



CIGNA MEDICAL COVERAGE POLICY

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Subject Minimally Invasive Treatment of Back and Neck Pain

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Coverage Policy

Trigger Point Injection

CIGNA covers initial trigger-point injection(s) of anesthetic and/or corticosteroid (CPT codes 20552, 20553) for subacute or chronic back, or neck pain, or subacute or chronic myofascial pain syndrome as medically necessary when pain has persisted despite appropriate conservative treatment (e.g., pharmacological therapy, physical therapy, exercise).

CIGNA covers repeat trigger-point injection(s) of anesthetic and/or corticosteroid as medically necessary if improvement following the initial injection(s) is unsatisfactory, to determine whether trigger point injection(s) may provide therapeutic benefit.

CIGNA covers additional trigger-point injections of-anesthetic and/or corticosteroid for subacute or chronic back pain, neck pain, or myofascial pain syndrome as medically necessary when the prior injection resulted in subjective and objective improvement (e.g., improvement in pain, functioning, activity tolerance) and BOTH of the following criteria are met:

- A minimum of three weeks has elapsed since the prior injection
- Injections are provided in conjunction with an active therapy program, including a home exercise program.

CIGNA does not cover long-term, repeated or maintenance trigger point injection for any indication because it is considered not medically necessary.

CIGNA does not cover dry needling of trigger points for any indication because it is considered experimental, investigational, or unproven.

CIGNA does not cover ultrasound guidance (76942) for trigger point injections for any indication because it is considered not medically necessary.

Epidural Steroid Injection/Selective Nerve Root Block

CIGNA covers epidural steroid injection/selective nerve root block (CPT codes 62310, 62311, 64479-64484, 77003) as medically necessary for the treatment of acute or recurrent cervical, thoracic or lumbar radicular pain (e.g. sciatica) when improvement is not seen following at least three weeks of conservative management (e.g., pharmacological therapy, physical therapy, exercise).

CIGNA covers up to two subsequent epidural steroid injections/selective nerve root blocks block as medically necessary when there was at least three weeks of temporary, partial relief of symptoms following the prior injection, but radicular pain has persisted or worsened.

CIGNA does not cover long-term, repeated or maintenance epidural steroid injection /selective nerve root block for any indication because it is considered not medically necessary.

CIGNA does not cover EITHER of the following because each is considered experimental, investigational or unproven:

- Epidural steroid injection/selective nerve root block for acute, subacute, or chronic back pain
- Epidural steroid injection with ultrasound guidance (0231T, 0232T) for any indication

Intradiscal Steroid Injection

CIGNA does not cover intradiscal steroid injection for the treatment of acute, subacute, or chronic back or neck pain because it is considered experimental, investigational, or unproven.

Facet Joint Injection

CIGNA covers a diagnostic facet joint injection (CPT codes 64490-64495) as medically necessary when used to determine whether chronic neck or back pain is of facet joint origin when ALL of the following criteria are met:

- Pain is exacerbated by extension and rotation, or is associated with lumbar rigidity
- Pain has persisted despite appropriate conservative treatment (e.g., nonsteroidal anti-inflammatory drugs (NSAIDs), exercise)
- Clinical findings and imaging studies suggest no other obvious cause of the pain (e.g., spinal stenosis, disc degeneration or herniation, infection, tumor, fracture)

CIGNA does not cover therapeutic facet joint injection (CPT codes 64490-64495) for the treatment of acute, subacute, or chronic neck or back pain or radicular syndromes because it is considered experimental, investigational, or unproven.

CIGNA does not cover diagnostic or therapeutic facet joint injection with ultrasound guidance (CPT codes 0213T-0218T) for any indication because it is considered experimental, investigational, or unproven.

Sacroiliac (SI) Joint Injection

CIGNA covers SI joint injection (CPT code 27096, HCPCS code G0260) for the treatment of back pain associated with localized SI joint pathology (e.g., inflammatory arthritis) confirmed on imaging studies.

CIGNA does not cover EITHER of the following because each is considered experimental, investigational, or unproven:

- SI joint injection (CPT code 27096) for the diagnosis or treatment of acute, subacute, or chronic back pain or radicular syndromes
- ultrasound guidance (76942) for SI joint injection for any indication

Ablative Treatment

CIGNA covers initial radiofrequency ablation/neurolysis of paravertebral facet joint nerves (CPT codes 64622-64627, 77003) for the treatment of chronic back or neck pain as medically necessary when ALL of the following criteria are met:

- There is severe pain unresponsive to at least six months of conservative medical management. (e.g., pharmacological therapy, physical therapy, exercise).
- Facet joint origin of pain is suspected and medial branch block/injection of facet joint with local anesthetic results in elimination or marked decrease in intensity of pain.
- Clinical findings and imaging studies suggest no other obvious cause of the pain (e.g., spinal stenosis, disc degeneration or herniation, infection, tumor, fracture)

CIGNA covers repeat radiofrequency ablation/neurolysis of paravertebral facet joint nerves at the same level for the treatment of chronic back or neck pain as medically necessary when BOTH of the following criteria are met:

- At least six months have elapsed since the previous radiofrequency ablation/neurolysis of paravertebral facet joint nerves
- More than 50% relief is obtained, with associated functional improvement, for at least ten weeks following the previous treatment

CIGNA does not cover long-term, repeated or maintenance radiofrequency ablation/neurolysis of paravertebral facet joint nerves for any indication because it is considered not medically necessary.

CIGNA does not cover ANY of the following ablative procedures for the treatment of back or neck pain because each is considered experimental, investigational or unproven (this list may not be all-inclusive);

- Pulsed radiofrequency (CPT code 64999)
- Cryoablation/cryoneurolysis/cryodenevation (CPT code 64999)
- Chemical ablation (e.g., alcohol, phenol, glycerol) (CPT codes 64622-64627)
- Laser ablation (CPT code 64999)
- Sacroiliac (SI) joint ablation by any method (CPT code 64640)

Other Procedures

CIGNA does not cover ANY of the following procedures because each is considered experimental, investigational or unproven (this list may not be all-inclusive):

- automated percutaneous lumbar discectomy (APLD)/automated percutaneous nucleotomy (CPT code 62287, HCPS codes C2614)
- Coblation[®] Nucleoplasty[™], disc nucleoplasty, decompression nucleoplasty plasma disc decompression (CPT code 62287)
- devices for anular repair (e.g., Inclose[™] Surgical Mesh System, Xclose[™] Tissue Repair System (Anulex Technologies, Inc., Minnetonka, MN)
- endoscopic epidural adhesiolysis (CPT code 64999)
- epiduroscopy, epidural myelotomy, epidural spinal endoscopy (CPT code 64999)
- intervertebral disc biacuplasty (CPT code 22899)
- intradiscal electrothermal annuloplasty (e.g., intradiscal electrothermal therapy [IDET[™]])
- percutaneous laminotomy/laminectomy, percutaneous spinal decompression (e.g., mild[®] procedure) (CPT codes 22899, 64999, 0274T, 0275T, HCPCS code C9729))
- percutaneous laser discectomy /decompression, laser-assisted disc decompression (LADD) (CPT code 62287)
- percutaneous epidural adhesiolysis, percutaneous epidural lysis of adhesions, Racz procedure (CPT codes 62263, 62264)
- percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), intradiscal radiofrequency thermomodulation or percutaneous radiofrequency thermomodulation (CPT codes 22526, 22527, HCPCS code S2348)

General Background

Back pain is a frequent cause of chronic pain and disability, affecting approximately 15% of the U.S. population during their lifetime. Most episodes of low back pain improve substantially within a month without formal medical intervention. In a small minority of patients, back pain may be persistent and disabling. Conservative treatment may include pharmacological therapy (e.g., analgesics, anti-inflammatory drugs, muscle relaxants), exercise, spinal manipulation, acupuncture, cognitive-behavioral therapy, and physical therapy. If these measures are unsuccessful, a number of interventional techniques and procedures may be considered that attempt to target specific structures or spinal abnormalities considered to be potential sources of pain, including back muscles and soft tissues, degenerated facet or sacroiliac joints, spinal canal stenosis, and degenerated or herniated intervertebral discs (Chou et al., 2009).

Surgery may be appropriate for medical conditions with remediable underlying pathology (e.g. herniated disc) when confirmed and correlated with imaging findings. There is evidence that surgical discectomy provides significant pain relief in selected patients with lumbar disc prolapse with sciatica that fails to improve with conservative treatment. Discectomy was originally performed in an open operation over the spine called hemilaminectomy, in which the muscles are dissected away from the spine and access to the intervertebral disc is obtained by cutting away a piece of spinal bone (i.e., lamina). This technique remains the treatment of choice in some patients, including those with severe pain or weakness and complicated herniations. Microsurgical discectomy (i.e., microdiscectomy) is a less invasive technique that evolved in an effort to decrease postoperative morbidity and recovery time. Microdiscectomy employs direct visualization but is performed through a smaller (15–25 mm) central incision with the use of an operating microscope. Microdiscectomy outcomes are similar to outcomes seen with open discectomy, and microdiscectomy is considered the standard treatment by which to compare other minimally invasive therapies.

Management of back pain that is persistent and disabling despite the use of recommended conservative treatment is challenging. Numerous diagnostic and therapeutic injections and other interventional and surgical treatments have therefore been proposed for the treatment back pain.

Literature Review Injection Therapies

Trigger point injections, epidural steroid injections, intradiscal steroid injections, and facet joint injections and blocks have been employed in the treatment of acute, subacute, and chronic back pain. Although the evidence for the efficacy of these diagnostic and therapeutic injections discussed below is not strong, several have gained widespread use as alternatives to more invasive interventions.

Trigger point injections involve injection of anesthetic or corticosteroids into distinct, focal hyper-irritable spots (i.e., trigger points) located in a tight band of skeletal muscle. Myofascial pain syndrome is a chronic form of muscle pain centered around trigger points. Pain may be perceived at the site of the trigger point or can be referred to other parts of the body, including the back and neck. Trigger point injections involve injection of local anesthetic, saline, dextrose, and/or cortisone into the trigger point.

A Cochrane systematic review was conducted to determine if injection therapy is more effective than placebo or other treatments for patients with subacute or chronic low back pain (Staal et al., 2008). This updated review evaluated 18 randomized controlled trials (n=1179) of injection therapy involving epidural, facet or local sites (i.e., tender or trigger points) in patients with non-radicular pain. The injected drugs included corticosteroids, local anesthetics, and a variety of other drugs. Overall, the results indicated that there was no strong evidence for or against the use of any type of injection therapy. The authors concluded that there is insufficient evidence to support the use of injection therapy in subacute and chronic low back pain, but it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy.

Peloso et al. (2007) conducted a Cochrane systematic review to determine the effects of medication and injections on primary outcomes (e.g., pain) for adults with mechanical neck disorders and whiplash. The review evaluated 36 trials that examined the effects of steroid injections, anesthetic agents, psychotropic agents, and NSAIDs. The authors stated that lidocaine injection into myofascial trigger points appeared effective in two trials.

Guidelines on injection therapies, low-back pain, and lumbar fusion published by the American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (Resnick et al., 2005), based on a systematic review of studies evaluating trigger point injections, facet joint injections, and epidural steroid injections, concluded that there is conflicting evidence suggesting that the use of local trigger point injections can be effective for the short-term relief of low-back pain. There are no data to suggest that trigger point injections with either steroids or anesthetics alone provide lasting benefit for patients suffering from chronic low-back pain.

American College of Occupational and Environmental Medicine (ACOEM) evidence-based practice guidelines on low back disorders, updated in 2007, state that trigger and/or tender point injections are not recommended for treatment of acute low back pain because there are other more efficacious treatment strategies available. These injections may be reasonable as second or tertiary options for subacute or chronic low back pain that is not resolving with conservative treatment (e.g., NSAID, progressive aerobic exercises, and other exercises). The guideline states that injections should consist solely of topical anesthetic (e.g., bupivacaine), and that there is no evidence that steroid is required for efficacy of these injections. Repeat injections should be linked to subjective and objective improvements and be a component of an active therapy program. The ACOEM guideline recommends an interval of at least three to four weeks between injections. If the results are unsatisfactory after the first set, the injections may be repeated. If subjective and objective improvements are not seen, further injections are not recommended.

Dry Needling of trigger points has been proposed as a treatment of myofascial pain in various parts of the body, including low back pain. Dry-needling involves the insertion of a needle (acupuncture needle or other type of needle) into a trigger point without injecting any medication in an effort to deactivate the trigger point. The needle is not left in place; it is removed and is often followed by stretching exercises.

A Cochrane systematic review of acupuncture and dry needling (Furlan, et al., 2003, updated 2011) concluded that there is insufficient evidence to make any recommendation regarding acupuncture or dry needling for acute low back pain. For chronic low back pain, acupuncture and dry needling may be useful adjuncts to other therapies. Because most studies were of poor methodological quality, however, there is a need for higher quality trials in this area.

There is insufficient evidence to demonstrate the efficacy of dry needling for the treatment of acute or chronic back pain.

Epidural steroid injections/selective nerve root blocks may be used to treat back pain with radicular features by reducing inflammation and relieving inflammation-associated pressure. Epidural injections may be performed using caudal, interlaminar or transformational approaches. Transforaminal epidural injections, also referred to as selective nerve root blocks, are performed using fluoroscopy guidance in order to increase the accuracy of needle placement, avoid accidental intravascular injection, and ensure visualization of anatomical anomalies (Canale and Beatty, 2007).

The results of the Cochrane systematic review of injection therapy discussed above (Staal, et al. 2008) indicated that there was no strong evidence for or against the use of any type of injection therapy. The authors concluded that there is insufficient evidence to support the use of injection therapy in subacute and chronic low back pain, but it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy.

Novak et al. (2008) conducted a systematic review to evaluate the evidence in support of guidelines on frequency and timing of epidural steroid injections in order to help determine what sort of response should occur to repeat an injection. The review included 11 randomized controlled trials, one prospective controlled trial, and two prospective cohort studies. The authors stated that many of the problems with this type of research stem from a lack of understanding of the underlying mechanisms of radicular pain and a lack of understanding of how epidural steroid injections provide an effect. The underlying mechanism of glucocorticoid activity is not clearly understood, and there is no indication for repeat injection based solely on the characteristics of the medication itself. The authors concluded that there is limited evidence to suggest guidelines for frequency and timing of epidural steroid injections or to help define an appropriate partial response that would trigger a repeat injection. Research suggests that repeat injections may improve outcomes, but conclusions cannot be made due to methodological limitations of the available evidence. The authors concluded that there does not appear to be any evidence to support the common practice of a series of injections.

American Society of Interventional Pain Physicians (ASIPP) Evidence-Based Practice Guidelines in the Management of Chronic Spinal Pain (Manchicanti, et al., 2009).state that there is no consensus among interventional pain management specialists regarding the type, dosage, frequency, total number of injections, or other interventions. The frequency and total number of injections have been considered important issues, although controversial and poorly addressed. The authors recommend that administration be based solely on patient response, safety profile of the drug, experience of the patient, and pharmacological and chemical properties, such as duration of action and suppression of adrenals.

The following recommendations are used throughout the 2009 guideline, based on strength of recommendations and quality of evidence:

- IA: Strong recommendation, high-quality evidence
- IB: Strong recommendation, moderate quality evidence
- IC: Strong recommendation, low-quality or very low-quality evidence
- 2A: Weak recommendation, high-quality evidence
- 2B: Weak recommendation, moderate quality evidence
- 2C: weak recommendation, low quality or very low quality evidence

The guideline includes the following recommendations for caudal epidural steroid injections:

- IB/strong., in managing lumbar spinal pain with disc herniation and radiculitis
- IB or IC/strong for caudal epidural injections in managing patients with post-lumbar laminectomy syndrome and spinal stenosis

The guideline includes the following recommendations for blind lumbar interlaminar epidural steroid injections for disc herniation and radiculitis

- IC/strong for short-term relief
- 2B/Weak for long term relief

The recommendation for lumbar tranforaminal epidural injections in managing chronic low back and lower extremity pain is IC/strong.

The ACOEM evidence-based practice guidelines on low back disorders (2007) state that epidural glucocorticosteroid injections are an option for acute or subacute radicular pain syndromes. The injection may provide short-term improvement to allow time to determine whether conservative care will succeed. Epidural steroid injections may be appropriate for radicular pain syndromes lasting at least three weeks, when there is no evidence of trending towards spontaneous resolution following treatment with NSAIDs. The guideline also states that epidural steroid injections may be considered as a second-line treatment for acute flare-ups of spinal stenosis, when symptoms have persisted for one to two months despite treatment with NSAIDs and exercise. Epidural steroid injections are not recommended for acute, subacute, or chronic low back pain in the absence of significant radicular symptoms.

The AANS guideline on injection therapies, low-back pain, and lumbar fusion (referenced above) concluded that there is no meaningful evidence in the medical literature that the use of epidural injections is of any long-term value in the treatment of patients with chronic low-back pain. The literature does indicate that the use of lumbar epidural injections can provide short-term relief in selected patients with chronic low-back pain.

Intradiscal steroid injections, in which glucocorticoids are injected directly into the intervertebral disc under fluoroscopy, has been proposed as a method to reduce the degree of disc herniation and/or produce an inflammatory response.

According to The ACOEM evidence-based practice guidelines on low back disorders (2007), intradiscal steroid injections are not recommended for the management of acute low back pain. The available evidence indicates that intradiscal steroid injections are not effective. There is no quality evidence that these injections improve on the natural history of the condition, or that they provide a treatment benefit compared to no treatment or treatment with epidural steroids. In addition, these injections may cause discitis, progression of disc degeneration, and calcification of the intervertebral disc. The guideline also states that intradiscal steroids are not recommended for subacute or chronic low back pain.

There is insufficient evidence in the published medical literature to determine the safety and efficacy of Intradiscal steroid injection for the treatment of back pain.

Facet joint injections/facet blocks have been used to treat back pain and/or to help determine whether the facet joint is a source of pain. Facet joints (i.e., zygapophysial joints) are located in the posterior compartment of the spinal column, and provide stability and allow the spine to bend and twist. Facet joints are well innervated by the medial branches of the dorsal rami, and can be subjected to significant strain during spine loading. Facet joints are thought to be a common source of chronic back pain.

A diagnostic facet joint injection involves fluoroscopy-guided injection of local anesthetic with or without a steroid into the facet joint or around the nerve supply to the joint (i.e., medial branch nerve). A diagnostic facet joint injection may be used to identify the source of spinal pain. If pain is relieved following the injection, the pain is presumed to be of facet joint origin, although the accuracy of this diagnostic method has not been definitely determined. Therapeutic facet joint injections of an anesthetic and corticosteroid have been proposed as treatment of pain considered to be of facet joint origin (i.e., significant relief following a diagnostic injection).

The results of the Cochrane systematic review of the effects of injection therapy involving epidural, facet or local sites, discussed above (Staal, et al. 2008), indicated that there was no strong evidence for or against the use of any type of injection therapy. The authors concluded that there is insufficient evidence to support the use of injection therapy in subacute and chronic low back pain, but it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy.

The ASIPP guideline referenced above (Manchicanti, et al., 2009) concluded that based on the available evidence, therapeutic intraarticular facet joint injections are not recommended.

The ASIPP guideline recommendation is IB or IC/strong for the use of therapeutic cervical, thoracic, and lumbar facet joint nerve blocks to provide both short-term and long-term relief in the treatment of chronic facet joint pain.

The ACOEM evidence-based practice guidelines on low back disorders (2007) states that one diagnostic facet joint injection may be recommended for patients with chronic low back pain that is significantly exacerbated by extension and rotation or associated with lumbar rigidity, and is not alleviated with other conservative treatments

e.g., NSAID, progressive aerobic exercises, other exercises, and manipulation). This diagnostic injection may determine whether specific interventions targeting the facet joint are recommended. Repeated diagnostic injections in the same location are not recommended. The guideline states that therapeutic facet joint injections are not recommended for acute, subacute, or chronic low back pain or for any radicular pain syndrome.

The AANS guideline on injection therapies, low-back pain, and lumbar fusion (referenced above) concluded that there is evidence that suggests that facet joint injections can be used to predict outcome of radiofrequency ablation of a facet joint. No evidence exists, however, to support the effectiveness of facet injections in the treatment of patients with chronic low-back pain.

Facet joint injections are typically performed using fluoroscopic guidance in order to identify the target facet joint and surrounding structures and to ensure accurate needle placement. Ultrasound guidance has recently been proposed as an alternative to fluoroscopic guidance. There are no published studies in the medical literature that compare the safety and efficacy of the use of ultrasound guidance compared to the current standard, fluoroscopic guidance.

SI joint injection of anesthetic and steroid, performed under fluoroscopic guidance, has been proposed as a method to confirm that pain originates from the SI joint. The SI joint lies between the sacrum and the ilium, and functions more for stability than for movement. The joint's stability is maintained in part by several large ligaments and muscle groups. Pain may arise in this highly innervated joint or in the related muscles and ligaments. Pain may be felt in the lower back or may radiate to one or both hips and/or one or both legs. If the injection does not alleviate the pain, alternative diagnoses may be considered (ECRI, 2008).

The ASIPP guideline referenced above (Manchicanti, et al., 2009) concluded that, based on the available literature and evidence, no recommendation could be provided for SI joint injections.

The ACOEM evidence-based practice guidelines on low back disorders (2007) state that SI joint injections are not recommended for acute low back pain, including low back pain thought to be SI joint related, or for subacute or chronic non-specific low back pain, including pain attributed to the SI joint, but without evidence of inflammatory sacroiliitis. The guideline also states that SI joint injections are not recommended for treatment of any radicular pain syndromes, and recommends SI joint injections as a treatment option only for patients with a specific known cause of sacroiliitis (i.e., proven rheumatologic inflammatory arthritis involving the SI joint).

American Pain Society: The following recommendations are included in an evidence-based clinical practice guideline from the American Pain Society, Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain (Chou et al., 2009):

- There is insufficient evidence to evaluate the validity or utility of diagnostic selective nerve root block, intra-articular facet joint block, medial branch block, or sacroiliac joint block as diagnostic procedures for low back pain with or without radiculopathy.
- In patients with persistent nonradicular low back pain, facet joint corticosteroid injection, and intradiscal corticosteroid injection are not recommended
- There is insufficient evidence to adequately evaluate benefits of local injection, epidural steroid injection, therapeutic medial branch block, radiofrequency denervation, or sacroiliac joint steroid injection, for nonradicular low back pain.
- In patients with persistent radiculopathy due to herniated lumbar disc, it is recommended that clinicians discuss risks and benefits of epidural steroid injection as an option. It is recommended that shared decision-making regarding epidural steroid injection include a specific discussion about inconsistent evidence showing moderate short-term benefits, and lack of long-term benefits.
- There is insufficient evidence to adequately evaluate benefits and harms of epidural steroid injection for spinal stenosis.

The authors recommend consideration of interdisciplinary rehabilitation with a cognitive/behavioral emphasis as a treatment option in patients with nonradicular low back pain who do not respond to usual, non-interdisciplinary interventions.

Summary– Injection Therapies

The evidence for the use of diagnostic and therapeutic injections in the treatment of acute, subacute and chronic back pain is limited. Based on the available evidence and specialty society recommendations and guidelines, trigger point injections may be appropriate for selected patients with persistent chronic back, neck or myofascial pain despite appropriate conservative treatment. Epidural steroid injections may be considered in the treatment of selected patients with radicular pain as part of an active therapy program. These injections may provide short-term improvement and allow a determination as to whether conservative treatment will be successful. There is insufficient evidence, however, to demonstrate that epidural steroid injections are effective in the treatment of back pain in the absence of radicular symptoms.

A diagnostic facet joint injection may be indicated for patients with low back pain that is significantly exacerbated by extension and rotation and not improved with conservative treatment. A diagnostic facet joint injection may assist in determining whether specific interventions targeting the facet joint are indicated. There is insufficient evidence to demonstrate that therapeutic facet joint injections are effective in the treatment of back pain, however.

SI joint injection may be considered as a treatment option for patients with localized SI joint pathology (e.g., inflammatory arthritis) that has been confirmed on imaging studies. There is insufficient evidence, however, to demonstrate that SI injections are effective in the diagnosis of treatment of back pain or radicular syndromes.

Minimally Invasive Surgical Procedures and Ablative Treatments

Radiofrequency Ablation/Percutaneous Radiofrequency Facet Denervation/Radiofrequency Neurotomy/Facet Rhizotomy/Rhizolysis

Radiofrequency ablation (RFA) (is referred to by numerous terms, including percutaneous radiofrequency facet denervation, percutaneous facet coagulation, percutaneous radiofrequency neurotomy, radiofrequency facet rhizotomy, and radiofrequency articular rhizolysis) was introduced as a treatment modality for patients with a variety of chronic spinal pain syndromes, including facet joint pain syndrome. RFA is a pain-reduction technique that may be considered for patients with back pain that is unresponsive to conservative therapy and for which there is no clear indication for surgery.

RFA may target areas adjacent to the dorsal root ganglion (DRG) and the medial branches. The dorsal and ventral roots of the 31 pairs of spinal nerves are attached to each segment of the spinal cord. Each spinal nerve attaches to the spinal cord by a dorsal (sensory) and a ventral (motor) root. The DRG is found on the posterior root of each spinal nerve and is composed of the nerve cell bodies of the sensory neurons of the nerve. Both somatic and visceral afferent fibers from potential nociceptors (pain receptors) in the spine have cell bodies in the DRG, indicating that the DRG conducts pain impulses inward to the spinal cord and brain from the peripheral parts of the body. The medial branch (ramus medialis, or internal branch) is a small nerve that arises from the dorsal ramus that in turn branches from the spinal cord. This nerve innervates the joint facet and carries nociceptive signals from the spine to the brain. It is, in addition to the DRG, a main target for RFA treatment of spinal pain. During RFA, an electrode introduced through the skin is used to deliver heat produced by radio waves in order to destroy the sympathetic nerve supply of the painful spinal structure. In most cases, diagnostic nerve blocks are undertaken prior to RFA, and only chronic back pain patients with a positive temporary response to the diagnostic blocks proceed to RFA.

Prushansky et al. (2006) evaluated radiofrequency neurotomy in a series of 40 patients with chronic whiplash injury-associated disorders. According to the authors, prior studies have focused solely on pain and psychological distress factors. The purpose of the study was to extend the assessment of the procedure's efficacy by adding other outcome measures. Patients were evaluated prior to and at two separate sessions following radiofrequency treatment. The evaluations included the Neck Disability Index, cervical range of motion, isometric cervical muscle strength, cervical pressure pain threshold, Symptom Check List-90 Revised, and subjective Self Report of Improvement (SRI). The authors reported that cervical radiofrequency neurotomy had a significantly positive effect on all measured parameters. Using strict cutoff values taking improvement followed by regression into account, between 30% and 60% of patients experienced measurable improvement. Evaluation of SRI results indicated that 80% of patients were satisfied with the procedure.

van Wijk et al. (2005) conducted a randomized, double-blind sham lesion-controlled trial to determine the efficacy of radiofrequency facet joint denervation as it is routinely performed. The study was designed to reflect common practice in that, although no interventions between trial treatment and three months' follow-up were

performed, further radiofrequency or injection procedures were allowed after this period if the initial treatment did not sufficiently alleviate pain. Patients were randomized to radiofrequency (n=40) or a sham treatment (n=41). The primary outcome was determined with a combined outcome measure comprised of VAS, physical activities and analgesic intake. Secondary outcome measures were the separate diary parameters, global perceived effect (i.e., complete relief, > 50% relief, no effect) of pain increase, and SF-36 Quality of Life Questionnaire. There was no difference between the two groups in the combined outcome measure or VAS, although both groups showed improvement in VAS scores. The global perceived effect, however, improved in the radiofrequency group. The researchers observed that the lack of improvement in physical function despite reduction pain scores underlines the need to combine these procedures with subsequent structured rehabilitation programs. The authors concluded that in selected patients, radiofrequency facet denervation appears to be more effective than sham treatment.

A Cochrane systematic review (Niemisto et al., 2002, updated 2005) evaluated randomized controlled trials of radiofrequency denervation for musculoskeletal pain disorders and concluded that there is limited evidence that radiofrequency denervation offers short-term relief for chronic neck pain of zygapophyseal joint origin and for chronic cervicobrachial pain. The authors reported conflicting evidence on the short-term effect of denervation on pain and disability in patients with low back pain of zygapophyseal joint origin and that there is a need for further randomized controlled trials with larger patient samples and data on long-term outcomes.

A technology assessment of percutaneous radiofrequency ablation for facet-mediated neck and back pain published in 2005 by the Institute for Clinical Systems Improvement (ICSI) concluded that the procedure is safe for patients correctly diagnosed with facet joint pain. Patients may experience pain relief within two to three weeks of the procedure, and pain relief may last for six to twelve months. The assessment further concluded that radiofrequency ablation may be an alternative for patients with cervical facet joint pain who have failed an adequate trial of conservative therapy, including therapeutic exercise, activity modification, medical therapy, joint injections and nerve blocks. The authors concluded that the scientific evidence to date does not permit a conclusion to be reached regarding the efficacy of radiofrequency ablation for lumbar facet joint pain.

The ACOEM evidence-based practice guidelines on low back disorders (2007) state that the evidence for radiofrequency denervation for presumed facet joint pain is poor. The authors were unable to estimate the net benefit of this procedure.

The American Society of Interventional Pain Physicians (ASIPP) practice guideline, *Interventional Techniques in the Management of Chronic Spinal Pain* (Manchicanti, et al., 2009), recommendation is IC/strong for cervical radiofrequency neurotomy and lumbar radiofrequency neurotomy. The authors state that neurotomy may be performed by radiofrequency thermoneurolysis utilizing a thermal or pulsed mode, cryoneurolysis, or laser denervation. Because of the paucity of the literature and emerging nature of multiple modalities of treatment, however, only thermal radiofrequency was considered in these guidelines.

The guidelines suggest a frequency for medial branch neurotomy of six months or longer, with a maximum of two times per year, provided that > 50% relief is obtained for 10–12 weeks. It is suggested that all regions be treated at the same time, provided all procedures can be performed safely.

Several alternatives to radiofrequency ablation have been proposed, including pulsed radiofrequency (discussed below), cryoneurolysis, laser ablation, and chemical ablation, in which a neurolytic substance (e.g., alcohol, phenol, glycerol) is injected into the affected nerve root. There is insufficient evidence in the published medical literature to determine the safety and efficacy of these emerging alternative modalities compared to radiofrequency ablation for the treatment of spinal pain.

Sacroiliac (SI) Joint Radiofrequency Ablation (RFA)/Neurotomy: RFA of facet joints has been used to treat spinal pain presumed to be of facet origin. RFA was also been explored for the treatment of SI joint pain.

Aydin et al. (2010) conducted a meta-analysis to assess the effectiveness of RFA of the SI joint for pain relief at three and six months. Ten articles were included in the analysis. The primary outcome measure was a reduction in pain by $\geq 50\%$. Analysis was conducted on seven groups from six studies. At three and six month follow-up, half or greater of the patients treated with RFA of the SI joint met the outcome measure of $\geq 50\%$ reduction in pain. The authors concluded that RFA of the SI joint appears to have a role in the treatment of patients with SI

joint pain refractory to more conservative measures. The study is limited, however, by the available literature and lack of randomized controlled trials.

According to the ASIPP practice guidelines referenced above (Manchicanti, et al., 2009), evidence is level II-III (limited) for radiofrequency neurotomy for SI joint pain.

There is insufficient evidence in the published medical literature to demonstrate the safety and efficacy of SI joint radiofrequency ablation (RFA).

Pulsed Radiofrequency

Pulsed radiofrequency has been introduced as a nonablative alternative to RFA. Pulsed radiofrequency delivers short bursts of radiofrequency current rather than the continuous flow utilized in standard RFA. Pulsed radiofrequency allows the tissue to cool between bursts, resulting in lower maximum temperatures compared to continuous radiofrequency. This technique is reported to reduce the risk of destruction of neighboring tissue. It does not destroy targeted nerves and therefore requires less precise electrode placement. The mechanism of action of pulsed radiofrequency is not well understood. It has been hypothesized that electrical fields reversibly disrupt the transmission of nerve impulses across small unmyelinated fibers, but the fibers are not destroyed, and larger fibers are not affected.

Studies of pulsed radiofrequency consist primarily of small trials with limited follow-up. Most studies are case series in which the safety and efficacy of pulsed radiofrequency cannot be evaluated against alternative treatment methods (Vallejo et al., 2006; Lindner et al., 2006; Martin et al., 2007).

Van Zundert et al. (2007) conducted a randomized sham-controlled trial evaluating pulsed radiofrequency for the treatment of chronic cervical radicular pain. Of 256 patients screened, 23 met the inclusion criteria. Patients were eligible if they reported neck pain radiating over the posterior shoulder to the arm persisting for > six months, had symptoms suggestive of cervical spinal nerve involvement, and were unresponsive to conventional therapy. The primary outcome was comprised of three measures three months after the intervention: success, defined as at least 50% pain improvement of the global perceived effect (GPE); a reduction of at least 20% in the VAS pain score; and reduced pain medication intake. An improvement of the GPE of at least 50% was achieved in 9/11 (82%) patients in the radiofrequency group and 4/12 (33%) in the sham group ($p=0.03$). A reduction of at least 20% in the VAS pain score was seen in 9/11 patients in the radiofrequency group (82%) compared to 3/12 (25%) in the sham group ($p=0.02$). A reduction in pain medication intake was noted in the radiofrequency group, but no significance was reached at three months. The need for pain medication was significantly reduced in the pulsed radiofrequency group after six months, however. The authors concluded that pulsed radiofrequency treatment of the cervical dorsal root ganglion may provide pain relief for a limited number of carefully selected patients. The authors stated that, since percutaneous pulsed radiofrequency is presumed to be less neurodestructive, this approach may have a better risk/benefit ratio than continuous radiofrequency lesioning, but this hypothesis needs to be confirmed in larger observational studies.

Tekin et al. (2007) conducted a randomized, controlled double-blind trial to compare conventional and pulsed radiofrequency denervation for treatment of chronic facet joint pain. Patients over age 17, with symptoms of greater than six months duration, were randomized to treatment with continuous radiofrequency ($n=20$), treatment with pulsed radiofrequency ($n=20$), or to a control group ($n=20$). Patients in the control group received local anesthetic alone. Radiofrequency treatment was subsequently made available to patients in the control group who experienced no pain relief. Pain relief was evaluated using a VAS and Oswestry Disability Scale (ODI) prior to the procedure, at the time of the procedure, and six and twelve months post-procedure. Pre-procedure VAS and ODI scores were similar in all groups. Mean pre-procedure VAS and ODI scores were higher than all post-procedure scores in all groups. Mean VAS and ODI scores were lower in both radiofrequency groups than in the control group at the post-procedure evaluation. The decrease in pain was maintained in the continuous radiofrequency group at six months and one year but was not maintained in the pulsed radiofrequency group. Analgesic usage was lower and patient satisfaction was higher in the continuous radiofrequency group.

The ASIPP practice guideline, *Interventional Techniques in the Management of Chronic Spinal Pain*, states that, the evidence for pulsed radiofrequency of medial branches in the cervical and lumbar region is indeterminate, and the evidence for pulsed radiofrequency of the SI joint is limited.

There is insufficient evidence in the published medical literature to demonstrate the safety and efficacy of pulsed radiofrequency in the treatment of spinal pain. Studies published to date do not allow conclusions regarding the safety, efficacy, and duration of effect of this technique. Additional well-designed trials are needed to determine how this treatment compares to other medical and surgical treatments for chronic spinal pain.

Automated Percutaneous Lumbar Discectomy (APLD)/Automated Percutaneous Nucleotomy: Automated percutaneous lumbar discectomy (APLD), also referred to as automated percutaneous nucleotomy, is a minimally-invasive surgical procedure used in the treatment of herniated lumbar intervertebral discs. In this procedure, a cannula is placed in the center of the disc under fluoroscopic guidance using a posterolateral approach. A probe connected to an automated cutting and aspiration device is then introduced through the cannula. The disc is then aspirated until no more nuclear material is obtained (NICE, 2004)

Hirsch et al. (2009) conducted a systematic evaluation of the literature to determine the effectiveness of APLD. The primary outcome measure was pain relief; short term effectiveness was defined as significant (>50%) pain relief at six months, and long term effectiveness was defined as significant pain relief at one year. Other outcome measures included functional improvement, improvement in psychological status, and return to work. The authors concluded that this systematic review indicates Level II-2 evidence for APLD; APLD may provide appropriate relief in properly selected patients with contained lumbar disc prolapse. (Level II-2 evidence, as defined by the U.S. Preventive Services Task Force as evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.). The authors acknowledged the paucity of randomized controlled trials in the literature as a limitation.

A Cochrane review of surgery for lumbar disc prolapse, published in 2003 and updated in 2007 (Gibson and Waddell), assessed the effects of available surgical interventions and states that trials of APLD suggest that clinical outcomes are at best fair and certainly worse than microdiscectomy, although the importance of patient selection is acknowledged. The authors stated that there is a need for high-quality randomized controlled trials on APLD and for long-term studies into the effects of surgery on the lifetime natural history of disc disease. The Cochrane review concluded that unless or until better scientific evidence is available, APLD should be regarded as a research technique.

An ECRI Health Technology Assessment on automated percutaneous nucleotomy (ECRI, 2004) concluded that the available evidence does not favor the use of automated percutaneous nucleotomy over microdiscectomy for treatment of patients with symptomatic herniated lumbar discs. The procedure leads to inferior combined pain and function scores compared to microdiscectomy, and it is more likely to fail, requiring additional surgery. The strength of evidence supporting these conclusions is weak, however due to the low number of studies and small number of patients.

Guidance issued by the National Institute for Health and Clinical Excellence (NICE) (United Kingdom) in 2005 states that current evidence suggests that although there are no safety concerns associated with automated percutaneous mechanical lumbar discectomy, and there is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, evidence from small randomized controlled trials shows conflicting results. The guidance states that in view of uncertainty about the efficacy of the procedure, it should not be done without special arrangements for consent and for audit or research.

ASIPP 2009 Practice Guidelines for the Management of Chronic Spinal Pain recommendation for APLD is IC/strong.

American College of Occupational and Environmental Medicine (ACOEM) evidence-based practice guidelines on low back disorders, surgical considerations (2007) states that there is no quality evidence that automated percutaneous discectomy is an effective treatment for any back or radicular pain problem.

There is insufficient evidence in the peer-reviewed medical literature to support the safety and efficacy of APLD. Results of published studies are inconsistent and do not demonstrate long-term improvement. There is no evidence that APLD is as effective as discectomy/microdiscectomy.

Laser Discectomy (Percutaneous or Laparoscopic)/, Laser Disc Decompression/Laser Assisted Disc Decompression (LADD): Laser-assisted discectomy, also called laser-assisted disc decompression (LADD) or laser disc decompression, is a minimally-invasive procedure proposed as an alternative to

discectomy/microdiscectomy. It is intended to provide symptomatic relief of pain caused by a contained herniated intervertebral disc. Laser light energy is used to vaporize part of the nucleus pulposus, resulting in a reduction in intradiscal pressure. Several approaches may be used, depending on the location of the disc and type of laser being used. With one method, a needle is inserted percutaneously into the disc approximately one centimeter (cm) posterior to the disc center, and a flexible optical quartz fiber is threaded through the needle into the disc, delivering laser energy to vaporize and coagulate the nucleus pulposus. In the laparoscopic approach, a trocar is inserted periumbilically and the abdomen is inflated with carbon dioxide. Additional trocars are placed above the pelvic brim. The large and small bowels are retracted, and the iliac bifurcation is identified. The posterior peritoneum is opened and retracted. The L5-S1 interspace is identified and its margins confirmed by x-ray. The annulus of the disc is opened and excised with the neodymium: yttrium-aluminum-garnet (Nd: YAG) laser.

A review of the literature published by Schenck et al. (2006) evaluated 16 clinical trials representing a total of 1579 patients. Most were case series with small sample sizes, making interpretation of success rates difficult. Generalization of the results into general clinical practice remains difficult due to different inclusion and exclusion criteria, laser types, and outcome measures as well as the variation in duration of follow-up. These shortcomings prevent a valid comparison to studies evaluating the outcome of conventional surgical treatment for lumbar disc herniation. The authors concluded that well-designed research of sufficient scientific strength comparing percutaneous laser disc decompression to both conventional surgery and conservative management is needed to determine whether this procedure has a role in the treatment of lumbar disc herniation.

An ECRI Health Technology Assessment (2004) evaluating laser discectomy for the treatment of herniated lumbar discs noted a lack of controlled trials comparing this procedure to either continued conservative care or other operative procedures such as open discectomy or microdiscectomy. Since laser discectomy is considered an alternative to open discectomy, the absence of a trial comparing these procedures is noteworthy. The authors stated that controlled trials are important when evaluating pain-relieving treatments to determine the influence of nonspecific effects and regression to the mean on pain-related outcome measures. Considering the natural history of herniated lumbar discs, pain relief may be as likely without invasive treatment as with invasive treatment. A controlled trial is needed to determine the actual extent to which laser discectomy achieves pain relief beyond the natural course of the disorder.

An ECRI Health Technology Assessment (2009) evaluating percutaneous disc decompression for cervical disc herniation focused on techniques that remove or ablate the nucleus pulposus, including APLD, percutaneous laser discectomy, and plasma disc decompression (PDD), also referred to as nucleoplasty. The report states that one low-quality small study and one moderate-quality randomized controlled trial suggest that percutaneous decompression reduces pain more than conservative medical or physical therapy. Differences in reporting between the two studies and the poor reporting of one study prevent conclusive determination of whether this effect is statistically significant or clinically meaningful. The randomized trial suggested significantly improved quality of life and reduced disability with percutaneous discectomy, but results of a single study cannot be used to draw firm evidence-based conclusions. The authors noted that no evidence addressed the questions of how the efficacy of percutaneous cervical disc decompression compares with other surgical procedures or how efficacy outcomes compare among different methods of percutaneous disc decompression.

A Cochrane systematic review of surgery for lumbar disc prolapse, published in 2003 and updated in 2007 (Gibson and Waddell), assessed the effects of available surgical interventions and states that trials of laser discectomy suggest that clinical outcomes are at best fair and certainly worse than microdiscectomy, although the importance of patient selection is acknowledged. The authors stated that there is a need for high-quality, randomized controlled trials on laser discectomy and for long-term studies into the effects of surgery on the lifetime natural history of disc disease. The Cochrane Review further concluded that unless or until further scientific evidence is available, laser discectomy should be regarded as a research technique.

The National Institute for Clinical Excellence (NICE) (United Kingdom) issued updated Interventional Procedure Guidance on percutaneous endoscopic laser lumbar discectomy in 2009, and issued guidance on percutaneous endoscopic laser cervical discectomy in 2009, stating that current evidence on the safety and efficacy of these procedures is inadequate in quantity and quality, and should only be used with special arrangements for consent and audit or research. Interventional Procedure Guidance on percutaneous endoscopic laser thoracic discectomy issued in 2004 states that current evidence on the safety and efficacy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research.

ASIPP 2007 Practice Guidelines for the Management of Chronic Spinal Pain state that the evidence for percutaneous laser discectomy is moderate for short-term relief and limited for long-term relief.

ACOE evidence-based practice guidelines on low back disorders, surgical considerations (2007) states that there is no quality evidence that laser discectomy is an effective treatment for any back or radicular pain problem.

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcome of laser discectomy. There are no randomized controlled trials that evaluate laser discectomy and compare this procedure to established treatment methods.

Percutaneous Laminotomy/Laminectomy

Laminectomy is a surgical procedure in which the posterior arch (lamina) of a vertebra is removed to relieve pressure on the spinal cord or nerve roots. In a laminotomy, only a portion of the lamina is removed. Frequent indications for laminectomy and laminotomy include spinal stenosis and spondylolisthesis. Percutaneous laminectomy and laminotomy have been proposed as minimally invasive alternative approaches.

mild[®] Procedure: The mild[®] Device Kit (Vertos Medical, Inc., Aliso Viejo, CA) received U.S. Food and Drug Administration (FDA) approval on February 4, 2010. The device kit is set of specialized arthroscopic surgical instruments intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions. The mild device is used for image-guided minimally invasive lumbar decompression, referred to as the mild procedure. The mild procedure is performed under fluoroscopic guidance through a dorsal approach to the spine. The instruments are inserted and positioned on the posterior spinal lamina, to the left or right of the spinous process. The tools are used to cut and remove tissue and bone from the posterior side of the lumbar spine to create a space inside the spine that can help decompress some of the spinal nerves. (FDA 510(k) database; clinicaltrials.gov website).

Deer and Kapurai (2010) published a retrospective review to evaluate the acute safety of the mild procedure. Charts of 90 consecutive patients who underwent the mild procedure for decompression of central lumbar stenosis were reviewed. No major adverse events or complications related to the devices or procedure were reported. There were no incidents of dural puncture or tear, blood transfusion, nerve injury, epidural bleeding or hematoma. Because the review did not include outcome data, no determination as to clinical efficacy can be made. The authors stated that prospective randomized studies have been initiated to collect patient outcomes data regarding post-treatment pain and functional capacity.

Chopka and Caraway (2010) published a preliminary report of MiDAS I (mild Decompression Alternative to Open Surgery, a multi-center prospective case series to evaluate the mild procedure for treatment of symptomatic lumbar spinal stenosis. The procedure was offered as an alternative to surgery or continued medical management. No major device or procedure-related complications were reported. At six weeks, statistically significant reduction of pain as measured by the Visual Analog Scale, Oswestry Disability Index, and Zurich Claudication Questionnaire, and Standard Form -12. (SF-12).

There is insufficient evidence in the medical literature to demonstrate the safety and efficacy percutaneous laminotomy/laminectomy approaches, including the mild procedure. Additional well designed trials with long-term outcome data are needed to determine how this procedure compares to available alternative treatments for lumbar stenosis.

Intradiscal Electrothermal Annuloplasty (e.g., intradiscal electrothermal therapy [IDET[™]])

Intradiscal electrothermal annuloplasty (IEA), also referred to as intradiscal electrothermal therapy (IDET[™]), intradiscal electrothermal percutaneous annuloplasty, intradiscal thermal annuloplasty, or targeted intradiscal thermal therapy, is a minimally invasive procedure that has been proposed as an alternative to spinal fusion for the treatment of chronic discogenic low back pain. Following a provocative discogram, IEA is performed by inserting a catheter into the annulus and threading a flexible electrode through the catheter and around the inside of the disc, pressing against the posterior edge of the annulus. The electrode is then heated to a temperature of 90° F for up to 17 minutes. Analgesics and/or antibiotics are then injected and the catheter is withdrawn. The heating of the electrode denatures the collagen of the annulus and coagulates the nerve endings, with the ultimate goal of relieving back pain.

A randomized, double-blind controlled trial was conducted by Freeman et al. (2005) to test the safety and efficacy of IEA compared with placebo for treatment of chronic discogenic low back pain. Patients with one- or two-level symptomatic disc degeneration with posterior or posterolateral annular tears who failed to improve after conservative therapy were considered for the study. Patients were randomized on a 2:1 ratio to IEA (n=38) or a sham procedure (n=19). An independent technician connected the catheter to the generator and delivered electrothermal energy to only the treatment group. Surgeon, patient, and independent outcome assessor were all blinded to the treatment. Low Back Outcome Score (LBOS), Oswestry Disability Index, SF-36, the Zung Depression Index (ZDI) and Modified Somatic Perceptions Questionnaire (MSPQ) were measured at baseline and at six months. Successful outcome was defined as no neurological deficit, improvement in LBOS of greater than seven points, and improvement in SF-36 subsets (i.e., physical function and bodily pain) of greater than one standard deviation. No patient in either group showed improvement of greater than seven points in LBOS or greater than one standard deviation in the specified SF-36 domains. Mean ODI was 41.42 at baseline and 39.77 at six months for the IEA group compared with 40.74 at baseline and 41.58 at six months for the placebo group. There was no significant change in ZDI or MSPQ for either group. The authors concluded that there was no significant benefit from IEA over placebo.

Pauza et al. (2004) conducted a prospective, randomized controlled trial comparing IEA with placebo. Sixty-four patients were randomized to receive IEA or sham treatment. The subjects were not aware of which treatment they received. Outcome tools used were the VAS, the SF-36, and the Oswestry Disability Scale. It is unclear whether the post-procedure outcome examiners were blinded regarding which patients received true IEA. The modest success rates reported in this trial were much less compelling than those from previously published uncontrolled studies. The investigators reported that both groups showed improvement, with mean improvements higher in the active treatment arm. Using the VAS, IEA demonstrated a 2.4-point decrease in the mean pain score. An 11-point decrease was reported in the mean Oswestry score. The baseline disability level of most of the patients was low, and recruitment methods may have led to patient selection bias. The sample size was insufficient to achieve adequate statistical power, and follow-up was limited to six months. In addition, eight patients who dropped out of the study were not included in the data analysis. While the results of this study suggest that IEA may improve outcomes for patients with discogenic low back pain, these methodological flaws make it impossible to draw valid conclusions about the efficacy of this technology.

A systematic review of percutaneous thermocoagulation intradiscal techniques for discogenic low back pain (Urrutia, et al., 2007) included six studies (283 patients) of IEA and percutaneous intradiscal radiofrequency thermocoagulation (PIRFT). The studies included in the review of IEA consisted of two randomized controlled trials (Freeman and Pauza, discussed above), and two nonrandomized trials. One of the nonrandomized trials assessed the effectiveness of IEA vs. a rehabilitation program consisting of physical therapy, exercise, education and counseling, and the other compared IEA to PIRFT. In both randomized controlled trials that assessed IEA vs. placebo, pain, disability, and quality of life were assessed for six months. There was a small difference in favor of IEA in one study (Pauza), although the difference in disability was clinically irrelevant, while there was no difference in the higher-quality, more recent study (i.e., Freeman). The Freeman study also assessed depression, sitting and work tolerance, medication and neurologic deficit, and found no difference between IEA and placebo. In the nonrandomized trial comparing IEA and a rehabilitation program, the proportion of patients with a $\geq 50\%$ reduction in pain was higher in the IEA group at both 12 and 24 months. The authors concluded that the available evidence does not support the efficacy or effectiveness of percutaneous thermocoagulation intradiscal techniques for the treatment of discogenic low back pain. The authors noted that previous case reports suggested that the procedure might be effective, but these reports, derived from data registries, could not take into account the effect of regression to the mean, the natural history of the condition, the placebo effect, and other potential confounders such as co-interventions and other mechanical and psychosocial factors.

Freeman (2006) conducted a systematic review of the evidence of the efficacy of IEA. The review included 11 prospective cohort studies, five retrospective studies, and two randomized controlled trials. The prospective cohort studies reported on a total of 256 patients with a mean follow-up of 17.1 months (range 12–28 months). The mean improvement in the VAS for back pain was 3.4 points (range 1.4–6.5), and the mean improvement in ODI was 5.2 points (range 4.0–6.4). The five retrospective studies included 379 patients and reported that between 13 and 23% of patients subsequently underwent surgery for low back pain within the study period. The two randomized controlled trials, Pauza, 2004 and Freeman, 2005, provided inconsistent evidence, as described above. The author concluded that the evidence for efficacy of IEA remains weak and has not passed the standard of scientific proof.

An ECRI Institute Emerging Technology Evidence Report on intradiscal electrothermal annuloplasty (IEA) for discogenic pain (2000, updated 2009) evaluated two randomized controlled trials with six-month follow-up (Pauza [2004] and Freeman [2005]), discussed above), three prospective case series, and one prospective case-control series. The studies included a total of 308 patients, and all studies had important design and reporting shortcomings that affect the reliability of results. The sample sizes were very small, follow-up times were very brief, and the results may not be generalizable to a larger population. In addition, none of the studies compared the effects of IEA to competing treatments for discogenic pain. The ECRI report states that the clinical significance of the IEA treatment effect cannot be definitively determined because the published randomized controlled trials reported conflicting very short-term outcomes, and because of the likely possibility of the placebo effect, given the waxing and waning nature of discogenic pain. It is also not possible to determine whether the reports of increased function and decreased pain in the reported case series data result from IEA or other factors (e.g., activity restriction, spontaneous improvement, or post-treatment therapy).

Updated National Institute for Clinical Excellence (NICE) (United Kingdom) guidance issued in 2009, consistent with guidance issued in 2004, states that current evidence on the safety and efficacy of percutaneous intradiscal electrothermal therapy for low back pain is inconsistent, and should only be used with special arrangements for clinical governance, consent and audit or research.

American Society of Interventional Pain Physicians (ASIPP) Evidence-Based Practice Guidelines in the Management of Chronic Spinal Pain (Manchicanti, et al., 2009). recommendation is 2A (weak recommendation, strong evidence) for the use of IDET.

The safety, efficacy, and long-term outcomes of intradiscal electrothermal annuloplasty in the treatment of patients with chronic discogenic low back pain have not been established in the published medical literature. This procedure has not been proven to achieve equivalent or improved patient outcomes compared to available and established alternatives. In addition, the long-term effect of thermal coagulation of intervertebral discs has not been determined.

Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)/ Intradiscal Radiofrequency Thermomodulation/Percutaneous Radiofrequency Thermomodulation

PIRFT may also be referred to as intradiscal radiofrequency thermomodulation or percutaneous radiofrequency thermomodulation. This procedure, used to treat chronic discogenic low back pain, is similar to intradiscal electrothermal therapy (IDET). With IDET, a catheter with a temperature-controlled, thermal-resistive coil is inserted under fluoroscopic guidance into the posterior anular wall of the affected disc, causing anular denervation. With PIRFT, the catheter is placed into the center of the disc rather than the annulus. The mechanism of reported clinical improvement with PIRFT is unclear, since the temperature at the annulus has been found to be well below the temperature required for anular denervation (Davis, 2003).

Urrutia et al. (2007) conducted a systematic review to evaluate the evidence for the percutaneous thermocoagulation intradiscal techniques IDET and PIRFT in the treatment of discogenic low back pain. Six studies with a total of 283 patients were included. Two randomized controlled trials, including the Barendse trial described below, showed no differences between PIRFT and placebo and between different PIRFT techniques. The authors stated that, although previous case reports and nonrandomized trials suggested positive results, results from randomized clinical trials show that PIRFT is not effective for the treatment of discogenic low back pain.

Barendse et al. (2001) conducted a randomized, double-blind, placebo-controlled trial of PIRFT using the Radionics discTRODE™ RF annuloplasty system. The Radionics system was approved by the U.S. Food and Drug Administration (FDA) through the 510(k) process in October 2000. A total of 28 patients were selected who had a history of at least one year of chronic low back pain, evidence of radiculopathy on neurological examination and a positive response to discography. Patients were randomly assigned to one of two treatment groups. Patients in the radiofrequency group (n=13) received a 90-second 70 degree centigrade (C) lesion of the intervertebral disc. Patients in the control group (n=15) underwent the same procedure but without the use of radiofrequency current. The treating physician and patients were blinded to group assignment. Patients were assessed by a blinded investigator before treatment and eight weeks after treatment. There was no difference between the two groups based on visual analog scores for pain, global perceived effect and the Oswestry disability scale. The treatment was considered a success in one patient in the radiofrequency group and two

patients in the control group. The authors concluded that PIRFT is not effective in reducing chronic discogenic low back pain.

Interventional procedure guidance on PIRFT issued by NICE in 2004 states that current evidence on the safety and efficacy of this procedure does not appear adequate to support its use without special arrangements for consent and for audit or research. The published guidance states that evidence is based on a small number of patients and is difficult to interpret. It is unclear whether improvements are the result of the procedure or the natural course of the condition.

According to the evidence-based clinical practice guideline from the American Pain Society, Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain (Chou et al., 2009), the level of evidence for PIRFT is poor. The authors were unable to estimate the net benefit of the procedure in the treatment of patients with nonradicular low back pain.

American College of Occupational and Environmental Medicine (ACOEM) practice guidelines on low back disorders, (2007) states that PIRFT is not recommended for treatment of acute, subacute, or chronic low back pain, particularly including discogenic low back pain.

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of PIRFT. There is no evidence that this procedure is as effective as established alternatives for the treatment of back pain.

Intervertebral Disc Biacuplasty

The Baylis TransDiscal™ system (Baylis Medical Inc., Montreal Canada) is used to perform intervertebral biacuplasty. The TransDiscal system received FDA approval through the 510(k) process on December 19, 2006. The system is designed to deliver controlled RF energy via two electrodes. Two TransDiscal Probes and the Pain Management Pump Unit, connected to the Baylis Pain Management Generator, work in concert to deliver RF energy. The system is intended to be used to create RF lesions in nervous tissue, including that which is situated in intervertebral disc material. Separate components of the system had previously received FDA approval; the 2006 approval combined the indications of the predicate devices. (U.S. FDA website).

Intervertebral biacuplasty using the TransDiscal system has been investigated in the treatment of lumbar discogenic pain. The procedure is performed using a bipolar approach in conjunction with internally water-cooled RF probes to coagulate and decompress disc material. Two introducers are placed bilaterally in the posterolateral discs and the TransDiscal probes are then inserted into the introducers. RF energy is applied and directed through the disc between the two probe electrodes. The cooling system is designed to maintain and balance the temperature in each probe, allowing RF energy to be delivered with greater power to heat a larger volume of disc tissue, while avoiding overheating of adjacent tissue (Baylis Medical website).

Kapural et al. (2008) conducted a pilot study (n=15) of intervertebral disc biacuplasty in the treatment of lumbar discogenic pain. Included patients had a history of chronic low back pain unresponsive to nonoperative care for greater than six months, back pain exceeding leg pain, concordant pain on provocative discography, disc height > 50% of control, and evidence of single- or two-level degenerative disc disease without evidence of additional changes on MRI. Outcomes were evaluated by questionnaire at one, three and six months. Median VAS pain score decreased from 7 cm at baseline to 4 cm at one month and 3 cm at six months. The Oswestry score improved from 23.3 to 16.5 at one month, with similar results at six months. The SF-36 physical functioning scores improved from 51 to 70 points at six months, and the Bodily Pain score improved from 38 to 54. There was no significant change from baseline in daily opioid use. No procedure-related complications were reported.

The ASIPP guideline referenced above (Manchicanti, et al., 2009) concluded that, based on the available literature and evidence, no recommendation could be provided for intradiscal biacuplasty.

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of intervertebral disc biacuplasty.

Coblation® Nucleoplasty™/Disc Nucleoplasty/Decompression Nucleoplasty/Plasma Disc Decompression
Coblation Nucleoplasty, also referred to as disc nucleoplasty, decompression nucleoplasty, or plasma disc decompression, is a minimally invasive technique for decompression of contained herniated discs using the

Arthrocare Perc-D Coblation Spine Wand. The Spine Wand is a bipolar radiofrequency device designed to decompress the disc nucleus with energy and heat. The tip of the wand is slightly curved to allow channeling. Nucleoplasty uses Coblation technology, which generates a low temperature plasma field intended to allow precise ablation with minimal risk of thermal injury. The tip temperature is 50–70 degrees C. A plasma field, a millimicron-thick layer of highly energized particles, causes molecular dissociation of the disc material directly in front of the tip. This creates a channel from the posterolateral annulus to the anteromedial annulus. During withdrawal, the coagulation mode is used. Six separate channels are typically created. The thermal effect is reported to result in denaturation of the Type II collagen, causing shrinkage of the surrounding collagen and widening of the channel (Sharps, et al., 2002; Singh, et al., 2003; Davis, 2003)

There are no published randomized controlled trials evaluating nucleoplasty in the medical literature; studies consist primarily of small uncontrolled case series (Sharp and Isaac [2002]; Singh et al. [2003]; Bhagia et al. [2006]).

A Cochrane review of surgery for lumbar disc prolapse (Gibson and Waddell, 2007) states that, unless or until better scientific evidence is available, Coblation therapy should be regarded as a research technique.

National Institute for Clinical Excellence (NICE) (United Kingdom) Interventional Procedure Guidance published in May 2006 states that although there are no major safety concerns associated with percutaneous disc decompression using Coblation for low back pain, and there is some evidence of short-term efficacy, this is not sufficient to support its use without special arrangements for consent and for audit or research. The published guidance states that 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, or to determine whether the benefits are sustained beyond 12 months.

The ASIPP 2009 Practice Guidelines for the Management of Chronic Spinal Pain recommendation is 2B/weak for nucleoplasty in the management of radicular pain due to contained disc herniation. No recommendation was made for the management of axial low back pain.

The evidence-based clinical practice guideline from the American Pain Society, Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain (Chou et al., 2009), states that there are no trials evaluating Coblation nucleoplasty. The authors were unable to estimate the net benefit of the procedure in the treatment of patients with back pain, with or without radiculopathy.

ACOEM evidence-based practice guidelines on low back disorders, surgical considerations (2007) states that there is no quality evidence that Coblation therapy is an effective treatment for any back or radicular pain problem.

The safety, efficacy and long-term outcomes of this Coblation nucleoplasty have not been demonstrated in the published medical literature. In addition, the long-term consequences of thermal denervation and tissue damage associated with this procedure are unknown.

Epiduroscopy/Epidural Myelography/Epidural Spinal Endoscopy, Racz Procedure, Epidural Adhesiolysis (Percutaneous or Endoscopic)

Epiduroscopy, the Racz procedure, percutaneous epidural adhesiolysis and spinal endoscopic adhesiolysis have been proposed as methods of diagnosing and/or treating intractable low back pain and lower extremity pain.

Epiduroscopy: Epiduroscopy, also referred to epidural myelography or epidural spinal endoscopy, is a technique that uses an epiduroscope to visualize the epidural space. It is used in the diagnosis and treatment of intractable low back pain, especially in patients with radiculopathy. Scarring of the epidural space occurs in approximately 50% of patients who have undergone multiple surgeries for back pain. This may lead to formation of epidural fibrosis, adhesions of the nerve root, causing recurrence of pain. In epiduroscopy, a needle is advanced into the sacral canal through which a guide-wire is inserted and advanced. The needle is replaced with an introducer sheath through which an endoscope is inserted. Saline is flushed through the system to expand the sacral space, which can then be examined through the endoscope. Although epiduroscopy may be performed as a diagnostic procedure, it is usually performed in conjunction with the Racz procedure or epidural

adhesiolysis. There is no evidence in the published medical literature to support the use of epiduroscopy as a diagnostic procedure. There is no evidence that this invasive technique provides clinically useful information not available with current noninvasive diagnostic methods.

Racz Procedure: The Racz procedure is a method of epidurolysis in which a Racz catheter is inserted under fluoroscopy into the epidural space and a mixture of local anesthetic, steroid, contrast dye and concentrated saline solution is injected. The procedure is performed under local anesthesia with intravenous sedation and analgesics, generally on an inpatient basis. The catheter remains in place overnight, and the injection is repeated on the second and third day. Percutaneous and endoscopic adhesiolysis are modifications of the Racz procedure but do not generally require an inpatient stay.

Epidural Adhesiolysis (Percutaneous or Endoscopic): Percutaneous epidural adhesiolysis, or percutaneous epidural lysis of adhesions is intended to eliminate the effects of scar formation which can prevent direct application of drugs used to treat chronic back and extremity pain. Percutaneous epidural adhesiolysis is intended to assure delivery of high concentrations of injected drugs to the target area. The procedure is generally performed by introducing a needle into the epidural space under fluoroscopy, performing a lumbar epidurogram to identify the filling defects, and inserting a Racz catheter through the needle to the area of the filling defect or site of pathology as determined by MRI, CT or patient symptoms. Adhesiolysis is performed by saline injections and mechanical manipulation of the catheter, followed by injection of anesthetic, steroid, and additional normal or hypertonic saline. Serious complications of epidurolysis may include paralysis, bowel/bladder dysfunction and acute bilateral vision loss during or shortly after the procedure. Less serious but more common complications include infection, subarachnoid block, lower body paresthesia, perineal numbness, neck pain, and headache requiring epidural and caudal blood patches.

Veihelmann et al. (2006) conducted a randomized controlled trial to evaluate epidural neuroplasty (i.e., adhesiolysis) compared to physiotherapy in patients with chronic low back pain and sciatica. Leg pain, back pain, and Oswestry disability scores were assessed by questionnaire prior to and following treatment. At three months' follow-up, the mean disability score had decreased from 23 ± 9 to 11 ± 7 in the adhesiolysis group, and had decreased from 21 ± 8 to 18 ± 8 in the physiotherapy group. This decrease was statistically significant. The mean leg pain score decreased 67% with adhesiolysis compared to a 16% decrease with physical therapy, and the mean back pain score decreased 68% with adhesiolysis compared to a 10% decrease with physical therapy. These improvements were also statistically significant. A significant limitation of this study is the fact that a total of 13 (25%) of the patients in the physical therapy group were not available for follow-up at three months. In addition, pain and disability were assessed at six and twelve months in patients who remained in the study, but 12 (23%) of the patients who remained and underwent physical therapy chose to undergo epidural adhesiolysis, and they were also excluded from the results. The authors stated that epidural neuroplasty seems to be an effective, safe, alternative treatment, but further prospective, randomized, double-blinded studies should be performed to prove the effectiveness of this procedure in comparison to placebo and in comparison to open discectomy procedures.

Manchicanti et al. (2004) conducted a randomized controlled trial to determine the effectiveness of percutaneous adhesiolysis and hypertonic saline administration in reducing pain and improving functional and psychological status of patients with chronic low back pain. A total of 75 patients were divided into three treatment groups. Group I, the control group, received catheterization without adhesiolysis followed by injection of local anesthetic, normal saline and steroid. Group II received catheterization and adhesiolysis followed by injection of local anesthetic, normal saline and steroid. Group III received adhesiolysis followed by injection of local anesthetic, hypertonic saline and steroid. The authors reported 72% of patients in group II and 60% of patients in group III showed significant improvement at 12-month follow-up, compared to 0% in group I. Patients in groups II and III received an average of 2.76 and 2.16 treatments respectively in the 12-month period. The duration of significant relief averaged 2.8 ± 1.49 months in group II and 3.8 ± 3.37 months in group III. The authors concluded that percutaneous adhesiolysis with or without hypertonic saline neurolysis is an effective treatment for chronic back pain. Of the 25 patients in the control group, however, one was lost to follow-up and 18 were unblinded prior to completion of the study. These findings cannot be generalized due to the small size of this study, lack of outcome data for patients in the control group, and lack of long-term outcomes.

Endoscopic epidural adhesiolysis is performed by inserting a needle into the sacral canal and inserting and advancing a guide wire. The needle is replaced with an introducer sheath through which a fiberoptic endoscope is inserted. Saline is flushed through the system to distend and decompress the epidural space, and mechanical

manipulation of the endoscope causes direct disruption of fibrosis, scar tissue or adhesions. Anesthetic and steroid are then injected.

Manchicanti et al. (2005) randomized 83 patients with chronic lower back pain to endoscopy at the sacral level without adhesiolysis, followed by injection of steroid and local anesthetic with steroid injection (n=33; group I) or to endoscopic adhesiolysis followed by injection of local anesthetic and steroid (n=50; group II). Endoscopic adhesiolysis was associated with significant improvements in all outcome measures at 12 months' follow-up. The mean pain score was reduced by 37% in group II compared to only 3% in group I, representing a statistically significant difference (p=0.001). The mean Oswestry disability score improved by 31% in group II compared to 3% in group I (p=0.001). Greater improvements in spinal range of motion and psychological status were also seen in group II. The average duration of > 50% pain relief was 7.6 ± 4.7 months. Although positive results were reported, it is difficult to draw definitive conclusions from this study, since 33 patients (40%) were not available for the 12-month follow-up.

There are few published studies that evaluate endoscopic epidural adhesiolysis. Manchicanti et al. (2003) published preliminary results of a small (n=39) randomized, double-blind trial to determine the ability of spinal endoscopic adhesiolysis to reduce pain and improve functional and psychological status. Patients randomized to group I (n=14) were treated with endoscopy without adhesiolysis followed by injection of local anesthetic and steroid. Patients randomized to group II (n=23) were treated with spinal endoscopy and adhesiolysis followed by injection of local anesthetic and steroid. The authors reported significant relief of pain in 13 of 23 patients in group II immediately after treatment and at one, three and six months, and significant improvement in psychological and behavior outcomes, while no patients in group I showed significant improvement at six months. Although designed as a double-blind study, 25 of 39 patients were unblinded at three months. These findings cannot be generalized due to the small size of this study and lack of long-term outcomes.

The American Society of Interventional Pain Physicians (ASIPP) practice guideline, *Interventional Techniques in the Management of Chronic Spinal Pain* (Manchicanti, et al., 2009), the recommendation is IB or IC/strong for percutaneous adhesiolysis in post-lumbar surgery syndrome, and IC/strong for endoscopic adhesiolysis in post lumbar laminectomy syndrome.

American College of Occupational and Environmental Medicine (ACOEM) practice guidelines on low back disorders, (2007) state that adhesiolysis is not recommended to treat acute, subacute or chronic low back pain, spinal stenosis, or radicular pain syndromes.

The National Institute for Clinical Excellence (NICE) (United Kingdom) issued updated *Interventional Procedure Guidance on therapeutic endoscopic division of epidural adhesions* in 2010, stating that current evidence is limited to some evidence of short-term efficacy, and there are significant safety concerns. This procedure therefore should only be used with special arrangements for consent and audit or research.

There is insufficient evidence in the published medical literature to support the use of epiduroscopy, the Racz procedure, or percutaneous/endoscopic epidural adhesiolysis in the diagnosis or treatment of back pain. There are no published, well-designed, prospective clinical trials of adequate size that evaluate these procedures nor is there information available regarding long-term outcomes. The safety, efficacy and long-term outcomes of these procedures have not been established.

Devices for Anular Repair Following Spinal Surgery

Discectomy procedures involve removal of a bony portion of the vertebral body to access the posterior side of the disc space, and removal of the impinging fragment from the disc. This fragment may be within the wall of the anulus, requiring incision into the anulus to remove it. Sutures may be placed to seal the anular defect to reduce recurrent herniation following discectomy. The Inclose™ Surgical Mesh System and the Xclose™ Tissue Repair System (Anulex Technologies, Inc., Minnetonka, MN) have been proposed for anular repair following discectomy as an alternative method to re-approximate the compromised tissue of the anulus fibrosus.

The Inclose Surgical Mesh System received FDA approval through the 510(k) process on August 18, 2005. According to the 510(k) summary, the device is comprised of a mesh implant and two suture assemblies (anchor bands). The mesh implant is an expandable braided patch that is inserted through the aperture of the tissue defect and affixed to surrounding soft tissue with the anchor bands. The product may be used to support soft

tissue where weakness exists, or for the repair of hernias requiring the addition of a reinforcing, or bridging material, such as the repair of groin hernias.

The Xclose Tissue Repair System received FDA approval through the 510(k) process on August 7, 2006. The system is described in the 510(k) summary as consisting of two non-absorbable braided surgical 3-0 suture and T-anchor assemblies connected with a loop of green 2-0 suture. The 2-0 suture loop is used to facilitate tightening, drawing the 3-0 suture assemblies together and re-approximating the tissue. The system is indicated for use in soft tissue approximation for procedures such as general and orthopedic surgery.

A randomized study to evaluate the benefits of annulus fibrosus repair with the Xclose system, compared to discectomy without annulus fibrosus repair, began in 2007 and is expected to be completed in late 2011. There are no published studies in the medical literature evaluating the Xclose system or the Inclose system. There is inadequate evidence to demonstrate the safety and efficacy of these devices or to determine the impact on patient outcomes compared to standard surgical techniques.

In addition to the procedures described above, several recently introduced techniques combine established surgical approaches for disc removal with additional procedures for which safety and efficacy has not been established, including radiofrequency, laser or other disc ablation and modulation procedures (e.g., Disc-Fx [Elliquency Innovations, Oceanside NY]), selective endoscopic discectomy (SED).

Summary

Most back pain will resolve spontaneously or can be treated with conservative therapies, such as pharmacological therapy (e.g., analgesics, anti-inflammatory drugs, muscle relaxants), exercise, physical therapy, spinal manipulation, and acupuncture. Trigger-point injections or epidural steroid injections may be considered for selected patients with pain that persists despite conservative treatment, although evidence on the long-term value of these injections is lacking. Consideration of an interdisciplinary approach with a cognitive-behavioral component is recommended for patients with nonradicular pain who do not respond to usual treatment. Standard open discectomy, or microdiscectomy, performed through a smaller (15–25 mm) central incision with the use of an operating microscope and direct visualization, may be performed for selected patients with remediable underlying pathology as determined by radiological findings. Laminectomy or laminotomy may be performed alone or in combination with discectomy to relieve pressure on the spinal cord or nerve roots.

A number of approaches and techniques have been proposed as alternatives to standard or microscopic discectomy, including pulsed radiofrequency, cryoablation, chemical ablation, laser ablation, sacroiliac (SI) joint ablation, automated percutaneous lumbar discectomy, percutaneous or laparoscopic laser discectomy, percutaneous intradiscal electrothermal annuloplasty (e.g., intradiscal electrothermal therapy [IDETTM]), intradiscal radiofrequency thermocoagulation (PIRFT), intervertebral disc biacuplasty, Coblation[®] Nucleoplasty[™], devices for annular repair (e.g., Inclose[™] Surgical Mesh System, Xclose[™] Tissue Repair System, epiduroscopy, Racz procedure, and percutaneous or endoscopic epidural adhesiolysis. Percutaneous laminectomy and laminotomy procedures (e.g., minimally invasive lumbar decompression [mild[®] procedure]) have also been proposed as minimally invasive alternatives to standard surgical approaches for laminectomy and laminotomy. There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of these procedures. There is no evidence that these procedures are as effective as established interventions for the treatment of back pain.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT ^{®*} Codes	Description
20552	Injection, single or multiple trigger point(s), one or two muscles
20553	Injection, single or multiple trigger point(s), three or more muscles
27096	Injection procedure for sacroiliac joint, arthrography and/or anesthetic/steroid

62310	Injection, single (not via indwelling catheter), not including neurolytic substances, with or without contrast(for either localization or epidurography), of diagnostic or therapeutic substance(s)(including anesthetic, antispasmodic, opioid, steroid, other solution), epidural or subarachnoid cervical or thoracic
62311	Injection, single (not via indwelling catheter), not including neurolytic substances, with or without contrast(for either localization or epidurography), of diagnostic or therapeutic substance(s)(including anesthetic, antispasmodic, opioid, steroid, other solution), epidural or subarachnoid, lumbar, sacral (caudal)
64479	Injection, anesthetic agent and/or steroid, transforaminal epidural; cervical or thoracic, single level
64480	Injection, anesthetic agent and/or steroid, transforaminal epidural; cervical or thoracic, each additional level
64483	Injection, anesthetic agent and/or steroid, transforaminal epidural; lumbar or sacral, single level
64484	Injection, anesthetic agent and/or steroid, transforaminal epidural; lumbar or sacral, each additional level
64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
64491	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level (List separately in addition to code for primary procedure)
64492	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure)
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
64494	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level (List separately in addition to code for primary procedure)
64495	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure)
64622	Destruction by neurolytic agent, paravertebral facet joint nerve; lumbar or sacral, single level
64623	Destruction by neurolytic agent, paravertebral facet joint nerve; lumbar or sacral, each additional level (List separately in addition to code for primary procedure)
64626	Destruction by neurolytic agent, paravertebral facet joint nerve; cervical or thoracic, single level
64627	Destruction by neurolytic agent, paravertebral facet joint nerve; cervical or thoracic, each additional level (List separately in addition to code for primary procedure)
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinal diagnostic or therapeutic injection procedures (epidural, transforaminal epidural, subarachnoid, paravertebral facet joint, paravertebral facet joint nerve, or sacroiliac joint), including neurolytic agent destruction

HCPSC Codes	Description
G0260	Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography

ICD-9-CM Diagnosis Codes	Description
353.1	Lumbosacral plexus lesions
353.2	Cervical root lesions, not elsewhere classified
353.3	Thoracic root lesions, not elsewhere classified
353.4	Lumbosacral root lesions, not elsewhere classified
721.0	Cervical spondylosis without myelopathy
721.1	Cervical spondylosis with myelopathy
721.2	Thoracic spondylosis without myelopathy
721.3	Lumbosacral spondylosis without myelopathy
721.41	Thoracic or lumbar spondylosis with myelopathy; thoracic region
721.42	Thoracic or lumbar spondylosis with myelopathy; lumbar region
722.0	Displacement of cervical intervertebral disc without myelopathy
722.10	Displacement of lumbar intervertebral disc without myelopathy
722.11	Displacement of thoracic intervertebral disc without myelopathy
722.4	Degeneration of cervical intervertebral disc
722.51	Degeneration of thoracic or thoracolumbar intervertebral disc
722.52	Degeneration of lumbar or lumbosacral intervertebral disc
722.71	Intervertebral disc disorder with myelopathy; cervical region
722.72	Intervertebral disc disorder with myelopathy; thoracic region
722.73	Intervertebral disc disorder with myelopathy; lumbar region
722.81	Postlaminectomy syndrome; cervical region
722.82	Postlaminectomy syndrome; thoracic region
722.83	Postlaminectomy syndrome; lumbar region
722.90- 722.93	Other and unspecified disc disorder
723.0	Spinal stenosis in cervical region
723.1	Cervicalgia
723.4	Brachial neuritis or radiculitis, NOS
723.8	Other syndromes affecting cervical region
723.9	Unspecified musculoskeletal disorders and symptoms referable to neck
724.00- 724.09	Spinal stenosis, other than cervical
724.1	Pain in thoracic spine
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache, unspecified
724.6	Disorders of sacrum
724.70- 724.79	Disorders of coccyx
724.8	Other symptoms referable to back
724.9	Other specified back disorders

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
22527	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; 1 or more additional levels (List separately in addition to code for primary procedure)
22899 [†]	Unlisted procedure, spine
62263	Percutaneous lysis of epidural adhesions using solution injection (e.g., hypertonic saline, enzyme) or mechanical means (e.g., catheter) including

	radiological localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days
62264	Percutaneous lysis of epidural adhesions using solution injection (e.g., hypertonic saline, enzyme) or mechanical means (e.g., catheter) including radiological localization (includes contrast when administered), multiple adhesiolysis sessions; 1 day
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disk, any method, single or multiple levels, lumbar (e.g., manual or automated percutaneous discectomy, percutaneous laser discectomy)
64640	Destruction by neurolytic agent; other peripheral nerve or branch
64999 [†]	Unlisted procedure, nervous system
76942 ^{††}	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation
0213T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level
0214T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; second level (List separately in addition to code for primary procedure
0215T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure)
0216T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level
0217T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; second level (List separately in addition to code for primary procedure)
0218T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure)
0228T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; single level
0229T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; each additional level (list separately in addition to code for primary procedure)
0230T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; single level
0231T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; each additional level (List separately in addition to code for primary procedure)
0274T	Percutaneous laminotomy/laminectomy (intradiscal approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic
0275T	Percutaneous laminotomy/laminectomy (intradiscal approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar

[†]**Note:** Experimental/Investigational/Unproven/Not Covered when used to report any procedure listed as such in this Coverage Policy including but not limited to cryoablation/cryoneurolysis/cryodestruction, laser ablation, sacroiliac joint radiofrequency ablation or dry needling of trigger points.

†† **Note: Not medically necessary when used to report ultrasound guidance for trigger point injections.**

HCPCS Codes	Description
C2614	Probe, percutaneous lumbar discectomy
C9729	Percutaneous laminotomy/laminectomy (intradiscal approach) for decompression of neural elements, (with ligamentous resection, discectomy, facetectomy and/or foraminotomy, when performed) any method under indirect image guidance, with the use of an endoscope when performed, single or multiple levels, unilateral or bilateral; lumbar
S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disk, using radiofrequency energy, single or multiple levels, lumbar

***Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	8/15/2008	0139	Minimally Invasive Treatment of Back Pain
Great-West Healthcare	6/21/2007	98.297.03	Epiduroscopy/Spinal Endoscopy/Flexible Fiberoptic Spinal Endoscopy
	6/21/2007	05.311.02	Epidurolysis
CIGNA HealthCare	04/15/2008	0039	Intradiscal Electrothermal Therapy (IDET™)
Great-West Healthcare	03/12/2007	00.208.05	Intradiscal Electrothermal Therapy™ (IDET)

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