MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Intradiscal Procedures**
Policy Number	**7.01.112**
Category	**Technology Assessment**
Original Effective Date	**02/01/25**
Committee Approval Date	**10/17/24**
Current Effective Date	**02/01/25**
Archived Date	**N/A**
Archive Review Date	**N/A**
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POLICY STATEMENT

I. Based upon our review and assessment of the peer-reviewed literature, intradiscal procedures have not been medically proven to be effective and, therefore, are considered **investigational** including but not limited to the following procedures:
   A. Annulo-nucleoplasty (Disc-FX procedure);
   B. Cervical intradiscal radiofrequency lesioning;
   C. Coblation percutaneous disc decompression;
   D. Intradiscal biacuplasty (IBD)/intervertebral disc biacuplasty/cooled radiofrequency;
   E. Intradiscal electrothermal annulaplasty (IEA);
   F. Intradiscal thermal annuloplasty (IDTA);
   G. Nucleoplasty (also known as percutaneous radiofrequency thermomodulation or percutaneous plasma discectomy);
   H. Percutaneous (or-plasma) disc decompression (PDD);
   I. Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)/intradiscal radiofrequency thermomodulation/percutaneous radiofrequency thermomodulation;
   J. Radiofrequency annuloplasty (RA);
   K. Targeted disc decompression (TDD);
   L. Intradiscal injections (not an all-inclusive list) (e.g., methylene blue, hyaluronate, ozone, oxygen/ozone, bone marrow concentrate, chymopapain, platelet rich plasma (PRP), mesenchymal stem cell, glucocorticoids, hyaluronidase, growth factor, etc.).

Refer to Corporate Medical Policy #7.01.113 Lumbar Decompression

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

DESCRIPTION

Back pain and sciatica related to herniated discs is an extremely common condition and a frequent cause of chronic disability. Although many cases of acute back pain will resolve with conservative care, a surgical decompression is often considered when the pain is unimproved and is clearly neuropathic in origin. The primary surgical procedure for disc herniation/prolapse has been open discectomy for the relief of nerve root compression by removing the herniated nuclear material. However, minimally invasive options have also been proposed to relieve nerve root compression without damaging surrounding tissues, allowing for a quicker recovery and minimizing post-operative complications.

Intradiscal Procedures are minimally invasive surgical procedures with the goal of to treat symptomatic individuals with discogenic pain attributed to annular disruption of contained herniated disc, to seal annular tears or fissures, or to destroy nociceptors for the purpose of relieving pain. These procedure techniques can include any of the following methods:

I. The percutaneous placement of an intradiscal probe into the suspected painful disc(s) and through the use of radiofrequency energy or electrothermal energy, produce heat to either coagulate and/or disrupt (shrink) type I collagen within the disc for decompression of the disc material (TIPs).
II. The injection of agents into the nucleus pulposus or annulus of the disc to decompress disc material.
III. Percutaneous procedures to decompress disc material using indirect/direct visualization.

Thermal Intradiscal Techniques are intradiscal procedure techniques that use single or multiple probes/catheters. They further utilize a resistance coil or other delivery system technology, are flexible or rigid, and are placed within the nucleus pulposus, the nuclear-annular junction or within the annulus.

Percutaneous discectomy (APD) is performed using local anesthetic, with or without conscious sedation. Under fluoroscopic guidance, a cannula is placed centrally within the disc using a posterolateral approach on the symptomatic side. A probe, connected to an automated cutting and aspiration device, is then introduced through the cannula. The disc is aspirated until no more nuclear material can be obtained. The Stryker DeKompressor Percutaneous Discectomy Probe (Stryker), the Nucleotome (Clarus Medical), and the SpineJet Hydrodiscectomy System (HydroCision) are examples of devices utilized in ADP.

Endoscopic techniques have also been developed to perform discectomy under local anesthesia. The procedure involves the percutaneous placement of a working channel under image guidance, followed by visualization of the working space and instruments through an endoscope. 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.

Intradiscal annuloplasty therapies utilize radiofrequency energy to thermally treat discogenic low back pain arising from annular tears and other forms of internal disc derangement. In contrast with disc nucleoplasty, which ablates disc material, 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 nocioceptors in the outer annulus.

Intradiscal electrothermal annuloplasty (IDET or IDTA) is a minimally invasive treatment for discogenic low back pain, intended to treat the protein wall of the disc and reduce the volume of disc material that causes nerve irritation. The procedure involves the insertion of a spinal catheter through a needle into the disc under fluoroscopy, then the use of indirect radiofrequency energy, heating the needle to 194 degrees Fahrenheit (90 degrees centigrade) for up to 20 minutes. The heat from which kills the invading nerves and tightens the surrounding ligaments, creating a new seal. Proposed advantages of indirect electrothermal delivery of radiofrequency energy with IDET/IDTA include precise temperature feedback and control, as well as the ability to provide electrothermocoagulation to a broader tissue segment than would be allowed with a direct radiofrequency needle.

Percutaneous intradiscal thermocoagulation (PIRFT) using the Radionics Disc Catheter System, use of radiofrequency probe placed into the center of the disc, rather than around the annulus, and the device is activated for only 90 seconds at a temperature of 70 degrees centigrade. The mechanism of action is not precisely understood, but it is thought to be related to reducing the nociceptive pain input from the free nerve ending in the outer annulus fibrosis. The Radionics Disc

Catheter System is similar in concept to IDET/IDTA; however, the methods of delivering the thermal energy are distinctly different. The proposed advantages of the electrothermal delivery of energy (as with IDET/IDTA), compared to the use of a radiofrequency needle (as with PIRFT) are due to the fact that IDET/IDTA provides electrothermal coagulation to a broader tissue segment and allows precise temperature control and temperature feedback.

Intradiscal biacuplasty, involves the use of two cooled radiofrequency electrodes that are placed on the posterolateral sides of the intervertebral annulus fibrosis. It is proposed that, by cooling the probes, a larger area may be treated than is possible with a regular needle probe.

Viable allograft supplemental disc regeneration (VAST), or Via Disc, is a therapeutic percutaneous injection of the lumbar spine using an allogeneic cellular or tissue-based product to replace or supplement the disc tissue. It repairs or reconstitutes a damaged intra-vertebral disc.

Disc nucleoplasty, which uses a bipolar radiofrequency device to provide heat treatment to the intervertebral disc, in order to remove tissue with minimal thermal damage to collateral tissue.

Radiofrequency ablation or disc nucleoplasty uses bipolar radiofrequency energy in a process called coblation technology, in which small, multiple electrodes ablate tissue with a low-temperature plasma field of ionized particles. The particles break organic molecular bonds within the tissue, creating small channels in the disc.

RATIONALE

2020 North American Spine Society (NASS) guidelines for Diagnosis and Treatment of Lower Back Pain address the treatment of lower back pain with electrothermal therapy and biacuplasty.

I. Intradiscal electrothermal annuloplasty is suggested to provide improvements in pain and function at up to two years. This treatment is limited in its effectiveness with roughly 40-50% of patients receiving a 50% reduction in pain. (Grade of recommendation B=Suggested).
II. Biacuplasty is an option to produce clinically and statistically significant improvements in pain at six (6) months in patients with discogenic low back pain. (Grade of recommendation C=May be considered).
III. There is insufficient evidence to make a recommendation for or against the use of percutaneous intradiscal radiofrequency thermocoagulation. (Grade of recommendation I=Insufficient).

Automated Percutaneous Discectomy

The Dekompressor (Stryker) and the Nucleotome (Clarus Medical) have received clearance from the FDA through the Section 510(k) process. Both have the same intended use label, e.g., “for use in aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine.” In 2003, HydroCision announced that the FDA had granted Section 510(k) clearance to market the SpineJet Hydrodiscectomy System for the cutting, resection, and removal of soft tissue in minimally invasive percutaneous spinal surgery.

The vast majority of the published literature addresses the use of ADP in lumbar disc herniation. Overall, based on conflicting evidence, the literature remains insufficient to determine the efficacy of ADP as a technique for disc decompression.

A Cochrane systematic review (Gibson et al., 2007) concluded that “trials of percutaneous discectomy provided moderate evidence that it produces poorer clinical outcomes than standard discectomy or chymopapain.” For example, Chatterjee et al. reported on the results of a study that randomized 71 patients with lumbar disc herniation to undergo either percutaneous discectomy or lumbar microdiscectomy. A successful outcome was reported in only 29% of those undergoing percutaneous discectomy, compared to 80% in the microdiscectomy group. The trial was halted early due to this inferior outcome. In a 1993 randomized study, Revel and colleagues compared the outcomes of percutaneous discectomy to chymopapain injection in 141 patients with disk herniation and sciatica. Treatment was considered successful in 61% of patients in the chymopapain group, compared to 44% in the percutaneous discectomy group. Another trial cited in the Cochrane review, Mayer et al., is not applicable, as the technique used modified forceps in addition to a suction probe. Finally, the last trial cited in the Cochrane review, Hermantin, et al., provided insufficient data to allow detailed analysis of results.

In the Lumbar Automated Percutaneous Discectomy Group (LAPDOG) study (Haines et al., 2002), a randomized trial was designed to compare percutaneous and open discectomy in patients with lumbar disc herniation. This trial was designed to recruit 330 patients but was able to recruit only 36 patients. Of the evaluable 27 patients, 41% of the percutaneous discectomy patients and 40% of the conventional discectomy patients were assessed as having successful outcomes at six months. The authors acknowledged that this trial was unable to enroll sufficient numbers of patients to reach a definitive conclusion and stated, "It is difficult to understand the remarkable persistence of percutaneous discectomy in the face of a virtually complete lack of scientific support for its effectiveness in treated lumbar disc herniation."

A task force of the American Society of Interventional Pain Physicians (Boswell et al., 2007) reported that percutaneous disc decompression remains controversial; although all observational studies were positive, the evidence from all four of the randomized published studies was negative. Questions also remain about the appropriate patient selection criteria (particularly related to the size and migration of the disc herniation) for this procedure.

The 2005 National Institute for Health and Excellence guidance for automated percutaneous mechanical lumbar discectomy concluded, "There is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, but evidence from small randomized controlled trials shows conflicting results. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and for audit or research."

Minimally Invasive Lumbar Decompression (MILD)

The largest RCT (Staats et al., 2016 and Benyamin et al., 2016) compared mild with ESIs (control) in 302 patients who had ligamentum flavum hypertrophy and who failed conservative therapy. Early results have suggested reductions in pain and improvements in function scores in the mild group versus the control group. The trial was unblinded, and there is evidence of differing expectations and follow-up in the two groups, suggesting a high risk of bias. The available evidence is insufficient to determine the efficacy of mild compared with placebo, or to determine the efficacy of mild compared with open decompression. Trials with relevant control groups could provide greater certainty on the risks and benefits of this procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.

The SpineCATH/Oratec Intradiscal Electrothermal Catheter received Section 510(k) premarket authorization from the United States Food and Drug Administration (FDA) in March 1998. The Radionics RF Disc Catheter Electrode System (Radionics, Inc., Burlington, MA) received Section 510(k) authorization in 2000. It is intended to create lesions in nervous tissue, and for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs. The Baylis Pain Management Cooled Probe, used for intradiscal biacuplasty (Baylis Medical, Inc., Montreal, Canada), received Section 510(k) authorization in 2005. It is intended for use "in conjunction with the Radio Frequency Generator to create radiofrequency lesions in nervous tissue." The Baylis Transdiscal System received Section 510(k) authorization in 2006. This system, "[u]sed in combination with the Baylis Pain Management Generator is intended for the creation of radiofrequency (RF) lesions in nervous tissue including that which is situated in intervertebral disc material."

Intradiscal Electrothermal Annuloplasty (IDET/IDTA)

Published clinical trials have not provided evidence to support the efficacy of IDET/IDTA. Published evidence consists mainly of case series. Results of two randomized, controlled trials (RCTs), each with methodological weaknesses, are inconsistent. Pauza et al. concluded that the treatment is effective; however, the researchers did not use an "intention to treat" analysis, and it is not clear that the reduction in reported pain is clinically significant. Freeman et al. conducted a randomized, sham-controlled study; no subject in either arm met criteria for successful outcome, and no significant benefit for IDET/IDTA over placebo was demonstrated.

Percutaneous Intradiscal Thermocoagulation (PIRFT)

There is little published clinical evidence regarding PIRFT. A 2001 double-blind trial randomized 28 patients with chronic low back pain to PIRFT or a sham control group. The primary outcome was the percentage of success at eight weeks, measured by changes in pain level, impairment, Oswestry disability scale, and analgesics taken. At the end of eight weeks,

there were two treatment successes in the sham group, compared to one in the treatment group. The authors concluded that PIRFT was not better than the placebo procedure in reducing pain and disability.

A 2007 evidence-based practice guideline from the American Society of Interventional Pain Physicians on the management of chronic spinal pain, created to provide recommendations to clinicians in the U.S., concluded that evidence is moderate for IDET/IDTA in the management of chronic discogenic low back pain. Complications included catheter breakage, nerve root injuries, post-IDET/IDTA disc herniation, cauda equine syndrome, infection, epidural abscess, and spinal cord damage. The same guideline concluded that evidence for radiofrequency posterior annuloplasty (PIRFT) was limited, with complications similar to IDET/IDTA.

A systematic review of IDET/IDTA and PIRFT was conducted, following the criteria recommended by the Cochrane Back Review Group. Four randomized and two non-randomized studies, totaling 283 patients, were included in the review. The report concluded that the available evidence does not support the efficacy or effectiveness of IDET/IDTA and PIRFT, and that these procedures are associated with potentially serious side effects. Evidence-based guidelines from the American Society of Interventional Pain Physicians concluded that the evidence is moderate for management of chronic discogenic low back pain with IDET/IDTA. Complications include catheter breakage, nerve root injuries, post-IDET/IDTA disc herniation, cauda equine syndrome, infection, epidural abscess, and spinal cord damage. The evidence for PIRFT was reported to be limited, with complications similar to IDET/IDTA.

Intradiscal Biacuplasty

In an industry-sponsored, multi-center, RCT (Desai et al., 2016), 63 patients with lumbar discogenic pain were treated with intradiscal biacuplasty plus conservative medical management or with medical management alone. A significant effect was found for the primary outcome measure (mean reduction in visual analog scale score for pain at six months), but not the secondary outcome measures. Additional sham-controlled trials in a broader population of patients are needed, to confirm treatment efficacy.

The Viable Allograft Supplemented Disc Regeneration in the Treatment of Patients with Low Back Pain with or without Disc Herniation (VAST) Trial was a prospective, randomized, parallel-arm, multi-center study approved to enroll up to 220 subjects at up to 15 clinical sites. The aim of the trial was to investigate the clinical relevance of treating painful intervertebral disc tissue by a supplementary transplantation of viable cellular allograft disc matrix and compare the cellular allograft with a saline placebo or continued treatment with sustained conservative care. This interim analysis enrolled 24 subjects who were randomized 3.5:1:1 to receive allograft (n=16) or saline (n=4) at either one or two levels or continue nonsurgical management (NSM) (n=4). Back pain with a visual analog scale (VAS) and disability by the Oswestry Disability Index (ODI) were assessed, as were adverse events. After three months, all subjects in the NSM cohort crossed over to allograft treatment. At 12 months, the VAS improved from 54.81, 55.25, and 62.255 in the allograft, saline, and NSM subjects, respectively, to 12.27 in the allograft group and 19.67 in the saline group. At 12 months, ODI improved from 53.73, 49.25, and 55.75 in the allograft, saline, and NSM subjects, respectively, to 15.67 in the allograft group and 9.33 in the saline group. Adverse events were transient and resolved in all cohorts.

Indications approved by the U.S. Food and Drug Administration (FDA) for the Homium YAG laser include discectomy. The FDA granted Section 510(k) premarket approval for the use of Arthrocare's Perc-D SpineWand with the ArthroCare System 2000 for ablation, coagulation, and decompression of disk material.

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 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 patients should be informed of the range of treatment options available.

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 nucleoplasty, there are two randomized, controlled trials (RCT), 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 one year), that 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.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN)*

CPT Codes

Code	Description
22526 **(E/I)**	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
22527 **(E/I)**	one or more additional levels (list separately in addition to code for primary procedure)
62287 **(E/I)**	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 (e.g., manual or automated percutaneous discectomy, percutaneous laser discectomy)
0274T **(E/I)**	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (e.g., fluoroscopic, CT), single or multiple levels, unilateral or bilateral; cervical or thoracic
0627T **(E/I)**	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level
0628T **(E/I)**	each additional level (List separately in addition to code for primary procedure)
0629T **(E/I)**	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level
0630T **(E/I)**	with CT guidance, lumbar; each additional level (List separately in addition to code for primary procedure)

HCPCS Codes

Code	Description
C2614 **(E/I)**	Probe, percutaneous lumbar discectomy

Code	Description
G0276	Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial
S2348 **(E/I)**	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

ICD10 Codes

Code	Description
M43.12-M43.17	Spondylolisthesis (code range)
M48.02 – M48.07	Spinal stenosis (code range)
M50.20-M50.23	Other cervical disc displacement (code range)
M50.30-M50.33	Other cervical disc degeneration (code range)
M51.06	Intervertebral disc disorders with myelopathy, lumbar region
M51.16	Intervertebral disc disorders with radiculopathy, lumbar
M51.17	Intervertebral disc disorders with radiculopathy, lumbosacral region
M51.24-M51.27	Other intervertebral disc displacement (code range)
M51.34-M51.37	Other intervertebral disc degeneration (code range)
M51.9	Unspecified thoracic, thoracolumbar and lumbosacral intervertebral disc disorder

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*Key Article

KEY WORDS

Automated percutaneous discectomy, DeKompressor, hydrodiscectomy, Nucelotome, Percutaneous discectomy, IDET, IDTA, intradiscal electrothermotherapy, intradiscal biacuplasty, percutaneous intradiscal thermocoagulation, PIRFT, radiofrequency annuloplasty, thermal annuloplasty, Radiofrequency coblation, laser discectomy, disc nucleoplasty, plasma disc decompression, radiofrequency thermocoagulation nucleoplasty (RFTC), percutaneous laser discectomy /decompression, laser-assisted disc decompression (LADD), targeted percutaneous laser disc decompression (targeted PLDD), coblation percutaneous disc decompression.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis (150.13). Please refer to the following NCD website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=358&DocID=150.13] accessed 09/25/24.

There is currently a National Coverage Determination (NCD) for Thermal Intradiscal Procedures (TIPS) (150.11). Please refer to the following NCD website for Medicare Members: [http://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=324] accessed 09/25/24.

There is currently a National Coverage Determination (NCD) for Laser Procedures (140.5). Please refer to the following NCD websites for Medicare Members: [https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=69] accessed 09/25/24.