Automated Percutaneous and Percutaneous Endoscopic Discectomy

MEDICAL POLICY – 7.01.18

Introduction

The bones that make up the spine are called vertebrae. Between each of the vertebra is a disc, which prevents the bones from rubbing together. When the disc deteriorates, the gel-like material that's inside it can leak out and irritate nerves. Cutting away part of the disc is one way to relieve pain and other symptoms. The usual way of performing this surgery is by making an open incision (cut). Newer methods are being studied. One uses a probe and special tools that cut away the disc herniations and suction them out. Another new method uses a small scope with a camera at the end and specialized tools. Both of these methods are considered unproven (investigational). There is not enough medical evidence to show how effective they are.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

Discectomy | Investigational
--- | ---
- Automated percutaneous discectomy
- Percutaneous endoscopic discectomy

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

Coding

CPT code 62287 specifically describes a percutaneous decompression procedure of the lumbar spine. This code is specifically limited to the lumbar region. Although most percutaneous discectomies are performed on lumbar vertebrae, FDA labeling of the Stryker DeKompressor Percutaneous Discectomy Probe and the Nucleotome includes the thoracic and cervical vertebrae.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0274T</td>
<td>Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic</td>
</tr>
<tr>
<td>0275T</td>
<td>Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar</td>
</tr>
<tr>
<td>62287</td>
<td>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 the use of an endoscope, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar</td>
</tr>
<tr>
<td>62380</td>
<td>Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with the use of an endoscope, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar</td>
</tr>
</tbody>
</table>
### Code Description

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>disc, 1 interspace, lumbar</td>
</tr>
</tbody>
</table>

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### Related Information

**Benefit Application**

Percutaneous discectomy may be performed by surgeons, but anesthesiologists or other physicians whose practices focus on pain management may also perform this procedure.

### Evidence Review

**Description**

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

**Background**

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

Minimally invasive options have also been researched, in which some portion of the disc 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 decompression (see Related Policies). Intradiscal electrothermal annuloplasty is another minimally invasive approach to low back pain. In this technique, radiofrequency energy is used to treat the surrounding disc annulus (see Related Policies).

This policy addresses automated percutaneous and endoscopic discectomy, in which the disc decompression is accomplished by the physical removal of disc material rather than its ablation. Traditionally, discectomy was performed manually through an open incision, using cutting forceps to remove nuclear material from within the disc annulus. This technique was modified by automated devices that involve placement of a probe within the intervertebral disc and aspiration of disc material using a suction cutting device. Endoscopic techniques may be intradiscal or may involve 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.

Summary of Evidence

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

For individuals who have herniated intervertebral disc(s) who receive automated percutaneous discectomy, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The published evidence from small RCTs is insufficient to evaluate the impact of automated percutaneous discectomy on net health outcomes. 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 1 RCT from a different center in Europe reported a trend toward increased complications and reherniations using an endoscopic approach. There are few reports from the United States. Results from a number of moderately large ongoing RCTs are 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 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02742311</td>
<td>EuroPainClinics® Study V Prospective Observational Study (EPCSV)</td>
<td>500</td>
<td>Jan 2019</td>
</tr>
<tr>
<td>NCT02602093</td>
<td>(Cost) Effectiveness of Percutaneous Transforaminal Endoscopic Discectomy vs. Open Microdiscectomy for Patients With Symptomatic Lumbar Disc Herniation</td>
<td>682</td>
<td>Dec 2019</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02441959</td>
<td>Full-Endoscopic vs Open Discectomy for the Treatment of Symptomatic Lumbar Herniated Disc: A Prospective Multi-Center Randomized Study</td>
<td>200</td>
<td>Jul 2018 (terminated)</td>
</tr>
<tr>
<td>NCT01622413a</td>
<td>Transforaminal Endoscopic Surgery Cost Outcome Research Trial (TESCORT)</td>
<td>0</td>
<td>Sep 2017 (withdrawn)</td>
</tr>
<tr>
<td>NCT02358291</td>
<td>Microendoscopic Discectomy Vs Transforaminal Endoscopic Lumbar Discectomy Vs Open Discectomy for the Treatment of Lumbar Disc Herniation</td>
<td>240</td>
<td>Mar 2017 (unknown)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.
Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

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, the 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 was limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, and evidence from small RCTs showed conflicting results.36 The guidance indicated that, in view of uncertainty about the efficacy of the procedure, it should not be done without special arrangements for consent and for audit or research. The guidance was considered for update in 2009, but failed review criteria; the 2005 guidance is therefore considered to be current.

A NICE guidance on percutaneous transforaminal endoscopic lumbar discectomy for sciatica was published in 2016.37 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, and location and size of prolapsed disc.

A NICE guidance on percutaneous interlaminar endoscopic lumbar discectomy for sciatica was also published in 2016.38 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 guidelines from the American Society of Interventional Pain Physicians indicated that the evidence for percutaneous disc decompression with the Dekompressor was limited.\textsuperscript{14} There were no recommended indications for the DeKompressor.

**North American Spine Society**

In 2014, the North American Spine Society published clinical guidelines on the diagnosis and treatment of lumbar disc herniation.\textsuperscript{39} Table 2 summarizes recommendations specific to percutaneous endoscopic discectomy and automated percutaneous discectomy.

**Table 2. Recommendations for Lumbar Disc Herniation with Radiculopathy**

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


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

The 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 Dekompressor.40

Medicare National Coverage

There is no national coverage determination.

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.

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/97</td>
<td>Add to Surgery Section - New Policy</td>
</tr>
<tr>
<td>08/13/02</td>
<td>Replace Policy - Policy reviewed without literature review; new review date only</td>
</tr>
<tr>
<td>07/13/04</td>
<td>Replace Policy - Policy reviewed without literature review; new review date only.</td>
</tr>
<tr>
<td>06/14/05</td>
<td>Replace Policy - Policy revised with literature review; now considered investigational; references provided. Status changed to BC. Title changed by removing Lumbar. Hold for notification; publish 11/1/05.</td>
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<tr>
<td>06/16/06</td>
<td>Replace Policy - Policy reviewed with literature search; no change in policy statement; Scope and Disclaimer updated.</td>
</tr>
<tr>
<td>11/13/07</td>
<td>Replace Policy - Policy reviewed with literature search; no change in policy statement; references added.</td>
</tr>
<tr>
<td>05/13/08</td>
<td>Cross Reference Update - No other changes</td>
</tr>
<tr>
<td>10/14/08</td>
<td>Cross Reference Update - No other changes.</td>
</tr>
<tr>
<td>01/13/09</td>
<td>Replace Policy - Policy reviewed with literature search; no change in policy statement; references added.</td>
</tr>
<tr>
<td>03/09/10</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement. References added.</td>
</tr>
<tr>
<td>05/10/11</td>
<td>Replace Policy - Policy updated with literature review, rationale section extensively revised, no change in policy statement. Title changed to “Automated Percutaneous Discectomy”. ICD-10 codes added to policy.</td>
</tr>
<tr>
<td>04/10/12</td>
<td>Replace policy. Endoscopic discectomy added to policy with literature review through October 2011; Rationale revised; references added and reordered; 1 reference removed; title changed to “Automated Percutaneous and Endoscopic Discectomy”. Endoscopic discectomy is considered investigational.</td>
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<tr>
<td>09/26/12</td>
<td>Update Related Policies – Add 7.01.126; ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>06/10/13</td>
<td>Replace policy. Policy updated with literature review through January 9, 2013; references added and reordered; clinical input reviewed; policy statement clarified to read “back pain and/or radiculopathy”.</td>
</tr>
<tr>
<td>09/30/13</td>
<td>Update Related Policies. Change title to 7.01.72 and 7.01.93.</td>
</tr>
<tr>
<td>01/21/14</td>
<td>Update Related Policies. Add 7.01.551.</td>
</tr>
<tr>
<td>03/11/14</td>
<td>Coding Update. Code 80.59 was removed per ICD-10 mapping project; this code is not utilized for adjudication of policy.</td>
</tr>
<tr>
<td>06/19/14</td>
<td>Annual Review. Policy updated with literature review through March 27, 2014, references 13-14 and 18 added; policy statements unchanged. Diagnosis and procedure codes removed (ICD-9 and ICD-10) – performed outpatient.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
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<tr>
<td>06/17/15</td>
<td>Annual Review. Policy updated with literature review through March 23, 2015; references 17-18, 27, and 34 added; policy statements unchanged. CPT codes 0274T and 0275T added to the policy Coding section.</td>
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<tr>
<td>08/25/15</td>
<td>Update Related Policies. Remove deleted policy 7.01.537.</td>
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<tr>
<td>07/01/16</td>
<td>Annual Review, approved June 14, 2016. Policy updated with literature review through February 23, 2016; references 10 and 18 added. Policy statements unchanged.</td>
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<tr>
<td>01/01/17</td>
<td>Coding update. Added new CPT code 62380 effective 1/1/17.</td>
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<tr>
<td>01/01/19</td>
<td>Annual Review, approved December 19, 2018. Policy updated with literature review through June 2018; reference 21 added. Policy statements unchanged.</td>
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<tr>
<td>02/01/19</td>
<td>Minor update, added 7.01.560 to related policies.</td>
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</table>

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  Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
  Email AppealsDepartmentInquiries@Premera.com

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- U.S. Department of Health and Human Services
  200 Independence Avenue SW, Room 509F, HHH Building
  Washington, D.C. 20201, 1-800-368-1019, 1-800-537-7697 (TDD)
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 khoảng thời gian để được giúp đỡ.

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