

Automated Percutaneous and Percutaneous Endoscopic Discectomy

Effective: September 1, 2018

Next Review: July 2019

Last Review: July 2018

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

These are techniques used to remove spinal disc material for treatment of herniated discs.

MEDICAL POLICY CRITERIA

Note: This policy does *not* address intradiscal electrothermal annuloplasty (IDET), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), or laser discectomy and radiofrequency disc decompression which are considered in separate medical policies (see Cross References below).

Automated percutaneous and percutaneous endoscopic discectomy are considered **investigational** as techniques for intervertebral disc decompression in patients with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. [Percutaneous Intradiscal Electrothermal Annuloplasty \(IDET\) and Percutaneous Intradiscal Radiofrequency](#)

- [Thermocoagulation](#), Surgery, Policy No. 118
- [Decompression of Intervertebral Discs Using Laser Energy \(Laser Discectomy\) or Radiofrequency Energy \(Nucleoplasty\)](#), Surgery, Policy No. 131
- [Image-Guided Minimally Invasive Spinal Decompression \(IG-MSD\) for Spinal Stenosis](#), Surgery, Policy No. 176

BACKGROUND

Back pain or radiculopathy related to herniated discs is an extremely common condition and a frequent cause of chronic disability. Surgical decompression is often considered when the pain is unimproved with conservative therapy and is clearly neuropathic in origin, resulting from irritation of the nerve roots.

This policy addresses automated percutaneous and percutaneous endoscopic removal of disc material as minimally invasive alternatives to open surgical excision for disc decompression. Automated percutaneous discectomy involves placement of a probe within the intervertebral disc and aspiration of disc material using a suction cutting device. 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. Endoscopic discectomy may also be referred to as arthroscopic discectomy.

REGULATORY STATUS

The Stryker DeKompressor® Percutaneous Discectomy Probe (Stryker), Herniatome Percutaneous Discectomy Device (Gallini Medical Devices), and the Nucleotome® (Clarus Medical) are examples of percutaneous discectomy devices that received clearance from the U.S. Food and Drug Administration (FDA) through the 510(k) process. Both have the same labeled intended use, i.e., “for use in aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine.”

A variety of endoscopes and associated surgical instruments have received marketing clearance through the FDA’s 510(k) process.

EVIDENCE SUMMARY

The primary beneficial outcomes of interest for treatment of spinal pain are relief of pain and improved function. Both outcomes are subjective and can be influenced by nonspecific effects, placebo response, and the variable natural history of the disease. Therefore, large, blinded, randomized controlled trials (RCTs) with long-term follow-up are necessary to establish the safety and efficacy of automated percutaneous and percutaneous endoscopic discectomy compared with open surgical discectomy, the current standard of care for surgical removal of damaged intervertebral disc material. These comparisons are necessary to determine whether any beneficial treatment effects of percutaneous and endoscopic discectomy outweigh any risks and provide a significant advantage over conventional open discectomy techniques.

AUTOMATED PERCUTANEOUS DISCECTOMY (APD)

SYSTEMATIC REVIEWS

A number of systematic reviews have been published since 2007.^[1-7] Four comparative trials have been published on APD, two comparing APD to chymopapain chemonucleolysis^[8,9] and two comparing APD to microdiscectomy^[10,11]. These trials suggested that APD produced

inferior results to either of the established procedures, though the patient selection criteria may have been inappropriate in the Revel (1993) trial^[8]. The authors of the systematic reviews reached similar conclusions, that while there is considerable evidence of efficacy for conventional surgical discectomy, there is insufficient evidence on percutaneous discectomy techniques including APD to draw firm conclusions. “Trials of automated percutaneous discectomy and laser discectomy suggest that clinical outcomes following treatment are at best fair and certainly worse than after microdiscectomy, although the importance of patient selection is acknowledged.^[1]” A 2015 network meta-analysis found that percutaneous discectomy was one of the least effective treatment strategies for sciatica of 21 assessed.^[12]

The four RCTs reviewed in the systematic reviews had a number of methodological limitations including small size, high loss to follow-up, inadequate randomization procedure, between-group heterogeneity, and other significant design flaws. For example, the LAPDOG study was initially designed to recruit 330 patients, but only was able to recruit 36 patients for reasons that were not readily apparent to the authors.^[11] Of the evaluable 27 patients, 41% of the percutaneous discectomy patients and 40% of the conventional discectomy patients were assessed as having successful outcomes at six months. The authors concluded that this trial was unable to enroll sufficient numbers of patients to reach a definitive conclusion. The authors stated, “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.”

In a 2013 review for their practice guideline^[13], the American Society of Interventional Pain Physicians noted that “the available literature on Dekompessor illustrates the common shortcomings of observational studies of interventions. Even though Dekompessor may be considered a new interventional modality, the early studies were published approximately eight years ago. Consequently, one would expect that the technique’s continued use would be supported by more recent, high quality evaluations. Even though all the studies are of moderate quality, they lack scientific rigor because of their observational, albeit prospective, design. Further, these studies do not include sufficiently large numbers of patients.”

RANDOMIZED CONTROLLED TRIALS

No RCTs were identified after the search dates of the systematic review.

ENDOSCOPIC DISCECTOMY

SYSTEMATIC REVIEWS

A meta-analysis by Alvi (2018) included 14 RCTs or quasi-randomized trials (total n=1,707), and compared open/microdiscectomy (OD/MD) to minimally invasive procedures including percutaneous discectomy, percutaneous endoscopic discectomy (PED), and tubular discectomy (TD) for lumbar disc herniation.^[14] All of the studies were determined to have a serious risk of bias and were judged to be of low or very low quality. No differences were seen between groups for visual analogue scale (VAS) score. Oswestry disability index (ODI) score was lower for TD than for other procedures at one year (mean difference 1.17, 95% confidence interval [CI] 0.10 to 2.24, p=0.03), and at last follow-up, ODI scores were worse with OD/MD compared to TD and PED (mean difference 2.61, 95% CI 0.88 to 4.65, p=0.03). Open procedures were also associated with longer hospital stays and greater blood loss. TD was associated with a greater rate of complications and recurrent herniations than the other

procedures, while MD/OD had significantly lower rates of recurrent herniations and revision surgery than TD or PED.

A meta-analysis by Ding (2018) compared percutaneous transforaminal endoscopic discectomy (PTED) to fenestration discectomy (FD) in patients with lumbar disc herniation.^[15] There were 17 studies included in the analysis, and all were retrospective studies. There were 733 patients who had PTED and 657 who had FD. There was no difference between groups for VAS score, but the PTED group had shorter operation, bed rest, and hospitalization times (all $p < 0.00001$), less bleeding ($p < 0.00001$), and a lower postoperative ODI score ($p = 0.02$). Long-term outcomes were not assessed in this study.

Phan (2017) published a systematic review comparing full endoscopic discectomy (FED) and micro-endoscopic 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 length of stay (LOS), and blood loss. MED was favorable compared with open discectomy in 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. The authors concluded that FED and MED are safe alternatives to other procedures, but more RCTs are needed to investigate and validate these as options for discectomies.

Li (2016) published a systematic review comparing FED with traditional discectomy surgery.^[17] The search was conducted in January 2015 and resulted in the inclusion of four RCTs and two non-RCTs. FED for herniation (both cervical and lumbar) was favorable compared with traditional discectomy in operative duration, blood loss, length of stay, and return to work days. Clinical outcomes were comparable between FED and traditional discectomy. The authors concluded FED is effective, but larger RCTs with long-term follow-up are needed.

A 2016 meta-analysis identified nine RCTs (total $n = 1,092$ patients) that compared endoscopic to open discectomy for lumbar disc herniation.^[18] Endoscopic discectomy resulted in clinical outcomes similar to open discectomy, but had significantly greater patient satisfaction, lower intraoperative blood loss, and shorter hospital lengths of stay.

He (2016) reported results from another meta-analysis of five RCTs ($n = 501$ patients) comparing outcomes from MED and open discectomy for patients with lumbar herniation.^[19] Pooled analysis found no difference in VAS, ODI, or complication between the two groups. MED was associated with less blood loss, shorter length of hospital stay, and longer operation time.

A Cochrane review (2014) of literature through 2013 evaluated 11 studies of minimally invasive discectomy compared with microdiscectomy/open discectomy. Seven of the studies reviewed^[10,20-25] were rated as having a high risk of bias and the remaining four studies^[26-29] were rated as having a low risk of bias. Included in the review were eight RCTs or quasi-RCTs that evaluated percutaneous endoscopic lumbar discectomy.^[30] Also included were three studies on transmuscular tubular microdiscectomy and automated percutaneous lumbar discectomy. The review concluded that minimally invasive discectomy may be inferior in terms of relief of leg pain, low back pain, and rehospitalization; however, differences in pain relief appeared to be small and may not be clinically important. In addition, potential advantages of minimally invasive discectomy are a lower risk of surgical site infection and shorter hospital

stay. Because of these potential advantages, the authors concluded that more research was needed to define the indications for minimally invasive discectomy.

Smith (2013) published a systematic review of MED for lumbar disc herniation.^[31] A search was conducted for controlled trials published after the 2007. The Gibson and Waddel (2007) Cochrane review through September 2012 identified four RCTs. None of the studies found a significant difference in ODI scores compared with open discectomy or microdiscectomy. In the largest study, which included 240 patients, Teli (2010) reported an increase in the number of severe complications in the microendoscopic discectomy group.^[28] In another large study with 112 patients Garg (2011) found a shorter hospital stay with no significant changes in ODI or complication rates but recommended that microendoscopic discectomy should not be attempted without appropriate training.^[20] The two other trials included in the review were small, with 22^[21] and 40^[22] patients.

RANDOMIZED CONTROLLED TRIALS

The following is a summary of randomized or quasi-randomized trials that were not included in the above systematic reviews.

Cervical disc decompression

Ruetten (2009) compared anterior endoscopic discectomy with anterior cervical discectomy and fusion (ACDF) in 120 patients with mediolateral cervical disc herniations.^[32] The duration of pain ranged from 4 to 128 days. The mean operating time was 32 minutes for the endoscopic discectomy compared to 62 minutes for ACDF. In the endoscopic discectomy group, bone resection was required to reach the epidural space or the foramen in 55% of cases. At 24 months, 103 patients (86%) were available for follow-up examinations. The revision rate was 6.1% for ACDF and 7.4% for endoscopic discectomy; these were not significantly different. Excluding four patients who were revised by ACDF, 85 patients (85.9%) had no arm pain; there were no significant differences in clinical outcomes between the two groups. Advantages and disadvantages of the anterior endoscopic approach were discussed, including a difficult learning curve.

Lumbar disc decompression

Chen (2018) published the interim results of an ongoing trial that randomized 153 patients with lumbar disc herniation to PTED or MED.^[33] The primary outcome was ODI score one-year postsurgery. At one year, 89.5% (137) of patients completed follow-up. Primary and secondary outcomes did not differ significantly between treatment groups at prespecified follow-up points ($p>0.05$). The aggregate complication rate over the course of one year was 13.75% in the percutaneous endoscopic discectomy group and 16.44% in the MED group ($p=0.642$). Five (6.25%) patients in the PTED group and 3 (4.11%) patients in the MED group suffered from residue/recurrence of herniation, for which reoperation was required.

Gibson (2017) published a RCT comparing transforaminal endoscopic discectomy (TED) with microdiscectomy.^[34] Patients with single-level lumbar prolapse and radiculopathy were randomized to TED 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 three months, one year, and two years compared with baseline. The trial noted limitations including being non-blinded.

Hussein (2014) reported the outcomes of 200 patients randomized to either microendoscopic lumbar discectomy (n=95) or to a control group in which patients underwent open lumbar discectomy (n=90).^[35] The patients and investigators were not blinded to the treatment assignments. By eight years follow-up, data was available for 185 patients; 15 patients were lost to follow-up, 10 due to subsequent same-level fusion, three due to death unrelated to surgery, and two who did not respond to telephone calls. Relief of leg pain was statistically significant for both groups, with no significant between-group difference. Back pain was significantly improved in the endoscopic group throughout the entire follow-up period. However, in the control group the significant improvement in back pain following surgery deteriorated over time; by eight years follow-up, back pain scores in this group had worsened significantly from preoperative scores. There were no serious complications in either group.

PRACTICE GUIDELINE SUMMARY

AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS (ASIPP)^[13]

In 2013, a task force of the ASIPP published updated guidelines for interventional techniques in the management of chronic spinal pain. The evidence for APD and for percutaneous lumbar discectomy was rated as limited for short- and long-term relief based on all observational studies. An evidence rating of “limited” is defined as evidence insufficient to assess effects on health outcomes because of limited number or inadequate power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or execution, gaps in the chain of evidence, or lack of information on important health outcomes. The ASIPP concluded that this technique may be performed when indicated, but did not provide patient selection criteria. Nor was the recommendation graded; the authors indicated only that this recommendation was based on “individual experience and the large amount of literature.” Therefore, this recommendation is not considered evidence-based.

NORTH AMERICAN SPINE SOCIETY (NASS)^[36]

The 2012 practice guidelines from the NASS on the diagnosis and treatment of lumbar disc herniation with radiculopathy recommended that endoscopic percutaneous discectomy or automated percutaneous discectomy could be considered for the treatment of these patients. Both recommendations were grade C recommendations (from poor quality evidence). However, a separate recommendation stated that evidence is insufficient to recommend for or against use of automated percutaneous discectomy compared with open discectomy.

SUMMARY

There is not enough research to show that automated percutaneous or percutaneous endoscopic discectomy improves health outcomes for people with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine. Therefore, automated percutaneous or percutaneous endoscopic discectomy is considered investigational for people with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine.

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CODES

NOTE: CPT code 62287 specifically describes a percutaneous aspiration or decompression procedure of the lumbar spine. This code does not distinguish between an aspiration procedure (addressed in this policy) and a laser decompression procedure (addressed in separate medical policies). Also, note that this code is specifically limited to the lumbar region. Although the majority of percutaneous discectomies are performed on lumbar vertebrae, the FDA labeling of the Stryker DeKompressor Percutaneous Discectomy Probe includes the thoracic and cervical vertebrae.

Codes	Number	Description
CPT	62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disk, 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	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance
	64999	Unlisted procedure; nervous system
HCPCS	C2614	Probe, percutaneous lumbar discectomy

Date of Origin: October 2005