MEDICAL POLICY – 7.01.93

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

BCBSA Ref. Policy: 7.01.93
Effective Date: July 1, 2020
Last Revised: June 4, 2020
Replaces: N/A

RELATED MEDICAL POLICIES:
7.01.18 Automated Percutaneous and Percutaneous Endoscopic Discectomy
7.01.72 Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty
7.01.126 Image-Guided Minimally Invasive Decompression for Spinal Stenosis
7.01.551 Lumbar Spine Decompression Surgery: Discectomy, Foraminotomy, Laminotomy, Laminectomy

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

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

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>
</tr>
</thead>
<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>
</tr>
<tr>
<td>HCPCS</td>
<td>Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar</td>
</tr>
</tbody>
</table>

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 (yttrium aluminum garnet), KTP (potassium titanyl phosphate), 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.

Radiofrequency 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 February 2020 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.\textsuperscript{13} 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.\textsuperscript{14} 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.\textsuperscript{15,16}

American Society of Interventional Pain Physicians

Practice guidelines on lumber disc compression and chronic spinal pain were published in 2009 and updated in 2013, respectively, by the American Society of Interventional Pain Physicians.\textsuperscript{17,18} The systematic reviews informing the 2013 guidelines found limited evidence for percutaneous laser disc decompression and limited to fair evidence for nucleoplasty.\textsuperscript{2,7}

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.
References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<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>
</tr>
<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>
</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 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 “Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)”.</td>
</tr>
<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>
</tr>
<tr>
<td>04/17/12</td>
<td>Related Policies updated: the title of 7.01.18 now includes endoscopic discectomy.</td>
</tr>
<tr>
<td>09/11/12</td>
<td>Replace policy. Policy updated with literature review through May 2012; policy statement unchanged.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>09/26/12</td>
<td>Update Related Policy – Add 7.01.126.</td>
</tr>
<tr>
<td>01/21/14</td>
<td>Update Related Policies. Add 7.01.551.</td>
</tr>
<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>
</tr>
<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>
</tr>
<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>
</tr>
</tbody>
</table>

**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). ©2020 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.
Discrimination Is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
• Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  • Qualified sign language interpreters
  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  • Qualified interpreters
  • Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5952, 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)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.
Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):
لا يمكن لأي أن يXA الطيار يسك مع نهاية معلومات طبي أو طبي يكلم هذه التقنية معلومات طبية في هذا الإعلان. وقد تحتاج إلى إخطار في حالة تولي معلومات طبية على تدابير تحريرية منها أو للمستخدمين أو للمستخدمين أو للمستخدمين أو للمستخدمين أو للمستخدمين.
Call 800-722-1471 (TTY: 800-842-5357).

Italian (Italian):
Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente.
Chiamare 800-722-1471 (TTY: 800-842-5357).

Chinese (Chinese):
本通知有重要之訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險之重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):

Deutsche (German):

Hmoob (Hmong):

Ilokano (Ilocano):
Daytoy a pakdaar mabalini nga adba ket naglaon iti Napateg nga Impormasyon. Daytoy a pakdaar mabalini nga adba ket naglaon iti Napateg nga Impormasyon maiapanggep iti aplikasyon nga woon coverage babaen iti Premera Blue Cross. Daytoy ket mabalini dagiti importante a palsa iti daytoy a pakdaar. Mabalini nga adba rumbena nga aramideny nga addag sabbay dagiti partikular a naituding nga adlaw tapno mapagtalaideny diliy diliy nga coverage ug salo-ayo nga tungong kadagit gastos. Adda karbenganyo a mangala iti daytoy nga impormasyon ken tungong iti bukodjoy a pangasao nga awan ti bayadan. Tumawag wii numero nga 800-722-1471 (TTY: 800-842-5357).

Oromoo (Cushite):

Spanish (French):
This notification may contain important information about your coverage or costs. You have the right to receive this information and assistance in your language. Please call (TTY: 800-842-5357) for assistance.

Romanian (Romanian):

Russian (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Spanish (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

Thai (Thai):
ประกาศนี้มีสาระสำคัญ ประกาศนี้มีสาระสำคัญเกี่ยวกับการเปลี่ยนแปลงหรือการสิ้นสุดประกันชีวิตของคุณ Premera Blue Cross และการปฏิบัติการในกรณีที่คุณจะต้อง ด้านประกันการได้รับปัญหาที่เกิดขึ้นในประกาศนี้จะมีผลกระทบสิทธิ์ของคุณในการอนุญาตให้ คุณจะได้รับคุ้มครองและดูแลกรณีในกรณีที่คุณมีการได้รับวันที่ โทร 800-722-1471 (TTY: 800-842-5357).

Український (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує ймовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):
Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hỗ trợ bảo hiểm của quý vị qua 800-722-1471 (TTY: 800-842-5357).

Polski (Polish):

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir dados importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e em custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

日本語 (Japanese):
この通知には重要な情報が含まれています。この通知には、Premera Blue Crossの申請または保険範囲に関する重要な情報が含まれている場合があります。この通知には記載されている情報が重要な日程をご確認ください。健康保険や有料サポートを維持するには、特定の日程までに行動を取らなければならない場合があります。ご希望の言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

한국어 (Korean):
본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 귀하는 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 도움을 귀하의 언어에 비용 부담이 없을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357)로 전화하십시오.