Intradiscal Procedures

Number: 0602

Policy
*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers thermal intradiscal procedures (TIPs) experimental and investigational for relief of discogenic pain or other indications because their effectiveness has not been established. Thermal intradiscal procedures are also known as:

- Annulo-nucleoplasty (The Disc-FX procedure)
- Cervical intradiscal radiofrequency lesioning
- Coblation percutaneous disc decompression
- Intradiscal biacuplasty (IDB)/intervertebral disc biacuplasty/cooled radiofrequency
- Intradiscal electrothermal annuloplasty (IEA)
- Intradiscal electrothermal therapy (IDET)
- Intradiscal thermal annuloplasty (IDTA)
- Nucleoplasty (also known as percutaneous radiofrequency thermomodulation or percutaneous plasma diskectomy)
- Percutaneous (or plasma) disc decompression (PDD)
- Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)/intradiscal radiofrequency thermomodulation/percutaneous radiofrequency thermomodulation
- Radiofrequency annuloplasty (RA)
- Targeted disc decompression (TDD)

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Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes
Aetna considers the following intradiscal procedures experimental and investigational because their effectiveness has not been established (not an all-inclusive list):

- Intradiscal infiltration with plasma rich in growth factors for the treatment of low back pain
- Intradiscal implantation of stromal vascular fraction plus platelet rich plasma for the treatment of degenerative disc disease
- Intradiscal glucocorticoid injection for the treatment of low back pain
- Intradiscal methylene blue injection for the treatment of low back pain

**Note:** TIPs are also identified or labeled based on the name of the catheter/probe that is used (e.g., Accutherm, discTRODE, SpineCath, or TransDiscal electrodes).

**Note:** This policy addresses intradiscal electrothermal procedures only and should be distinguished from radiofrequency neuroablation, which is the destruction of nerves using heat.

See also [CPB 0016 - Back Pain - Invasive Procedures](#).

**Background**

**Thermal Intradiscal Procedures**

Electrothermal intradiscal therapies (also referred to as thermal intradiscal procedures [TIP]) are percutaneous spinal procedures that are designed to treat back pain utilizing heat that is applied to the disc or disc wall (annulus). Several techniques have been introduced.

The evolution of TIPs involved the use of electrical and radiofrequency energy to apply or create heat within the disc to treat discogenic pain. Percutaneous thermocoagulation
Intradiscal techniques involve the insertion and heating of a catheter/probe in the disc under fluoroscopic guidance (Urrutia et al, 2007). Derby et al (2008) stated, “The goals of thermal disc treatments are to remove unwanted tissue such as herniated discs, create a seal to limit expression of matrix components, shrink collagen tissue, and destroy nociceptors. Although intradiscal heating can be accomplished through a variety of means, including electrocautery, thermal cautery, laser, and radiofrequency energy (RFE), most current intradiscal thermal treatments are performed using RFE.” A review of the current literature reveals that the mechanism of non-specific chronic low back pain, as well as the mechanism of action of the thermal intradiscal procedures remain uncertain. There are numerous catheters that have received 510(K) clearance from the FDA for use in thermal procedures. Some catheters have a specific indication for use in the intervertebral disc and many are indicated for the creation of heat lesions for the relief of pain.

Intradiscal electrothermal therapy (IDET), also known as intradiscal electrothermal annuloplasty (IDTA) or IEA, is a minimally invasive surgical procedure that uses a catheter and a flexible electrode that is inserted into the affected disc in order to heat the entire posterior edge of the annulus. This technique has been proposed for the treatment of lower back pain caused by internal disc disruption. IDET was designed to reduce pain via two mechanisms: heat-induced changes in the structure of the collagen within the disc and ablation of the nerve endings in the outer third of the annulus. The procedure is conducted using fluoroscopic guidance in which a heating element is inserted via a catheter into a disc. The disc is heated to 90 degrees Celsius for up to 20 minutes, which may result in the contraction and shrinkage of the fibers that comprise the disc wall. The procedure is suggested to be an alternative to spinal fusion surgery in which the disc is destroyed and the two vertebrae are fused together. An example of a device used for IDET includes, but may not be limited to, the SpineCATH Intradiscal Catheter.

Intradiscal electrothermal therapy is used to treat patients with chronic, nonspecific low back pain attributed to degenerative disc disease and who met the criteria for interbody fusion surgery.
The IDET technique is commonly identified with the use of the SpineCath Intradiscal catheter. Original 510(k) clearance was obtained by Oratec Interventions, Inc., (Menlo Park, CA). In 2002 Oratec was acquired by Smith & Nephew. The targeted patients have no clinical or radiologic evidence of significant disc herniation or nerve root compression. The procedure involves placing a thermal catheter within an intervertebral disc via a 17-gauge introducer needle under fluoroscopic guidance and heating the tip to 90°C over 13 minutes and maintaining that temperature for 4 minutes. This thermal therapy is postulated to alleviate discogenic pain by shrinking collagen and denervating nerve endings in the disc annulus. Despite its use at various centers around the country, there are few published clinical studies that assess the efficacy of this procedure. Intradiscal electrothermal therapy would not directly treat sciatica and is not currently recommended by the manufacturer for patients with sciatica. Proponents believe that IDET works best when the painful disc has not collapsed more than 50%.

However, because of the lack of prospective randomized controlled clinical trials with adequate follow up demonstrating the effectiveness of IDET, the procedure is considered experimental and investigational and is not covered. In addition, there are unresolved issues about the long-term effects of this treatment on the biomechanics of the disc. The disc is a viscoelastic structure and possesses various biomechanical properties that are necessary for proper spinal function. The heat of the probe denatures and alters the collagen within the disc, affecting the biomechanics of the disc. The long-term (after 2 to 5 years) maintenance of good results with IDET is also not known at this point in time. In an editorial accompanying a study reporting on the 2-year outcomes of IDET (Saal and Saal, 2002), Dr. Timothy S. Carey of the University of North Carolina School of Medicine, acknowledged that "patients who undergo IDET do significantly improve over a 2-year period of time." However, because the study did not include a comparison group, "we don't know whether (patients) are doing better or worse than if they would have had another procedure," he told Reuters Health on May 8, 2002. The bottom line, he said, is that more study is needed. "A randomized (comparison) trial is urgently needed.
before we expose patients to a technique that has not been (rigorously) evaluated," Carey said.

Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) is a similar technique to IDET. PIRFT, however, uses a radiofrequency probe that is placed into the center of the disc rather than around the annulus. The device is activated for 90 seconds at a temperature of 70 degrees Celsius. PIRFT does not ablate the disc material but instead alters the biomechanics of the disc or destroys nociceptive pain fibers. PIRFT is performed using the Radionics RF Disc Catheter System or the DiscTRODE.

One should note that positive results, similar to IDET, were reported in uncontrolled cohort studies of a similar procedure, percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), also known as percutaneous radiofrequency thermomodulation. However, subsequently performed randomized controlled clinical studies demonstrated that PIRFT had no significant effect compared to placebo (Barendse et al, 2001). Azulay and colleagues (2008) assessed a technique for radiofrequency heating of the lumbar intervertebral disc by a needle placed into the nucleus pulposus. The method was tested in 17 patients according to the criteria used in previous intradiscal radiofrequency studies. Before and after treatment, disability was assessed by the Oswestry disability score. A pain reduction of at least 50 % was considered a success. Fifteen patients were responders at 1 month (88 %), 9 at 3 months (53 %), and 12 at 6 months (70.6 %). No complications were observed. The authors concluded that a new method of providing discal radiofrequency treatment for lower back pain had a substantial clinical benefit in 71 % of the observed patients. Moreover, they stated that a prospective study comparing this new method with placebo should be conducted to confirm these initial results.

The developers of this procedure have commented that long-term studies and randomized controlled clinical trials are needed to validate the effectiveness of IDET (Saal and Saal, 1999):
"Further study is necessary to define the mechanism and reasons for clinical improvement. Placebo-controlled trials and histologic and biomechanical studies are needed to answer many of the
remaining questions. Additional validation of these positive results in placebo-controlled randomized trials and studies that compare IDET with alternative treatments is needed. ... These positive results should be validated in placebo-controlled randomized trials and studies that compare IDET with alternative treatments."

In a patient information statement, the American Academy of Orthopedic Surgeons has commented on the need for prospective randomized controlled studies of IDET (AAOS, March 2002): "The long-term results of this procedure are still unknown. IDET was introduced in 1997 and case series without controls have reported encouraging results. However, these results need to be confirmed in prospective, randomized trials. Additionally, there is debate about how the procedure actually works."

An American Pain Society Bulletin concluded that "[c]learly, IDET is in its infancy and demands the scrutiny of prospective, double-blinded, placebo-controlled studies" (Arends, 2001). In a recent review, Barndes et al (2002) commented: "IDET is an innovative tool for the treatment of discogenic back pain. Initial reports suggest that IDET is effective in 60 to 70 % of patients with chronic discogenic low back pain who have not improved with a comprehensive non-operative program. Intradiscal electrothermal therapy is minimally invasive and has a low complication rate and therefore might offer advantages over surgery. However, the outcomes and cost of IDET have not been compared with those of fusion and chronic pain management. Validation of the initial reports of IDET in placebo-controlled randomized trials is needed."

Technology assessments from several state agencies have also emphasized the need for prospective randomized controlled clinical studies of IDET. A Minnesota Health Technology Advisory Committee Technology Assessment of IDET (2001) concluded: "While the initial data are promising, large randomized controlled trials are needed to determine safety, cost, effectiveness, and long-term outcome. Published research is limited and unrefined due to small sample size, poor study design, and lack of long-term
A technology assessment by the Institute for Clinical Systems Improvement (2002) concluded as follows: "There is no convincing evidence that shows the short or long-term clinical efficacy of this procedure. Only subjective outcomes from case series and one non-randomized trial have been reported. Blinded, randomized studies comparing the procedure to a placebo treatment or alternative treatments such as spinal fusion have not been done and are needed to develop any conclusion about efficacy of the procedure... The long-term effects of thermal coagulation of the disk are unknown at this time."

The State of Oregon Workman Compensation System (2001) reached similar conclusions regarding IDET: "IDET is a new procedure that is currently being promoted by some medical providers as an effective treatment for chronic low back pain. However, there is significant concern that this procedure has not undergone rigorous scientific investigation and therefore is experimental or unproven. There are no randomized studies of its effectiveness, no animal research regarding the long term effects of disc heating, and no evidence of long-term safety."

The Canadian Coordinating Office of Health Technology Assessment (2003) concluded that the available evidence for IDET is of "poor quality" and that "[t]he long-term safety and effectiveness of IDET, and whether patients will require retreatment to maintain pain relief, is not yet known." A structured evidence review conducted by the BlueCross BlueShield Association Technology Evaluation Center (2004) concluded: "The evidence does not permit conclusions as to whether percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic low back pain improves health outcomes or is as beneficial as established alternatives."

The California Technology Assessment Forum (CTAF) conducted a technology review (2003) of IDET and concluded that IDET with the Radionics Radiofrequency system and with the Oratec IDET system did not meet CTAF technology assessment criteria.
The National Institute for Clinical Excellence (2004) concluded that "[c]urrent evidence on the safety and efficacy of percutaneous intradiscal electrothermal therapy for lower back pain does not appear adequate" and that "[t]he natural history of this condition, the difficulty in assessing pain and the potential for a placebo effect all present problems when interpreting the evidence on this procedure."

At this time, this surgery is only done in the lumbar region. In the early stages of investigation, IDET appears promising; however, additional prospective, randomized controlled clinical studies are needed to compare efficacy against other intradiscal heating procedures, to determine the precise pathology most successfully treated by the procedure, and to assess the long-term outcomes of this procedure as compared to other more conventional therapies.

A Cochrane systematic review (Gibson, 2005) concluded that the effectiveness of IDET remained unproven.

The European Guidelines for the Management of Chronic Nonspecific Low Back Pain (Airaksinen et al. 2006) reported that the diagnosis of internal disc disruption was surrounded by controversy and that the effect of IDET was not well understood. The authors summarized the evidence as follows: (i) there is conflicting evidence that procedures aimed at reducing the nociceptive input from painful intervertebral discs using either intradiscal radiofrequency thermocoagulation or IDET, in patients with discogenic low back pain, are not more effective than sham treatments (level C); and (ii) there is limited evidence that radiofrequency lesioning of the ramus communicans is effective in reducing pain up to 4 months after treatment (level C). The authors stated, "We cannot recommend the use of intradiscal radiofrequency, electrothermal coagulation or radiofrequency denervation of the rami communicans for the treatment of either nonspecific or "discogenic" low back pain."

ECRI (2007) determined that the evidence base for IEA for discogenic pain was rated low for quantity, quality, consistency and robustness. Adverse events for this technology were not well
In a review on IDET for the treatment of chronic discogenic low back pain, Wetzel et al (2002) stated that the studies published so far suggest that the pain resulting from lumbar disc disease may be diminished by intradiscal electrothermal annuloplasty. All these studies project a positive therapeutic effect. However, all the studies suffer from the same methodologic flaws. A prospective cohort design or a non-randomized prospective design is used with a biased control. The authors stated that a randomized prospective study is needed. Additionally, more investigation into the basic science of the action of intradiscal electrothermal annuloplasty is required.

Pauza and colleagues (2004) from the East Texas Medical Center presented data from a randomized, double-blind, placebo-controlled trial evaluating the efficacy of IDET for the treatment of chronic discogenic low back pain with 6 month outcomes. The investigators reported significant improvement in the visual analog scale (VAS), 36-Item Short Form Health Survey (SF-36), Beck Depression Scale, Oswestry Low Back Pain Disability Questionnaire. The authors concluded, “Nonspecific factors associated with the procedure account for a proportion of the apparent efficacy of IDET, but its efficacy cannot be attributed wholly to a placebo effect. The results of this trial cannot be generalized to patients who do not fit the strict inclusion criteria.” This is a small, short-term single-institutional study involving the private practice of a single investigator. Because of unanswered questions about the durability of results and generalization of these findings, this single study is not sufficient to draw conclusions about the effect of IDET on health outcomes.

Freeman et al (2005) reported on 57 patients who were randomized to either IDET (n = 38) or sham (n = 19). The objective of the study was to test the safety of IDET compared with sham treatment for low back pain of at least 3 months duration. Study participants were chosen from consecutive patients of 3 spine surgeons if they satisfied eligibility criteria. Randomization occurred after catheter placement via sealed envelope by an independent technician who was responsible to
covertly connect the catheter if the patient was to receive active treatment. All subjects followed a common rehabilitation program. Patient evaluations occurred at 6 weeks and 6 months by an independent investigator. Outcomes measures were recorded at baseline and 6 months and included the VAS, low back pain outcome score (LBOS), Oswestry Disability Index (ODI), SF-36, Zung Depression index, the modified somatic perception questionnaire, sitting tolerance, work tolerance, medication, and the presence of any neurologic deficit. Success was defined a priori as a composite measure: no neurologic deficit resulting from the procedure, an improvement in the LBOS of 7 or more points, and an improvement in the SF-36 subscales of bodily pain and physical functioning of greater than 1 standard deviation from the mean. Sample size was calculated before the study and using a 2:1 allocation with 80% power, 75 patients were required. The authors reported that no serious adverse events in either arm of the study occurred, without defining serious adverse events. The authors also reported, “Transient radiculopathy (less than 6 weeks) was reported in 4 study participants who underwent IDET and in 1 study participant who underwent the sham procedure.” The authors concluded that IDET was no more effective than placebo for the treatment of chronic discogenic low back pain.

An assessment of IDET prepared for the Ohio Bureau of Workers' Compensation (2004) concluded that "[t]he more recent medical literature has not found outcomes as good as those previously reported regardless of the measure used in the study" and that "[a]dditional outcomes studies are needed."

Urrutia et al (2007) conducted a systematic review of the evidence of percutaneous thermocoagulation intradiscal techniques (IDET and PIRFT), which concluded that "available evidence does not support the efficacy or effectiveness of percutaneous thermocoagulation intradiscal techniques for the treatment of discogenic low back pain." The investigators reviewed available databases to identify non-randomized controlled trials and randomized controlled trials on these techniques. The investigators identified 6 studies that met inclusion criteria, involving a total of 283 patients. Two open,
non-randomized trials (95 patients) showed positive results for IDET compared with rehabilitation and PIRFT. Results from 2 randomized controlled trials showed no differences between PIRFT and placebo, and between different PIRFT techniques. Two randomized controlled trials compared IDET to placebo. One suggested differences only in pain and disability, while the best quality randomized controlled trial showed no differences.

In a review of the evidence for non-surgical interventional therapies for low back pain (LBP) for the American Pain Society, Chou and colleagues (2009) concluded that there is good or fair evidence that PIRFT is not effective. These investigators also noted that there is insufficient (poor) evidence from randomized trials (conflicting trials, sparse and lower quality data, or no randomized trials) to reliably evaluate IDET and coblation Nucleoplasty.

Intradiscal biacuplasty (also referred to as simply "biacuplasty") is a newer minimally invasive intradiscal radiofrequency technique that is proposed as another treatment for back pain. This technique utilizes the Bialys TransDiscal System. During the procedure, two probes are inserted into each side of the disc. Internally circulated water-cooled radiofrequency energy is delivered between the two probes, which heats the area immediately around them and within the disc. As the RF energy heats the tissue, internally circulating water helps cool the tissue to prevent damaging nearby tissue.

Intradiscal biacuplasty (IDB) (Baylis Medical Inc., Montreal, Canada) is a new minimally invasive transdiscal radiofrequency technique for treatment of back pain. Intradiscal biacuplasty uses two internally water-cooled radiofrequency probes to lesion nociceptors in the intervertebral disc. The bilateral approach is intended to facilitate controlled lesioning between the electrodes in the disc. The Bialys TransDiscal System was cleared by the FDA based on a 510(k) premarket notification. Kapural and Mekhail (2007) reported the treatment of severe axial discogenic pain in a young man using IDB. The investigators reported that there were no intra- and post-operative complications, and significant improvements in patient functional capacity and pain scores were
noted. At 6-month follow-up, visual analog scale pain scores decreased from 5 cm to 1 cm, Oswestry disability scores improved from 14 points (28 % or moderate disability) to 6 points (12 % or minimal disability) and SF-36-PF (physical function) score changed from 67 to 82. These findings need to be confirmed by well designed controlled clinical studies.

Kapural and colleagues (2008) stated that IDB is a novel bipolar cooled radiofrequency system for the treatment of degenerative disk disease. These researchers presented the results of a pilot trial with 6-month follow-up. A total of 15 patients, 22 to 55 years old, underwent 1- or 2-level IDB treatment of their painful lumbar discs. All had chronic LBP for greater than 6 months, back pain exceeding leg pain, concordant pain on provocative discography, disc height greater than 50 % of control, and evidence of 1- or 2-level degenerative disc disease (DDD) without evidence of additional changes on magnetic resonance imaging. Intra-discal biacuplasty was performed under fluoroscopy using 2 RF probes positioned bilaterally in the intervertebral disc. Thirteen patients completed follow-up questionnaires at 1, 3, and 6 months. Pain disability was evaluated with Oswestry and Short Form (SF)-36 questionnaires. Median VAS pain scores were reduced from 7 (95 % confidence interval [CI]: 6 to 8) to 4 (2 to 5) cm at 1 month, and remained at 3 (2 to 5) cm at 6 months. The Oswestry improved from 23.3 (SD 7.0) to 16.5 (6.8) points at 1 month and remained similar after 6 months. The SF-36 Physical Functioning scores improved from 51 (18) to 70 (16) points after 6 months, while the SF-36 Bodily Pain score improved from 38 (15) to 54 (23) points. Daily opioid use did not change significantly from baseline: from 40 (95 % CI: 40 to 120) before IDB to 5 (0 to 40) mg of morphine sulfate equivalent 6 months after IDB. No procedure-related complications were detected. The authors concluded that patients showed improvements in several pain assessment measures after undergoing IDB for discogenic pain. Moreover, they stated that a randomized controlled trial (RCT) is needed to address the effectiveness of the procedure.

Kapural et al (2010) reported the effects of intradiscal biacuplasty in the treatment of thoracic discogenic pain in 3 patients. No intra-operative and post-operative complications were reported.
Improvements in functional capacity and pain scores were noted in 2 patients. Visual analog scale pain scores changed from 10 to 2 cm and 7 to 3 cm in 2 patients who claimed improvements at 12 months follow-up. In patient 1 VAS went from 7 to 8 cm claiming no improvements after the procedure. In patients 1 and 3, ODI improved from 24 to 8 and 10 points, respectively, and SF-36 physical function score changed from 55 to 80 and 45 to 82, respectively. Patient 2 showed no improvements with ODI (28 to 32) and SF-36 physical function score (50 to 45) at 12 months after intradiscal biacuplasty. Patient 1 stopped using his oxycodone/acetaminophen 5/325 mg that he used previously at 6 tablets a day, patient 3 decreased use of his duragesic patch from 75 microg/hr to 25 microg/hr. Patient 2 continued with significant use of opioids (100 microg/hr of transdermal fentanyl). The authors concluded that intradiscal biacuplasty may be an effective and readily available treatment for thoracic discogenic pain if future comparison studies show benefits of such procedure.

Kallewaard et al (2010) noted that various interventional treatment strategies for chronic discogenic LBP unresponsive to conservative care include reduction of inflammation, ablation of intradiscal nociceptors, lowering intra-nuclear pressure, removal of herniated nucleus, and radiofrequency ablation of the nociceptors. Unfortunately, most of these strategies do not meet the minimal criteria for a positive treatment advice. In particular, single-needle radiofrequency thermocoagulation of the discus is not recommended for patients with discogenic pain. Moreover, there is currently insufficient evidence to recommend intra-discal electrothermal therapy and intradiscal biacuplasty.

In a review on “Effectiveness of thermal annular procedures in treating discogenic low back pain”, Helm et al (2012) stated that the evidence is fair for IDET and poor for discTRODE and biacuplasty procedures regarding whether they are effective in relieving discogenic LBP. Since 2 RCTs are in progress on that procedure, assessment of biacuplasty may change upon publication of those studies.

In a randomized, placebo-controlled trial, Kapural et al (2013)
compared the effectiveness of IDB with that of placebo treatment for discogenic LBP. Subjects were randomized on a 1:1 basis to IDB and sham groups. Follow-ups were conducted at 1, 3, and 6 months. Subjects and coordinators were blinded to randomization until 6 months. Of the 1,894 subjects screened, 64 subjects were enrolled, and 59 were treated: 29 randomized to IDB and 30 to sham. All subjects had a history of chronic LBP for longer than 6 months. Two cooled RF electrodes placed in a bipolar manner in affected discs to lesion the nociceptive fibers of the annulus fibrosus. The sham procedure was identical to the active treatment except that probes were not directly inserted into the disc space, and RF energy was not actively delivered. The principal outcome measures were physical function, pain, disability, and opioid usage. Patients in the IDB group exhibited statistically significant improvements in physical function ($p = 0.029$), pain ($p = 0.006$), and disability ($p = 0.037$) at 6-month follow-up as compared to patients who received sham treatment. Treatment patients reported a reduction of 16 mg daily intake of opioids at 6 months; however, the results were not statistically different from sham patients. The authors concluded that these findings suggested that the clinical benefits observed in this study were the result of non-placebo treatment effects afforded by IDB; and IDB should be recommended to select the patients with chronic discogenic LBP. There were several drawbacks with this study; (i) lack of a formal assessment of blinding effectiveness, (ii) short follow-up period (6 months), (iii) small sample size ($n = 29$), and lack of difference in post-intervention daily opioid intake between treatment and control groups. Furthermore, these investigators stated that additional studies are needed to ascertain the effectiveness of IDB as compared with other treatment modalities such as conservative therapy, other minimally invasive modalities or surgery.

Lu and colleagues (2014) carried out a systematic evaluation of the literature to examine current non-operative management for the treatment of discogenic LBP. PubMed, Embase and Cochrane Central Register of Controlled Trials (CENTRAL) were searched for clinical studies evaluating non-operative methods of treating discogenic back pain that were published between 2000 to 2012. Only prospective RCTs that compared a non-surgical intervention
with sham or placebo therapy were included. After removal of duplicate citations, a total of 226 articles were initially identified from the search terms. From these, these researchers identified 11 RCTs from which data analysis was performed. The 11 RCTs investigated traction therapy, injections and ablative techniques. Results from 5 RCTs investigating methylene blue injection, steroid injection, ramus communicans ablation, IDET and biacuplasty favored intervention over sham therapy. However, results from the study on methylene blue injections have not been replicated in other RCTs. Evaluation of the selection criteria utilized in the studies on ramus communicans ablation and intradiscal biacuplasty and a stratified analysis of results from the RCTs on IDET casted doubt on whether the conclusions from these RCTs can be applied to the general discogenic pain patient population. The authors concluded that there are few high quality studies evaluating non-operative treatments for reducing discogenic LBP. Moreover, they stated that although conclusions from several studies favor intervention over sham, it is unclear whether these interventions confer stable long-term benefit. There is some promise in newer modalities such as biacuplasty; however, more inclusive studies need to be performed.

In a feasibility study, Dreyfuss and colleagues (2008) examined if single-site, long-duration intradiscal radiofrequency (RF) at 2 different positions could generate adequate heating throughout the intervertebral disc to potentially ablate intradiscal nociceptors. The disarticulated cervical spines from 4 fresh frozen cadavers were studied. Temperature recording was completed from 2 different positions of the RF needle. The needle was either placed in the middle of the disc in 4 discs, or it was inserted in the posterior quarter of the disc, in 8 discs. Thermocouple measurements were made every 2 mins from 3 positions: (i) middle of the disc, (ii) postero-lateral aspect of the disc, and (iii) in the anterior third of the disc. Intradiscal RF lesioning was carried out in the middle and posterior portion of the cervical disc at 85 degrees C for 10 mins. Outcome measures included local temperature within the disc. Lesioning in either the middle or posterior portion of the disc failed to provide sufficient temperature increases throughout the cervical disc to achieve adequate denervation. The authors concluded that as in
the lumbar spine, intradiscal cervical RF provides too focal a thermal profile to effectively denervate the disc even in an ex vivo experiment. Thus, single-site, long-duration cervical intradiscal RF lesioning in vivo can not be recommended.

The Centers for Medicare & Medicaid Services (CMS) has issued a national non-coverage determination for TIPs, after a review of the clinical evidence did not demonstrate that TIPs improved health outcomes. A decision memo on TIPs from the Centers for Medicare & Medicaid Services (2008) concluded, "For TIPs, the mechanisms of action remain theoretical. A thorough review of the empirical evidence on TIPs is adequate to demonstrate the lack of benefit to health outcomes from these procedures. Two randomized controlled trials provided evidence of no benefit to health outcomes and one randomized controlled trial failed to demonstrate confidence of any benefit to the Medicare population. The quality of many of the other studies is disappointing and the lack of sufficient documentation of adverse events and long term outcomes is disconcerting. Therefore, we propose that TIPs are not reasonable and necessary."

Targeted disc decompression (TDD) is a minimally invasive spinal procedure that uses thermal energy to treat herniated discs directly at the site of the actual herniation. A catheter is inserted into the disc and coiled inside it until the catheter lies directly adjacent to the disc herniation. The heat energy applied through the coil causes the disc to shrink, thereby reducing discal pressure. An example of a device used for this procedure is the Acutherm Decompression Catheter, which is used in conjunction with the Electrothermal 20S Spine System. Acutherm uses a shorter catheter than is utilized with IDET.

Disc nucleoplasty (also known as percutaneous radiofrequency thermomodulation, percutaneous plasma discectomy or plasma disc decompression [PDD]) is a minimally invasive procedure to treat individuals with symptomatic low back and leg pain caused by herniated discs. The procedure utilizes a device called the ArthroCare Perc-D SpineWand, which includes the Perc DLR (designed to be used in larger discs), the Perc DLG (used when longer access is needed) and the Perc DC (designed to be used in
the cervical portion of the spine). The SpineWand is designed to relieve pressure on spinal nerves adjacent to the disc by removing disc material. This procedure relies on a patented technology referred to as Coblation, in which the SpineWand applies a high-frequency electric current directly to the saline medium inside the disc, generating a tightly focused field of highly energized molecules around the tip of the wand. These particles have sufficient energy to convert soft tissue within the disc into a gas at relatively low temperatures and this gas escapes through the wand. The wand is introduced into the intervertebral disc through a small needle, and is advanced and withdrawn across the diameter of the disc several times, alternately dissolving disc material and thermally coagulating the channels left behind after removal of tissue.

Nucleoplasty (also known as percutaneous radiofrequency thermomodulation or percutaneous plasma diskectomy) is a percutaneous method of decompressing herniated vertebral discs that uses radiofrequency energy (Coblation [ArthroCare Corp., Sunnyvale, CA]) for ablating soft tissue, and thermal energy for coagulating soft tissue, combining both approaches for partial disc removal.

Azzazi and colleagues (2011) evaluated the safety and clinical outcome of Nucleoplasty in well-selected cases. Coblation technology was used in 50 patients, who had radicular leg pain due to contained disc herniation or focal protrusion, from 2005 to 2008. Clinical outcome was assessed by the VAS and Oswestry Disability Index Questionnaire. Reduction in analgesic treatment was also recorded. The procedure was performed under local anesthesia. The mean VAS score decreased from 8.2 to 1.3 at the 1 year evaluation (p = 0.001). The Oswestry Disability Index Questionnaire decreased from 62.2 to 9.6 at the 1 year follow-up (p = 0.001). Analgesic consumption was reduced or stopped in 90% of cases after 1 year. There was complete resolution of symptoms in 40 patients after 1 year. There were 4 patients who underwent conventional microdiscectomy. Five cases had post-operative discitis that cleared clinically and radiologically within 2 months without sequelae in 4 of them. One patient had to undergo operative instrumental fusion at the affected level. The
authors concluded that Nucleoplasty does not require general anesthesia, offers less morbidity and shortens recovery time. Contained herniated disc or focal protrusion are the most important inclusion criteria. Hence this technique is a promising tool in well-selected cases.

Coblation ablates tissue via a low-temperature, molecular dissociation process to create small channels within the disc. While monitoring the patient, a series of channels are created by advancing a catheter (Perc-D Coblation Channeling Wand) into the disc while ablating tissue. After stopping at a pre-determined depth, the catheter is slowly withdrawn. On withdrawal, the channels are thermally treated, producing a zone of thermal coagulation. The catheter is then rotated clockwise, and another channel is created. Approximately 6 channels are created, depending on the desired amount of tissue reduction. The Nucleoplasty procedure is performed on an outpatient basis under local anesthesia and fluoroscopic guidance, with the patient in a lateral or prone position.

Nucleoplasty is designed to avoid the substantial thermal injury risks of Intradiscal Electrothermal Annuloplasty (IDET), because Nucleoplasty produces lower temperatures within the disc annulus. Data from ArthroCare using cadaveric models shows that IDET generates substantially higher tissue temperatures within the nucleus and superior endplates of the vertebral disc than the Nucleoplasty procedure. Increased temperatures play a detrimental role with respect to cartilaginous vertebral endplates and surrounding tissues.

An assessment by the National Institute for Clinical Excellence (2004) concluded: “Current evidence on the safety and efficacy of percutaneous disc decompression using Coblation for lower back pain does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research.... The lack of data makes it difficult to draw conclusions regarding the efficacy of the procedure. The lack of long-term and comparative data also makes it difficult to distinguish between the treatment effect and the natural history of the disease, as well as determine whether the benefits of this
procedure are sustained beyond 12 months.”

An assessment by the Washington State Department of Labor and Industries (2004) found that no randomized trials have been conducted to study the efficacy of nucleoplasty. The assessment concluded that, because only case series studies have been conducted to examine the efficacy of this procedure, it is considered investigational.

Marin (2005) stated that Nucleoplasty is a promising minimally invasive technique for the treatment of symptoms associated with contained herniated disc. However, randomized controlled studies are required to know with more precision the role of this procedure. Cohen and colleagues (2005) ascertained determine the treatment outcomes of 16 consecutive patients with lumbar radicular pain secondary to a herniated disc who underwent Nucleoplasty as their primary therapy. These investigators concluded that Nucleoplasty is not an effective long-term treatment for lumbar radiculopathy, either alone or with IDET.

A technology assessment by the California Technology Assessment Forum (CTAF, 2002) concluded that Nucleoplasty percutaneous disc decompression does not meet CTAF's assessment criteria.

An assessment of radiofrequency techniques (nucleoplasty, percutaneous thermocoagulation, and electrothermal annuloplasty) by the Institute for Clinical Effectiveness and Health Policy (Lopez et al, 2005) reached the following conclusions: “Radiofrequency techniques are new technologies and little information is published about them. The data come mostly from observational studies of poor-level evidence whose main limitation is lack of comparison against control groups treated using conventional strategies (analgesics and physical therapy). This limitation is particularly significant in pathologies such as low back pain which presents a high rate of spontaneous resolution. This makes it difficult to draw conclusions about the efficacy of the procedures and their mid and long term safety... The evidence currently available on the three techniques does not support the use of these procedures on routine basis beyond the research
Marin (2005) stated that Nucleoplasty may be an effective minimally invasive technique for the treatment of symptoms associated with contained herniated disc. However, randomized controlled studies are needed to ascertain with more precision the role of this procedure.

Bhagia et al (2006) reported the short-term side effects and complications after percutaneous disc decompression utilizing Coblation technology (Nucleoplasty). Following institutional review board approval, consecutive patients who were to undergo percutaneous disc decompression using Nucleoplasty were prospectively enrolled. Patients were questioned pre-operatively, post-operatively, and 24 hours, 72 hours, 1 week, and 2 weeks post-procedure by an independent reviewer regarding 17 possible symptom complications, which included bowel or bladder symptoms, muscle spasm, new pain, numbness/tingling or weakness, fevers/chills, rash/pruritus, headaches, nausea/vomiting, bleeding, and needle insertion site soreness. Statistical analysis was performed using Wilcoxon's signed-rank test. A total of 53 patients enrolled, of whom 4 patients dropped out. Two patients had increased symptoms and opted for surgery. Two patients could not be contacted. The most common side effects at 24 hours post-procedure was soreness at the needle insertion site (76 %), new numbness and tingling (26 %), increased intensity of pre-procedure back pain (15 %), and new areas of back pain (15 %). At 2 weeks, no patient had soreness at the needle insertion site or new areas of back pain; however, new numbness and tingling was present in 15 % of patients. Two patients (4 %) had increased intensity of pre-procedure back pain. There were statistically significant reductions in visual analog scale (VAS) score for back pain and leg pain (p < 0.05). The authors concluded that based on this preliminary data, Nucleoplasty seems to be associated with short-term increased pain at the needle insertion site and increased pre-procedure back pain and tingling numbness but without other side effects.

In a prospective, non-randomized, longitudinal, cohort study, Gerszten et al (2006) assessed pain, functioning, and quality of
life (QOL) in patients with radicular leg and back pain who underwent Nucleoplasty-based percutaneous disc decompression. A total of 67 patients (mean age of 41 years) with primarily radicular pain due to a contained disc herniation underwent Nucleoplasty-based decompression in an outpatient setting. Patients completed the Medical Outcomes Study 36-Item Short Form (SF-36) Health Survey, EuroQol 5D (EQ5D), and a VAS for pain pre-operatively, and at 3 and 6 months after surgery. Post-operative QOL differences were assessed using the Wilcoxon signed-rank test. A surgical probe, the Perc-DLE SpineWand, was placed percutaneously into the disc after application of a local anesthetic or induction of general anesthesia to remove part of the disc (i.e., a percutaneous discectomy). Nucleoplasty-treated levels were L2 to L3 (1 case), L3 to L4 (5 cases), L4 to L5 (44 cases), and L5 - S1 (40 cases); there were 22 multiple treatment levels and 42 bilateral treatments. There were no infections or nerve root injuries associated with the procedure. Compared with pre-operative QOL, there was a statistically significant improvement in QOL at 3 months as measured using the SF-36 Physical Component Summary (PCS) scale (mean score improvement 4.4 [p = 0.014]), the EQ5D (mean score improvement 0.22 [p = 0.001]), and the VAS for pain (mean score improvement 0.13 [p = 0.021]). Six-month results in 36 patients continued to reflect improvement as measured using the SF-36 PCS (mean score improvement 7.6 [p = 0.002]) and the EQ5D (mean score improvement 0.27 [p = 0.001]). The authors concluded that Nucleoplasty-based percutaneous disc decompression in patients with symptomatic contained disc herniations is safe and improves QOL as measured by the SF-36, EQ5D, and VAS for pain, 3 generic QOL outcome instruments. Nucleoplasty is an effective minimally invasive surgical treatment alternative in patients with symptomatic contained disc herniations. They noted that further follow-up evaluation is underway to determine the durability of QOL improvement after Nucleoplasty.

The National Institute for Health and Clinical Excellence's guideline on percutaneous disc decompression using coblation for LBP (2006) stated that "[c]urrent evidence suggests that there are no major safety concerns associated with the use of
percutaneous disc decompression using coblation for lower back pain. There is some evidence of short-term efficacy; however, this is not sufficient to support the use of this procedure without special arrangements for consent and for audit or research....Further research will be useful in reducing the current uncertainty, and clinicians are encouraged to collect long-term follow-up data”. The guideline also stated that the Specialist Advisors expressed uncertainty regarding the efficacy of this procedure.

In a retrospective, non-randomized case series, Yakovlev et al (2007) assessed the effect of Nucleoplasty on pain and opioid use in improving functional activity in patients with radicular or axial low back pain secondary to contained herniated discs. A total of 22 patients who had undergone Nucleoplasty were included in the analysis. Patients were evaluated at 1, 3, 6, and 12 months post-operatively, and were asked to quantify their pain using a VAS ranging from 0 to 10. Patients were also surveyed in regards to their pain medication use, and functional status was quantified by a physical therapist who also used patient reports of ability to perform activities of daily living to assess status. Data were compared between baseline and at 1, 3, 6, and 12 months post-treatment. Reported pain and medication use were significantly decreased and functional status was improved at 1, 3, 6, and 12 months following Nucleoplasty (p values less than or equal to 0.0010 for all outcome measures at all time periods). There were no complications associated with the procedure and continued improvements were observed over time. The authors concluded that Nucleoplasty appears to be safe and effective; however, they noted that randomized, controlled studies are needed to further evaluate its long-term effectiveness.

Calisaneller and colleagues (2007) examined the early post-operative radiological changes after lumbar Nucleoplasty and evaluated the short-term effects of this procedure on discogenic LBP and leg pain. A total of 29 patients between the ages of 32 and 59 years (mean of 44.14) were included in the study. Visual analog scale scores of patients were recorded in the pre-operative period and 24 hours, 3 months and 6 months after the procedure. Additionally, pre-operative and post-operative lumbar
magnetic resonance imaging (MRI) examinations of these patients were compared. The mean pre-operative VAS score was 6.95 (range of 3.0 to 10.0) and the mean post-operative VAS scores at 24 hours, 3 months and 6 months were 2.46 (range of 0 to 8.0), 4.0 (range of 0 to 10.0) and 4.53 (range of 0 to 10.0), respectively. There were statistically significant reductions (p < 0.001) in VAS scores for all post-operative time points when compared to pre-operative values. Nucleoplasty did not produce obvious changes at least on the early post-operative MRI examination. The authors concluded that although Nucleoplasty appeared to be a safe minimally invasive procedure, the value of this new technique for the treatment of discogenic LBP remains as yet unproven. They stated that further RCTs with longer follow-up are needed to elucidate the effects of Nucleoplasty on discogenic LBP and leg pain.

Freeman and Mehdian (2008) stated that over the past 10 years, there has been a surge of minimally invasive techniques aimed at treating both discogenic LBP and radicular pain. These investigators evaluated the current evidence for 3 such treatments: (i) IDET, (ii) percutaneous discectomy, and (iii) Nucleoplasty. An electronic search of the literature was performed using the Cochrane Library database (2007) and Medline (1966 to 2007); 77 references relating to IDET, 363 to percutaneous discectomy, and 36 to Nucleoplasty were identified. Two RCTs assessed the effectiveness of IDET; 1 demonstrated a positive effect on pain severity only, whereas the other reported no substantial benefit. Trials of automated percutaneous discectomy suggested that clinical outcomes after treatment are at best fair and often worse when compared with microdiscectomy. Other RCTs reported that Nucleoplasty is ineffective for the treatment of discogenic LBP.

In a systematic review, Gerges et al (2010) examined the clinical effectiveness of the Nucleoplasty procedure for treating back pain from symptomatic, contained disc herniation and to evaluate the methodological quality of the included studies. The relevant literature for Nucleoplasty was identified through a search of the following databases: PubMed, Ovid Medline, and the Cochrane library, and by a review of the bibliographies of the included
A review of the literature of the effectiveness of the Nucleoplasty procedure for managing discogenic pain was performed according to the criteria for observational studies using a "Quality Index" scale to determine the methodological quality of the literature. The level of evidence was classified as Level I, II, or III based on the quality of evidence developed by the U.S. Preventive Services Task Force (USPSTF) for therapeutic interventions. Recommendations were based on the criteria developed by Guyatt et al. The main outcome measures evaluated were the percentage of pain relief based on VAS or numeric rating scale (NRS), percentage of patients with more than 50% reduction in pain, percentage of patients meeting one or more success criteria after Nucleoplasty, and improvement in patient function. Secondary measures noted were reports of complications and the Quality Index scores of each study that was evaluated. The quality of evidence for improvement in pain or function after a Nucleoplasty procedure is Level II-3. The recommendation is 1C/strong for the Nucleoplasty procedure based on the quality of evidence available. The median Quality Index score was 16 (range of 12 to 19), indicating adequate methodological quality of the available literature. None of the studies reported major complications related to Nucleoplasty. The authors concluded that observational studies suggest that Nucleoplasty is a potentially effective minimally invasive treatment for patients with symptomatic disc herniations who are refractory to conservative therapy. The recommendation is a level 1C, strongly supporting the therapeutic efficacy of this procedure. However, the authors stated that prospective, RCTs with higher quality of evidence are needed to confirm effectiveness and risks, and to determine ideal patient selection for this procedure.

Zhu et al (2011) evaluated longer-term efficacy over a 2-year follow-up of coblation Nucleoplasty treatment for protruded lumbar intervertebral disc. A total of 42 cases of protruded lumbar intervertebral disc treated by coblation Nucleoplasty followed-up for 2 years were analyzed. Relief of LBP, leg pain and numbness after the operation were assessed by VAS. Function of lower limb and daily living of patients were evaluated by the ODI. Operations were performed successfully in all cases. Three
patients had recurrence within a week of the procedure. Evaluation of the 42 patients demonstrated significant improvement rate of VAS: defined as 66.2 % in back pain, 68.1 % in leg pain, and 85.7 % in numbness at 1-week after the operation; 53.2 %, 58.4 %, 81.0 % at 1-year; and 45.5 %, 50.7 %, 75.1 % at 2-year follow-up. One week after the operation, obvious amelioration occurred in all the patients, but the tendency decreased. Before operation, the mean value of ODI was 68.2 +/- 10.9 %. The value at 1 week was 28.6 +/- 8.2 %; 1-year at 35.8 +/- 6.5 %; and 2-years at 39.4 +/- 5.8 %. The authors concluded that coblation Nucleoplasty may have satisfactory clinical outcomes for treatment of protruded lumbar intervertebral disc for as long as 2-year follow-up, but longer-term benefit still needs verification.

In a narrative review, Helm et al (2009) evaluated the effectiveness of thermal annular procedures (TAPs) in reducing LBP in patients with intradiscal disorders. The literature was evaluated according to Cochrane Review criteria for RCTs and according to the Agency for Healthcare Research and Quality (AHRQ) criteria for observational studies. The level of evidence was classified as Level I, II, or III based on the quality of evidence developed by the USPSTF. Pain relief was the primary outcome measure. Other outcome measures were functional improvement, improvement of psychological status, and return to work. Short-term effectiveness was defined as 1-year or less and long-term effectiveness was defined as greater than 1-year. Systematic review of IDET identified 2 RCTs and 16 observational studies with an indicated evidence of Level II-2. Systematic review of radiofrequency annuloplasty identified no RCTs but 2 observational studies with an uncertain evidence of Level II-3. Systematic review of IDB identified 1 pilot study. The level of evidence is lacking with Level III. The authors concluded that IDET offers functionally significant relief in approximately 50 % of appropriately chosen chronic discogenic LBP patients. The authors found minimal evidence supporting the use of radiofrequency annuloplasty and IDB. A critique of this systematic evidence review by the Centre for Review and Dissemination (2010) noted that the results were mainly extracted from observational studies in settings where the
studied procedure was performed routinely; hence there was a bias risk in favor of the procedure (this limitation was acknowledged by the authors). The critique stated that the conclusions of this systematic evidence review were non-specific. The authors supported the use of thermal annular procedure in selected patients despite the fact that the level of evidence was low.

In a prospective, parallel, randomized and gender stratified, double-blind placebo-controlled study, Kvarstein et al (2009) evaluated the long-term effect and safety aspects of PIRFT with the discTRODE probe. A total of 20 patients with chronic LBP and a positive 1-level pressure-controlled provocation discography were randomized to either intra-annular PIRFT or intra-annular sham treatment. A blinded interim analysis was performed when 20 patients had been followed for 6 months. The 6-month analysis did not reveal any trend towards overall effect or difference between active and sham treatment for the primary endpoint: change in pain intensity (0 to 10). The inclusion of patients was therefore discontinued. After 12 months, the overall reduction from baseline pain had reached statistical significance, but there was no significant difference between the groups. The functional outcome measures (ODI, and SF 36 subscales and the relative change in pain) appeared more promising, but did not reach statistical significance when compared with sham treatment. Two actively treated and 2 sham-treated patients reported increased pain levels, and in both groups a higher number was unemployed after 12 months. The study did not find evidence for a benefit of PIRFT, although it can not rule out a moderate effect. The authors stated that considering the high number, reporting increased pain in this study, they would not recommend intra-annular thermal therapy with the discTRODE probe.

In a prospective, multi-center, randomized, controlled trial, Gerszten and colleagues (2010) assessed clinical outcomes with percutaneous plasma disc decompression (PDD) as compared with standard care using fluoroscopy-guided trans-foraminal epidural steroid injection (TFESI) over the course of 2 years. A total of 90 patients (18 to 66 years old) who had sciatica (VAS
score greater than or equal to 50) associated with a single-level lumbar contained disc herniation were enrolled. In all cases, their condition was refractory to initial conservative care and 1 epidural steroid injection had failed. Participants were randomly assigned to receive either PDD (n = 46) or TFESI (n = 44, up to 2 injections). Patients in the PDD group had significantly greater reduction in leg pain scores and significantly improved ODI and SF-36, physical function, bodily pain, social function, and physical components summary scores than those in the TFESI group. During the 2-year follow-up, 25 (56%) of the patients in the PDD group and 11 (28%) of those in the TFESI group remained free from having a secondary procedure following the study procedure (log-rank p = 0.02). A significantly higher percentage of patients in the PDD group showed minimum clinically important change in scores for leg and back pain and SF-36 scores that exceeded literature-based minimum clinically important changes. Procedure-related adverse events, including injection site pain, increased leg or back pain, weakness, and light-headedness, were observed in 5 patients in the PDD group (7 events) and 7 in the TFESI group (14 events). The authors concluded that in patients who had radicular pain associated with a contained lumbar disc herniation, PDD resulted in significantly reduced pain and better quality of life scores than repeated TFESI. In addition, significantly more PDD patients than TFESI patients avoided having to undergo a secondary procedure during the 2-year study follow-up. This study compared plasma disc decompression with trans-foraminal epidural steroid injection, which does not seem to be the same as accepted standard steroid epidural injections.

Helm et al (2012) evaluated the effectiveness of TAPs in treating discogenic LBP and assessed complications associated with those procedures. The quality assessment and clinical relevance criteria utilized were the Cochrane Musculoskeletal Review Group criteria for interventional techniques for randomized trials, and the criteria developed by the Newcastle-Ottawa Scale criteria for observational studies. The level of evidence was classified as good, fair, or poor based on the quality of evidence developed by the U.S. Preventive Services Task Force. Data sources included relevant literature identified through searches of PubMed and
EMBASE from 1966 through December 2011, and manual searches of the bibliographies of known primary and review articles. The primary outcome measure was pain relief of at least 6 months. Secondary outcome measures were improvements in functional status. For this systematic review, a total of 43 studies were identified. Of these, 3 RCTs and 1 observational study met the inclusion criteria. Using current criteria for successful outcomes, the evidence is fair for IDET and poor for discTRODE and biacuplasty procedures regarding whether they are effective in relieving discogenic LBP. Since 2 RCTs are in progress on that procedure, assessment of biacuplasty may change upon publication of those studies. The authors concluded that the evidence is fair for IDET and poor for discTRODE; and biacuplasty is being evaluated in 2 ongoing RCTs. The limitations of this systematic review included the paucity of literature and non-availability of 2 RCTs which are in progress for biacuplasty.

Grewal et al (2012) stated that a variety of non-operative interventions are available to treat back pain. Careful assessment, discussion, and planning need to be performed to individualize care to each patient. These researchers discussed good to fair evidence from RCTs that injection therapy, PIRFT, IDET, and prolotherapy are not effective. Evidence is poor from RCTs regarding local injections, Botox, and Coblation nucleoplasty; however, with a focused approach, the right treatment can be provided for the right patient. The authors stated that to be more effective in management of back pain, further high-grade RCTs on safety and effectiveness are needed.

In a systematic review, Manchikanti et al (2013) examined the effectiveness of mechanical lumbar disc decompression with nucleoplasty. The available literature on mechanical lumbar disc decompression with nucleoplasty was reviewed. The quality assessment and clinical relevance criteria utilized were the Cochrane Musculoskeletal Review Group criteria as utilized for interventional techniques for randomized trials and the criteria developed by the Newcastle-Ottawa Scale criteria for observational studies. The level of evidence was classified as good, fair, and limited or poor based on the quality of evidence developed by the USPSTF. Data sources included relevant
literature identified through searches of PubMed and EMBASE from 1966 to September 2012, and manual searches of the bibliographies of known primary and review articles. Pain relief and functional improvement were the primary outcome measures. Other outcome measures were improvement of psychological status, reduction in opioid intake, and return to work. Short-term effectiveness was defined as 1 year or less, whereas long-term effectiveness was defined as greater than 1 year. For this systematic review, a total of 37 studies were considered for inclusion. Of these, there was 1 randomized trial and 14 observational studies meeting inclusion criteria for methodological quality assessment. Based on USPSTF criteria, the level of evidence for nucleoplasty is limited to fair in managing radicular pain due to contained disc herniation. The authors concluded that this systematic review illustrated limited to fair evidence for nucleoplasty in managing radicular pain due to contained disc herniation. The main drawback of this review was a paucity of literature with randomized trials.

Ogbonnaya and colleagues (2013) evaluated the effectiveness of nucleoplasty in the management of discogenic radicular pain. The medical notes of 33 patients, admitted for nucleoplasty between June 2006 and September 2007, were reviewed retrospectively. All had radicular pain, and contained herniated disc as seen on MRI of lumbosacral spine. Patients were followed-up at 1 and 3 months post-procedure. The outcome measures employed in this study were satisfaction with symptoms and self-reported improvement. A total of 33 cases were examined (18 males and 15 females); 27 procedures were performed with no complications and 6 were abandoned due to anatomical reasons. There were 18 and 15 cases of disc herniation at L5/S1 and L4/5 levels, respectively. Four weeks following the procedure, 13 patients reported improvement in symptoms, and 14 remained symptomatically the same and subsequently had open microdiscectomy. The authors concluded that nucleoplasty has been shown to be a safe and minimal-access procedure. Less than 50 % of the authors’ selected cohort of patients reported symptomatic improvement at 1-month follow-up. The authors noted that they no longer offer this procedure to their patients.
Ren et al (2015) evaluated the effectiveness of percutaneous nucleoplasty using coblation technique for the treatment of chronic non-specific LBP, after 5 years of follow-up. From September 2004 to November 2006, 172 patients underwent percutaneous nucleoplasty for chronic LBP in the authors’ department; 41 patients were followed-up for a mean period of 67 months. Nucleoplasty was performed at L3/L4 in 1 patient; L4/L5 in 25 patients; L5/S1 in 2 patients; L3/L4 and L4/5 in 2 patients; L4/L5 and L5/S1 in 7 patients; and L3/L4, L4/L5, and L5/S1 in 4 patients. Patients were assessed pre-operatively and at 1 week, 1 year, 3 years, and 5 years post-operatively. Pain was graded using a 10-cm VAS and the percentage reduction in pain score was calculated at each post-operative time-point. The ODI was used to assess disability-related to lumbar spine degeneration, and patient satisfaction was assessed using the modified MacNab criteria. There were significant differences among the pre-operative, 1-week post-operative, and 3-year post-operative VAS and ODI scores, but not between the 3- and 5-year post-operative scores. There were no significant differences in age, sex, or pre-operative symptoms between patients with effective and ineffective treatment, but there were significant differences in the number of levels treated, Pfirrmann grade of intervertebral disc degeneration, and provocative discography findings between these 2 groups. Excellent or good patient satisfaction was achieved in 87.9 % of patients after 1 week, 72.4 % after 1 year, 67.7 % after 3 years, and 63.4 % at the last follow-up. The authors concluded that although previously published short- and medium-term outcomes after percutaneous nucleoplasty appeared to be satisfactory, the long-term follow-up results showed a significant decline in patient satisfaction over time.

In a prospective, randomized, cross-over, multi-center trial, Desai et al (2016) compared the effectiveness of IDB versus conventional medical management (CMM) in the treatment of lumbar discogenic pain. A total of 63 subjects with lumbar discogenic pain diagnosed via provocation discography were randomized to IDB + CMM (n = 29) or CMM-alone (n = 34). At 6-months patients in the CMM-alone group were eligible for cross-over if desired. The primary outcome measure was the
change in VAS from baseline to 6-months. Secondary outcome measures included treatment "responders", defined as the proportion of subjects with a 2-point or 30% decrease in VAS scores. Other secondary measures included changes from baseline to 6-months in: (i) short form (SF) 36-physical functioning (SF36-PF), (ii) ODI, (iii) Beck Depression Inventory (BDI), (iv) Patient Global Impression of Change (PGIC), (v) EQ-5D VAS, and (vi) back pain-related medication usage. In the IDB cohort the mean VAS score reduction exceeded that in the CMM cohort (-2.4 versus -0.56; p = 0.02), and the proportion of treatment responders was substantially greater (50% versus 18%). Differences in secondary measures favored IDB; no differences in opioid utilization were noted between groups. The authors concluded that superior performance of IDB with respect to all study outcomes suggested that it is a more effective treatment for discogenic pain than CMM-alone. (Level of Evidence: 2)

Streitparth and Disch (2015) stated that over the last decades a number of different minimally invasive interventions have been proposed for the treatment of intervertebral disc herniation and degeneration. All of these interventions aim at relieving pressure from compressed nerve roots by mechanical ablation, chemical dissolution, evaporation or coagulation of disc tissue. Standard treatment is microsurgical sequestrectomy with direct visualization of the spinal canal; while treatment innovations include minimally invasive intradiscal interventions (e.g., chemonucleolysis, manual and automated disc decompression, laser disc decompression, nucleoplasty and thermal annular RF techniques with posterolateral access to the intervertebral disc). In a literature review, these investigators compared the safety and effectiveness of the different minimally invasive procedures to the standard surgical procedure. For patients with disc herniation requiring surgery, microsurgical sequestrectomy is the treatment of choice, while discectomy is obsolete. The authors stated that intradiscal procedures have a low level of evidence while long-term results are still lacking; RCTs are needed to generate evidence-based results.

In a prospective cohort study, McCormick et al (2016) determined
long-term outcomes of Dekompressor PLDD for discogenic radicular pain. Consecutive patients (12/2004 to 11/2005) with discogenic lumbosacral radicular pain who underwent PLDD with Dekompressor were included in this study; NRS leg pain score and ODI score data were collected at 6 months and 1 year. These 2 measures, 5-point Likert scale patient satisfaction, and surgical rate data were collected at 8 years. A total of 70 patients underwent PLDD; 40 and 25 patients were successfully contacted at 1-year and 8-year follow-up, respectively. Using intention-to-treat analysis, at 1 year and 8 years, NRS leg pain scores were reduced greater than 50 % in 47 % (95 % CI: 35 % to 59 %) and 29 % (95 % CI: 18 % to 40 %) of patients, respectively; ODI score improved greater than 30 % in 43 % (CI: 32 % to 55 %) and 26 % (CI: 19 % to 41 %) of patients, respectively. Of the patients who were followed-up at 8 years, 36 % (CI: 17 % to 55 %) had undergone surgery and the median satisfaction was "4" (interquartile range of 2 to 5). The authors concluded that while limited by loss-to-follow-up, the findings of this study suggested that treatment of discogenic lumbosacral radicular pain with Dekompressor resulted in decreased leg pain and disability and favorable satisfaction at long-term follow-up. Moreover, they stated that further study with adequate follow-up retention is needed to confirm that Dekompressor spares open spinal surgery.

Ong et al (2016) stated that open discectomy remains the standard of treatment for patients with lumbar radicular pain secondary to a prolapsed intervertebral disc. Open discectomy performed in patients with small, contained herniations may result in poor outcomes. The various techniques of PDD have been developed to address this population. These researchers performed a literature search on articles, which address PDD for lumbar radicular pain. Published techniques include chymopapain chemonucleolysis, percutaneous laser disc decompression (PLDD), automated percutaneous lumbar discectomy (APLD), Dekompressor, nucleoplasty, and targeted disc decompression (TDD). In addition, the rationale of provocative discography, selective nerve root injections, and intra-op discograms before performing PDD was discussed in detail. Dekompressor and nucleoplasty have the best level of evidence with a score of 2B+. The chymopapain
chemonucleolysis has the most publications, but it is also accompanied by the most significant adverse complications and so it is scored as a 2B+/−. The other techniques were supported mainly by observational studies and thus their scores range between 0 and 2B+/−. There was no supporting evidence for provocative discography in patients with lumbar radicular pain. The evidence for a positive selective nerve root injection as an inclusion criteria or the need for an intra-operative discogram showed mixed results. The authors concluded that nuleoplasty and Dekompressor have a weak positive recommendation for the treatment of patients with lumbar radicular pain. There is no role for provocative discography in this group of patients, although the evidence for a selective nerve root injection or an intra-operative discogram is inconclusive.

Annulo-Nucleoplasty (The Disc-FX Procedure):

Kumar and colleagues (2014) stated that back pain due to lumbar disc disease is a major clinical problem. The treatment options range from physiotherapy to fusion surgery. A number of minimally invasive procedures have also been developed in the recent past for its management. Disc-FX is a new minimally invasive technique that combines percutaneous discectomy, nuclear ablation and annular modification. Literature on its role in the management of lumbar disc pathology is scarce. These researchers included 24 consecutive patients who underwent the Disc-FX for back pain due to lumbar disc pathology non-responsive to non-operative treatment for a period of at least 6 months. Based on MRI these patients fell into 2 groups: (i) those with DDD (n = 12) and (ii) those with a contained lumbar disc herniation (CLDH) (n = 12). They were evaluated using the VAS, ODI and SF-36 scores pre-operatively and post-operatively. The mean age was 37.9 years (21 to 53 years). There were 17 males and 7 females; 1 patient in each subgroup was excluded from the final evaluation. Significant improvement was seen in all outcome measures. The overall rate of re-intervention for persistent symptoms was 18.18 % (4/22); in the CLDH subgroup, it was 36.36 % (4/11). The authors concluded that early results after the Disc-FX procedure suggested that it is a reasonable treatment option for patients with back pain due to lumbar disc
disease, especially for those with DDD who fail conservative treatment. It could be an alternative to procedures like fusion or disc replacement. Moreover, they stated that this study presented level IV evidence; however, longer term prospective studies are needed to prove this and to evaluate its role in the treatment of patients with CLDH.

Intradiscal Procedures

_Intradiscal Infiltration with Plasma Rich in Growth Factors for the Treatment of Low Back Pain:_

In a retrospective, observational, pilot study, Kirchner and Anitua (2016) examined the clinical outcome of plasma rich in growth factors (PRGF-Endoret) infiltrations (1 intradiscal, 1 intra-articular facet, and 1 transforaminal epidural injection) under fluoroscopic guidance-control in patients with chronic LBP. Patients with a history of chronic LBP and DDD of the lumbar spine who met inclusion and exclusion criteria were recruited between December 2010 and January 2012. One intradiscal, 1 intra-articular facet, and 1 transforaminal epidural injection of PRGF-Endoret under fluoroscopic guidance-control were performed in 86 patients with chronic LBP in the operating theater setting. Descriptive statistics were performed using absolute and relative frequency distributions for qualitative variables and mean values and standard deviations for quantitative variables. The non-parametric Friedman statistical test was used to determine the possible differences between baseline and different follow-up time-points on pain reduction after treatment. Pain assessment was determined using a VAS at the 1st visit before (baseline) and after the procedure at 1, 3, and 6 months. The pain reduction after the PRGF-Endoret injections showed a statistically significant drop from 8.4 ± 1.1 before the treatment to 4 ± 2.6, 1.7 ± 2.3, and 0.8 ± 1.7 at 1, 3, and 6 months after the treatment, respectively, with respect to all the time evaluations (p < 0.0001) except for the pain reduction between the 3rd and 6th month whose significance was lower (p < 0.05). The analysis of the VAS over time showed that at the end-point of the study (6 months), 91 % of patients showed an excellent score, 8.1 % showed a moderate improvement, and 1.2 % were in the inefficient score. The
authors concluded that fluoroscopy-guided infiltrations of intervertebral discs and facet joints with PRGF in patients with chronic LBP resulted in significant pain reduction assessed by VAS.

This study had several drawbacks: (i) the absence of a control (placebo) group, (ii) these investigators did not perform a previous diagnostic block for patients’ selection, and therefore the diagnosis and selection of patients relied on a careful clinical examination, (iii) the lack of measurement of physical activity levels before and after the treatment, and (iv) to limit the bias of a single assessment, the self-reported VAS pain scale should have been associated with other health survey questionnaires that encompass pain and functional evaluation. The authors stated that taking into account of the afore-mentioned drawbacks and in the light of these preliminary data, they stated that a RCT is considered imperative.

Monfett and colleagues (2016) provided an overview of clinical and translational research on intradiscal platelet-rich plasma (PRP) as a minimally invasive treatment for discogenic LBP. These investigators performed a literature review of in-vitro, in-vivo, and clinical studies. They noted that there is strong in-vitro evidence that supports the use of intradiscal PRP for discogenic LBP. There are also promising findings in select pre-clinical animal studies. A clinical study of 29 participants who underwent intradiscal PRP injections for discogenic LBP found statistically and clinically significant improvements in pain and function through 2 years of follow-up. The authors concluded that intradiscal PRP is a safe and a possibly effective treatment for discogenic LBP. Moreover, they stated that future studies are needed to determine (i) the best candidates for this treatment, (ii) what the optimal injectate is, and (iii) what relationships exist between patient-reported outcomes and radiological findings.

In a prospective, clinical trial, Levi and associates (2016) evaluated changes in pain and function in patients with discogenic LBP after an intradiscal injection of PRP. Patients were diagnosed with discogenic LBP by clinical means, imaging, and exclusion of other structures. Provocation discography was used in a minority of the patients. Patients underwent a single
treatment of intradiscal injection of PRP at 1 or multiple levels. Patients were considered a categorical success if they achieved at least 50% improvement in the VAS and 30% decrease in the ODI at 1, 2, and 6 months post-treatment. A total of 22 patients underwent intradiscal PRP; 9 patients underwent a single-level injection, 10 at 2 levels, 2 at 3 levels, and 1 at 5 levels. Categorical success rates were as follows: 1 month: 3/22 = 14% (95% CI: 0% to 28%), 2 months: 7/22 = 32% (95% CI: 12% to 51%), 6 months: 9/19 = 47% (95% CI: 25% to 70%). The authors concluded that the findings of this trial demonstrated encouraging preliminary results at 6 month, using strict categorical success criteria, for intradiscal PRP as a treatment for presumed discogenic LBP. They stated that randomized, placebo-controlled trials are needed to further evaluate the effectiveness of this treatment.

_Intradiscal Implantation of Stromal Vascular Fraction plus Platelet Rich Plasma for the Treatment of Degenerative Disc Disease:_

Kristin and colleagues (2017) noted that stromal vascular fraction (SVF) can easily be obtained from a mini-lipoaspirate procedure of fat tissue and platelet rich plasma (PRP) can be obtained from peripheral blood. The SVF contains a mixture of cells including adipose tissue-derived stem cells (ADSCs) and growth factors and has been depleted of the adipocyte population. These researchers evaluated the safety and effectiveness of administering SVF and PRP intradiscally into patients with DDD. A total of 15 patients underwent a local tumescent liposuction procedure to remove approximately 60 ml of fat tissue. The fat was separated to isolate the SVF and the cells were delivered into the disc nucleus of patients with DDD. Subjects were then monitored for adverse events (AE), range of motion (ROM), VAS, present pain intensity (PPI), ODI, BDI, Dallas Pain Questionnaire (DPQ) and SF-12 scores over a 6-month period; safety events were followed for 12 months. No severe AEs (SAEs) were reported during a 12-month follow up period with no incidences of infection. Patients demonstrated statistically significant improvements in several parameters including flexion, pain ratings, VAS, PPI, and SF-12 questionnaires. In addition, both ODI and BDI data were trending positive and a majority of patients
reported improvements in their DPQ scores. The authors concluded that patients were pleased with the treatment results. More importantly, the procedure demonstrated a strong safety profile with no SAEs or complications linked to the therapy. While the current study provided encouraging feasibility data regarding intradiscal stem cell treatment and suggested some clinical benefit of the SVF therapy in degenerative disc patients, these investigators stated that a true evaluation of safety and effectiveness would require larger phase II/III studies.

Although the findings of this study suggested that the use of SVF is safe and feasible, the general under-powering of the study coupled with the lack of placebo control necessitated additional studies to determine the true clinical effect of the treatment. In addition, several patients were lost to follow-up that could have created patient bias. Given the encouraging results on this small sample size (n = 15) with statistical significance, large appropriately powered clinical studies blinded to both clinical staff and patients are needed.

Intradiscal Glucocorticoid Injection for the Treatment of Low Back Pain:

In a prospective, parallel-group, double-blind, randomized, controlled study, Nguyen and colleagues (2017) evaluated the effectiveness of a single glucocorticoid intradiscal injection (GC-IDI) in patients with chronic LBP with active discopathy. A total of 135 patients with chronic LBP with active discopathy on MRI were included in this analysis. Subjects received a single GC-IDI (25 mg prednisolone acetate) during discography (n = 67) or discography alone (n = 68). The primary outcome was the percentage of patients with LBP intensity less than 40 on an 11-point NRS (0 [no pain] to 100 [maximum pain] in 10-point increments) in the previous 48 hours at 1 month after the intervention. The main secondary outcomes were LBP intensity and persistent active discopathy on MRI at 12 months and spine-specific limitations in activities, health-related QOL, anxiety and depression, employment status, and use of analgesics and non-steroidal anti-inflammatory drugs (NSAIDs) at 1 and 12 months. All randomly assigned patients were included in the primary efficacy analysis.
At 1 month after the intervention, the percentage of responders (LBP intensity less than 40) was higher in the GC-IDI group (36 of 65 [55.4 %]) than the control group (21 of 63 [33.3 %]) (absolute risk difference, 22.1 percentage points [95 % CI: 5.5 to 38.7 percentage points]; p = 0.009). The groups did not differ in LBP intensity at 12 months and in most secondary outcomes at 1 and 12 months. The authors concluded that in chronic LBP associated with active discopathy, a single GC-IDI reduced LBP at 1 month but not at 12 months.

Intradiscal Methylene Blue Injection for the Treatment of Low Back Pain:

In an observational study, Zhang and colleagues (2016) examined the clinical outcomes and MRI changes of intradiscal methylene blue injection (MBI) for the treatment of discogenic LBP. A total of 33 subjects were selected to be treated with intradiscal MBI. The clinical outcomes were evaluated by NRS and ODI at pre-treatment, 1 month, 3, 6, and 12 months after treatment. The MRI changes of involved intervertebral discs were assessed by apparent diffusion coefficient and T2 values at pre-treatment, 3, 6, and 12 months following treatment. All of the patients were followed-up to 12 months. The mean NRS scores at pre-treatment, 1 month, 3, 6, and 12 months after treatment were 6.54, 2.98, 3.23, 3.66, and 4.72, respectively. There was a minimum of 2 points reduction at 1 month, 3, and 6 months after treatment, but less than 2 points reduction at 12 months. There was at least 50 % improvement on the ODI at 1 month, 3, and 6 months after treatment, but not at 12 months. The mean apparent diffusion coefficient and T2 value were significantly higher at 6 and 12 months following treatment compared to pre-treatment, but there was no significant difference between pre-treatment and 3 months after treatment. The authors concluded that intradiscal MBI might be an effective therapy for discogenic LBP for the short-term and could improve disc degeneration condition to some extent. The main drawbacks of this study were; (i) it was an observational study, (ii) relatively small sample size (n = 33), and (iii) short-term (up to 12 months) follow-up. These preliminary findings need to be validated by well-designed studies.
In a multi-center, prospective, pilot study, Kallewaard and associates (2016) collected information about safety, effectiveness, and acceptability of intradiscal MBI, gain and burden of outcome measures, and sample size assumptions for a potential following RCT. If this study demonstrated that this treatment is potentially safe and effective, and the methods and procedures used in this study are feasible, a RCT would follow. Patients were selected on clinical criteria, MRI findings, and a positive provocative discogram. The primary outcome measure was mean pain reduction at 6 months. A total of 15 consecutive patients with chronic lumbar discogenic pain enrolled in 2 interventional pain treatment centers in the Netherlands. At 6 months after the intervention, 40 % of the patients claimed at least 30 % pain relief. In patients who responded, physical function improved and medication use diminished. These researchers observed no procedural complications or AEs; predictors for success were Pfirrmann grading of 2 or less and higher QOL mental component scores. The authors concluded that the findings of 40 % positive respondents, and no complications, gave reason to set up a randomized, double-blind, placebo-controlled, trial.

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<th>CPT Codes / HCPCS Codes / ICD-10 Codes</th>
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<td>Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by &quot;+&quot;:</td>
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<td>ICD-10 codes will become effective as of October 1, 2015:</td>
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<td>CPT codes not covered for indications listed in the CPB:</td>
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<tr>
<td>HCPCS codes not covered for indications listed in the CPB:</td>
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Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

ICD-10 codes not covered for indications listed in CPB (not all-inclusive):

- M08.1 Juvenile ankylosing spondylitis
- M25.78 Osteophyte, vertebrae
- M43.00 - M43.9 Other deforming dorsopathies
- M45.0 - Spondylopathies
- M49.89
- M50.00 - M54.9 Other dorsopathies
- M67.88 Other specified disorders of synovium and tendon, other site
- M96.1 Postlaminectomy syndrome, not elsewhere classified

The above policy is based on the following references:

**Nucleoplasty**

4. Singh V. Percutaneous disc decompression using


22. Gerges FJ, Lipsitz SR, Nedeljkovic SS. A systematic review on
the effectiveness of the Nucleoplasty procedure for


Other Thermal Intradiscal Procedures (TIPs):


3. Karasek M, Bogduk N. Twelve-month follow-up of a controlled trial of intradiscal thermal anuloplasty for back


15. American Academy of Orthopaedic Surgeons. IDET (intradiscal electrothermal annuloplasty). AAOS Online


58. Helm II S, Deer TR, Manchikanti L, et al. Effectiveness of thermal annular procedures in treating discogenic low back


Intradiscal Procedures:


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Amendment to
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There are no amendments for Medicaid.

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