EFFECTIVE DATE: 10|01|2004
POLICY LAST UPDATED: 02|03|2015

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.

PRIOR AUTHORIZATION:
Not Applicable

POLICY STATEMENT:
BlueCHiP for Medicare and Commercial

Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, percutaneous intradiscal radiofrequency thermocoagulation, and intradiscal biacuplasty), disc nucleoplasty, laser discectomy, automated percutaneous and endoscopic discectomies are considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

MEDICAL CRITERIA:
None

BACKGROUND:
Intradiscal annuloplasty therapies use energy sources to thermally treat discogenic low back pain arising from annular tears. Thermal annuloplasty techniques are designed to decrease pain arising from the annulus and enhance its structural integrity.

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. With the intradiscal electrothermal annuloplasty procedure (IDET™, Oratec SpineCath System), a navigable catheter with an embedded thermal resistive coil is inserted posterolaterally into the disc annulus or nucleus. The catheter is then snaked through the disc circuitously to return posteriorly. Using indirect radiofrequency energy, electrothermal heat is generated within the thermal resistive coil at a temperature of 90 degrees C; the disc material is heated for up to 20 minutes. Proposed advantages of indirect electrothermal delivery of radiofrequency energy with IDET™ include precise temperature feedback and control and the ability to provide electrothermocoagulation to a broader tissue segment than would be allowed with a direct radiofrequency needle.

Another procedure, referred to as percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), uses direct application of radiofrequency energy. With PIRFT, the radiofrequency probe is placed into the center of the disc, and the device is activated for only 90 seconds at a temperature of 70 degrees 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.

A more recently developed annuloplasty procedure, referred to as intradiscal biacuplasty (Baylis Medical, Inc., Montreal, Canada) involves the use of 2 cooled radiofrequency 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.

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 radiofrequency energy is directed into the disc to ablate tissue.

Patients considered candidates for DISC nucleoplasty™ or laser discectomy include patients with bulging discs and sciatica. 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 according to the length of treatment, but typically the laser is activated for brief periods only.

The Disc nucleoplasty™ procedure uses bipolar radiofrequency energy in a process referred to as coblation technology. The technique consists of small, multiple electrodes that emit a fraction of the energy required by traditional radiofrequency energy systems. The result is that a portion of nucleus tissue is ablated, not with heat but with a low-temperature plasma field of ionized particles. These particles have sufficient energy to break organic molecular bonds within tissue, creating small channels in the disc. The proposed advantage of this coblation technology is that the procedure provides for a controlled and highly localized ablation, resulting in minimal therapy damage to surrounding tissue.

Traditionally, discectomy and microdiscectomy are performed manually through an open incision. Percutaneous discectomy describes techniques by which disc decompression is accomplished by the physical removal of disc material rather than its ablation. These techniques have been modified by the use of automated devices that involve placement of a probe within the intervertebral disc and aspiration of disc material using a suction cutting device. Removal of disc herniations under endoscopic visualization is also being investigated. 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, a 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.

Traditional discectomy has been 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 the extraction of non-contained and sequestered disc fragments from inside the spinal canal using an interlaminar or transforaminal approach. Following insertion of the endoscope, the decompression is performed under visual control.

There is limited evidence on the efficacy of intradiscal thermal annuloplasty, consisting of a small number of randomized controlled trials and case series. The two randonized controlled trials (RCTs) on intradiscal electrothermal annuloplasty report different results, with one reporting benefit for IDET and the other reporting no benefit. There is a lack of evidence to support a role for radiofrequency annuloplasty with a single probe. One recent RCT on biacuplasty suggests that this procedure may provide modest benefit in a

proportion of highly selected patients; confirmation of these results in a broader population is needed. Overall, evidence is insufficient to conclude that these procedures improve health outcomes. Therefore, annuloplasty (i.e., IDET™, PIRFT, and biacuplasty) is considered not medically necessary as there is no proven efficacy.

While numerous case series and uncontrolled studies report improvements in pain and functioning following laser discectomy and nucleoplasty, the lack of well-designed and conducted controlled trials limits interpretation of reported data. Questions remain about the safety and efficacy of these treatments. These procedures are considered not medically necessary as there is no proven efficacy.

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. There is insufficient evidence obtained from well-designed and executed randomized controlled trials to evaluate the impact of automated percutaneous discectomy on net health outcome. In addition, evidence from small randomized controlled trials does not support the use of these procedures; therefore, automated percutaneous discectomy is considered not medically necessary as there is no proven efficacy.

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. The evidence consists of a number of randomized controlled trials. At this time, evidence is considered insufficient to evaluate health outcomes from endoscopic discectomy in U.S. centers. Therefore, it is considered not medically necessary as there is no proven efficacy.

COVERAGE:

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

CODING:

BlueCHiP for Medicare and Commercial

The following codes are considered **not medically necessary**:

22526 **22527** **S2348** **62287**

RELATED POLICIES:

None

PUBLISHED:

Provider Update, April 2015
Provider Update, Jan 2014
Provider Update, September 2012
Provider Update, August 2010
Provider Update, November 2009
Provider Update, February 2009
Policy Update, February 2008

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