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Subject: Percutaneous and Endoscopic Spinal Surgery
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Description/Scope

This document addresses percutaneous and endoscopic spinal discectomy and disc decompression, as well as image-guided minimally invasive spinal decompression procedures.

During a percutaneous, endoscopic, or image-guided spinal procedure, the surgeon does not have direct visualization of the anatomic site with the naked eye. Visual guidance is provided indirectly using fluoroscopy or, if an endoscope is used, a video monitor. During open and minimally invasive procedures, the surgeon is able to directly visualize the operative site. This document does not address discectomy and disc decompression procedures under direct visualization with the naked eye, microscope, or loupe.

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

- SURG.00052 Percutaneous Vertebral Disc and Vertebral Endplate Procedures
- SURG.00073 Epiduroscopy
- SURG.00111 Axial Lumbar Interbody Fusion
- SURG.00134 Interspinous Process Fixation Devices

Position Statement

Investigational and Not Medically Necessary:

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

Rationale

Percutaneous Discectomy and Disc Decompression

Automated percutaneous lumbar discectomy (APLD) was introduced in the 1980s using a suction curettage device for disc removal. 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 the percutaneous discectomy group and 40% of the 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 included a lack of randomization for comparison of surgical versus non-surgical therapies and its small size.

In a 2007 Cochrane review of 40 randomized controlled trials of surgical interventions treating spinal disc disease, Gibson and Waddell found that microdiscectomy gives broadly comparable results to standard open discectomy. This review also concluded that considerable evidence exists that surgical discectomy provides effective clinical relief for select individuals with sciatica due to lumbar disc prolapse that fails to resolve with conservative management. Evidence suggested that surgical discectomy provides faster relief from an acute attack of sciatica, but its impact on the long-term natural history of underlying disc disease was unclear. There was a lack of evidence to establish the efficacy and safety of automated percutaneous discectomy, coblation therapy, and laser discectomy.

In a 2014 Cochrane review, Rasouli and colleagues compared the benefits and harms of minimally invasive discectomy (MID) procedures to microdiscectomy or open discectomy. They included 11 randomized controlled trials or quasi-controlled trials (n=1172) that compared conventional surgery to percutaneous endoscopic lumbar discectomy (PELD), transmuscular tubular microdiscectomy, or APLD. Primary outcomes included pain related to sciatica or low back pain (as measured by a VAS) and sciatic specific outcomes. They found that 7 out of 11 studies had a high overall risk of bias. MID procedures were found to be potentially inferior for relief of leg pain, lower back pain and rehospitalization. Differences in pain relief were small and may not have been clinically significant. MID had the advantage of lower risk of infection. They recommended more research to define appropriate indications for MID as an alternative to conventional surgery.

Percutaneous Laser Discectomy and Disc Decompression

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 studies.

In a multicenter, randomized controlled trial, Brouwer and colleagues (2015) compared the effectiveness of percutaneous laser disc decompression to traditional surgical microdiscectomy for individuals with sciatica from lumbosacral disc herniation. The researchers included 115 subjects who were randomized 1:1. Inclusion criteria included sciatica refractory to 6-8 weeks of conservative management, ages 18-70, disc herniation verified by magnetic resonance imaging (MRI), and herniated fragment size smaller than one-third of the spinal canal. The primary outcome was self-reported functional disability on the Roland Morris Disability Questionnaire (RDQ) for sciatica. At a 1-year follow-up, the primary outcome was analyzed for the laser group (n=53) and the surgery group (n=54). The RDQ showed non-inferiority of the laser group at 8 weeks (–0.1; 95% confidence interval [CI], –2.3 to 2.1) and at 52 weeks (–1.1; 95% CI, –3.4 to 1.1) compared to the surgery group. The surgery group had a higher speed of recovery (hazard ratio [HR] 0.64; 95% CI, 0.42 to 0.97) and less re-operations; a total of 24 subjects (44%) in the laser group underwent additional surgery during the first year compared to 9 subjects (16%) in the surgery group. For 5 subjects (9%), the laser treatment could not be performed due to laser malfunction or inability to reach the disc space. At a 2-year follow-up (laser group n=48, surgery group n=51), the researchers did not find a significant difference between the two groups (Brouwer, 2017). However, the re-operation rate for the laser group was 52% compared to 21% in the surgery group. The researchers concluded that percutaneous laser disc decompression, followed with surgery when symptoms were not relieved, had comparable outcomes to traditional microdiscectomy surgery alone. They stated that further comparative studies are needed.

Percutaneous Nucleoplasty Discectomy and Disc Decompression

Nardi and colleagues (2005) studied 50 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.

Gerszten and colleagues (2006) reported a prospective nonrandomized longitudinal cohort study of 67 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 postoperatively. 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 and colleagues (2008) reported 1-year outcomes for lumbar nucleoplasty, which 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 VAS scores post-operatively as compared to preoperative 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.

Abrishamkar and colleagues (2018) reported on a randomized clinical trial that compared open cervical discectomy to nucleoplasty. A total of 70 subjects were enrolled; however, 13 subjects discontinued the study leaving 28 in the nucleoplasty group and 29 in the cervical discectomy group. The subjects were followed for 6 months and evaluated using the VAS for pain. The researchers did not find a significant pain difference between the two groups and did not observe any discitis, infection, or hematomas. In the nucleoplasty group, 1 subject had a repeat procedure, and 1 subject continued to have pain after 6 months. In the cervical discectomy group, 1 subject continued to have radicular pain 6 months post-surgery. Overall satisfaction was not significantly different between the two groups. The authors concluded that nucleoplasty was as effective as traditional cervical discectomy. The study was limited by a small sample size and limited follow-up duration.

Percutaneous Endoscopic Discectomy and Disc Decompression

Lee and colleagues (2009) compared percutaneous endoscopic lumbar discectomy (PELD) with open lumbar microdiscectomy (OLM) in a retrospective study. Between December 2004 and May 2006, 54 individuals who underwent surgery, either PELD (25 subjects) or repeated OLM (29 subjects), due to recurrent disc herniation at L4-5 level, were selected and divided into two groups according to the surgical methods with sequestrated disc, calcified disc, severe neurological deficit, or instability. Pain analysis before and after surgery was assessed using the VAS scoring (0-10) and function was assessed by the Oswestry Disability Index (ODI) in percent (0-100%). Radiographs and MRI imaging were also reviewed pre- and post-operatively. The PELD procedure used local anesthesia and fluoroscopic guidance to reach the treatment site. An obturator was inserted along the guide wire and hammered into place when reaching the annulus allowing a working cannula to the disc. An endoscope was inserted and the blue-stained disc material was removed. The OLM procedure was performed under general anesthesia. A 2-3 cm incision was made and paravertebral muscles were dissected. The operating field was exposed and viewed via surgical microscope for discectomy and decompression. The authors found that the outcomes were favorable in both groups; PELD having the advantage with anesthesia, operative time and hospital stay. However, due to the size and design of the study, no firm clinical conclusions could be drawn regarding efficacy.

Peng and colleagues (2009) indicated that while PELD is a relatively new technique, few studies have reported the clinical outcome of PELD regarding QOL and return to work. In a retrospective study of 55 subjects, clinical outcomes were reviewed using the North American Spine Score (NASS), Medical Outcomes Study Short Form-36 scores (SF-36), the VAS, and return to work. The treatment sites varied as well as the disc status. A total of 39 subjects (70.9%) had L4-L5 discectomy, 12 (21.8%) had L5-S1 discectomy, 2 (3.6%) had L3-L4 and 2 (3.6%) had two levels L4-L5 and L5-S1 performed. There were 44 (80%) disc protrusions, 10 (18.2%) extrusions and 1 (1.8%) sequestrated disc. The mean follow-up period was 3.4 years (range 2.0-6.5 years). All who were working preoperatively returned to work. The mean time to return to work was 24.3 days (range 10-60 days). Back pain and lower limb symptoms were confirmed by reduced NASS and VAS scores (p<0.05) at 6 months and 2 years. There were improvements in QOL (SF-36, p<0.05) scores except for general health at 6 months and 2 years post-surgery. The recurrence rate was 5% or 3 subjects who subsequently underwent lumbar fusion for persistent back pain. The limitations of the study were that it was retrospective, uncontrolled, and limited in size.

Coverage Policy Recommendations from the North American Spine Society (NASS) state that endoscopic discectomy should "be covered treatment of lumbar disc herniation with radiculopathy." According to information on the NASS website, the Coverage Policy Recommendations were created using "an evidence-based approach to spinal care when possible. In the absence of strict evidence-based criteria, policies reflect the multidisciplinary and non-conflicted experience and expertise of the authors in order to reflect reasonable standard practice indications in the United States." 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).

Zhou and colleagues (2018) performed a retrospective study to assess the complications of percutaneous endoscopic lumbar discectomy (n=320) and percutaneous endoscopic interlaminar discectomy (n=106). The researchers evaluated subjects at least 1 year post-procedure and based their assessment on the VAS and ODI. Common complications included: incomplete removal of herniated discs (1.4%; 6/426), recurrence (2.8%; 12/426), nerve root injury (1.2%; 5/426), dural tear (0.9%; 4/426), and nerve root induced hyperalgesia or burning-like nerve root pain (2.3%; 10/426). Less common complications included: the working channel passing through the canal into the disc space (1 case), super-elastic nerve hook trapped by exiting nerve root (1 case), epidural hematoma (1 case), radicular artery injury and massive bleeding (1 case), and intraoperative seizure (1 case). The authors concluded:

Because of the difficult learning curve and the lack of skill with requisite surgical techniques and clinical care of postoperative patients, different kinds of problems can arise with some frequency, especially when unique complications cause severe injury for the patient. Surgeons should vigilantly make adequate technical considerations and thoroughly understand patient anatomy to avoid unusual complications. Also, a high index of suspicion and early detection are important to prevent progressive neurological deficits or other adverse events.

Microendoscopic discectomy (MED)

Microendoscopic discectomy has been proposed as treatment of symptomatic lumbar herniated disc. Schizas and colleagues (2005) reported the results of a small study of 28 individuals, 14 having MED and 14 having microdiscectomy. They found no difference of clinical significance between the outcomes of the two groups. The authors concluded that MED was as least as effective as microdiscectomy for the treatment of uncontained or large contained disc herniations.

Righesso and colleagues (2007) reported a randomized study comparing MED with open discectomy (OD). A total of 19 participants were in the OD group and 21 were assigned to the MED group. The only statistically significant differences found were for size of the incision, length of hospital stay, and operative time. The former were greater in the OD group while operative time was greater in the MED group. Those differences did not affect the overall clinical and neurological outcomes which were comparable between the two groups.

Liu and colleagues (2010) conducted a retrospective study in consecutive subjects with lumbar disc herniation treated with percutaneous lumbar discectomy (PLD) or MED in a single hospital from January 2000 to March 2002. A total of 104 PLD subjects and 82 MED subjects were included in the study with a mean follow-up period of 6.64 ± 0.67 years and 6.42 ± 0.51 years, respectively. There were no significant differences between the two groups in age, number of lesions, major symptoms and physical signs, and radiological findings. All subjects were followed up with MacNab criteria and self-evaluation questionnaires comprising the ODI and Medical Outcomes Study 36-Item Short-Form Health Survey. The PLD procedure was performed by interventional radiologists utilizing automated percutaneous discectomy instrumentation under fluoroscopic guidance. The MED procedure was performed by orthopedists using a guide wire and serial dilators to access the operative site followed by an endoscope used as an operative channel. A total of 10 subjects underwent subsequent open surgery in different durations, after PLD (8 subjects) and 2 subjects after MED. According to the MacNab criteria, 75.96% in the PLD group and 84.15% in the MED group achieved excellent or good results, respectively; this was statistically significant (p=0.0402). Findings of the Medical Outcomes Study 36-Item Short-Form Health Survey were 75.88 (PLD) vs. 81.86 (MED) group (p=0.0582). Two subjects (2.44%) in the MED group had complications while there were no complications in the PLD group. Although both PLD and MED showed an acceptable long-term efficacy for treatment of lumbar disc herniation, the long-term satisfaction was lower in the PLD groups. The authors acknowledged limitations of the study in the areas of follow-up, lack of long-term radiological examinations, and the low number of participants given the incidence of discogenic pathology. Other limitations included the retrospective, non-randomized study design.

Casal-Moro and colleagues (2011) reported a case series of 120 individuals who underwent MED for lumbar disk herniation in a prospective study with a 5-year follow up. The participants had symptomatic disk herniation with contained, non- contained, migrated or foraminal herniation. The most commonly affected level was L5-S1. Post operatively, statistically significant reductions in the VAS pain score (to evaluate preoperative and postoperative back and leg pain) and ODI scores (to evaluate functional state) were reported. The modified MacNab classification (see definitions) was also used as an outcome measure. Using the MacNab criteria, the authors reported good results in 89 individuals, fair results in 22 individuals, and poor results in 9 individuals. No excellent results were reported. Seven participants experienced intraoperative complications. Incidental durotomy occurred in 5 individuals; of this group, 3 required open surgery for repair. Other complications included a bayoneted rongeurs rupture requiring open surgery and a nerve root puncture. The study was limited by the lack of a control group comparison.

Garg and colleagues (2011) conducted a randomized controlled study to compare the outcomes of MED versus open discectomy for lumbar disc herniation. A total of 80 men and 32 women between the ages of 26-57 with a single-level disc herniation were randomized to undergo MED (n=55) or open (fenestration/laminotomy) discectomy (n=57). The participants were assessed pre- and post-operatively (at week 6, month 6, and year 1). Assessments included a clinical examination, radiological examination including MRI, and an electrophysiological study. Functional outcomes and low back pain were self-evaluated using the Oswestry low back pain disability questionnaire13 and were assessed by an independent observer. The outcome was considered satisfactory if radicular symptoms ceased, tension signs became negative, and the individual returned to his/her previous occupation or normal activities. In the MED group, surgical and anesthesia times were significantly longer, but blood loss and hospital stay were significantly reduced. Improvement in the Oswestry score in both groups was significant at week 1 but not at other follow-ups. The rate of complication was similar in both groups. One participant in the MED group experienced a recurrence of disc herniation after 7 months and was treated with open discectomy. The authors concluded that both methods are equally effective in relieving radicular pain. MED resulted in a shorter hospital stay, less morbidity, and earlier return to work. The authors cautioned that with the MED, the surgical technique is demanding and should not be attempted without specific instruction and training. Limitations of this study included the short follow-up period (12-18 months) and the lack of quantitative outcome assessment. The authors also did not describe the method of randomization. Larger groups of participants with longer follow-up are needed to confirm these results.

Hussein and colleagues (2014) reported the outcomes of 200 individuals randomized to receive either microendoscopic lumbar discectomy (n=95) or open lumbar discectomy (n=90). Study participants and investigators were not blinded to the treatment assignments. At 8 years follow-up, data was available for 185 subjects. A total of 15 subjects were lost to follow-up, 10 due to subsequent same-level fusion, 3 due to death which was unrelated to the surgical procedure, and 2 who did not respond to follow-up telephone calls. Primary outcomes data included the Numerical Rating Scale (NRS) for back and leg symptoms and the ODI to quantify pain and disability. Objective outcomes data included blood loss, operative time, postoperative analgesics, length of hospital stay, time to return to work, reoperation and complication rate, participant satisfaction index (PSI), and modified (MacNab) criteria. Relief of leg pain was statistically significant for both groups, with no significant difference between the groups. Amongst participants in the endoscopic group, back pain was significantly improved throughout the entire follow-up period. However, in the open lumbar discectomy group, the significant improvement in back pain after surgery deteriorated over time; at the 8 years follow-up, back pain scores in this group had worsened significantly from preoperative scores. No serious complications were reported in either group. Additional well-designed RCTs with long-term follow-up are needed to confirm these results.

Image-guided minimally invasive lumbar decompression (MILD®) for Spinal Stenosis

Image-guided minimally invasive lumbar decompression (MILD) is being investigated as a treatment for lumbar spinal stenosis. Lingreen and colleagues (2010) conducted a retrospective review of self-reported improvement and post-procedure findings after MILD. A total of 42 consecutive subjects between the ages of 52-86, with spinal stenosis and ligamentum flavum hypertrophy as the primary feature on MRI, were included in the study. All of the surgical procedures were performed by two interventional pain management physicians working at the same center. The results of self-reported pre- and post-procedure VAS, markers of global function, major and minor adverse events, self-reported outcomes, and need for follow-up procedures were evaluated. Measurements of functional improvement were assessed by ability to stand and ambulate for greater than 15 minutes, whereas prior to the procedure

98% reported significant functional limitations. VAS decreased by 40% from baseline and no major adverse events were reported. The most frequently reported minor adverse event was soreness lasting 3.8 days. Five of the study participants requested post-procedure opioid analgesia. Thirty-six participants indicated they would recommend this procedure, 1 was unsure, and 5 indicated they would not recommend the procedure. A total of 8 participants reported marginal improvement (change < 3 on VAS) yet 4/8 participants in this category still stated they would recommend MILD to others. The authors concluded that the MILD procedure appears to be a safe and likely effective option. Limitations of this study include its uncontrolled design and small size.

Chopko and colleagues (2010) assessed the safety and functional outcomes of the MILD procedure as a treatment of symptomatic central canal spinal stenosis. This multicenter, non-blinded prospective study consisted of 78 participants who underwent the MILD procedure. Measures of outcomes included the VAS, ODI, Zurich Claudication Questionnaire (ZCQ), and SF-12v2 Health Survey at baseline and at 6 weeks post-treatment. The authors reported that at 6 weeks post-treatment the VAS, ZCQ, and SF-12v2 all reflected a reduction in pain. The ODI, ZCQ, and SF-12v2 reflected an improvement in physical function and mobility. The authors concluded that the MILD procedure was safe, improved mobility, and reduced the pain associated with lumbar spinal canal stenosis. Limitations of the study included the lack of a control group and short follow-up.

Brown and colleagues (2012) reported the results of a double-blind, randomized, prospective study of epidural steroid injections (ESI) and the MILD procedure at a single pain management center. A total of 38 individuals with symptomatic lumbar spinal stenosis (LSS) participated in the study and were randomized into two treatment groups: 21 participants in the MILD arm and 17 individuals in the ESI arm. Outcome measures were reported using the VAS, the ODI, and ZCQ patient satisfaction score. The authors reported that at 6 weeks, the MILD participants improved from an average VAS baseline of 6.3 (95% CI ± 0.7) to a mean of 3.8 (95% CI ± 1.3). The ESI group had a mean VAS score of 6.4 (95% CI ± 1.0) at baseline compared with 6.3 (95% CI ± 1.4) at 6 weeks follow-up. Using the ODI, at 6 weeks follow-up, participants in the MILD group demonstrated a decrease from a baseline mean ODI from 38.8 (95% CI ± 4.2) to 27.4 (95% CI ± 7.0). In the ESI group, the initial ODI was 40.5 (95% CI ± 5.9) and at 6 weeks follow-up, the ODI was 34.8 (95% CI ± 8.2). In the MILD group, there was no significant change in the VAS and ODI scores from weeks 6 to 12. Participants in the ESI group were not measured at week 12. The ZCQ difference between the MILD group and the ESI group was not significant at week 6. Participants were allowed to cross over from the ESI group to the MILD group before 12 weeks, and eventually all of the participants in the ESI group had the MILD procedure. A total of 14 of the 17 participants in the cross-over ESI group experienced an improvement in their VAS scores after the MILD procedure. Some of the limitations of the study included its small size and short follow-up.

In another study, Chopko (2013) evaluated the long-term effectiveness and safety of MILD as a treatment of neurogenic claudication associated with lumbar spinal stenosis. The 2-year data are reported for 45 participants that were treated with MILD at 11 U.S. facilities. Outcome measurements included the VAS, ODI, and ZCQ. Interim data on the participants are included for 1 week, 6 months, and 1 year follow-up. The authors reported that at 2 years, the subjects demonstrated a statistically significant reduction of pain as measured by VAS and significant improvement in physical function and mobility as measured by ZQC and ODI. The authors also reported major improvement occurred by 1 week follow-up and showed no difference between each subsequent follow-up, suggesting considerable stability and durability of the initial result over time. There were no major adverse events or complications related to the procedure. Limitations of this study include its uncontrolled design and small size.

In 2014, the Centers for Medicare & Medicaid Services (CMS) determined that percutaneous image guided lumbar decompression (PILD) for lumbar spinal stenosis (LSS) is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act. The decision memo also states the following regarding the PILD procedure for LSS:

> In reviewing the evidence on PILD we are confronted with weak studies, questions about missing information, questions about adverse events and conflicts of interest. After thoroughly reviewing the evidence for PILD for LSS, we have determined the evidence does not support a conclusion of improved health outcomes for our Medicare beneficiaries. However, we recognize that LSS is a real and important source of pain and functional limitation for patients, and that the development of effective minimally invasive procedures could have a potential place in the treatment armamentarium, but that more evidence is clearly needed. In order to support additional research on the development of effective minimally invasive procedures for the treatment of LSS, we will cover this procedure under section 1862(a)(1)(E) of the Social Security Act (CMS, 2014).

Benyamin and colleagues (2016) performed the industry-supported, multicenter, MiDAS ENCORE randomized controlled trial to assess outcomes of MILD compared to ESI in individuals with lumbar spinal stenosis and neurogenic claudication symptoms. A total of 302 subjects were enrolled who were 65 years old or older, had refractory neurogenic claudication for at least 3 months, and had ligamentum flavum greater than 2.5 mm. After 28 subjects withdrew before the study started, the remaining subjects received the MILD procedure (n=143) or up to four epidural steroid injections (n=131). At a 1-year follow-up, there were no significant differences between the groups for medication usage. However, for the MILD group, the ODI was significantly higher (58.0% versus 27.1%; p<0.001), as were the numeric pain rating scale (NPRS) scores (difference of 30.2%; p<0.001), ZCQ scores (difference of 20.0%; p=0.001), and the satisfaction score (2.4 ± 0.1 versus 3.1 ± 0.1; p<0.001). A total of 2 subjects in each group had adverse events, the worst being 1 MILD subject having a non-serious procedural hemorrhage and 1 ESI subject having sinus bradycardia after treatment that was resolved with no complications. The authors concluded that MILD is statistically superior to epidural injections for lumbar spinal stenosis with neurogenic claudication. Limitations of the study included lack of blinding in the subjects, potential high non-responder rates, enrollment not limited to subjects that had never received epidural steroid injections, and loss to follow-up (22 subjects in the MILD group and 32 in the ESI group withdrew before the 1-year follow-up).

Staats and colleagues (2018) published 2-year results of the MiDAS ENCORE study (Benyamin, 2016) to establish long-term safety and efficacy of MILD for the treatment of lumbar spinal stenosis with neurogenic claudication. At 2 years, 99 out of the original 143 subjects were available for follow-up. At 2 years, ODI improved by 22.7 points (95% CI, 18.5 to 26.9), NPRS improved by 3.6 points (95% CI, 3.1 to 4.2), and ZCQ symptom severity improved by 1.0 point (95% CI, 0.8 to 1.2) and physical function domains improved by 0.8 point (95% CI, 0.6 to 0.9). The mean change from baseline exceeded the clinically meaningful threshold and achieved statistical significance for all efficacy end points and follow-up times (p<0.001). Responder rates for ODI, NPRS, and ZCQ symptom severity, physical function and patient satisfaction were 72.4%, 71.7%, 73.5%, 59.6% and 76.8%, respectively. None of the subjects underwent a subsequent MILD procedure; however, out of the original 143 subjects, 8 underwent a subsequent surgical procedure at the index level, 22 had an ESI or nerve block at the level of surgery (1 of which also received a spinal cord stimulator), 1 received a rhizotomy at the index level, and 1 received an intrathecal infusion pump. There were no serious adverse events reported. Limitations of the study included lack of a control group at 2 years and loss to follow-up.

Other Percutaneous and/or Endoscopic Spine Surgery Procedures

Chen and colleagues (2015) reported the results of an 8 year study highlighting the effectiveness of a computed tomography (CT)-assisted endoscopic procedure in the treatment of infectious spondylodiscitis in the thoracic and lumbar spine of immunocompromised individuals. A total of 41 participants with infectious spondylodiscitis underwent percutaneous endoscopic surgery with local anesthesia, and 13 subjects (5 males and 8 females) with lesions on the thoracic or upper lumbar spine were selected for evaluation. The participants were between the ages of 49-84 years (median age of 65.6 years) and had a variety of comorbidities including but

not limited to congestive heart failure, diabetes mellitus, coronary heart disease and hypertension. In the study, there was no mention of what happened to the other 28 participants or how participants were selected to have their lesions evaluated. Additionally, the authors lacked a comparison to the gold standard of CT-guided incision and drainage.

Researchers are exploring the use of percutaneous posterior cervical nerve root decompression using an expandable intervertebral cervical cage and concomitant posterior arthrodesis as a treatment for single-level cervical radiculopathy due to spondylosis. McCormack and colleagues (2013) reported the 1-year results of a prospective multicenter single-arm study that assessed clinical and radiographic outcomes of individuals with cervical radiculopathy due to spondylosis and stenosis who were treated at a single level with the DTRAX® Facet System (Providence Medical Technology, Walnut Creek, California, United States). A total of 60 individuals with symptomatic clinical radiculopathy and who had failed conservative treatment were included in the study. Preoperative assessments were conducted using the Neck Disability Index, VAS, QOL questionnaire (Short Form-12 version 2), CT scans, MRI, and dynamic radiographs. All participants underwent percutaneous posterior bilateral facet implantation consisting of a screw and expandable washer and iliac crest bone aspirate. Study participants were assessed postoperative at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year with validated outcome questionnaires. Changes in segmental and overall cervical lordosis, foraminal dimensions, device retention and fusion criteria were evaluated for up to 1 year with CT reconstructions and radiographs. Fusion criteria were defined as bridging trabecular bone between the facets, translational motion less than 2 mm, and angular motion less than 5°. All participants were postoperatively followed for 1 year. Participants in the study ranged from 40 to 75 years, with a mean of 53 years. A total of 42 individuals were treated at C5-6, 8 at C6-7, 7 at C4-5, and 3 at C3-4. Of the 60 participants, 56 had bilateral implants; 4 had unilateral implants due to intraoperative facet fracture (n=2) and inability to access the facet (n=2). The Neck Disability Index, VAS, and QOL questionnaire were significantly improved at 2 weeks and continued to be significantly improved up to 1 year. At the treated level, 93% of participants demonstrated intrafacet bridging trabecular bone on CT scans, translational motion was less than 2 mm in 100% and angular movement was less than 5° in 83% at the 1-year follow-up. There was no significant alteration in overall cervical lordosis. There was a 1.6° decrease in segmental lordosis at the treated level at 1 year that was significant. Foraminal width, volume, and posterior disc height had significantly increased at the 6 month follow-up but returned to baseline levels by 1 year. No significant decline in foraminal width and height at adjacent levels was reported. No reoperations or surgery- or device-related complications, including implant failure or retained hardware, were reported. Based on the results of this study, the authors concluded that the DTRAX Facet System is a safe and effective treatment for cervical radiculopathy. Limitations of this study include the lack of a control group and the limited follow-up duration (1 year).

Sieminonow and colleagues (2016) reported the 2-year clinical and radiographic results of treatment for single-level cervical radiculopathy using the DTRAX cage. A total of 53 of the original 60 participants reported on in the study reported by McCormack and colleagues in 2013 (88%) were available at the 2-year follow-up. The 2-year clinical and radiologic outcomes were similar to those reported at 1 year. The mean preoperative and 2-year scores were VAS Neck Pain: 7.4 versus 2.6 (p<0.0001); VAS Arm Pain: 7.4 versus 2.6 (p<0.0001); SF-12 Physical Component Summary: 34.6 versus 43.6 (p<0.0001), NDI: 32.3 versus 9.1 (p<0.0001); and SF-12 Mental Component Summary: 40.8 versus 51.4 (p<0.0001). Participants experienced a slight but statistically significant decrease in the posterior disk height at the treated level at 2-year follow-up. Radiographic fusion rate was 98.1%. No device failure, implant lucency or surgical reinterventions were reported. The authors concluded that indirect decompression and posterior cervical fusion using the expandable intervertebral cage may be an effective tissue-sparing option in select individuals with single-level cervical radiculopathy. As with the initial report by McCormack, this study is limited by the lack of a control group and relatively short follow-up duration (now 2 years). Several authors in both studies had consulting relationships with the study sponsors. Sieminonow noted that a randomized controlled study would be needed to show the comparative effectiveness of the DTRAX technique.

Gibson and colleagues (2017) conducted a randomized controlled trial to compare transforaminal endoscopic discectomy (TED) (n=70) to traditional surgical microdiscectomy (n=70). Outcome measures were assessed preoperatively and at 3, 12, and 24 months. Inclusion criteria included ages 25-70, single-level prolapse with exiting and/or traversing nerve root compression, failure of conservative management > 6 weeks. Exclusion criteria included upper lumbar disc disease (L2/3 or above), previous disc prolapse, massive sequestered disc prolapse, weight > 115 kg, and malignancy. After 2 years post-procedure, there was not a significant difference in the QOL measurement on the short-form 6D survey nor postoperative work status. The TED group had a shorter length of hospital stay (0.7 days ± 0.7, range 0-2 versus 1.4 days ± 1.3, range 0-9; p<0.001). The VAS leg pain score was significantly less for the TED group (1.9 ± 2.6 versus 3.5 ± 3.1; p=0.002). While there were no major complications for either group, 2 subjects from the TED group had significant headaches post-procedure (resolved after bed rest) and 4 subjects had dysaesthesia (resolved within 2-4 weeks); a subject in the microdiscectomy group had foot drop. The revision rate was higher in the TED group (5 subjects versus 2; RR 2.62 [0.49 to 14.0]). The authors concluded that TED had comparable outcomes to microdiscectomy. Limitations of the study included lack of blinding, small sample size, a difference in anesthesia techniques, and loss to follow-up (13 subjects; 9.3%).

Summary

Additional well-designed studies comparing conventional (open approach) procedures to a percutaneous, endoscopic, or image-guided spinal 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.

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 discectomy and disc decompression have been investigated over the years as a treatment of back pain related to disc disease and bone structure.

Techniques using imaging for guidance 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 probe 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. Complications following percutaneous disc procedures include reherniation, disc instability, and device malfunction.

Microendoscopic discectomy is performed by passing an endoscope or dilating tube equipped with a camera to the operative site. The operative site is viewed on a monitor. In MED, the surgeon does not view the operative site directly. This technique has a steep learning curve. The advantages of this type of surgical technique are smaller incisions, less trauma to surrounding structures, and less recovery time than micro or open discectomy.

Minimally invasive lumbar decompression (MILD)

MILD (also known as image-guided minimally invasive lumbar decompression) is a percutaneous spinal decompression procedure used as a treatment of spinal stenosis. The MILD procedure is performed with the assistance of a contrast medium and fluoroscopic guidance. According to the manufacturer, the "*mild* Devices are designed to access the interlaminar space from the posterior lumbar spine, enabling the user to remove small portions of the lamina and preferentially resect and debulk the thickened ligamentum flavum, accomplishing a lumbar decompression." This procedure does not involve a discectomy. The procedure can be performed on an outpatient basis under local anesthesia (Vertos Medical Mild Device Kit).

The original FDA premarket approval for the X-Sten MILD Tool Kit was granted in 2006 and is a set of specialized surgical instruments intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions. In 2010, the FDA granted 510(k) premarket approval (K093062) for the modification of the X-Sten MILD Tool Kit (Vertos, San Jose, CA). According to the FDA approval letter, the Vertos Medical MILD Device Kit is substantially equivalent to the X-Sten MILD Tool Kit (K062038) and the Baxano Ultra Low Profile Rongeur and Access Tools (K062711) which had been granted FDA premarket approval at an earlier date. According to the Vertos MILD instructions for use, the device should be used for tissue resection at the perilaminar space, within the interlaminar space and at the ventral aspect of the lamina. The device is not intended to be used to remove the spinal disc.

Additional percutaneous discectomy devices have also been cleared by the FDA through the 510(k) substantial equivalence process, including the DeKompressor® Percutaneous Discectomy Probe (Stryker Instruments, Kalamazoo, MI), Herniatome Percutaneous Discectomy Device (Gallini Medical Devices, South Euclid, OH), and the Nucleotome® Probe Set (Clarus Medical, LLC, Minneapolis, MN). The FDA indications for these products is, "For aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine."

Other Percutaneous and/or Endoscopic Spine Surgery Procedures

Percutaneous posterior cervical nerve root decompression using an expandable intervertebral cervical cage has been explored as an alternative surgical treatment for single-level cervical radiculopathy. According to information on the FDA we site, the "PMT Cervical Cage is an intervertebral fusion device intended to be used in cervical spinal fusion surgery. The FDA premarket approval stipulates that the PMT cervical cage is intended to be used as follows:

> PMT Cervical Cage is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-C7) with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Devices are intended to be used with autogenous bone graft and supplemental fixation, such as an anterior plating system (USFDA PMT Cervical Cage, 2013).

Definitions

Chemonucleolysis: An injection of a drug to dissolve the disc, facilitating removal.

Curretage: The removal of unwanted tissue using a small, spoon shaped device called a curette.

Disc decompression: Reducing pressure within the disc by reducing the volume of nuclear material inside the disc.

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: Surgical removal of a part or all of an intervertebral disc, with or without removal of the nucleus pulposus. 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: Rupture of an intervertebral disc with protrusion of disc material and/or nucleus pulposus material into the intervertebral canal. This may result in nerve compression causing pain.

Lamina: A thin broad plate of bone forming the most posterior portion of the neural arch. The two laminae of each vertebra meet in the midline to form the spinous process.

Laminectomy: Surgical removal of a spinal lamina, often done to decompress underlying spinal nerves or to provide access for another surgical procedure.

Laminotomy: Partial removal of the spinal lamina to provide access to the neural canal.

Ligamentum flavum: Ligaments connecting adjacent spinal lamina.

Lumbar stenosis: A narrowing of the lumbar spinal canal.

The MacNab Clinical Outcome Measures:

- Excellent- No pain; no restriction of activity;
- Good- Occasional back or leg pain of sufficient severity to interfere with the ability to do normal work or capacity to enjoy leisure activities;
- Fair- Improved functional capacity but handicapped by intermittent pain of sufficient severity to curtail or modify work or leisure activities;

- Poor- No improvement or insufficient improvement to enable increase in activities; further operative intervention required.

Minimally invasive lumbar decompression (MILD): Decompression of the lumbar neural canal using indirect visualization (for example endoscopy or fluoroscopy).

Percutaneous: Access 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, 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.

Surgical approaches:

- Percutaneous - The surgeon uses fluoroscopic imaging or other forms of indirect visualization during the surgical procedure. The surgery is performed using instruments passed directly through the skin (percutaneous).
- Endoscopic - The surgeon uses video or camera guidance during the procedure and performs the surgery through the endoscope working channel.
- Minimally Invasive - The surgeon directly visualizes the anatomy being operated on with the naked eye. The operative field may be developed using small profile (tubular or other) retraction to limit damage to surrounding normal tissues. The surgeon uses standard microdiscectomy techniques and instrumentation. Visualization may be assisted with a microscope or an endoscope.
- Open - The surgeon directly visualizes the anatomy being operated on with the naked eye. The surgery performed through an open incision utilizing direct visualization and muscle stripping and retraction. Standard surgical instrumentation and techniques are used and may involve the removal of both bony and ligamentous structures.

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 utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar
0274T	Percutaneous laminotomy/laminectomy (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), single or multiple levels, unilateral or bilateral; cervical or thoracic
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), single or multiple levels, unilateral or bilateral; lumbar
64999	Unlisted procedure, nervous system [when specified as percutaneous decompression or laser procedures of cervical or thoracic spine]

HCPCS	
C2614	Probe, percutaneous lumbar discectomy
S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar [DISC nucleoplasty]

ICD-10 Procedure	
0R533ZZ-0R5B4ZZ	Destruction of vertebral disc, percutaneous or percutaneous endoscopic approach [cervical, cervicothoracic, thoracic or thoracolumbar; includes codes 0R533ZZ, 0R534ZZ, 0R553ZZ, 0R554ZZ, 0R593ZZ, 0R594ZZ, 0R5B3ZZ, 0R5B4ZZ]
0RB33ZZ-0RBB4ZZ	Excision of vertebral disc, percutaneous or percutaneous endoscopic approach [cervical, cervicothoracic, thoracic or thoracolumbar; includes codes 0RB33ZZ, 0RB34ZZ, 0RB53ZZ, 0RB54ZZ, 0RB93ZZ, 0RB94ZZ, 0RBB3ZZ, 0RBB4ZZ]
0RN33ZZ-0RNB4ZZ	Release vertebral disc, percutaneous or percutaneous endoscopic approach [cervical, cervicothoracic, thoracic or thoracolumbar; includes codes 0RN33ZZ, 0RN34ZZ, 0RN53ZZ, 0RN54ZZ, 0RN93ZZ, 0RN94ZZ, 0RNB3ZZ, 0RNB4ZZ]
0S523ZZ-0S544ZZ	Destruction of vertebral disc, percutaneous or percutaneous endoscopic approach [lumbar or lumbosacral; includes codes 0S523ZZ, 0S524ZZ, 0S543ZZ, 0S544ZZ]
0SB23ZZ-0SB44ZZ	Excision of vertebral disc, percutaneous or percutaneous endoscopic approach [lumbar or lumbosacral; includes codes 0SB23ZZ, 0SB24ZZ, 0SB43ZZ, 0SB44ZZ]
0SN23ZZ-0SN44ZZ	Release vertebral disc, percutaneous or percutaneous endoscopic approach [lumbar or lumbosacral; includes codes 0SN23ZZ, 0SN24ZZ, 0SN43ZZ, 0SN44ZZ]

ICD-10 Diagnosis	
	All diagnoses

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Index

AccuraScope DND
Automated Percutaneous Lumbar Discectomy (APLD)

Baxano iO-Flex® System
Cervical cage
Cervical Deuk Laser Disc Repair
Coblation
Disc Decompression
Discectomy

Disc-FX™ System
DTRAX
Herniatome Percutaneous Discectomy Device
Jho Procedure
Laser Discectomy
Microendoscopic Discectomy
Minimally Invasive Lumbar Decompression (MILD)
Nucleoplasty
Nucleotome Probe Set
Percutaneous Endoscopic Discectomy
Providence Cervical Cage

Selective Endoscopic Discectomy™(SED™)
Stryker DeKompressor Percutaneous Discectomy Probe
Yeung Endoscopic Spinal System (Y.E.S.S.)

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
	09/27/2023	Updated Coding section; added HCPCS code C2614.
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References section.
Reviewed	05/12/2022	MPTAC review. References were updated.
Reviewed	05/13/2021	MPTAC review. References and Index sections were updated.
Reviewed	05/14/2020	MPTAC review. The Background, Index and References sections were updated.
Reviewed	06/06/2019	MPTAC review. Rationale, References, and Websites sections updated.
Reviewed	07/26/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Rationale, References, and Websites sections updated.
Reviewed	08/03/2017	MPTAC review. Updated the Description/Scope, Rationale, Background/Overview, References, Websites for Additional Information, Index and History sections.
	01/01/2017	Updated Coding section with 01/01/2017 CPT changes and clarified Description/Scope section.
Reviewed	08/04/2016	MPTAC review. Updated the Description/Scope, Rationale, Definitions, Reference, Index and History sections. Removed ICD-9 codes from Coding section.
Reviewed	08/06/2015	MPTAC review. Updated Rationale, References and History sections.
Reviewed	08/14/2014	MPTAC review. Updated Rationale, References and History sections.
Reviewed	08/08/2013	MPTAC review. Updated document to address minimally invasive lumbar decompression (MILD). Updated Description/Scope, Rationale, Background/Overview, Definitions, References, Index and History sections.
Reviewed	05/09/2013	MPTAC review. References updated.
Reviewed	05/10/2012	MPTAC review. Rationale, Background, Definitions and References updated.
	01/01/2012	Updated Coding section with 01/01/2012 CPT code descriptor changes.
Reviewed	05/19/2011	MPTAC review. Description, Rationale, Background, Definitions and References updated. Updated Coding section with 07/01/2011 CPT and HCPCS changes; removed C9729 deleted 06/30/2011.
Reviewed	02/17/2011	MPTAC review. Description clarified. Additional information added to Rationale and Definitions. References updated. Updated Coding section with 04/01/2011 HCPCS changes.
	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

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.