Medical Coverage Policy | Minimally Invasive Intradiscal and Annular Procedures for Back Pain

EFFECTIVE DATE: 10|01|2004
POLICY LAST UPDATED: 07|18|2017

OVERVIEW
This policy addresses a variety of minimally invasive techniques that have been investigated over the years as treatment of low back pain related to disc disease. Techniques can be broadly divided into techniques that are designed to remove or ablate disc material, and thus decompress the disc, and those designed to alter the biomechanics of the disc annulus.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty), Laser discectomy and radiofrequency coblation (disc nucleoplasty) automated percutaneous discectomy and percutaneous endoscopic discectomy are considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

BACKGROUND
Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty
Electrothermal intradiscal annuloplasty therapies use radiofrequency energy sources to treat discogenic low back pain arising from annular tears. These annuloplasty techniques are designed to decrease pain arising from the annulus by thermocoagulating nerves in the disc and tightening of annular tissue.

Discogenic low back pain is a common, multifactorial pain syndrome that involves low back pain without radicular symptoms findings, in conjunction with radiologically confirmed degenerative disc disease. Typical treatment includes conservative therapy with physical therapy and medication management, with potential for surgical decompression in more severe cases.

A number of electrothermal intradiscal procedures have been introduced to treat discogenic low back pain; they rely on various probe designs to introduce radiofrequency (RF) energy into the disc. It has been proposed that heat-induced denaturation of collagen fibers in the annular lamellae may stabilize the disc and potentially seal annular fissures and that pain reduction may occur through the thermal coagulation of nociceptors in the outer annulus.

Some of the electrothermal intradiscal procedures are briefly described.

With the intradiscal electrothermal annuloplasty (IDEA) procedure, a navigable catheter with an embedded thermal resistive coil is inserted posterolaterally into the disc annulus or nucleus. Using indirect RF energy, electrothermal heat is generated within the thermal resistive coil at a temperature of 90°C; the disc material is heated for up to 20 minutes. Proposed advantages of indirect electrothermal delivery of RF energy with IDEA include precise temperature feedback and control, and the ability to provide electrothermocoagulation to a broader tissue segment than would be allowed with a direct RF needle.

Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) uses direct application of RF energy. With PIRFT, the RF probe is placed into the center of the disc, and the device is activated for only 90 seconds at a temperature of 70°C. The procedure is not designed to coagulate, burn, or ablate tissue. The Radionics RF Disc Catheter System has been specifically designed for this purpose.

Intradiscal biacuplasty involves use of 2 cooled RF electrodes placed on the posterolateral sides of the intervertebral annulus fibrosus. It is believed that by cooling the probes a larger area may be treated than could occur with a regular needle probe.

Annuloplasty using a laser-assisted spinal endoscopy kit to coagulate the disc granulation tissue (percutaneous endoscopic laser annuloplasty) has also been described.

For individuals who have discogenic back pain who receive intradiscal thermal annuloplasty, radiofrequency annuloplasty, or biacuplasty, the evidence includes a small number of randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The 2 RCTs on intradiscal electrothermal annuloplasty have conflicting results, with 1 reporting benefit for intradiscal electrothermal annuloplasty and the other reporting no benefit. There is a lack of evidence to support a role for radiofrequency annuloplasty with either a single or a double (biacuplasty) probe. One sham-controlled RCT on biacuplasty has suggested that this procedure may provide modest benefit in highly select patients; confirmation of these results in a broader population is needed. Further study in a sham-controlled trial with a representative population of patients is needed. The evidence is insufficient to determine the effects of the technology on health outcomes. Therefore, these services are considered not medically necessary for BlueCHiP for Medicare and Commercial products.

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

Laser energy (laser discectomy) and radiofrequency (RF) 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.

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.

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 rate 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 (eg, 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.

The ArthroCare SpineWand used coblation technology (ArthroCare, Austin, TX). ArthroCare was acquired by Smith & Nephew in 2014; as of 2017, Smith & Nephew has not provided any information about coblation devices specific to spine surgeries on its website.

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 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 1 trial, 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. Therefore, these services are considered not medically necessary for BlueCHiP for Medicare and Commercial products.

Automated Percutaneous and Percutaneous Endoscopic Discectomy

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.

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 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. 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.

Herein we address 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.

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 omplications 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. Therefore, this service is considered not medically necessary for BlueCHiP for Medicare and Commercial products.

CODING

BlueCHiP for Medicare and Commercial Products:

The following codes are considered not medically necessary:

22526 Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level

22527 Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; one or more additional levels List separately in addition to code for primary procedure)

S2348 Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

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 discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar (Revised Text 1/1/2017)

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 (New code effective 1/1/2017)

RELATED POLICIES:
None

PUBLISHED:
Provider Update, September 2017
Provider Update, January 2017
Provider Update, April 2015
Provider Update, January 2014
Provider Update, September 2012
Provider Update, August 2010
Provider Update, November 2009
Provider Update, February 2009

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