Protocol

Automated Percutaneous and Percutaneous Endoscopic Discectomy

(70118)

Medical Benefit		**Effective Date**: 10/01/18	**Next Review Date**: 07/21
Preauthorization	No	**Review Dates**: 02/07, 01/08, 01/09, 01/10, 01/11, 01/12, 01/13, 09/13, 07/14, 07/15, 07/16, 07/17, 07/18, 07/19, 07/20	

This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

RELATED PROTOCOLS

Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)

Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

Populations	Interventions	Comparators	Outcomes
Individuals: • With herniated intervertebral disc(s)	Interventions of interest are: • Automated percutaneous discectomy	Comparators of interest are: • Conservative therapy • Open discectomy or microdiscectomy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With herniated intervertebral disc(s)	Interventions of interest are: • Percutaneous endoscopic discectomy	Comparators of interest are: • Conservative therapy • Open discectomy or microdiscectomy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

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 instruments through an endoscope, and aspiration of disc material.

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

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

POLICY

Automated percutaneous discectomy is considered **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.

Percutaneous endoscopic discectomy is considered **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.

MEDICARE ADVANTAGE

For Medicare Advantage percutaneous image guided lumbar decompression (PILD) may have potential for coverage when provided through Coverage with Evidence Development (CED) for members with lumbar spinal stenosis who meet the criteria of and are enrolled in an approved clinical study.

Effective for services performed on or after December 7, 2016, there may be a potential for coverage through a prospective, longitudinal study of PILD procedures using an FDA-approved/cleared device that completed a CMS-approved randomized control trial (RCT) that met CMS criteria.

MEDICARE ADVANTAGE POLICY GUIDELINES

Approved studies will be identified on the CMS website - https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html.

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. Ablative techniques include laser discectomy and radiofrequency decompression (see the Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty) Protocol). 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 the Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty Protocol).

Herein this protocol 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.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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