with a rapid return to work activity after 20 days in 95% of cases, although 5% to 10% of patients will develop a recurrent disc herniation at some point in the future. Following a microdiscectomy surgery, a program of stretching, strengthening, and aerobic conditioning is recommended to help prevent recurrence of back pain or disc herniation.

Percutaneous lumbar discectomy (PLD) has greater overall safety than chymopapain injection, and has been recognized as providing mechanical debulking of the interior of contained disc herniations, but is contraindicated in non-contained disc herniations. PLD can be performed either manually or with an automated device. In manual PLD, using a pituitary type of instrument, nuclear material is removed from within the disc annulus by cutting forceps. Automated percutaneous lumbar discectomy (APLD) is accomplished by inserting a cannula/probe into the disc space under fluoroscopic guidance and, once in place, the APLD device is run at maximum cutting rate together with irrigation, aspiration and suction until the disc material
withdrawn from the irrigant line is minimized. The probe's small size (2 mm in diameter) minimizes the risk of with spinal cord or posterior elements injury, while its automated action permits rapid, safe removal of disc material. PLD is usually performed under local anesthesia and can be performed on an outpatient basis. Few patients are candidates for this procedure, and recurrent herniation from the same disk is common. Percutaneous discectomy is less efficacious than chymopapain injection therapy, and neither is as effective as standard discectomy or microdiscectomy.

Laser for treatment of lumbar disc disease is a very attractive technology because it has many advantages: (1) single-step insertion of a thin needle; (2) easy access to the often difficult to reach L5–S1 disc space; (3) nuclear ablation beyond what can be suctioned or physically removed; (4) a brief outpatient procedure; (5) absence of epidural scar and postoperative pain syndromes. The aim of percutaneous laser disc decompression (PLDD) is to vaporize a small portion of the nucleus pulposus of an intervertebral disc, thereby creating a central cavity believed to allow the nuclear material protruding through the annulus fibrosus and abutting the exiting nerve root to move back within the disc. The PLDD technique for entry into the disc space is identical to that described for the APLD. The needle is inserted through the annulus and into the nucleus pulposus to a depth of 1 cm. Several lasers are available (e.g., KTP/532 laser, Nd:YAG laser), each with differences in absorption, energy requirements, and rate of application. Generally, laser discectomy is believed to be equivalent to other percutaneous discectomy procedures, such as chemonucleolysis and automated percutaneous lumbar discectomy (APLD). Although the results achieved with PPLD vary widely from study to study, one can expect an overall success rate of 80%. Long-term pain relief has been reported in 70-80% of patients.

**Review History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
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<tbody>
<tr>
<td>October 2003</td>
<td>Medical Advisory Council</td>
</tr>
<tr>
<td>April 2006</td>
<td>Removed CPT 63030 from policy – no other revisions</td>
</tr>
<tr>
<td>April 2008</td>
<td>Removed references to coverage and reimbursement from the policy</td>
</tr>
<tr>
<td>July 2008</td>
<td>Added code comment regarding CPT-62287</td>
</tr>
<tr>
<td>2009</td>
<td>Policy title changed to Disc Decompression Procedures – Percutaneous and Laser</td>
</tr>
<tr>
<td>April 2011</td>
<td>Update – no revisions</td>
</tr>
<tr>
<td>September 2011</td>
<td>Update. Added Revised Medicare Table. Added Category III CPT Code 0275T. Removed note that Health Net considers use of endoscope investigational, since the approach is up to the Provider.</td>
</tr>
<tr>
<td>August 2012</td>
<td>Update – no revisions. Code updates</td>
</tr>
<tr>
<td>August 2013</td>
<td>Update – no revisions. Codes updated</td>
</tr>
<tr>
<td>August 2014</td>
<td>Update – no revisions. Codes updated</td>
</tr>
<tr>
<td>November 2014</td>
<td>Added Minimally Invasive Lumbar Decompression (mild; Vertos Medical Inc.) for Lumbar Spinal Stenosis as investigational since there is a paucity of peer-reviewed literature to support the efficacy of this procedure.</td>
</tr>
<tr>
<td>September 2015</td>
<td>Update – Based on peer-reviewed evidence based studies, and Position Statements, the policy statement has been changed to not medically necessary. Codes updated.</td>
</tr>
</tbody>
</table>

**This policy is based on the following evidence-based guidelines:**

References – Update September 2015

References – Update August 2014

References – Update August 2013

References – Update August 2012

References – Update September 2011

References – Update April 2011

References – Update April 2008
References


Important Notice

General Purpose.
Health Net's National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member's contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps. The policy provides for clearly written, reasonable and current criteria that have been approved by Health Net's National Medical Advisory Council (MAC). The clinical criteria and medical policies provide guidelines for determining the medical necessity criteria for specific procedures, equipment, and services. In order to be eligible, all services must be medically necessary and otherwise defined in the member's benefits contract as described this "Important Notice" disclaimer. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are
any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member’s benefits, nor is it intended to dictate to providers how to practice medicine.

**Policy Effective Date and Defined Terms.**
The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, prior notice or posting on the website is required before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

**Policy Amendment without Notice.**
Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, prior notice or website posting is required before an amendment is deemed effective.

**No Medical Advice.**
The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

**No Authorization or Guarantee of Coverage.**
The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

**Policy Limitation: Member’s Contract Controls Coverage Determinations.**
Statutory Notice to Members: The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. The determination of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member’s contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member’s contract shall govern. The Policies do not replace or amend the Member’s contract.

**Policy Limitation: Legal and Regulatory Mandates and Requirements**
The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

**Reconstructive Surgery**
CA Health and Safety Code 1367.63 requires health care service plans to cover reconstructive surgery. “Reconstructive surgery” means surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:

1. To improve function or
2. To create a normal appearance, to the extent possible.

Reconstructive surgery does not mean “cosmetic surgery,” which is surgery performed to alter or reshape normal structures of the body in order to improve appearance.

Requests for reconstructive surgery may be denied, if the proposed procedure offers only a minimal improvement in the appearance of the enrollee, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery.

**Reconstructive Surgery after Mastectomy**
California Health and Safety Code 1367.6 requires treatment for breast cancer to cover prosthetic devices or reconstructive surgery to restore and achieve symmetry for the patient incident to a mastectomy. Coverage for prosthetic devices and reconstructive surgery shall be subject to the co-payment, or deductible and coinsurance conditions, that are applicable to the mastectomy and all other terms and conditions applicable to other benefits. “Mastectomy” means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.

**Policy Limitations: Medicare and Medicaid**

Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.