### Introduction

Between each bone of the spine is a round, flat disc. The discs act as cushions between the bones of the spine and help hold them together, while also providing stability and allowing a wide range of motion. Should the discs break down, pain and nerve problems may result. Typical treatment includes physical therapy and/or pain medications. In more severe cases, surgery may be needed. In recent years, using heat from either lasers or radio waves to remove or destroy parts of the discs has been studied as a way to try to treat pain. These techniques are investigational (unproven). More studies are needed to find out if they are safe and effective.

**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

Service | Investigational
---|---
Laser discectomy and radiofrequency coblation | Laser discectomy and radiofrequency coblation (disc nucleoplasty) are considered investigational as techniques of disc decompression and treatment of associated pain.

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td>Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method, single or multiple levels, lumbar (eg, manual or automated percutaneous discectomy, percutaneous laser discectomy)</td>
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<tr>
<td>HCPCS</td>
<td>Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar</td>
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Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review
Description

Laser energy (laser discectomy) and radiofrequency coblation (nucleoplasty) are being evaluated for decompression of the intervertebral disc. For laser discectomy under fluoroscopic guidance, a needle or catheter is inserted into the disc nucleus, and a laser beam is directed through it to vaporize tissue. For disc nucleoplasty, bipolar RF energy is directed into the disc to ablate tissue. These minimally invasive procedures are being evaluated for the treatment of discogenic back pain.

Background

Discogenic Low Back Pain

Discogenic low back pain is a common, multifactorial pain syndrome that involves low back pain without radicular symptom findings, in conjunction with radiologically confirmed degenerative disc disease.

Treatment

Typical treatment includes conservative therapy with physical therapy and medication management, with potential for surgical decompression in more severe cases.

A variety of minimally invasive techniques have been investigated as treatment of low back pain related to disc disease. Techniques can be broadly divided into those designed to remove or ablate disc material, and thus decompress the disc, and those designed to alter the biomechanics of the disc annulus. The former category includes chymopapain injection, automated percutaneous lumbar discectomy, laser discectomy, and most recently, disc decompression using radiofrequency (RF) energy, referred to as a disc nucleoplasty.

Techniques that alter the biomechanics of the disc (disc annulus) include a variety of intradiscal electrothermal procedures, which are discussed in another policy (see Related Medical Policies).

A variety of different lasers have been investigated for laser discectomy, including YAG, KTP, holmium, argon, and carbon dioxide lasers. Due to differences in absorption, the energy requirements and the rates of application differ among the lasers. In addition, it is unknown how much disc material must be removed to achieve decompression. Therefore, protocols vary by the length of treatment, but typically the laser is activated for brief periods only.
RF coblation uses bipolar low-frequency energy in an electrical conductive fluid (e.g., saline) to generate a high-density plasma field around the energy source. This creates a low-temperature field of ionizing particles that break organic bonds within the target tissue. Coblation technology is used in a variety of surgical procedures, particularly related to otolaryngology. The disc nucleoplasty procedure is accomplished with a probe mounted with a RF coblation source. The proposed advantage of coblation is that the procedure provides for controlled and highly localized ablation, resulting in minimal damage to surrounding tissue.

Summary of Evidence

For individuals who have discogenic back pain or radiculopathy who receive laser discectomy, the evidence includes systematic reviews of observational studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. While numerous case series and uncontrolled studies have reported improvements in pain levels and functioning following laser discectomy, the lack of well-designed and well-conducted controlled trials limits interpretation of reported data. The evidence is insufficient to determine the effect of the technology on health outcomes.

For individuals who have discogenic back pain or radiculopathy who receive disc nucleoplasty with radiofrequency coblation, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. For nucleoplasty, there are 2 RCTs in addition to several uncontrolled studies. These RCTs are limited by the lack of blinding, an inadequate control condition in one, and inadequate data reporting in the second. The available evidence is insufficient to permit conclusions concerning the effect of these procedures on health outcomes due to multiple confounding factors that may bias results. High-quality randomized trials with adequate follow-up (at least 1 year), which control for selection bias, the placebo effect, and variability in the natural history of low back pain, are needed. The evidence is insufficient to determine the effect of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in March 2019 did not identify any ongoing or unpublished trials that would likely influence this review.
Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

In 2016, the National Institute for Health and Care Excellence (NICE) updated its guidance on laser lumbar discectomy for the treatment of sciatica. The guidance stated that current evidence “is inadequate in quantity and quality.”

NICE’s also updated its guidance on percutaneous disc decompression using coblation for lower back pain and sciatica in 2016. NICE stated: “Current evidence on percutaneous coblation of the intervertebral disc for low back pain and sciatica raises no major safety concerns. The evidence on efficacy is adequate and includes large numbers of patients with appropriate follow-up periods.” The guidance also noted that the patient should be informed of the range of treatment options available.

American Pain Society

American Pain Society practice guidelines (2009) on nonsurgical interventions for low back pain found that “there is insufficient (poor) evidence from randomized trials (conflicting trials, sparse and lower quality data, or no randomized trials) to reliably evaluate” a number of interventions including coblation.

American Society of Interventional Pain Physicians

Practice guidelines on lumbar disc compression and chronic spinal pain were published in 2009 and updated in 2013, respectively, by the American Society of Interventional Pain Physicians. The systematic reviews informing the 2013 guidelines found limited evidence for percutaneous laser disc decompression and limited to fair evidence for nucleoplasty.

Medicare National Coverage

The Centers for Medicare & Medicaid Services has determined that thermal intradiscal procedures, including percutaneous (or plasma) disc decompression or coblation, are not reasonable and necessary for the treatment of low back pain. Therefore, thermal intradiscal procedures, which include procedures that “employ the use of a radiofrequency energy source
or electrothermal energy to apply or create heat and/or disruption within the disc for the treatment of low back pain, are noncovered.”

The Centers for Medicare & Medicaid Services has not published a national coverage decision on laser discectomy; however, the Centers did indicate the following in its decision on laser procedures:

Medicare recognizes the use of lasers for many medical indications. Procedures performed with lasers are sometimes used in place of more conventional techniques. In the absence of a specific noncoverage instruction, and where a laser has been approved for marketing by the Food and Drug Administration, contractor discretion may be used to determine whether a procedure performed with a laser is reasonable and necessary and, therefore, covered.

Regulatory Status

A number of laser devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for incision, excision, resection, ablation, vaporization, and coagulation of tissue. Intended uses described in FDA summaries include a wide variety of procedures, including percutaneous discectomy. Trimedyne Inc. received 510(k) clearance in 2002 for the Trimedyne® Holmium Laser System Holmium:Yttrium, Aluminum Garnet (Holmium:YAG), in 2007 RevoLix Duo™ Laser System, and in 2009 Quanta System LITHO Laser System. All were cleared, based on equivalence with predicate devices for percutaneous cervical laser disc decompression/discectomy, including foraminoplasty, percutaneous cervical disc decompression/discectomy, and percutaneous thoracic disc decompression/discectomy. The summary for the Trimedyne® system states that indications for cervical and thoracic decompression/discectomy include uncomplicated ruptured or herniated discs, sensory changes, imaging consistent with findings, and symptoms unresponsive to 12 weeks of conservative treatment. Indications for treatment of cervical discs also include positive nerve conduction studies. FDA product code: GEX.

In 2001, the Perc-D SpineWand™ (ArthroCare) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to predicate devices. It is used in conjunction with the ArthroCare Coblation® System 2000 for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs. Smith & Nephew acquired ArthroCare in 2014; as of 2017, Smith & Nephew has not provided any information about coblation devices specific to spine surgeries on its website. FDA product code: GEI.


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<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>05/11/04</td>
<td>Add to Surgery Section - New Policy</td>
</tr>
<tr>
<td>03/08/05</td>
<td>Replace Policy - Policy reviewed; coding updated; no change to policy statement.</td>
</tr>
<tr>
<td>06/14/05</td>
<td>Replace Policy - Policy updated; references added. Policy statement originally limited to treatment of low back pain; this has been revised to remove this limitation such that treatment at all disc levels is considered investigational.</td>
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<tr>
<td>06/16/06</td>
<td>Replace Policy - Policy updated with literature review; no change in policy statement; reference added; HCPCS code added; Scope and Disclaimer updated.</td>
</tr>
<tr>
<td>11/13/07</td>
<td>Replace Policy - Policy reviewed; code updated; no change to policy statement. References added.</td>
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<tr>
<td>05/13/08</td>
<td>Cross Reference Update - No other changes</td>
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<tr>
<td>10/14/08</td>
<td>Cross Reference and Code Update - Cross reference and code 80.5 added; no other changes.</td>
</tr>
<tr>
<td>06/09/09</td>
<td>Replace Policy - Policy updated with literature search; no change in policy statement. References added.</td>
</tr>
<tr>
<td>09/14/10</td>
<td>Replace Policy - Policy updated with literature search; reference numbers 6, 7, and 22 added. No change has been made to the policy statement; the title reflects a slight change in wording from, &quot;Decompression of the Intervertebral Disc Using Laser (Laser Discectomy) or Radiofrequency Energy (DISC Nucleoplasty™)&quot; to &quot;Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)&quot;.</td>
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<tr>
<td>09/15/11</td>
<td>Replace Policy – Policy updated with literature review through April 2011; references 9, 12, 15 and 16 added; other references removed and references reordered; policy statement unchanged.</td>
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<tr>
<td>04/17/12</td>
<td>Related Policies updated: the title of 7.01.18 now includes endoscopic discectomy.</td>
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<tr>
<td>09/11/12</td>
<td>Replace policy. Policy updated with literature review through May 2012; policy statement unchanged.</td>
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<tr>
<td>09/26/12</td>
<td>Update Related Policy – Add 7.01.126.</td>
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<td>01/21/14</td>
<td>Update Related Policies. Add 7.01.551.</td>
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<tr>
<td>09/23/14</td>
<td>Annual Review. Policy updated with literature review through June 3, 2014; policy statement unchanged. CPT code 77002 removed from the policy; it does not apply.</td>
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<tr>
<td>06/01/16</td>
<td>Annual Review, approved May 10, 2016. Policy updated with literature review; reference added. No change to policy statement.</td>
</tr>
<tr>
<td>04/01/17</td>
<td>Annual Review, approved March 14, 2017. Policy updated with literature review through November 7, 2016; Rationale revised and some references removed. Policy statement unchanged.</td>
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<tr>
<td>10/24/17</td>
<td>Policy moved to new format; no change to policy statements.</td>
</tr>
<tr>
<td>07/01/19</td>
<td>Annual Review, approved June 20, 2019. Policy updated with literature review through February 2019; no references added. Policy statement unchanged.</td>
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**Disclaimer**: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2019 Premera All Rights Reserved.

**Scope**: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
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  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
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  - Qualified interpreters
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PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

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

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