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## Medical Policy



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**\*Current Policy Effective Date: 11/1/24**  
(See policy history boxes for previous effective dates)

### **Title: Spinal Surgery: Automated Percutaneous and Endoscopic Discectomy**

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#### **Description/Background**

Traditionally, discectomy and microdiscectomy are performed manually through an open incision. Percutaneous discectomy describes techniques by which disc decompression is accomplished by the physical removal of disc material rather than its ablation. These techniques have been modified by the use of automated devices that involve placement of a probe within the intervertebral disc and aspiration of disc material using a suction cutting device. Removal of disc herniations under endoscopic visualization is also being investigated.

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, a 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 material is removed or ablated, although these techniques are not precisely targeted at the offending extruding disc material. Ablative techniques include laser discectomy and radiofrequency (RF) decompression. In addition, intradiscal electrothermal annuloplasty is another minimally invasive approach to low back pain. In this technique, RF 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. A discectomy is performed manually through an open incision, using cutting forceps to remove

nuclear material from within the disc annulus. This technique has been 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 non-contained and sequestered disc fragments from inside the spinal canal using an interlaminar or transforaminal approach. Following insertion of the endoscope, the decompression is performed under visual control.

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### **Regulatory Status:**

The Stryker DeKompressor® Percutaneous Discectomy Probe (Stryker) 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.” FDA product code: HRX.

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

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### **Medical Policy Statement**

Automated percutaneous discectomy and endoscopic discectomy are considered experimental/investigational. There is insufficient evidence obtained from well-designed and executed randomized controlled trials to evaluate the impact of automated percutaneous discectomy and endoscopic discectomy on net health outcome.

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### **Inclusionary and Exclusionary Guidelines**

N/A

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**CPT/HCPCS Level II Codes** *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

#### **Established codes:**

N/A

#### **Other codes (investigational, not medically necessary, etc.):**

62287

62380

C9757

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## Rationale

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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

## **AUTOMATED PERCUTANEOUS DISCECTOMY**

### **Clinical Context and Therapy Purpose**

The purpose of automated percutaneous discectomy in individuals who have herniated intervertebral disc(s) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

### **Populations**

The relevant population of interest are individuals 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 post-surgical 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**

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- 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 2015 systematic review and network meta-analysis by Lewis et al compared trials of 21 different treatment strategies for sciatica.<sup>1</sup> 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 the comparators nucleolysis and chemonucleolysis, rather than open discectomy or microdiscectomy. The global effects odds ratio for the category of percutaneous discectomy compared with inactive control was 0.82 (95% confidence interval [CI], 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% CI, -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 for our evidence review is limited.

## **Randomized Controlled Trials**

The 2002 LAPDOG trial compared automated percutaneous discectomy with open discectomy in patients with lumbar disc herniation.<sup>2</sup> No additional RCTs have been identified since the

2002 LAPDOG trial. 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 conventional 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." The tables below more fully describe key characteristics, results, and limitations of the LAPDOG trial.

**Table 1. Characteristics of the LAPDOG Trial**

Study	Countries	Sites	Dates	Participants	Interventions
Haines et al (2002) <sup>2</sup>	US., Canada	10	NR	Patients with predominantly unilateral leg pain or paresthesia with no previous treatment for lumbar spinal disease, at least 2 of 4 objective signs, and an imaging study confirming disc herniation at the appropriate level	Automated percutaneous discectomy vs. conventional discectomy

LAPDOG: Lumbar Automated Percutaneous Discectomy Outcomes Group; NR: not reported.

**Table 2. Results of the LAPDOG Trial**

Study	Treatment Success <sup>a</sup> (at 6 months)	Treatment Failure <sup>b</sup> (at 6 months)	SF-36 Physical Functioning Subscore	SF-36 General Health Subscore	Modified Roland Score
Haines et al (2002) <sup>2</sup>					
N	27	27	NR	NR	NR
Automated percutaneous discectomy	7 (41%)	10 (59%)	Pre- vs. postoperative mean difference: 35.7	Pre- vs. postoperative mean difference: 5.0	Pre- vs. postoperative mean difference: 9.7
Conventional discectomy	4 (40%)	6 (60%)	Pre- vs. postoperative mean difference: 36.1	Pre- vs. postoperative mean difference: 8.0	Pre- vs. postoperative mean difference: 10.6
p	0.95	0.95	0.96	0.58	0.74

LAPDOG: Lumbar Automated Percutaneous Discectomy Outcomes Group; NR: not reported; SF-36: 36-Item Short-Form Health Survey.

<sup>a</sup>Success was defined as either an excellent or good result as defined by an outcome matrix.

<sup>b</sup>Failure was defined as not achieving success or requiring a second procedure during the follow-up period.

**Table 3. Study Relevance Limitations of the LAPDOG Trial**

Study	Population <sup>a</sup>	Intervention <sup>b</sup>	Comparator <sup>c</sup>	Outcomes <sup>d</sup>	Duration of Follow-Up <sup>e</sup>
Haines et al (2002) <sup>2</sup>	4. Investigators believed that study inclusion criteria reflected an existing population with lumbar disc disease; however, results from only 27			4. Primary outcomes of "success" or "failure" largely subjective in nature; investigators admit that the outcome measurement tool	1,2. Outcomes reported only for 6 months of follow-up; 12 month follow-up was achieved for only 19

	patients were eventually analyzed from a planned enrollment of 330 patients			used cannot be precisely reproduced	patients and the study did not report any of these results
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LAPDOG: Lumbar Automated Percutaneous Discectomy Outcomes Group.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

<sup>a</sup>Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

<sup>b</sup>Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

<sup>c</sup>Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

<sup>d</sup>Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

<sup>e</sup>Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

**Table 4. Study Design and Conduct Limitations of the LAPDOG Trial**

Study	Allocation <sup>a</sup>	Blinding <sup>b</sup>	Selective Reporting <sup>c</sup>	Data Completeness <sup>d</sup>	Power <sup>e</sup>	Statistical <sup>f</sup>
Haines et al (2002) <sup>2</sup>		1,2. Blinding did not appear to occur		1. Of 34 initially randomized patients, 9 were lost to follow-up, 6 month follow-up data was obtained on only 27 patients, and 12 month follow-up data was obtained for only 19 patients	3. Power estimates led the investigators to plan enrollment of 330 patients in order to reliably identify a difference in success rate of 15% or greater; results were analyzed on 27 patients	1. Beyond the cursory discussion of lack of power, a discussion of the statistical analyses is nonexistent

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

<sup>a</sup>Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

<sup>b</sup>Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

<sup>c</sup>Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

<sup>d</sup>Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

<sup>e</sup>Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

<sup>f</sup>Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

All published trials have focused on lumbar disc herniation. There were no RCTs of automated 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 Dekompessor [disc removal system] 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."<sup>3</sup>

### 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. 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.

## **PERCUTANEOUS ENDOSCOPIC DISCECTOMY**

### **Clinical Context and Therapy Purpose**

The purpose of percutaneous endoscopic discectomy in individuals who have herniated intervertebral disc(s) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

### **Populations**

The relevant population of interest are individuals 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.

### **Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

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

### **Systematic Reviews**

A number of systematic reviews have evaluated the efficacy and safety of percutaneous endoscopic discectomy compared to open discectomy or microendoscopic discectomy. A comparison of the trials included in more recent systematic reviews (2016 to present) is shown in Table 5. The systematic reviews included a total of 67 trials published between 1993 and 2020. Characteristics and results of these reviews are summarized in Tables 6 and 7.

**Table 5. Trials Included in Systematic Reviews of Percutaneous Endoscopic Discectomy vs. Other Discectomy Procedures**

Trials	Systematic Reviews							
	Phan et al (2017) <sup>4</sup> ,	Shi et al (2019) <sup>5</sup> ,	Yu et al (2019) <sup>6</sup> ,	Zhou et al (2020) <sup>7</sup> ,	Xu et al (2020) <sup>8</sup> ,	Bai et al (2021) <sup>9</sup> ,	Gadjraj et al (2021) <sup>10</sup> ,	Zhao et al (2022) <sup>11</sup> ,
Ma et al (2022) <sup>12</sup> ,								●
Wang et al (2021) <sup>13</sup> ,								●
Rajamani et al (2021) <sup>14</sup> ,								●
Jing et al (2021) <sup>15</sup> ,								●
Jarebi et al (2021) <sup>16</sup> ,								●
Meyer et al (2020) <sup>17</sup> ,								●
Chen et al (2020) <sup>18</sup> ,								●
Kim et al (2019) <sup>19</sup> ,								●
Ahn et al (2019) <sup>20</sup> ,								●
Liu et al (2018) <sup>21</sup> ,								●
Sun et al (2017) <sup>22</sup> ,								●
Jeong et al (2006) <sup>23</sup> ,								●
Akcakaya et al (2016) <sup>24</sup> ,							●	
Choi et al (2018) <sup>25</sup> ,							●	
Dai et al (2020) <sup>26</sup> ,							●	
Krappel et al (2001) <sup>27</sup> ,							●	



Tacconi et al (2019) <sup>28</sup> .							●	
Tacconi et al (2020) <sup>29</sup> .							●	
Tao et al (2018) <sup>30</sup> .							●	
Wang et al (2017) <sup>31</sup> .							●	
Xu et al (2020) <sup>32</sup> .							●	
Ahn et al (2016) <sup>33</sup> .						●		●
Chang et al (2018) <sup>34</sup> .						●	●	●
Liu et al (2017) <sup>35</sup> .						●		●
Pan et al (2016) <sup>36</sup> .						●	●	●
Yao et al (2017) <sup>37</sup> .						●		
Yao et al (2017) <sup>38</sup> .						●		●
Gibson et al (2017) <sup>39</sup> .				●			●	●
Hsu et al (2013) <sup>40</sup> .				●				●
Kim et al (2007) <sup>41</sup> .				●		●		●
Qu et al (2017) <sup>42</sup> .				●				
Wang et al (2013) <sup>43</sup> .				●				●
Zhao et al (2012) <sup>44</sup> .				●				
Yoon et al (2012) <sup>45</sup> .	●	●	●		●			
Li et al (2015) <sup>46</sup> .	●				●			●
Sinkemani et al (2015) <sup>47</sup> .	●	●	●		●			●

Song et al (2017) <sup>48</sup> .		●	●		●			●
Tu et al (2017) <sup>49</sup> .					●			
Liu et al (2018) <sup>21</sup> .		●	●	●	●	●		
Li et al (2018) <sup>50</sup> .		●	●	●	●			●
Abdurexiti et al (2018) <sup>51</sup> .		●	●		●			
Chen et al (2018) <sup>52</sup> .		●	●	●	●	●		●
Liu et al (2012) <sup>53</sup> .			●					
Wu et al (2009) <sup>54</sup> .		●						
Yang et al (2015) <sup>55</sup> .		●		●				
Duan et al (2016) <sup>56</sup> .		●						
Zhao et al (2016) <sup>57</sup> .		●						
Ding et al (2017) <sup>58</sup> .		●						●
Li et al (2017) <sup>59</sup> .		●						
Liu et al (2017) <sup>60</sup> .		●						
Luo et al (2017) <sup>61</sup> .		●						
Qu et al (2017) <sup>62</sup> .		●						
Chen et al (2018) <sup>63</sup> .		●						
Wu et al (2018) <sup>64</sup> .		●						
Belykh et al (2016) <sup>65</sup> .		●						
Chen et al (2015) <sup>66</sup> .	●							●
Choi et al (2016) <sup>67</sup> .	●			●				●
Garg et al (2011) <sup>68</sup> .	●							

Hermantin et al (1999) <sup>69</sup> .	●						●	
Huang et al (2005) <sup>70</sup> .	●							
Hussein et al (2014) <sup>71</sup> .	●							
Kleinpeter et al (1995) <sup>72</sup> .	●							
Lee et al (2009) <sup>73</sup> .	●					●		●
Martin-Laez et al (2012) <sup>74</sup> .	●							
Mayer et al (1993) <sup>75</sup> .	●			●		●	●	●
Ohya et al (2016) <sup>76</sup> .	●							
Pan et al (2014) <sup>77</sup> .	●							●
Righesso et al (2007) <sup>78</sup> .	●							
Ruetten et al (2008) <sup>79</sup> .	●							
Ruetten et al (2009) <sup>80</sup> .	●					●		
Sasaoka et al (2006) <sup>81</sup> .	●							
Schizas et al (2005) <sup>82</sup> .	●							
Teli et al (2010) <sup>83</sup> .	●							
Ruetten et al (2007) <sup>84</sup> .	●							
Ruetten et al (2008) <sup>85</sup> .						●		

Lee et al (2006) <sup>86</sup> .						●		
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**Table 6. Summary of Systematic Reviews of Percutaneous Endoscopic Discectomy Versus Other Discectomy Procedures**

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Zhao et al (2022) <sup>11</sup> .	To May 2022	33	Patients with lumbar disc herniation who underwent PTED, MED or other surgical procedures	6467 (20-1856)	7 RCTs; 26 non-randomized controlled retrospective studies	Not reported
Bai et al (2021) <sup>9</sup> .	To February 2018	14	Patients with lumbar disc herniation who underwent PELD or other surgical procedures	2528 (74-902)	4 RCTs; 10 cohort studies	Not reported
Gadjradj et al (2021) <sup>10</sup> .	To April 2020	14	Patients with lumbar disc herniation who underwent PTED or open microdiscectomy	1465 (30-462)	9 RCTs; 5 prospective nonrandomized comparative studies	Follow-up: 3 to 12 months
Xu et al (2020) <sup>8</sup> .	Search dates not stated; included trials from 2012 to 2018	9	Patients with single-level lumbar disc herniation who underwent PELD or MED for treatment	984 (51-216)	1 RCT; 8 retrospective nonrandomized comparative studies	Follow-up: 1 to > 6 years
Zhou et al (2020) <sup>7</sup> .	To October 2018	12	Patients with lumbar disc herniation who underwent PELD or MED for treatment	2400 (40-915)	4 RCTs; 8 retrospective nonrandomized comparative studies	Follow-up: 3 to 46 months
Yu et al (2019) <sup>6</sup> .	To August 31, 2018	8	Patients with lumbar disc herniation who underwent PTED or MED procedures and were followed for at least 6 months	805 (51-216)	1 RCT; 7 observational studies	Follow-up: 6 months to 5 years
Shi et al (2019) <sup>5</sup> .	To July 2018	18	Patients with single-level lumbar disc herniation with sciatica who underwent PELD or MED for treatment	2161 (51-273)	8 prospective studies; 10 retrospective studies	Follow-up: 3 months to >6 years
Phan et al (2017) <sup>4</sup> .	To February 2016	23	Patients who underwent either an endoscopic or open approach for disc herniation; the endoscopic approach consisted of patients who underwent either FED or MED while the open approach included those who underwent	28,487 (20-26,612)	10 RCTs; 4 prospective observational studies; 9 retrospective observational studies	Follow-up: 3 to 104 months

			open discectomy or micro-discectomy			
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FED: full-endoscopic technique discectomy; MED: microendoscopic discectomy; PELD: percutaneous endoscopic lumbar discectomy; PTED: percutaneous transforaminal endoscopic discectomy; RCT: randomized controlled trial

**Table 7. Results of Systematic Reviews of Trials of Percutaneous Endoscopic Discectomy Versus Other Discectomy Procedures**

Study	Length of stay	Leg pain VAS	Lower back pain VAS	ODI	Overall complication rate	Reoperation	Recurrence or residue
Zhao et al (2022) <sup>11</sup> .							
Total (N)	1231	1487	1372	1687	2,372	2,226	2,621
Pooled effect (95% CI); p value	MD, -2.42 (-3.21 to -1.63);.0001	MD, -0.23 (-0.61 to 0.15);.60	MD, -0.49 (-0.84 to -0.14);.006	MD, -2.21 (-4.17 to -0.25);.03	OR, 0.94 (0.67 to 1.32);.71	OR, 1.67 (1.17 to 2.36);.004	OR, 1.55 (1.07 to 2.24);.02
I <sup>2</sup> (p)	95%;.00001	51%;.03	90%;.00001	88%;.00001	0%;.65	0%;.89	0%;.93
Bai et al (2021) <sup>9</sup> .							
Total (N)	NR	NR	NR	NR	NR		NR
Pooled effect (95% CI); p value	MD, -2.59 (-3.87 to -1.31); <.001	MD, 0.00 (-0.10 to 0.10);.991	MD, -0.17 (-0.55 to 0.21);.384	MD, -0.29 (-1.00 to 0.43);.434	relative risk, 0.86 (0.63 to 1.18);.361		relative risk, 1.65 (1.08 to 2.52);.021
I <sup>2</sup> (p)	72.1%;.001	0.0%;.996	88.3%; <.001	0.0%;. 996	51.5%;.024		26.1%;.220
Gadjradj et al (2021) <sup>10</sup> .							
Total (N)		621 and 152		621 and 152			
Pooled effect (95% CI)		3 to 6 month MD, 0.05 (-0.10 to 0.21) 12 month MD, 0.11 (-0.30 to 0.53)		3 to 6 month MD, -0.09 (-0.24 to 0.07) 12 month MD, -0.11 (-0.45 to 0.24)			
I <sup>2</sup> (p)		30%;.23		9%;.83			
Xu et al (2020) <sup>8</sup> .							
Total (N)	NR	NR	NR	NR	NR	NR	NR
Pooled effect (95% CI); p value	OR -1.041 (-1.493 to -0.583);.000	6 months to 2 years OR, -0.138 (-0.384 to 0.108);.270 2 years OR, 0.020 (-	6 months to 2 years OR, -0.456 (-0.947 to 0.034);.068 2 years OR, -0.856 (-	6 months to 2 years OR, -0.077 (-0.370 to 0.215);.604 2 years OR, -0.425 (-	OR, 0.972 (0.635 to 1.488);.896	OR, 1.136 (0.415 to 3.108);.805	OR, 1.306 (0.664 to 2.566);.439

		0.193 to 0.233);,855	1.488 to - 0.224);,008	0.724 to - 0.127);,005			
I <sup>2</sup> (p)		53.8%;,090; 6 months to 2 years 4.4%;,351; 2 years	88%;,000; 6 months to 2 years 86.7%;,001; 2 years	75.3%;,000; 6 months to 2 years 52.7%;,121; 2 years			
Zhou et al (2020) <sup>7</sup> .							
Total (N)						787	972
Pooled effect (95% CI); p value						OR, 1.77 (1.18 to 2.64);,006	OR, 1.60 (1.01 to 2.53);,05
I <sup>2</sup> (p)						0%;,97	0%;,94
Yu et al (2019) <sup>6</sup> .							
Total (N)	707	NR	NR	NR	659		443
Pooled effect (95% CI); p value	MD, -1.92 (-2.90 to -0.94); <.001	1 year postop or last follow-up: MD, -0.07 (-0.22 to 0.08);,38	1 year postop or last follow-up: MD, -0.41 (-0.76 to -0.06);,02	1 year postop or last follow-up: MD, -0.27 (-1.71 to 1.16);, 71	MD, 1.01 (0.60 to 1.69);,98		MD, 1.31 (0.54 to 3.17);,54
I <sup>2</sup> (p)	88%				0%		0%
Shi et al (2019) <sup>5</sup> .							
Total (N)	1717	742	742	1337	1527	805	928
Pooled effect (95% CI); p value	MD, -2.29 (3.03 to -1.55); <.00001	At last follow-up: MD, -0.18 (-0.45 to 0.09);,19	At last follow-up: MD, -0.77 (-1.31 to -0.24);,005	At last follow-up: MD, -0.30 (-1.02 to 0.42);,41	OR, 0.96 (0.65 to 1.43);,85	OR, 2.67 (1.07 to 6.67);,04	OR, 2.22 (1.02 to 4.83);,05
I <sup>2</sup> (p)	96%; <.00001	88%; <.00001	95%; <.00001	55%;,01	0%;,90	0%;,79	0%;,86
Phan et al (2017) <sup>4</sup> .							
Total (N)	685	390		303	27,699	995	1081
Pooled effect (95% CI); p value	MD, -4.79 (-6.52 to -3.07); <.00001	MD, -0.04 (-0.37 to 0.30);,84		MD, -1.88 (-4.06 to 0.29);,09	OR, 0.77 (0.45 to 1.31);,33	OR, 1.46 (0.33 to 6.43);,61	OR, 1.12 (0.60 to 2.09);,73
I <sup>2</sup> (p)	99%; <.00001	70%;,003		67%;,03	60%;,004	66%;,004	0%;,97

CI: confidence interval; MD: mean difference; NR: not reported; ODI: Oswestry Disability Index; OR: odds ratio; VAS: visual analogue scale.

Results from the systematic reviews were fairly consistent with a significantly reduced length of hospitalization observed with endoscopic discectomy and sometimes significant improvements

in VAS or ODI, but only at specific time points. Overall, no consistently significant improvement in VAS, ODI, total complication rate, reoperation, or recurrence was observed with endoscopic discectomy versus other interventions. Authors of the systematic reviews noted multiple limitations including the innate flaws of included studies (i.e., observational designs, a limited number of studies meeting criteria for inclusion, small sample sizes, lack of allocation concealment and blinding), different methodologies contributing to heterogeneity in analyses, loss of usable and sufficient data resulting in difficulty performing accurate analysis of outcomes, and that a majority of the more recently completed studies were completed in China, which may affect the generalizability of the results to other populations.

### Randomized Controlled Trials

More recent RCTs not included in any of the systematic reviews were also identified.<sup>87,88,89,90</sup> Results of these trials are similar to those seen in the more comprehensive systematic reviews - percutaneous endoscopic discectomy was associated with a significant reduction in length of stay with no consistent or clinically meaningful improvements in patient-reported outcome measures such as VAS and ODI. Two of the 4 RCTs evaluated treatment-related morbidities, and reported a reduced incidence of intraoperative and postoperative complications and repeat surgeries with percutaneous endoscopic discectomy. Key characteristics, results, and limitations of these RCTs are summarized in the following tables.

**Table 8. Characteristics of RCTs of Percutaneous Endoscopic Discectomy**

Study	Countries	Sites	Dates	Participants	Interventions
Liu et al (2023) <sup>90</sup>	Korea	1	July 2016 to July 2021	Patients with L5-S1 lumbar disc herniation	Interlaminar endoscopic lumbar discectomy vs microscopic lumbar discectomy
Gadjradj et al 2022 <sup>80</sup> ,	Netherlands	4	February 2016 to April 2019	Patients with sciatica caused by lumbar disc herniation	PTED vs microendoscopic discectomy
Ran et al 2021 <sup>81</sup> ,	China	1	August 2016 to February 2020	Patients with highly migrated lumbar disc herniation	PELD with computerized tomography navigation vs open discectomy
Wang et al 2019 <sup>82</sup> ,	China	1	July 2015 to July 2016	Patients with single-segment lumbar disc herniation with imaging results consistent with symptoms	PTED vs microendoscopic discectomy

PELD: percutaneous endoscopic lumbar discectomy; PTED: percutaneous transforaminal endoscopic discectomy; RCT: randomized controlled trials.

**Table 9. Results of RCTs of Percutaneous Endoscopic Discectomy**

Study	Length of stay (days)	Leg pain VAS	Lower back pain VAS	ODI	SF-36 PCS	Complication rates	Repeat surgery within 1 year
Liu et al (2023) <sup>90</sup> .							
N	28	28				28	
Mean difference at 12 months (95% CI)		0.71 (-2.54 to 1.12)	0.08 (-2.25 to 2.42)	8.48 (-1.67 to 18.63)			
Interlaminar endoscopic lumbar discectomy	3.69±1.60 days					Blood loss: 44±26.67 mL	
Microscopic lumbar discectomy	5.47±1.36 days					Blood loss: 20±20.99 mL	
p-value	.003					.009	
Gadjradj et al 2022 <sup>80</sup> .							
N	420	413	413	413	413	420	420
Pooled effect at 12 months (95% CI)	Median (IQR) PTED: 0 (0 to 0) Microendoscopic discectomy: 1 (1 to 1)	MD 7.1 (2.8 to 11.3)	MD 6 (2 to 10)	MD 5.3 (3.0 to 7.7)	MD -2.8 (-4.1 to -1.6)	PTED vs microendoscopic discectomy: Dural tears (n=0 vs 8) Nerve root injury (n=0 vs 1) Wound infection (n=3 vs 0) Cerebrospinal fluid leakage (n=1 vs 0)	PTED vs microendoscopic discectomy: n=9 (5%) vs 14 (6%)
p-value							
Ran et al 2021 <sup>81</sup> .							
N		66				66	
PELD with computerized tomography navigation at 12 months		0.58 ± 0.90				Infection, n=0 Recurrence, n=1	



Open discectomy at 12 months		0.75 ± 0.84				Infection, n=1 Recurrence, n=0	
p-value		.58				>.99	
N	90	90	90	90			
PTED	Postoperative: 3.01 ± 0.52	Preoperative mean score vs. 6 months after surgery: 7.21 vs. 1.05	Preoperative mean score vs 6 months after surgery: 6.40 vs. 1.36	Preoperative mean score vs 6 months after surgery : 58.21% vs. 17.05%			
Microendoscopic discectomy	Postoperative: 6.68 ± 0.30	Preoperative mean score vs. 6 months after surgery: 7.09 vs. 0.98	Preoperative mean score vs 6 months after surgery: 6.34 vs. 1.65	Preoperative mean score vs 6 months after surgery : 57.17% vs. 16.98%			
p-value	.001	.097	.523	.864			
				2.6			

IQR: interquartile range; MD: mean difference; ODI: Oswestry Disability Index; PELD: percutaneous endoscopic lumbar discectomy; PTED: percutaneous transforaminal endoscopic discectomy; RCT: randomized controlled trials; SF-36 PCS: Short-Form-36 Physical Component Score; VAS: visual analogue scale.

**Table 10. Study Relevance Limitations of the RCTs of Percutaneous Endoscopic Discectomy**

Study	Population <sup>a</sup>	Intervention <sup>b</sup>	Comparator <sup>c</sup>	Outcomes <sup>d</sup>	Duration of Follow-up <sup>e</sup>
Liu et al (2023) <sup>90</sup> .	4. Limited to participants from single site in Korea			1. Morbidity-related outcomes such as complications and reoperation were limited	
Gadjradj et al 2022 <sup>80</sup> .	4. Limited to participants from 3 sites in the Netherlands				

Ran et al 2021 <sup>81</sup> .	4. Limited to participants from single site in China	4. PELD was used with computerized tomography navigation		1. Morbidity-related outcomes such as complications were limited	
Wang et al 2019 <sup>82</sup> .	4. Study population similar to other trials with regard to age, sex; however, included patients from a single Chinese hospital			1. Morbidity-related outcomes such as complication and reoperation rates were not reported	1,2. Outcomes reported only for 6 months of follow-up

PELD: percutaneous endoscopic lumbar discectomy; RCT: randomized controlled trials.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

<sup>a</sup>Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

<sup>b</sup>Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

<sup>c</sup>Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

<sup>d</sup>Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

<sup>e</sup>Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

**Table 11. Study Design and Conduct Limitations of the RCTs of Percutaneous Endoscopic Discectomy**

Study	Allocation <sup>a</sup>	Blinding <sup>b</sup>	Selective Reporting <sup>c</sup>	Data Completeness <sup>d</sup>	Power <sup>e</sup>	Statistical <sup>f</sup>
Liu et al (2023) <sup>90</sup> .		1,2. Blinding did not occur			1. No mention of power	
Gadjradj et al 2022 <sup>80</sup> .	4. A proportion of patients with a strong preference for PTED who were randomised to open microdiscectomy dropped out of the study after randomization	1,2. Blinding did not occur				
Ran et al 2021 <sup>81</sup> .	3. Allocation concealment unclear	1,2. Blinding did not appear to occur			1. Power calculations not reported	
Wang et al 2019 <sup>82</sup> .	3. Allocation concealment unclear	1,2. Blinding did not appear to occur			1. Power calculations not reported	

PTED: percutaneous transforaminal endoscopic discectomy; RCT: randomized controlled trials.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

<sup>a</sup>Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

<sup>b</sup>Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

<sup>c</sup>Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

<sup>d</sup>Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

<sup>e</sup>Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

<sup>f</sup>Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

## Observational Studies

Yu et al (2021) published the results of a retrospective multicenter study that followed patients for 2 years after receipt of transforaminal percutaneous endoscopic discectomy (n=632) and microendoscopic discectomy (n=421) for lumbar disc herniation.<sup>91</sup> Mean blood loss (p<.001) and mean duration of hospital stay (p=.018) were significantly less with transforaminal percutaneous endoscopic lumbar discectomy compared to microendoscopic discectomy. Rates of complications, recurrence, and revisions were similar in both groups. Visual analogue pain scores did not differ between groups after the first postoperative day. At 1 month postoperatively there was a significant difference in ODI scores between groups (p=.016) in favor of transforaminal percutaneous endoscopic discectomy, but there was no difference at other time points.

Saghebdoost et al (2023) published the results of a retrospective study in 434 patients with lumbar disc herniation who underwent transforaminal endoscopic lumbar discectomy or open microdiscectomy.<sup>92</sup> At the end of the 7-year follow-up period, records for 412 patients were evaluable. A similar proportion of patients in both groups had outcomes that were rated as excellent or good (about 88%) according to the modified MacNab criteria. Perioperative complications were similar between groups, but intraoperative blood loss (p<.05) and length of hospital stay (p<.05) were significantly less in the transforaminal endoscopic lumbar discectomy group. Recurrence that required reoperation occurred in 21 patients in the transforaminal endoscopic lumbar discectomy group and 9 patients in the open microdiscectomy group (p<.05).

Yu et al (2021) published the results of a retrospective multicenter study that followed patients for 2 years after receipt of transforaminal percutaneous endoscopic discectomy (n=632) and microendoscopic discectomy (n=421) for lumbar disc herniation.<sup>6</sup> Mean blood loss (p<.001) and mean duration of hospital stay (p=.018) were significantly reduced with transforaminal percutaneous endoscopic lumbar discectomy compared to microendoscopic discectomy. Rates of complications, recurrence, and revisions were similar in both groups. The VAS pain scores did not differ between groups after the first postoperative day. At 1 month postoperatively, there was a significant difference in ODI scores between groups (p=.016) in favor of transforaminal percutaneous endoscopic discectomy, but there was no significant difference at other time points.

Song et al (2021) published a retrospective single-center study that compared percutaneous endoscopic lumbar discectomy (n=306) and microendoscopic discectomy (n=116) in patients undergoing same day ambulatory surgery for lumbar disc herniation.<sup>48</sup> Mean blood loss and mean duration of hospital stay were significantly less with percutaneous endoscopic lumbar discectomy (both p<.001 compared to microendoscopic discectomy). After 3 years of follow-up, visual analogue pain scores for the back were also significantly lower in the percutaneous

endoscopic lumbar discectomy group compared to the microendoscopic discectomy group (p=.001) but there was no difference between groups in pain scores for the legs (p=.224). Overall recurrence rates (p=.201) and ODI scores (p=.220) were also similar between groups.

A number of observational studies have also assessed the learning curve<sup>93-95</sup> and the need for longer follow-up for endoscopic discectomy.<sup>96-97</sup> 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 percutaneous endoscopic lumbar discectomy over a 12-year period.<sup>88</sup> 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. Many of the more recent RCTs are conducted at institutions within China. There are few reports from the United States. Overall, results from RCTs and systematic reviews reveal a significantly reduced length of hospitalization with endoscopic discectomy and occasionally significant improvements in VAS or ODI, but only at specific time points. No consistently significant improvement in VAS, ODI, total complication rate, reoperation, or recurrence was observed with percutaneous endoscopic discectomy versus other interventions.

**SUMMARY OF EVIDENCE**

For individuals who have herniated intervertebral disc(s) who receive automated percutaneous discectomy, the evidence includes randomized controlled trials (RCTs) and systematic reviews of observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment related morbidity. The published evidence is insufficient to evaluate the impact of automated percutaneous discectomy on net health outcomes. 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. 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 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. Reporting from a number of moderately large ongoing RCTs is anticipated in the next 2 to 3 years. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 12.

**Table 12. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date

<b>Ongoing</b>			
99	Percutaneous Transforaminal Endoscopic Discectomy (PTED) vs. Microendoscopic Discectomy (MED) for the treatment of Lumbar Disc Herniation: A Prospective Randomized Controlled Study	125	Aug 2023
NCT02602093	Percutaneous Transforaminal Endoscopic Discectomy vs. Open Microdiscectomy for Lumbar Disc Herniation (PTED-study)	682	May 2024
<b>Unpublished</b>			
NCT02742311	EuroPainClinics® Study V Prospective Observational Study (EPCSV)	500	Dec 2021
NCT01997086	Percutaneous Transforaminal Endoscopic Discectomy (PTED) vs. Microendoscopic Discectomy (MED) for the treatment of Lumbar Disc Herniation: A Prospective Randomized Controlled Study	125	Aug 2023

NCT: national clinical trial

<sup>a</sup> Denotes industry-sponsored or cosponsored trial

## SUPPLEMENTAL INFORMATION

### Clinical Input Obtained Through 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.

#### 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 Clinical Excellence

The National Institute for Health and Clinical Excellence (NICE) published guidance in 2005 on automated percutaneous mechanical lumbar discectomy, indicating that there is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, and evidence from small randomized controlled trials shows conflicting results.<sup>99</sup> The guidance states 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 update in 2009, but failed review criteria; the 2005 guidance is therefore considered current.

A NICE guideline on percutaneous transforaminal endoscopic lumbar discectomy for sciatica went in development in March 2016.<sup>100</sup> 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 prolapsed disc.

A NICE guidance on percutaneous interlaminar endoscopic lumbar discectomy for sciatica was also published in 2016.<sup>101</sup> 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, and location and size of prolapsed disc.

### American Society of Interventional Pain Physicians

The 2013 guideline update from the American Society of Interventional Pain Physicians states that the evidence for percutaneous disc decompression with Dekompessor is limited.<sup>3</sup> There were no recommended indications for DeKompessor.

### North American Spine Society

In 2014, the North American Spine Society published clinical guidelines on the diagnosis and treatment of lumbar disc herniation.<sup>102</sup> Table 13 summarizes recommendations specific to percutaneous endoscopic discectomy and automated percutaneous discectomy.

**Table 13. NASS Recommendations for Lumbar Disc Herniation With Radiculopathy**

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

LOE: level of evidence; NASS: North American Spine Society

<sup>a</sup> 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 (e.g., <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 2009 clinical practice guidelines from the American Pain Society 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 Disc Dekompessor.<sup>103</sup>

### American Society of Pain and Neuroscience

The American Society of Pain and Neuroscience (ASPN; 2022) published clinical guidance for interventional treatments for low back pain.<sup>104</sup> The guideline states that discectomy procedures (such as percutaneous and endoscopic disc procedures) have favorable safety and efficacy

profiles for the treatment of lumbar disc herniation with persistent radicular symptoms; however, it is stated that further research is needed to evaluate complications rates in order for these procedures to supplant classic open microdiscectomy. Recommendations specific to percutaneous endoscopic discectomy are summarized in Table 13.

**Table 13. Recommendations for Percutaneous and Endoscopic Procedures**

Recommendation	Grade <sup>a</sup>	Level of Evidence <sup>b</sup>	Level of Certainty [Net Benefit] <sup>c</sup>
Percutaneous Endoscopic Discectomy	B	I-a	High

<sup>a</sup> Grade B: (The ASPN Back Group recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial..

<sup>b</sup> Evidence Level: I-A: At least one controlled and randomized clinical trial, properly designed

## Government Regulations

### National/ Local:

There are no national or local coverage determinations on this topic. 62380 is not on the Medicare Fee schedule. 62287 can be used for TIPS procedures and is not covered for that indication; however 62287 is payable for procedures that are not considered TIPS procedures.

National Coverage Determination, Publication 100-3, Manual Section Number 150.11. Percutaneous thermal intradiscal procedures (TIPs) involve the insertion a catheter(s)/probe(s) into the spinal disc under fluoroscopic guidance in order to produce, or apply, heat and/or disruption within the disc to relieve low back pain.

Although not meant to be a complete list, TIPs are commonly identified as

- Intradiscal electrothermal therapy (IDET);
- Intradiscal thermal annuloplasty (IDTA);
- Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT);
- Radiofrequency annuloplasty (RA);
- Intradiscal biacuplasty (IDB);
- Percutaneous (or plasma) disc decompression (PDD) or ablation; or
- Targeted disc decompression (TDD).

CR 6291 announces that CMS has concluded that the evidence does not demonstrate that TIPs improve health outcomes; and has therefore determined that **TIPs are not reasonable and necessary** for the treatment of low back pain.

*(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.*

## Related Policies

- Spinal Surgery: Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)
- Spinal Surgery: Percutaneous Intradiscal Electrothermal Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty

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*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through July 2024, the date the research was completed.*

### Joint BCBSM/BCN Medical Policy History

<b>Policy Effective Date</b>	<b>BCBSM Signature Date</b>	<b>BCN Signature Date</b>	<b>Comments</b>
6/8/02	6/8/02	6/8/02	Joint policy established
11/18/03	11/18/03	11/18/03	Policy retired
5/1/08	3/5/08	5/1/08	Policy unretired, status changed to investigational
3/1/09	12/9/08	12/9/08	Title changed to Percutaneous Discectomy and thoracic and cervical spine added as diagnoses. Effective 3/1/12, this policy is consolidated into another policy, "Spinal Surgery-Percutaneous, Endoscopic, Laser and/or Radiofrequency Decompression"
3/1/12	12/13/11	12/21/11	Joint consolidated policy established
11/1/13	8/22/13	8/27/13	Policies split apart to mirror BCBSA policies. This policy addresses automated percutaneous and endoscopic discectomies only.
3/1/15	12/12/14	12/29/14	Routine review of experimental/investigational service. No substantive changes to policy. Updated rationale and references.
3/1/16	12/10/15	12/10/15	Routine policy maintenance. No change in policy status.
3/1/17	12/13/16	12/13/16	Routine policy maintenance, updated rationale section and added references 10, 18, 34-37. Added code 62380 effective 1/1/17
11/1/17	8/15/17	8/15/17	Updated rationale and CMS sections. Added references 15, 16, 21, 45 and 46. Routine policy maintenance.
11/1/18	8/21/18	8/21/18	Routine policy maintenance. No change in policy status.
11/1/19	8/20/19		Updated rationale section, added reference #21. Added clinical input. No change in policy status.



11/1/20	8/18/20		Updated rationale section, added reference # 15 and 22. No change in policy status.
11/1/21	8/17/21		Rationale section completely reorganized, tables added, references added. Reference section renumbered. No change in policy status.
11/1/22	8/16/22		Rationale section updated, added references 80-82. No change in policy status.
11/1/23	8/15/23		Routine policy update, no change in policy status. Vendor managed: Turning Point. (ds)
11/1/24	8/20/24		Rationale updated, added references 90 & 92. No change in status. Vendor managed: Turning Point (ds)

Next Review Date: 3<sup>rd</sup> Qtr. 2025

**BLUE CARE NETWORK BENEFIT COVERAGE**  
**POLICY: SPINAL SURGERY: AUTOMATED PERCUTANEOUS AND ENDOSCOPIC**  
**DISCECTOMY**

**I. Coverage Determination:**

<b>Commercial HMO (includes Self-Funded groups unless otherwise specified)</b>	Not covered.
<b>BCNA (Medicare Advantage)</b>	Please see government section.
<b>BCN65 (Medicare Complementary)</b>	Coinsurance covered if primary Medicare covers the service.

**II. Administrative Guidelines:**

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.