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## Medical Policy



**Title: Automated Percutaneous and Percutaneous Endoscopic Discectomy**

Related Policies:	<ul style="list-style-type: none"> <li><i>Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty and Intraosseous Basivertebral Nerve Ablation</i></li> </ul>
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<b>Professional / Institutional</b>
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Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>With herniated intervertebral disc(s)</li> </ul>	Interventions of interest are:	Comparators of interest are: <ul style="list-style-type: none"> <li>Conservative therapy</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Symptoms</li> <li>Functional outcomes</li> </ul>

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Populations	Interventions	Comparators	Outcomes
	<ul style="list-style-type: none"> <li>Automated percutaneous discectomy</li> </ul>	<ul style="list-style-type: none"> <li>Open discectomy or microdiscectomy</li> </ul>	<ul style="list-style-type: none"> <li>Quality of life</li> <li>Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>With herniated intervertebral disc(s)</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Percutaneous endoscopic discectomy</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Conservative therapy</li> <li>Open discectomy or microdiscectomy</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Symptoms</li> <li>Functional outcomes</li> <li>Quality of life</li> <li>Treatment-related morbidity</li> </ul>

## 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. Endoscopic discectomy involves the percutaneous placement of a working channel under image guidance, followed by visualization of the working space and instrumentation 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 a 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. Intradiscal electrothermal annuloplasty is another minimally invasive approach to low back pain.

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This evidence review 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 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.

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## **POLICY**

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

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## **RATIONALE**

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through May 5, 2023.

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 1 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

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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 is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals with herniated intervertebral disc(s).

The following PICO was used to select literature to inform this review.

### ***Populations***

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

### ***Interventions***

The therapy being considered is automated percutaneous 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 may 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 treatment-related morbidity including surgical success/failure and complications. 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.

## **REVIEW OF EVIDENCE**

### **Systematic Reviews**

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Systematic reviews have assessed automated percutaneous discectomy compared to other interventions; however, the majority of these reviews contained observational studies published more than a decade ago with generally small patient populations and inconsistent results. Lewis et al (2015) published the most recent systematic review and network meta-analysis comparing trials of 21 different treatment strategies for sciatica.<sup>1</sup> Examples of the 21 treatment strategies included in the analysis include 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 [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%, -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.

### **Randomized Controlled Trials**

The 2002 Lumbar Automated Percutaneous Discectomy Outcomes Group (LAPDOG) trial is a RCT to compare 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.

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**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	.95	.95	.96	.58	.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.

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**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>	4.3. Investigators believed that study inclusion criteria reflected an existing population with lumbar disc disease; however, results from only 27 patients were eventually analyzed from a planned enrollment of 330 patients			4. Primary outcomes of "success" or "failure" largely subjective in nature; investigators admit that the outcome measurement tool used can not be precisely reproduced	1,2. Outcomes reported only for 6 months of follow-up; 12 month follow-up was achieved for only 19 patients and the study did not report any of these results

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. 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 (e.g., proposed as an adjunct but not tested as such); 5: Other.

<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; 5. Other.

<sup>d</sup> Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

<sup>e</sup> Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

**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	3. Power estimates led the investigators to plan enrollment of 330 patients in order to reliably identify a	1. Beyond the cursory discussion of lack of power, a discussion of the statistical analyses is nonexistent

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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>
				was obtained for only 19 patients	difference in success rate of 15% or greater; results were analyzed on 27 patients	

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 is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals with herniated intervertebral disc(s).

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### ***Populations***

The relevant population of interest is 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 treatment-related morbidity including surgical success/failure and complications. 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.

## **REVIEW OF EVIDENCE**

### **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 (2017 to present) is shown in Table 5. Characteristics and results of these reviews are summarized in Tables 6 and 7.

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**Table 5. Trials Included in Systematic Reviews of Percutaneous Endoscopic Discectomy Versus 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> ,	Gadjradj 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> ,							●	

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Trials	Systematic Reviews							
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> ,				●				●

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Trials	Systematic Reviews							
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> ,		●						

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Trials	Systematic Reviews						
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> ,	●						

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Trials	Systematic Reviews							
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

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Study	Dates	Trials	Participants	N (Range)	Design	Duration
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 open discectomy or micro-discectomy	28,487 (20-26,612)	10 RCTs; 4 prospective observational studies; 9 retrospective observational studies	Follow-up: 3 to 104 months

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

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Study	Length of stay	Leg pain VAS	Lower back pain VAS	ODI	Overall complication rate	Reoperation	Recurrence or residue
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 (-0.193 to 0.233);.855	6 months to 2 years -0.456 (-0.947 to 0.034);.068 2 years OR -0.856 (-1.488 to -0.224);.008	6 months to 2 years -0.077 (-0.370 to 0.215);.604 2 years OR -0.425 (-0.724 to -0.127);.005	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
I <sup>2</sup> (p)		53.8%;.090; 6 months to 2 years	88%;.000; 6 months to 2 years	75.3%;.000; 6 months to 2 years			

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Study	Length of stay	Leg pain VAS	Lower back pain VAS	ODI	Overall complication rate	Reoperation	Recurrence or residue
		4.4%;.351; 2 years	86.7%;.001 ; 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

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Study	Length of stay	Leg pain VAS	Lower back pain VAS	ODI	Overall complication rate	Reoperation	Recurrence or residue
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; RR: risk ratio; VAS: visual analogue scale; WMD: weighted mean difference

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 (ie, 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</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 3 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.

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

Study	Countries	Sites	Dates	Participants	Interventions
Gadjradj et al 2022 <sup>87</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>88</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>89</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
Gadjradj et al 2022 <sup>87</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)	PTED vs microendoscopic discectomy: n=9 (5%) vs 14 (6%)

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Study	Length of stay (days)	Leg pain VAS	Lower back pain VAS	ODI	SF-36 PCS	Complication rates	Repeat surgery within 1 year
						Cerebrospinal fluid leakage (n=1 vs 0)	
p-value							
Ran et al 2021 <sup>88</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			

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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>
Gadjradj et al 2022 <sup>87</sup> ,	4. Limited to participants from 3 sites in the Netherlands				
Ran et al 2021 <sup>88</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>89</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.

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**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>
Gadjradj et al 2022 <sup>87</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>88</sup> ,	3.Allocation concealment unclear	1,2. Blinding did not appear to occur			1. Power calculations not reported	
Wang et al 2019 <sup>89</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

Comparative observational studies with at least a 2-year follow-up are summarized below.

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

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microendoscopic discectomy (n=421) for lumbar disc herniation. 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. 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, the VAS 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>90,91,92</sup>, and the need for longer follow-up for endoscopic discectomy.<sup>93,94</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>95</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, systematic reviews, and comparative observational studies with at least 2 years of follow up. 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.

### **SUPPLEMENTAL INFORMATION**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### **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

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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**

Clinical input was sought to help determine whether the use of automated percutaneous discectomy or endoscopic percutaneous discectomy for individuals with herniated intervertebral discs would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 3 respondents, including 2 specialty society-level response(s); no physician-level responses identified through a specialty society; 1 physician-level response identified through an academic medical center.

For individuals who have herniated intervertebral discs who receive automated percutaneous discectomy or percutaneous endoscopic discectomy, clinical input does not support a clinically meaningful improvement in net health outcome and does not indicate this use is consistent with generally accepted medical practice. Clinical input suggests that automated percutaneous discectomy 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. Similarly, clinical input suggests that endoscopic percutaneous discectomy may be an appropriate treatment option for the highly selected patient who has a small focal disc herniation causing lumbar radiculopathy. However, respondents were mixed in the level of support for this indication, and overall the clinical input is not generally supportive of a clinically meaningful improvement in net health outcome.

### **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**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### **National Institute for Health and Care Excellence**

The 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.<sup>96</sup> 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

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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.<sup>97</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 the prolapsed disc.

A NICE (2016) guidance on percutaneous interlaminar endoscopic lumbar discectomy for sciatica was also published.<sup>98</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, 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.<sup>3</sup> 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<sup>99</sup>. Table 12 summarizes recommendations specific to percutaneous endoscopic discectomy and automated percutaneous discectomy.

**Table 12. Recommendations for Lumbar Disc Herniation With Radiculopathy**

<b>Recommendations</b>	<b>Grade or LOE<sup>a</sup></b>
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.

<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 (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.

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### 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.<sup>100</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. [Sayed D, Grider J, Strand N, et al. *The American S...*; 15: 3729-3832. PMID 36510616] 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

### 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 14.

**Table 14. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
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

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<b>NCT No.</b>	<b>Trial Name</b>	<b>Planned Enrollment</b>	<b>Completion Date</b>
NCT02602093	Percutaneous Transforaminal Endoscopic Discectomy vs. Open Microdiscectomy for Lumbar Disc Herniation (PTED-study)	682	May 2024
<b><i>Unpublished</i></b>			
NCT02742311	EuroPainClinics® Study V Prospective Observational Study (EPCSV)	500	Dec 2021

NCT: national clinical trial.

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

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## CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

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.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

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 (e.g., 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 (e.g., fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar
C2614	Probe, percutaneous lumbar discectomy

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.
	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.

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<b>REVISIONS</b>	
01-01-2012	In Coding section: <ul style="list-style-type: none"> <li>Revised CPT code nomenclature: 62287</li> </ul>
02-14-2012	In Title: <ul style="list-style-type: none"> <li>Added "and Endoscopic" to read, "Automated Percutaneous and Endoscopic Discectomy"</li> </ul>
	Updated Description section
	In Policy section: <ul style="list-style-type: none"> <li>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."</li> <li>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."</li> </ul>
	Updated Rationale section
	Updated References
09-25-2013	Description section updated
	In Policy section: <ul style="list-style-type: none"> <li>Policy statements clarified with the addition of "and/or radiculopathy" to read, "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."</li> </ul>
	In Coding section: <ul style="list-style-type: none"> <li>Coding information updated</li> </ul>
	Rationale section updated
	References updated
11-06-2015	Description section updated
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> <li>Updated Coding notations.</li> </ul>
	References updated
06-09-2017	In Title revised to "Automated Percutaneous and Percutaneous Endoscopic Discectomy" from "Automated Percutaneous and Endoscopic Discectomy"
	Description section updated
	In Policy section: <ul style="list-style-type: none"> <li>In Item B added "Percutaneous" to read "Percutaneous endoscopic discectomy is considered experimental / investigational..."</li> </ul>
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> <li>Added CPT Codes: 62380, 0274T, 0275T</li> <li>Added HCPCS Code: C2614</li> <li>Updated coding notations.</li> </ul>

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<b>REVISIONS</b>	
	References updated
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
08-21-2020	Rationale section updated
	References updated
07-28-2021	Description section updated
	Rationale section updated
	References updated
07-26-2022	Updated Description Section
	Update Rationale Section
	Updated References Section
08-08-2023	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-10 Diagnosis Box
	Updated References Section
08-08-2023	Archived

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**No review or update is scheduled on this Medical Policy. Blue Cross and Blue Shield of Kansas will continue to monitor published literature for any updated information. If there are questions about coverage of this service, please contact Blue Cross and Blue Shield of Kansas customer service, or your professional / institutional relations representative.**

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