Title: Automated Percutaneous and Percutaneous Endoscopic Discectomy

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DESCRIPTION
Surgical management of herniated intervertebral discs most commonly involves discectomy or microdiscectomy, performed manually through an open incision. Automated percutaneous discectomy involves placement of a probe within the intervertebral disc under image guidance with aspiration of disc material using a suction cutting device. Removal of disc herniations under endoscopic visualization is also being investigated. Endoscopic discectomy involves the percutaneous placement of a working channel under image guidance, followed by visualization of the working space and instruments through an endoscope, and aspiration of disc material.

Objective
The objective of this evidence review is to evaluate whether the use of automated percutaneous discectomy or endoscopic percutaneous discectomy improves the net health outcome in individuals with herniated intervertebral discs.

Background
Back pain or radiculopathy related to herniated discs is an extremely common condition and a frequent cause of chronic disability. Although many cases of acute low back pain and radiculopathy will resolve with conservative care, surgical decompression is often considered when the pain is unimproved after several months and is clearly neuropathic in origin, resulting from irritation of the nerve roots. Open surgical treatment typically consists of discectomy in which the extruding disc material is excised. When performed with an operating microscope, the procedure is known as microdiscectomy.

Minimally invasive options have also been researched, in which some portion of the disc is removed or ablated, although these techniques are not precisely targeted at the offending extruding disc material. Ablative techniques include laser discectomy and radiofrequency decompression. Intradiscal electrothermal annuloplasty is another minimally invasive approach to low back pain. In this technique, radiofrequency energy is used to treat the surrounding disc annulus.

This policy addresses automated percutaneous and endoscopic discectomy, in which the disc decompression is accomplished by the physical removal of disc material rather than its ablation. Traditionally, discectomy was performed manually through an open incision, using cutting forceps to remove nuclear material from within the disc annulus. This technique was modified by automated devices that involve placement of a probe within the intervertebral disc and aspiration of disc material using a suction cutting device. Endoscopic techniques may be intradiscal or may involve the extraction of noncontained and sequestered disc fragments from inside the spinal canal using an interlaminar or transforaminal approach. Following insertion of the endoscope, decompression is performed under visual control.
Regulatory Status
The DeKompressor® Percutaneous Discectomy Probe (Stryker), Herniatome Percutaneous Discectomy Device (Gallini Medical Devices), and the Nucleotome® (Clarus Medical) are examples of percutaneous discectomy devices that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA indication for these products is for “aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine.” FDA product code: HRX

A variety of endoscopes and associated surgical instruments have also been cleared for marketing by FDA through the 510(k) process.

POLICY
A. Automated percutaneous discectomy is considered experimental / investigational as a technique of intervertebral disc decompression in patients with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine.

B. Percutaneous endoscopic discectomy is considered experimental / investigational as a technique of intervertebral disc decompression in patients with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine.

RATIONALE
This evidence review has been updated with searches of the MEDLINE database. The most recent literature update was performed through April 18, 2019.

The following is based on a view of the evidence, including, but not limited to, published evidence and clinical expert opinion, via BCBSA's Clinical Input Process.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality
and credibility of the evidence depend on study design and conduct, minimizing bias and
confounding that can generate incorrect findings. The randomized controlled trial (RCT) is
preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be
adequate. RCTs are rarely large enough or long enough to capture less common adverse events
and long-term effects. Other types of studies can be used for these purposes and to assess
generalizability to broader clinical populations and settings of clinical practice.

Automated Percutaneous Discectomy
Clinical Context and Therapy Purpose
The purpose of automated percutaneous discectomy in patients who have herniated
intervertebral disc(s) is to provide a treatment option that is an alternative to or an improvement
on existing therapies.

The question addressed in this evidence review is: Does the use of automated percutaneous
discectomy improve the net health outcome in individuals with herniated intervertebral disc(s)?

The following PICOs were used to select literature to inform this review.

Patients
The relevant population of interest is individual with herniated intervertebral disc(s).

Interventions
The therapy being considered is automated percutaneous discectomy.

Percutaneous discectomy is provided in a hospital setting with specialized staff and equipped to
perform the surgical procedure and postsurgical care.

Comparators
The following therapies and practices are currently being used to treat herniated intervertebral
disc(s): conservative therapy and open discectomy or microdiscectomy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, and
treatment-related morbidity. Specific outcomes measured by specific instruments include
improvements in functional outcomes assessed on the Oswestry Disability Index (ODI),
reductions in pain using a visual analog scale (VAS), improvements in quality of life measured on
the 36-Item Short-Form Health Survey (SF-36) and Euro-QOL-5D, and reductions in medication
usage.

To assess outcomes, follow-up at 1 year is considered appropriate.

Study Selection Criteria
a. Methodologically credible studies were selected using the following principles:
   To assess efficacy outcomes, comparative controlled prospective trials were sought, with a
   preference for RCTs;
   b. In the absence of such trials, comparative observational studies were sought, with a
   preference for prospective studies.
   c. To assess longer term outcomes and adverse events, single-arm studies that capture longer
   periods of follow-up and/or larger populations were sought.
Systematic Reviews
A systematic review and network meta-analysis by Lewis et al (2015) compared trials of 21 different treatment strategies for sciatica. Examples of the 21 treatment strategies included in the analysis are conservative care, disc surgery, intraoperative interventions, epidural injections, biologic agents, and percutaneous discectomy. Under the category of "percutaneous discectomy," reviewers combined automated percutaneous discectomy, percutaneous automated nucleotomy, nucleoplasty, and laser discectomy. They searched 28 databases and trial registries through December 2009. Ninety studies were included and 10 involved the percutaneous discectomy category as an intervention. Of the 10, 4 are relevant to this evidence review: 2 case-control studies of percutaneous endoscopic discectomy (2006, 2007), 1 RCT of percutaneous endoscopic discectomy (1993), and 1 RCT of automated percutaneous discectomy (1995). The remaining studies were published in a foreign language or involved other comparators (nucleolysis, chemonucleolysis). The global effects odds ratio for the category of percutaneous discectomy compared with inactive control was 0.82 (95% confidence interval, 0.39 to 1.72), which was inferior to disc surgery, epidural injections, and intraoperative interventions. The pain intensity weighted mean difference for the category of percutaneous discectomy compared with inactive control was 11.5 (95% confidence interval, -18.6 to 41.6). Reviewers concluded that there was no support for the effectiveness of percutaneous discectomy for the treatment of sciatica. Due to the inclusion of additional interventions into the broad category of percutaneous discectomy in this review, the relevance of these results to this evidence review is limited.

A Cochrane review of literature through November 2013 by Rasouli et al (2014) evaluated 11 studies compared minimally invasive discectomy (MID) with microdiscectomy or open discectomy. Included in the MID category were 8 RCTs or quasi-RCTs on percutaneous endoscopic lumbar discectomy (PELD), 2 studies on transmuscular tubular microdiscectomy, and 1 study on automated percutaneous lumbar discectomy (APLD). Seven of the studies had a high risk of bias. For the analysis, reviewers combined all MID procedures. They reported that MID may be inferior in terms of relief of leg and low back pain, and rehospitalizations; however, differences in pain relief appeared to be small and might not be clinically meaningful. Potential advantages of MID included a lower risk of surgical site infection and shorter length of stay (LOS).

Manchikanti et al (2013) conducted 2 systematic reviews. One investigated the effectiveness of APLD, with a search of databases from 1966 to September 2012. Studies were included if the following criteria were met: for RCTs, greater than 50% of the criteria adapted from the Cochrane Back Review Group; for cohort studies, 7 of 10 criteria from the Newcastle-Ottawa Scale for assessing the quality for cohort studies; and for case-control studies, 5 of 10 criteria from the Newcastle-Ottawa Scale for case-control studies. No RCTs met the inclusion criteria. Nineteen observational studies met the criteria and were identified for this review. With no RCTs meeting the criteria, a meta-analysis could not be performed. Within the 19 observational studies, 5515 patients underwent automated percutaneous discectomy, with 4412 reporting positive results. The range of positive results reported in the studies was 45% to 88%. Despite a large number of studies, reviewers concluded that the literature was limited, because no RCTs met quality inclusion criteria and because the most recent study, published in 2010, reported results from a study conducted in 2000-2002. The second review by Manchikanti et al (2013) focused specifically on disc decompression using the Dekompressor. This review used the same criteria described above. No RCTs met the study inclusion criteria; 3 observational studies did and
were included. Reviewers acknowledged that the Dekompressor appeared to decrease pain, but because meta-analysis could not be conducted, the 3 trials selected were relatively small (total N=164 patients), and none provided follow-up data beyond 8 years, they concluded the evidence was limited for use of the Dekompressor device for the treatment of lumbar disc herniation.

Vorobeychik et al (2012) and Singh et al (2009) also conducted reviews on the Dekompressor. Vorobeychik identified the same 3 observational studies as Manchikanti et al (2013) plus a case series, while Singh identified the same observational studies as Manchikanti et al (2013). The authors of both reviews also concluded that pain relief was achieved, but the evidence lacked sufficient rigor to support conclusions.

Hirsch et al (2009) published a systematic review on APLD, searching databases from 1966 to April 2009. Cochrane review criteria (50 of 100 points were needed for inclusion) were used to assess the quality of RCTs and Agency for Healthcare Research and Quality criteria (50 of 100 points were needed for inclusion) were used to assess observational studies. Reviewers assessed 4 RCTs and 76 observational studies evaluating APLD. One RCT (by Revel et al [1993]) met inclusion criteria and is detailed in the next section on RCTs. The other 3 RCTs failed to meet study quality criteria. In discussing the results of the Revel trial, which showed a lower success rate than the observational studies, reviewers noted that APLD might not have been successful in this trial due to inappropriate patient selection, failure to recruit the number of patients indicated by sample size calculations, and lack of follow-up beyond 6 months. Ten observational studies met methodologic quality criteria for inclusion. Results were consistent among the observational studies, showing APLD effective among approximately 75% of patients. APLD appeared to compare favorably with open discectomy, microdiscectomy, and chymopapain injection, though evidence lacked RCTs. The evidence for the use of APLD for short- and long-term pain relief was assessed as level II-2 (well-designed cohort or case-control studies), using the U.S. Preventive Services Task Force criteria.

Freeman and Mehdian (2008) assessed the evidence for 3 minimally invasive techniques used to treat discogenic low back pain and radicular pain: electrothermal therapy (intradiscal electrothermal therapy), percutaneous discectomy, and nucleoplasty. They reported that trials of automated percutaneous discectomy suggested clinical outcomes were at best fair and often worse than with microdiscectomy.

Gibson and Waddell (2007) updated a Cochrane review on surgical interventions for lumbar disc prolapse, concluding that there was insufficient evidence on percutaneous discectomy techniques to draw firm conclusions. In the same year, a task force of the American Society of Interventional Pain Physicians reported that percutaneous disc decompression remained controversial. Although all observational studies provided positive findings, the evidence from 4 randomized trials was negative. Questions also lingered about appropriate patient selection criteria for this procedure, particularly related to the size and migration of the disc herniation.

Randomized Controlled Trials
The RCTs described next were considered poor quality and, in general, failed to meet most inclusion criteria of the systematic reviews discussed above.

The 2002 LAPDOG trial compared automated percutaneous discectomy with open discectomy in patients with lumbar disc herniation. Enrolled patients had no prior lumbar spinal surgery, no
coexistent lumbar spinal disease, and radiographic evidence of disc herniation. The trial was designed to recruit 330 patients but enrolled 36 patients for reasons not readily apparent. Twenty-seven patients were available at follow-up, with efficacy reported by 41% of those undergoing automated percutaneous discectomy and by 40% of those undergoing open discectomy. The trialists concluded that "It is difficult to understand the remarkable persistence of percutaneous discectomy in the face of a virtually complete lack of scientific support for its effectiveness in treated lumbar disc herniation."

Chatterjee et al (1995) reported on 71 patients with lumbar disc herniation randomized to percutaneous discectomy or to lumbar microdiscectomy. A satisfactory outcome was reported in 29% of patients undergoing percutaneous discectomy compared with 80% in the microdiscectomy group. The trial was terminated early due to the inferior outcome.

Revel et al (1993) compared percutaneous discectomy with chymopapain injection in 141 patients with disc herniation and sciatica in a randomized trial. Treatment was considered successful in 61% of patients in the chymopapain group and in 44% of patients in the percutaneous discectomy group. Thirty-two patients withdrew from the trial, citing therapeutic failure. Within 6 months of the trial, 20% of the patients underwent open laminectomy.

No additional RCTs have been identified since the 2002 LAPDOG trial. All trials have focused on lumbar disc herniation. There were no RCTs of percutaneous discectomy for cervical or thoracic disc herniation. A review of the evidence from American Society of Interventional Pain Physicians (2013) noted that "even though Dekompressor may be considered a new interventional modality, the early studies were published approximately 8 years ago. Consequently, one would expect that the technique's continued use would be supported by more recent, high-quality evaluations."

**Section Summary: Automated Percutaneous Discectomy**
The evidence for automated percutaneous discectomy in individuals who have herniated intervertebral disc(s) includes small RCTs and systematic reviews of RCTs. Evidence from small RCTs does not support the use of this procedure. Well-designed and executed RCTs are needed to determine the benefits and risks of this procedure. Clinical input suggests this intervention may be an appropriate treatment option for the highly selected patient who has a small focal disc fragment compressing a lumbar nerve causing radiculopathy in the absence of lumbar stenosis or severe bony foraminal stenosis. However, the clinical input is not generally supportive of a clinically meaningful improvement in net health outcome. Further details from clinical input included in the Clinical Input section later in the review and the Appendix.

**Percutaneous Endoscopic Discectomy**
Clinical Context and Therapy Purpose
The purpose of percutaneous endoscopic discectomy in patients who have herniated intervertebral disc(s) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of percutaneous endoscopic discectomy improve the net health outcome in individuals with herniated intervertebral disc(s)?

The following PICOs were used to select literature to inform this review.
Patients
The relevant population of interest is individual with herniated intervertebral disc(s).

Interventions
The therapy being considered is percutaneous endoscopic discectomy.

Comparators
The following therapies and practices are currently being used to treat herniated intervertebral disc(s): conservative therapy and open discectomy or microdiscectomy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Specific outcomes measured by specific instruments include improvements in functional outcomes assessed on the ODI, reductions in pain using a VAS, improvements in quality of life measured on the SF-36 and Euro-QOL-5D, and reductions in medication usage.

To assess outcomes, follow-up at 1 year is considered appropriate.

Percutaneous endoscopic discectomy is provided in a hospital setting with specialized staff and equipped to perform the surgical procedure and postsurgical care.

Study Selection Criteria
a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Systematic Reviews
A number of systematic reviews have compared endoscopic discectomy to open discectomy or MED.

Yu et al (2019) compared percutaneous transforaminal endoscopic discectomy to MED in a systematic review of 8 comparative studies with a total of 805 patients.15 Hospital stay, time in bed, incision length were shorter with PTED, but there were not differences between the interventions in surgical time or intraoperative blood loss. VAS back and leg pain scores were similar between groups at most time points, with the exception of lower leg pain VAS score at 1 week in the PTED group.

Phan et al (2017) published a systematic review and meta-analysis comparing full endoscopic discectomy (FED) and microendoscopic discectomy (MED) with open discectomy for the treatment of lumbar disc herniation.16 A database search through February 2016 identified 23 studies for inclusion. FED was favorable compared with open discectomy in surgery duration, hospital LOS, and blood loss. MED was favorable compared with open discectomy in terms of LOS and blood loss. Both endoscopic procedures were comparable to open discectomy, as
measured on a VAS for leg pain and ODI score. In terms of patient satisfaction, FED was more favorable than open discectomy, and MED was comparable to open discectomy.

A systematic review and meta-analysis published by Li et al (2016) compared FED with traditional discectomy surgery. A literature search was conducted in January 2015 and resulted in the inclusion of 4 RCTs and 2 non-RCTs. FED for herniation (both cervical and lumbar) was favorable compared with traditional discectomy in surgery duration, blood loss, LOS, and return to work days. Clinical outcomes were comparable between FED and traditional discectomy.

A meta-analysis by Cong et al (2016) identified 9 RCTs (total N=1092 patients) published through August 2014 that compared endoscopic with open discectomy for lumbar disc herniation. Endoscopic discectomy resulted in clinical outcomes similar to open discectomy, but had significantly greater patient satisfaction, lower intraoperative blood loss, and shorter hospital LOS.

Smith et al (2013) published a systematic review of endoscopic discectomy for lumbar disc herniation. A search for controlled trials published through September 2012 identified 4 RCTs. None found a significant difference in ODI scores for endoscopic discectomy compared with open discectomy or microdiscectomy. The largest study (Teli et al [2010], described below; N=240) reported an increase in the number of severe complications in the MED group. Another trial (Garg et al [2011], also described below; N=112) found a shorter hospital LOS with no significant changes in ODI scores or complication rates but recommended that MED not be attempted without appropriate training. The 2 other trials included in the review were small, with 22 and 40 patients.

**Randomized Controlled Trials**

Several of the larger trials included in the systematic reviews above, larger trials on cervical disc herniation, and trials published subsequent to the systematic review literature searches are discussed next.

Wang et al (2019) compared percutaneous transforaminal endoscopic discectomy to MED in a RCT of 90 patients with lumbar disc herniation at a single center in China. Patients in the percutaneous transforaminal endoscopic discectomy group had significantly better surgical and immediate postoperative outcomes (length of surgical incision, bleeding, postoperative bedridden time and hospital stay), while the MED group had shorter surgical time. Both groups improved from baseline on low back pain VAS scores at 3 days, 3 months, and 6 months. Both groups also improved on ODI scores and there were no differences between groups postoperatively or up to 6 months after surgery.

Chen et al (2018) published an RCT comparing percutaneous transforaminal endoscopic discectomy with MED. Patients with persistent signs and symptoms of radiculopathy with corresponding imaging-confirmed lumbar disc herniation were randomized to percutaneous transforaminal endoscopic discectomy (n=80) or the MED group (n=73). Of 153 patients randomized, 89.5% (137 patients) completed 1 year of follow-up. Primary (ODI score 1 year after surgery) and secondary outcomes (SF-36, Euro-QOL-5D, and VAS scores for back pain and leg pain) did not differ significantly between the treatment groups at each prespecified follow-up point (p>0.05). The total complication rate over 1 year was 13.75% in the percutaneous transforaminal endoscopic discectomy group and 16.44% in the MED group (p=0.642).
Gibson et al (2017) published an RCT comparing transforaminal endoscopic discectomy with microdiscectomy.24 Patients with single-level lumbar prolapse and radiculopathy were randomized to transforaminal endoscopic discectomy under conscious sedation (n=70) or to microdiscectomy under general anesthesia (n=70). Both procedures resulted in comparable improvements in outcomes (ODI scores, VAS back pain, VAS leg pain, SF-36 scores) at 3 months, 1 year, and 2 years compared with baseline.

Eight-year follow-up from a quasi-RCT assessing endoscopic lumbar discectomy and open discectomy was reported by Hussein et al (2014).25 The trial included 185 patients with a large uncontained lumbar disc herniation. Surgery times were similar for both groups. Postsurgical mean hospital LOS was 10.4 hours for the endoscopic group and 82.38 hours (p<0.05) for the open group. Mean time to return to work/normal activities after endoscopic surgery (8.5 days) was significantly shorter than after open surgery (31.4 days; p<0.05). The percentages of adverse events were similar between groups, and 8.1% of patients in each group required reoperation during the follow-up. Improvements in leg pain (1.05), back pain (1.43), and ODI scores (21.5%) persisted at 8 years in the endoscopic group but deteriorated for back pain (7.53) and ODI scores (59.6%) in the open group.

Garg et al (2011) reported on a trial randomizing 112 patients with a single-level disc herniation to microendoscopic lumbar discectomy or to open discectomy.21 The method of randomization and whether patients and assessors were blinded were not reported. Surgical time was significantly longer in the endoscopic group (84 minutes vs 56 minutes) while blood loss (41 mL vs 306 mL), and hospital LOS (3 days vs 12 days) were reduced. ODI scores were similar at baseline (endoscopic, 25.78 vs open discectomy, 21.02) and all follow-up visits through 1 year postoperatively (endoscopic; 1.75 vs open discectomy 2.14).

Teli et al (2010) reported on an RCT comparing endoscopic discectomy with microdiscectomy or open discectomy in 240 patients with posterior lumbar disc herniation.20 Most herniations (60%) were extrusions. The average surgical time was longer in the endoscopic group (56 minutes) than in the micro- or open discectomy groups (43 minutes and 36 minutes, respectively). Follow-up assessments were performed at 6, 12, and 24 months by an independent investigator; 212 (91%) patients completed the 24-month evaluation. Intention-to-treat analysis showed no significant differences in outcomes (VAS, ODI, and SF-36 scores). The endoscopic procedure led to more dural tears (8.7% vs 2.7% or 3%), root injuries (3% vs 0% or 0%), and recurrent herniations (11.4% vs 4.2% or 3%) than the microdiscectomy or open approaches, respectively, although differences were not statistically significant.

Ruetten et al (2008, 2009) published 4 RCTs comparing FED with conventional techniques in the lumbar and cervical spine.26,27,28,29 All studies were randomized or quasi-randomized, with assignment described as order of presentation or balanced block. Follow-up examinations were conducted at day 1 and at months 3, 6, 12, and 24 by physicians not involved in the surgeries. The 4 trials were not blinded due to observable differences in the surgical approaches, and are described below.

• Patients with mediolateral cervical disc herniations (N=120) were randomized to full endoscopic anterior decompression or to conventional anterior cervical decompression with fusion (ACDF).29 Mean surgery time was 32 minutes for full endoscopic anterior decompression and 62 minutes for ACDF. At 24 months, 103 (86%) patients were available...
for follow-up examinations. Revision rates for ACDF (6.1%) and full endoscopic anterior decompression (7.4%) did not differ significantly. There were no significant differences in clinical outcomes (pain, VAS arm, VAS neck) between groups.

- Patients with clinically symptomatic lateral cervical disc herniation (N=200) were randomized to full endoscopic posterior cervical foraminotomy or conventional microsurgical ACDF. At 24 months postsurgery, 175 (88%) patients were available for follow-up. Ten patients had revisions due to persistent arm pain, recurrences of herniation, or failure of the implant (6 endoscopic patients, 4 ACDF). Postoperative pain was significantly reduced in the endoscopic group (data not reported), and postoperative work disability was shorter (19 days vs 34 days). Other clinical outcomes (VAS scores for neck and arm pain, a German version of the North American Spine Society Instrument [Hilibrand criteria]) were similar between groups throughout the 24-month follow-up.

- Patients with clinically symptomatic lumbar disc herniation (N=200) were randomized to FED or to conventional microdiscectomy. Mean surgery time for endoscopic discectomy (22 minutes) was nearly 50% faster than for conventional microdiscectomy (43 minutes), and the complication rate was significantly lower. Postoperative pain and pain medication usage were significantly reduced in the endoscopic group (data not reported), and the postoperative work disability was shorter (25 days vs 49 days). At 24 months after surgery, 178 (89%) patients were available for follow-up. The 2 groups had similar reductions in leg pain, with 85% of endoscopic discectomy and 79% of microdiscectomy patients reporting being pain-free. More patients in the microdiscectomy group (5% vs 1%) underwent revision spinal canal expansion and fusion.

- Patients with recurrent lumbar disc herniation following conventional discectomy who were in need of a revision (N=100) were randomized to FED or to conventional microdiscectomy. Surgery time was significantly shorter with the endoscopic approach (24 minutes vs 58 minutes), and access-related osseous resection was much less frequent in the endoscopic group (3 [6%] cases vs 47 [94%] cases). There were 4 cases of dura injury (1 endoscopic discectomy, 3 microdiscectomy). Overall, serious complication rates were significantly higher in the microdiscectomy group (21% vs 6%). Postoperative pain and pain medication usage were significantly reduced in the endoscopic group, as was postoperative work disability (28 days vs 52 days). At 24 months, 87 (87%) patients were available for follow-up. Seventy-nine percent had no leg pain at follow-up, and there were no significant differences between groups in clinical outcomes (VAS, North American Spine Society Instrument, ODI scores).

An RCT by Hermantin et al (1999) was rated as having a low risk of bias in the 2014 Cochrane review. Sixty patients who had objective evidence of a single intracanalicular herniation of a lumbar disc were randomized into 2 groups: endoscopic microdiscectomy or open laminotomy and discectomy. A similar percentage of patients was considered to have a satisfactory outcome (97% of the microendoscopic group vs 93% of the open group). The mean duration of narcotic pain relief use (7 days vs 25 days) and return to work (27 days vs 49 days) were significantly reduced in the microendoscopic group. This trial did not use validated outcome measures.

**Observational Studies**

Gotecha et al (2016) published a prospective study on the use of transforaminal PELD for the treatment of lumbar disc herniation. Efficacy and limitations of the procedure were studied on 120 patients with lumbar disc herniation. Using McNab criteria, 89% achieved excellent (no pain or restrictions) or good (occasional back/leg pain) status at 6 months of follow-up. The authors noted a limitation of the procedure is that during surgery on patients with L5 through S1 lumbar
disc herniation, the iliac crest may interfere with the angle necessary to perform a successful discectomy.

A number of observational studies have also assessed the learning curve\textsuperscript{32,22,33} and the need for longer follow-up for endoscopic discectomy.\textsuperscript{34,35,36} The largest and longest follow-up to date has been reported by Choi et al (2015), who examined 10,228 patients at their institution who had had PELD over a 12-year period.\textsuperscript{36} They found that 4.3% of cases required reoperation in the first 6 weeks due to incomplete removal of herniated discs (2.8%), recurrence (0.8%), persistent pain (0.4%), and approach-related pain (0.2%).

Section Summary: Percutaneous Endoscopic Discectomy
The evidence for percutaneous endoscopic discectomy in individuals who have herniated intervertebral disc(s) includes a number of RCTs and systematic reviews of RCTs. Many of the RCTs were conducted at a single center in Europe. Some trials have reported outcomes at least as good as traditional approaches with an open incision, while an RCT from a different center in Europe reported a trend toward increased complications and reherniations using an endoscopic approach. There are few reports from the United States. Clinical input suggests this intervention may be an appropriate treatment option for the highly selected patient who has a small focal disc herniation causing lumbar radiculopathy according to clinical input expert opinion. However, respondents were mixed in the level of support of this indication, and overall there was not a preponderance of clinical input support in general cases. Further details from clinical input included in the Clinical Input section later in the review and the Appendix.

Summary of Evidence
The following conclusions are based on a view of the evidence, including, but not limited to, published evidence and clinical expert opinion, via BCBSA’s Clinical Input Process.

For individuals who have herniated intervertebral disc(s) who receive automated percutaneous discectomy, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The published evidence from small RCTs is insufficient to evaluate the impact of automated percutaneous discectomy on the net health outcome. Well-designed and executed RCTs are needed to determine the benefits and risks of this procedure. Clinical input suggests this intervention may be an appropriate treatment option for the highly selected patient who has a small focal disc fragment compressing a lumbar nerve causing radiculopathy in the absence of lumbar stenosis or severe bony foraminal stenosis. However, the clinical input is not generally supportive of a clinically meaningful improvement in net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have herniated intervertebral disc(s) who receive percutaneous endoscopic discectomy, the evidence includes a number of RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Many of the RCTs were conducted at a single center in Europe. Some trials have reported outcomes at least as good as traditional approaches with an open incision, while 1 RCT from a different center in Europe reported a trend toward increased complications and reherniations using an endoscopic approach. There are few reports from the United States. Clinical input suggests this intervention may be an appropriate treatment option for the highly selected patient who has a small focal disc herniation causing lumbar radiculopathy according to clinical input.
expert opinion. However, respondents were mixed in the level of support of this indication, and overall there was not a preponderance of clinical input support in general cases. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Clinical Input From Physician Specialty Societies and Academic Medical Centers**
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

**2018 Input**
In response to requests, clinical input on automated percutaneous discectomy and percutaneous endoscopic discectomy for herniated intervertebral disc(s) was received from 3 respondents, including 2 specialty society-level responses and including physicians with academic medical center affiliation, while this policy was under review in 2018.

Evidence from clinical input is integrated within the Rationale section summaries and the Summary of Evidence.

**2013 Input**
In response to requests, input was received from 4 physician specialty societies and 3 academic medical centers while this policy was under review in 2013. Overall, input agreed that percutaneous and endoscopic discectomy are investigational. Most reviewers considered discectomy with tubular retractors to be a variant of open discectomy, with the only difference being the type of retraction used.

**Practice Guidelines and Position Statements**

**National Institute for Health and Care Excellence**
The National Institute for Health and Care Excellence (NICE; 2005) published guidance on automated percutaneous mechanical lumbar discectomy, indicating there was limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, and evidence from small RCTs showed conflicting results. The guidance indicated that, in view of uncertainty about the efficacy of the procedure, it should not be done without special arrangements for consent and for audit or research. The guidance was considered for an update in 2009, but failed review criteria; the 2005 guidance is therefore considered current.

A NICE (2016) guidance on percutaneous transforaminal endoscopic lumbar discectomy for sciatica was published. The guidance stated that current evidence is adequate to support the use of percutaneous transforaminal endoscopic lumbar discectomy for sciatica. Choice of operative procedure (open discectomy, microdiscectomy, or percutaneous endoscopic approaches) may be influenced by symptoms, location, and size of the prolapsed disc.

A NICE (2016) guidance on percutaneous interlaminar endoscopic lumbar discectomy for sciatica was also published. The guidance stated that current evidence is adequate to support the use of percutaneous interlaminar endoscopic lumbar discectomy for sciatica. Choice of operative procedure (open discectomy, microdiscectomy, or percutaneous endoscopic approaches) may be influenced by symptoms, location, and size of the prolapsed disc.
American Society of Interventional Pain Physicians
The guidelines from the American Society of Interventional Pain Physicians (2013) indicated that the evidence for percutaneous disc decompression with the Dekompressor was limited.14 There were no recommended indications for the Dekompressor.

North American Spine Society
The North American Spine Society (2014) published clinical guidelines on the diagnosis and treatment of lumbar disc herniation.40 Table 1 summarizes recommendations specific to percutaneous endoscopic discectomy and automated percutaneous discectomy.

Table 1. Recommendations for Lumbar Disc Herniation With Radiculopathy

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Grade or LOEa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscopic percutaneous discectomy is suggested for carefully selected patients to reduce early postoperative disability and reduce opioid use compared with open discectomy.</td>
<td>B</td>
</tr>
<tr>
<td>There is insufficient evidence to make a recommendation for or against the use of automated percutaneous discectomy compared with open discectomy.</td>
<td>I</td>
</tr>
<tr>
<td>Endoscopic percutaneous discectomy may be considered for treatment.</td>
<td>C</td>
</tr>
<tr>
<td>Automated percutaneous discectomy may be considered for treatment.</td>
<td>C</td>
</tr>
<tr>
<td>Patients undergoing percutaneous endoscopic discectomy experience better outcomes if &lt;40 years and symptom duration &lt;3 months.</td>
<td>II</td>
</tr>
</tbody>
</table>

LOE: level of evidence.

a Grade B: fair evidence (level II or III studies with consistent findings; grade C: poor quality evidence (level IV or V studies). Level of evidence II: lesser quality randomized controlled trial (eg, <80% follow-up, no blinding, or improper randomization), prospective comparative study, systematic review of level II studies or level I studies with inconsistent results; level of evidence III: case control, retrospective, systematic review of level III studies; level of evidence IV: case series; level of evidence V: expert opinion.

American Pain Society
The clinical practice guidelines from the American Pain Society (2009) found insufficient evidence to evaluate alternative surgical methods to standard open discectomy and microdiscectomy, including laser or endoscopic-assisted techniques, various percutaneous techniques, coblation nucleoplasty, or the Dekompressor.41

U.S. Preventive Services Task Force Recommendations
Not applicable.

Ongoing and Unpublished Clinical Trials
Currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>(Cost) Effectiveness of Percutaneous Transforaminal Endoscopic Discectomy vs. Open Microdiscectomy for Patients With Symptomatic Lumbar Disc Herniation</td>
<td>682</td>
<td>Dec 2019</td>
</tr>
<tr>
<td>Unpublished</td>
<td>EuroPainClinics® Study V Prospective Observational Study (EPCSV)</td>
<td>500</td>
<td>Jan 2019 (unknown)</td>
</tr>
<tr>
<td></td>
<td>Full-Endoscopic vs Open Discectomy for the Treatment of Symptomatic Lumbar Herniated Disc: A Prospective Multi-Center Randomized Study</td>
<td>200</td>
<td>Jul 2018 (terminated)</td>
</tr>
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</table>
CODING
The following codes for treatment and procedures applicable to this policy 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. 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.

CPT/HCPCS
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 use of an endoscope, 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 (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; cervical or thoracic
0275T Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar
C2614 Probe, percutaneous lumbar discectomy

DIAGNOSIS
Experimental / Investigational for all diagnoses related to this medical policy.

REVISIONS
02-08-2010 The Automated Percutaneous Discectomy medical policy is a new freestanding policy developed from the Minimally Invasive Procedures for Spine Pain medical policy which was effective October 18, 2004. The Minimally Invasive Procedures for Spine Pain is no longer an active medical policy.
06-27-2011 Description updated.
Rationale updated.
### REVISIONS

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01-01-2012</td>
<td>In Coding section: The diagnoses codes were removed from the policy because the policy is experimental / investigational and the diagnoses codes are not needed. References updated.</td>
</tr>
<tr>
<td>02-14-2012</td>
<td>In Title: Added “and Endoscopic” to read, “Automated Percutaneous and Endoscopic Discectomy” Updated Description section</td>
</tr>
<tr>
<td></td>
<td>In Policy section: Added “Automated” to A to read, “Automated percutaneous discectomy is considered experimental / investigational as a technique of intervertebral disc decompression in patients with back pain related to disc herniation in the lumbar, thoracic, or cervical spine.” Added item B to the policy as a new criteria to read, “Endoscopic discectomy is considered experimental / investigational as a technique of intervertebral disc decompression in patients with back pain related to disc herniation in the lumbar, thoracic, or cervical spine.” Updated Rationale section Updated References</td>
</tr>
<tr>
<td>09-25-2013</td>
<td>Description section updated In Policy section: Policy statements clarified with the addition of “and/or radiculopathy” to read, &quot;A. Automated percutaneous discectomy is considered experimental / investigational as a technique of intervertebral disc decompression in patients with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine. B. Endoscopic discectomy is considered experimental / investigational as a technique of intervertebral disc decompression in patients with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine.” In Coding section: Coding information updated Rationale section updated References updated</td>
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<tr>
<td>11-06-2015</td>
<td>Description section updated Rationale section updated In Coding section: Updated Coding notations. References updated</td>
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<tr>
<td>06-09-2017</td>
<td>In Title revised to &quot;Automated Percutaneous and Percutaneous Endoscopic Discectomy&quot; from &quot;Automated Percutaneous and Endoscopic Discectomy&quot; Description section updated In Policy section: In Item B added &quot;Percutaneous&quot; to read &quot;Percutaneous endoscopic discectomy is considered experimental / investigational...&quot; Rationale section updated In Coding section: Added CPT Codes: 62380, 0274T, 0275T Added HCPCS Code: C2614 Updated coding notations. References updated</td>
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</table>
REVISIONS

01-30-2019  Rationale section updated
In Coding section:
- Coding notations updated
References updated

08-28-2019  Rationale section updated
In Coding section:
- Coding notations updated
References updated

REFERENCES


15. NA