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Medical Coverage Policy

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Minimally Invasive Spine Surgery Procedures and Trigger Point Injections

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Overview

This Coverage Policy addresses minimally invasive spine procedures, injection therapy and other intradiscal and/or annular procedures for treatment of back pain conditions.

Coverage Policy

INJECTION THERAPY: TRIGGER POINT

Diagnostic/Stabilization Phase
Trigger-point injection(s) of anesthetic and/or corticosteroid (CPT codes 20552, 20553) for diagnosis/stabilization of subacute or chronic back, or neck pain, or subacute or chronic myofascial pain syndrome is considered medically necessary when pain has persisted despite appropriate conservative treatment, including pharmacological therapy, physical therapy, and/or a home exercise program.

A maximum of four injection sessions for diagnosis and stabilization may be performed at minimum intervals of one week when provided to determine whether injections provide therapeutic benefit.

Therapeutic Phase
Therapeutic trigger-point injections of anesthetic and/or corticosteroid (CPT codes 20552, 20553) are considered medically necessary when prior diagnostic/stabilization injections resulted in a beneficial clinical response (e.g., improvement in pain, functioning, activity tolerance) and BOTH of the following criteria are met:

- subacute or chronic back pain, neck pain, or myofascial pain syndrome persists
- injections are provided in conjunction with an active treatment program, which may include pain management, physical therapy, and/or a home exercise program

A maximum of six treatment sessions for injection of the same muscle may be performed at a minimum interval of two months, if the preceding therapeutic injection resulted in more than 50% relief for at least six weeks.

More than ten (10) trigger point injections in total provided during a rolling 12 month period is considered not medically necessary.

Ultrasound guidance (CPT code 76942) for trigger point injections is not covered or reimbursable.

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INJECTION THERAPY: INTRADISCAL STEROID INJECTION

Intradiscal steroid injection for the treatment of acute, subacute, or chronic back or neck pain is considered experimental, investigational, or unproven.

ENDOSCOPIC DISC/NERVE ROOT DECOMPRESSION OF THE CERVICAL, THORACIC OR LUMBAR SPINE

Single level lumbar endoscopic disc and/or nerve root decompression (CPT code 62380) for treatment of disc herniation or spinal stenosis and unremitting radiculopathy is considered medically necessary when ALL of the following criteria are met:

- physical examination findings and imaging studies correlate with the level being treated
- clinically significant functional impairment (e.g., inability to perform household chores or prolonged standing, interference with essential job functions)
- in the absence of progressive neurological compromise, failure of at least six weeks of conservative medical management

  Please note: As noted below, when endoscopic decompression is combined with procedures such as annuloplasty, ablation, and/or laser the procedure is considered experimental, investigational or unproven.

Each of the following lumbar endoscopic decompression spinal procedures is considered experimental, investigational or unproven:

- Yeung endoscopic spinal system (YESS)/ selective endoscopic discectomy (SED) when combined with ablation, laser or other thermal methods utilized for disc removal (CPT code 62380)
- endoscopic disc decompression ablation, or annular modulation using the Disc-FX® System (CPT codes 22899, 62380, 64999)
- multilevel endoscopic disc/nerve root decompression of the lumbar spine (CPT codes 22899, 64999)

Cervical and/or thoracic endoscopic disc/nerve root decompression, including ANY of the following procedures, is considered experimental, investigational or unproven.

- cervical endoscopic decompression with microforaminotomy (e.g., Jho procedure) (CPT codes 22899, 64999)
- endoscopic, anterior cervical disc decompression (e.g., Cervical Deuk Laser Disc Repair) (CPT codes 22899, 64999)

PERCUTANEOUS LAMINECTOMY AND DISC DECOMPRESSION PROCEDURES OF THE CERVICAL, THORACIC, OR LUMBAR SPINE

Each of the following minimally invasive percutaneous spine procedures is considered experimental, investigational or unproven:

- automated percutaneous lumbar discectomy (APLD)/automated percutaneous nucleotomy (CPT code 62287, HCPCS code C2614)
- percutaneous diskectomy (PELD) (CPT code 64999)

- percutaneous laminotomy/laminectomy, percutaneous spinal decompression (e.g., mild® procedure) (CPT codes 0274T, 0275T)
- percutaneous laser discectomy /decompression, laser-assisted disc decompression (LADD) (CPT code 62287), targeted percutaneous laser disc decompression (targeted PLDD) (CPT code 62287)

THERMAL INTRADISCAL PROCEDURES

Each of the following procedures is considered experimental, investigational or unproven:

- intervertebral disc biacuplasty (CPT code 22899)
- intradiscal electrothermal annuloplasty (e.g., intradiscal electrothermal therapy [IDET™]) (CPT codes 22526, 22527)
- percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), intradiscal radiofrequency thermomodulation or percutaneous radiofrequency thermomodulation (CPT code 22899, HCPCS code S2348)
- Coblation® Nucleoplasty™, disc nucleoplasty, decompression nucleoplasty plasma disc decompression, radiofrequency thermocoagulation nucleoplasty (RFTC) (CPT code 62287)
- targeted disc decompression (CPT code 22899)

OTHER PROCEDURES

A bone-anchored annular device (i.e., Barricaid® Annular Closure Device [ACD] [Intrinsic Therapeutics, Washington, DC]) is considered medically necessary for treatment of a large annular defect resulting from a primary discectomy when ALL of the following criteria are met:

- The individual is skeletally mature
- Presence of radiculopathy (with or without back pain) resulting from a posterior or posterolateral herniation
- Magnetic resonance imaging demonstrates neural compression
- Annular defect measures between 4 - 6 mm tall and 6 -10 mm wide
- Performed as part of primary single level discectomy between L4-S1

***Note:** Annular closure, with or without use of a Barricaid® device, is considered integral to the primary discectomy procedure.

Intraosseous radiofrequency nerve ablation of the basivertebral nerve (i.e., INTRACEPT® Intraosseous Nerve Ablation System) is considered medically necessary for treatment of chronic, vertebrogenic low back for at least 12 months duration and at no more than three adjacent vertebral bodies (i.e., between L3-S1), during which time ALL of the following criteria have been met:

- Unremitting back pain and significant functional impairment continues despite at least six (6) consecutive months of structured*, physician supervised conservative medical management, including ALL of the following components:
  - exercise, including core stabilization exercises
  - nonsteroidal and/or steroidal medication (unless contraindicated)
  - physical therapy, including passive and active treatment modalities
  - activity/lifestyle modification

  - participation in 3 or more individual or group cognitive behavioral therapy (CBT) sessions provided by a licensed healthcare professional (e.g., physical therapist, [PT], occupational therapist [OT], psychiatrist, psychologist, social worker, psychiatric nurse, other licensed professional) with competence in principles and practice of CBT and providing individualized treatment that includes ALL of the following elements:
    - disease education
    - activity and lifestyle modification
    - stress management (stress management typically also includes strategies to deal with emotions such as fear, anxiety, sadness that can interfere with pain management)
- Imaging studies confirm Modic Type I changes on MRI report (i.e., hypointense T1 and hyperintense T2 in the vertebral endplates) at a maximum of three vertebrae between L3 and S1) or Type I and Type II changes on MRI (hyperintense T1 and hyperintense T2 in the vertebral endplates) at a maximum of three vertebrae between L3 and S1)
- Statement from a primary care physician, neurologist, physiatrist, psychiatrist, psychologist, or other licensed behavioral and/or medical health care provider not involved with the recommended plan of treatment attesting to the absence of untreated, underlying mental health conditions/issues (e.g., depression, drug, alcohol abuse) as a major contributor to chronic back pain.

  ***Note:** Structured medical management consists of medical care that is delivered through regularly scheduled appointments, including follow-up evaluation, with licensed healthcare professionals.

Intraosseous radiofrequency nerve ablation of the basivertebral nerve (i.e., INTRACEPT® Intraosseous Nerve Ablation System) is considered not medically necessary for any other indication, including the following:

- Metabolic bone disease (eg, osteoporosis), treatment of spine fragility fracture, trauma/compression fracture or spinal cancer
- Spine infection or active systemic infection
- Neurogenic claudication, lumbar radiculopathy or radicular pain due to neurocompression (eg, HNP, spinal stenosis), as primary symptoms
- Spondylolistheses > 2mm
- Disc protrusion > 5mm
- Individuals with severe cardiac or pulmonary compromise
- Individuals with implantable pulse generators (eg, pacemakers, defibrillators) or other electronic implants unless specific precautions are taken to maintain patient safety
- Treatment of other than L3 -S1 vertebrae
- Treatment of more than three adjacent vertebral bodies (i.e., between L3-S1)
- Repeat treatment at the same level

The following procedures are each considered experimental, investigational or unproven:

- annular repair using the Inclose™ Surgical Mesh System, Xclose™ Tissue Repair System (Anulex Technologies, Inc., Minnetonka, MN) or any other device
- epiduroscopy, epidural myeloscopy, epidural spinal endoscopy (CPT code 64999)
- intradiscal injections (e.g., methylene blue, platelet rich plasma, mesenchymal stem cells, bone marrow concentrate, tumor necrosis factor [TNF] alpha), gelified ethanol [e.g.,

DiscoGel®], and/or paravertebral oxygen/ozone injection) (CPT codes 0627T, 0628T, 0629T, 0630T)
- spinal decompression using Baxano iO-Flex® System (e.g., Baxano Device)
- vertebral body tethering for adolescent idiopathic scoliosis (CPT codes 22836, 22837, 22838, 0656T, 0657T)
- hardware injections/blocks

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

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 treatment. In some patients, back pain may be persistent and disabling. Conservative treatment may include medications, such as analgesics, anti-inflammatory drugs and/or muscle relaxants, exercise, spinal manipulation, acupuncture, cognitive-behavioral therapy, and physical therapy. If these measures are unsuccessful, a number of other more invasive treatments may be considered. Treatments that are more invasive can target muscles of the back, degenerated facet or sacroiliac joints, narrowed areas of the spine, and degenerated or herniated intervertebral discs, which may also be a source of pain (Chou et al., 2009).

Injection Therapy

Trigger Point: Trigger point injection therapy involves the 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 near trigger points. Palpable nodules may be present in the taut band of the muscle which become painful when the tender zone is stimulated. 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.

Fluoroscopic or computed tomography guidance is performed with other types of injections used to diagnose and treat back and neck pain (e.g., epidural steroid injections, facet joint injections) to identify the surrounding structures and to ensure accurate needle placement to the target area. Guidance has also been performed with trigger point injections. Although there are no standard criteria, a common method of identifying a trigger point is through manual examination using a palpation technique; palpating the band leads to a local twitch response (LTR) where contraction of the muscle fibers in the taut band is observed. The diagnostic reliability of this method however is inconsistent. As a result, use of ultrasound has been investigated to identify the trigger point and to visualize the twitch response resulting from the injection. Particularly for deep muscles, such as the lower back, it has been purported the use of ultrasound is clinically useful to identify the LTR and therefore improve the efficacy of the injection (Rha, et al., 2011). Evidence in the published medical literature evaluating the efficacy of adding ultrasound or other guidance to

trigger point injections is limited to primarily pilot studies, case reports, case series, case control studies and literature reviews (Farrow, et al., 2023; Khumbare, et al., 2016; Shin, et al., 2014; Shankar, Reddy, 2012; Rha, et al., 2011; Sikdar, et al., 2009; Botwin, et al., 2008; Lewis and Tehan, 1999). Sample populations are small and reported clinical outcomes are inconsistent. A majority of comparative trials compare ultrasound guided trigger point injections to other non-trigger point forms of treatment. While some professional societies have published recommended guidelines for trigger point injections, they do not include the use of guidance for the trigger point injection. In the absence of well-designed comparative clinical trials evaluating the efficacy of trigger point injection with and without guidance, strong evidence based conclusions cannot be made. Further clinical validation is necessary to support improved health outcomes with the use of ultrasound guidance for trigger point injections. The application of an electrical stimulus to diagnose muscle pain followed by an injection technique that involves the bony attachment of the muscle as an alternative to palpation and trigger point injection has also been studied, however well designed, randomized controlled clinical trials with large sample populations are lacking to support clinical efficacy.

An American Society of Interventional Pain Physicians (ASIPP) Practice Guideline, Interventional Techniques in the Management of Chronic Pain, Part 2.0 (Manchikanti et al., 2001) included the following recommendations for trigger point injections:

- In the diagnostic or stabilization phase, a patient may receive trigger point injections at intervals of no sooner than one week and preferably two weeks.
- In the treatment or therapeutic phase (after the stabilization is completed), the frequency should be two months or longer between each injection provided that at least >50% relief is obtained for six weeks.
- In the diagnostic or stabilization phase, the number of trigger point injections should be limited to no more than four times per year.
- In the treatment or therapeutic phase, the trigger point injections should be repeated only as necessary judging by the medical necessity criteria and these should be limited to a maximum of six times for local anesthetic and steroid injections.
- Under unusual circumstances with a recurrent injury or cervicogenic headache trigger point injections may be repeated at intervals of six weeks after stabilization in the treatment phase.

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., 2009). This updated review evaluated 18 randomized controlled trials (n=1179) of injection therapy involving epidural, facet or local sites (i.e., tender- and 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.

Guidelines on injection therapies, low-back pain, and lumbar fusion published by the American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (Watters, et al., 2014; 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.

The 2021 American College of Occupational and Environmental Medicine (ACOEM) evidence-based practice guidelines on invasive treatments for low back disorders, state that trigger and/or tender point injections are not recommended for treatment of acute low back pain. 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), or dry needling without an injection. Glucocorticosteroids are not recommended for use in trigger point injections. 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 (Hegmann, et al., 2021).

In 2020 the North American Spine Society (NASS) published evidence based clinical guidelines for multidisciplinary spine care: Diagnosis and Treatment of Low Back Pain (NASS, 2020). Based on evidence reviewed NASS assigned one of the following levels of recommendation: Grade A (recommended), B (suggested), C (may be considered, is an option), or I (insufficient evidence for or against); the grades of recommendation indicate the strength of the recommendations made in the guideline based on the quality of the literature. According to these guidelines, regarding trigger point injections, there is insufficient evidence to make a recommendation for or against the use of trigger point injections in the treatment of low back pain (Grade of Recommendation: I (based on to level II studies).

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. These injections may provide short-term improvement and allow a determination as to whether conservative treatment will be successful.

Intradiscal Steroid: Intradiscal steroid injection, 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.

The authors of one randomized controlled trial (Nguyen, et al., 2018) evaluated intradiscal glucocorticoid injection during discography (n=67) compared with discography alone (n=68) for treatment of chronic low back (Nguyen, et al., 2018). At one month following the injection, pain reduction was higher in the experimental group, however beginning at three months pain scores increased and were higher than that of the control group. At 12 months the groups did not differ in pain intensity and in most secondary outcomes (e.g., pain intensity, activity limitations, and health related quality of life scores). At present, the evidence remains insufficient to determine the safety and efficacy of intradiscal steroid injection for the treatment of back pain.

According to the 2021 ACOEM evidence-based practice guidelines on low back disorders intradiscal steroid injections are not recommended for the management of acute, subacute, or chronic low back pain. The available evidence suggests that intradiscal steroid injections are not effective (Hegmann, et al., 2021).

In 2020 the North American Spine Society published evidence based clinical guidelines for multidisciplinary spine care: Diagnosis and Treatment of Low Back Pain. Based on evidence reviewed NASS assigned one of the following levels of recommendation to each question: A (recommended), B (suggested), C (may be considered, is an option), or I (insufficient evidence for or against). Within the guidelines, NASS reports that intradiscal steroids are "suggested" to

provide short-term improvement in pain and function in patients with modic changes (Grade of Recommendation: B [Fair evidence, level II or III studies with consistent findings). The recommendation is based on a RCT (Level 1) and a Comparative Cohort (Level 3) involving subjects with Modic Type I and/or II changes on MRI, and outcomes which included VAS scores and disability scores. At six month follow-up, reported clinical outcomes demonstrated significant improvements in pain and function. For patients with discogenic low back pain however, NASS reported there is insufficient evidence to support intradiscal steroid injections provide improvements in pain and function (Grade of Recommendation: I [insufficient or conflicting evidence]; based on one Level II study and one level IV study) (NASS, 2020).

Surgery

Surgery may be appropriate for medical conditions with remediable underlying pathology (e.g., herniated disc) when confirmed and correlated with imaging findings. There is sufficient evidence that surgical discectomy provides significant pain relief in selected patients with lumbar disc prolapse with sciatica that fails to improve with conservative treatment. Approaches to discectomy, such as open discectomy, microdiscectomy and endoscopic discectomy are well established as safe and effective.

Open Discectomy: 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 herniation.

Microdiscectomy: Microsurgical discectomy (i.e., microdiscectomy with direct visualization using either magnification loupes or a microscope) 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. 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.

Endoscopic Discectomy: Endoscopic discectomy is considered an alternative to open discectomy although it is performed with a smaller incision. The technique employs the use of an endoscope, camera and light to allow full, direct visualization of the surgical field.

Endoscopic Disc Decompression Procedures of the Spine

Endoscopic Disc Decompression: Endoscopic decompression procedures, with full visualization has been evaluated in the medical literature as an alternative to open and micro-endoscopic discectomy. Randomized controlled trials comparing endoscopic discectomy with a conventional microsurgical technique suggest that endoscopic discectomy is considered safe and effective for treatment of disc herniation or spinal stenosis (Markovic, et al., 2017; Komp, et al., 2015; Ruetten, et al., 2009; Ruetten, et al., 2008). Sample size within these trials ranged from 135 to 350 subjects and measured outcomes ranged from two to three years using primarily VAS and ODI scores. Overall the authors reported outcomes improved significantly in both groups and complication and recurrence-reoperation rates were low compared with the microdiscectomy groups.

In 2016 Kong et al. reported the results of a meta-analysis comparing endoscopic discectomy versus open discectomy for lumbar herniation. Their review included nine RCTs involving 1092 subjects. Compared with open discectomy endoscopic discectomy had slightly better outcomes using MacNab criteria (no clinical significance) significantly greater patient satisfaction rate ($p=0.03$), lower intraoperative blood loss volume, and shorter length of hospital stay. The authors

acknowledged endoscopic discectomy appeared to be a safe and effective alternative although cost effectiveness remains unproven and additional high quality RCTs with large sample populations are needed to evaluate cost effectiveness.

A systematic review and meta-analysis (Phan, et al., 2017) of 23 studies (RCTs, prospective and retrospective studies, observational studies) demonstrated no difference in overall complications, recurrence or reoperation rates, dural tears, root injury, wound infections, and spondylodiscitis between full endoscopic discectomy (FED) vs open discectomy (OD), or micro-endoscopic discectomy (MED) vs OD. The authors compared 23 studies including 421 full endoscopic discectomy (FE), 6914 microdiscectomy (MED), and 21,152 open discectomy (OD) cases. Based on the authors analysis, there were no significant differences found between FED and OD in regards to postoperative visual analog scale (VAS) leg pain scores (WMD 0.03, p=0.93). Similar results were obtained for MED vs OD (WMD 0.09, p=0.18). In terms of postoperative Oswestry Disability Index (ODI), both FED and MED were similar to OD (WMD -2.60, p=0.32 and WMD -1.00, p=0.21, respectively). FED had a significantly shorter operative duration compared to OD (54.6 vs 102.6min, p=0.0001). MED alone and endoscopic approaches overall (including MED and FED) demonstrated significantly lower estimated blood loss (44.3 vs 194.4mL, p=0.03 and 38.2 vs 203.5mL, respectively, both p<0.05). In comparison to OD, FED alone demonstrated a trend towards lower estimated blood loss (3.3 vs 244.9mL, p=0.07). Limitations noted by the authors include lack of blinding in the studies, use of self-reported outcomes in some studies, heterogeneity, various study designs, varying post-operative recovery protocols, and varying surgeon experience. The authors concluded both FED and MED were safe and effective alternatives to open discectomy although adequately powered RCTs are needed to further validate the results.

Zhang et al. (2018) published their results of a systematic review and meta-analysis evaluating transforaminal endoscopic discectomy (TED) versus conventional microdiscectomy (MD) for lumbar disc herniation (LDH). Included in the meta-analysis were nine trials, (five RCTs, four retrospective comparative trials), a total of 1527 subjects with follow-up ranging from 6.9 to 24 months in duration. Measured outcomes included VAS scores for leg pain, ODI for functional recovery, as well as operative time, hospital stay, complication rates, and rate of recurrence. Based on the authors analysis transforaminal endoscopic discectomy is superior to open microdiscectomy in the length of hospital stay (p<0.00001). No differences were noted in leg pain, functional recovery, and incidence of complications between TED and MD in treating LDH.

Ahn et al. (2019) published five year results of a comparative cohort of 335 subjects who underwent either transforaminal endoscopic lumbar discectomy (TELD) (n=146) or open microdiscectomy (n=152). Measured outcomes included VAS, ODI, and modified MacNab criteria. In both groups VAS and ODI improved significantly. A total of 88.36% of the TELD group demonstrated excellent or good outcomes compared to 87.5% in the open group. The reoperation rate was 4.2% and 3.3% in the TELD and open group, respectively. The authors noted there were no significant differences in clinical outcomes although the TELD group had significantly shorter operative time, hospital stay ad time to return to work (p<0.01). As noted by the authors the study is limited by lack of randomization and lack of radiographic changes evaluating degenerative changes over the long term.

Within a revised 2019 coverage policy recommendation NASS considers endoscopic decompression as treatment for primary or recurrent lumbar disc herniation with radiculopathy or spinal stenosis an alternative to open decompression unresponsive to appropriate nonoperative treatment (NASS, 2019).

Yeung Endoscopic Spinal Surgery (YESS): The Yeung Endoscopic Spinal System (Richard Wolf Surgical Instrument Corporation) is a specialized endoscope developed for spinal endoscopy and discectomy. This endoscope has multi-channel inflow and outflow ports, allowing visualization through one port and suction or other therapeutic services through the working port. The YESS is also used for other spinal procedures, including arthroscopic microdiscectomy, radiofrequency ablation, injection of intraoperative steroids, and laser disc decompression and ablation. Selective Endoscopic Discectomy (SED), performed with the YESS endoscope, is used to shrink and remove herniated discs. YESS may be used with or without adjunctive thermal techniques.

Selective Endoscopic Discectomy ™ (SED™): Selective endoscopic discectomy is a minimally invasive procedure in which an endoscope is used to view the disc space, degenerative and extruded portions of the disc are removed, and laser/radiofrequency of the disc wall defect is performed, allowing for decompression.

Endoscopic Disc Decompression/Ablation/Annular Modulation using Disc-FX® System (Elliquence LLC, Baldwin, NY): The Disc-FX™ system is a single-use disposable kit used to perform minimally invasive lumbar disc procedures, including endoscopic disc decompression, nucleus ablation to breakdown the nucleous, and annulus modulation.

There is a steep learning curve for procedures used to access and treat lesions with endoscopic guidance, in particular those combined with ablative methods. There are no prospective controlled clinical trials of the YESS or the Disc FX system, nor are there any prospective studies with long-term follow-up. The efficacy of endoscopic spinal surgery performed with the YESS or Disc FX System, has not been established in the peer-reviewed medical literature.

Endoscopic Anterior Cervical Disc Decompression: Cervical Deuk Laser Disc repair is a full endoscopic anterior cervical transdiscal laser assisted surgical procedure under investigation for treatment of symptomatic cervical disc disease (e.g., spondylosis, stenosis, herniations). The repair involves three procedures, a selective partial discectomy, foraminoplasty, and annular debridement. The procedure may be performed as an alternative to anterior cervical discectomy and fusion for treatment of cervical degenerative disc disease. In theory, the endoscopic approach does not require the removal of the intervertebral disc to reach the posterior disc complex, as a result there is no postoperative iatrogenic instability or deformity. In addition, it is not necessary to stabilize the spine with interbody devices, fusion, implants or biologics. At present, evidence in the peer-reviewed published scientific literature is insufficient to support the safety and efficacy of endoscopic anterior cervical disc decompression (i.e., Cervical Deuk Laser Disc repair).

Endoscopic Decompression with Microforaminotomy (e.g., Jho Procedure): In contrast to posterior total laminectomy, minimally invasive surgical interventions have been investigated as a treatment option to relieve impingement of the nerve root(s) and thereby eliminate symptoms caused by compression and injury to the nerves. The Jho procedure is described as a minimally invasive type of surgery that involves endoscopic decompression with microforaminotomy. A 2 cm incision is made, a small trocar is inserted, after which a small foraminotomy is made at the stenotic segment of the spine widening the narrowed spinal canal. Bone anatomy is preserved, and bony fusion and/or metal plate implantation is not required. There is insufficient evidence in the published peer-reviewed medical literature to assess the safety and efficacy of spinal endoscopic decompression surgery with microforaminotomy.

<u>Percutaneous Disc Decompression Procedures of the Spine</u>

A percutaneous approach is a minimally invasive approach to discectomy. Percutaneous access to the spine does not allow for visualization of the internal anatomy during the surgery. Small instruments, such as a cannula, are inserted through the skin into the disc space requiring little to

no incision and cause very little trauma. Visualization is via fluoroscopy. Percutaneous approaches, including a variety of other procedures (e.g., laser discectomy, percutaneous radiofrequency decompression, disc Nucleoplasty™) have been developed as alternatives to open, endoscopic and microsurgical techniques for treatment of back pain related to disc disease. However, evidence in the scientific literature is insufficient to draw firm conclusions regarding safety and effectiveness of these methods.

Percutaneous Disc Decompression Procedures: Percutaneous disc decompression involves surgical procedures performed to relieve pressure at the site of a herniated disc (e.g., chemical, thermal or mechanical).

Manchikanti et al. (2013) conducted a systematic review to evaluate the evidence for percutaneous disc decompression (PDD) with Dekompressor (a high rotation per minute device for mechanical disc decompression) in the management of chronic low back and lower extremity pain. The primary outcome was pain relief; secondary outcome measures included functional improvement, improvement of psychological status, opioid intake, and return to work. The authors stated that the evidence of effectiveness is limited, but the procedure may be recommended for patients with persistent pain after failure of other intervention techniques when microdiscectomy is not indicated.

Ceylan and Aşık (2019) retrospectively evaluated the efficacy of percutaneous decompression therapy using intradiscal navigable electrodes (L-Disq) on pain and functional movement index. A total of 209 subjects with herniated nucleus pulposus (HNP) were included in the study. An existing annular fissure was also treated, if present, using an ablation method, and according to the authors by treating both the disc and the fissure in the same session success rates would likely improve. Clinical outcomes were measured using VAS and ODI scores obtained at the onset of the study and at one, three, six and 12 months following treatment. Patient satisfaction was evaluated at final follow-up using a patient satisfaction scale (PSS). When compared to initial values, VAS and ODI scores revealed statistically significant improvement at all follow-up assessments ($p<0.001$). Mean VAS scores were 7.28 and 3.03 points ($p<0.001$) while mean ODI scores were 32.46 and 20.48 points ($p<0.001$) at the beginning and at the final follow-up, respectively. Overall satisfaction rate was 81%. The authors concluded L-Disq may be considered an appropriate option with low risk of complications for pain management in subjects with lumbar disc herniation resistant to conservative methods of treatment. Limitations of the study include the retrospective design and short term outcomes.

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 employing the use of an automated tissue removal instrument and is used for the removal 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. The goal of treatment is to remove herniated disc material that may be pressing on the nerve root resulting in pain and other symptoms.

A Cochrane review of surgery for lumbar disc prolapse by Gibson and Waddell (2007) 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.

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.

The 2021 American College of Occupational and Environmental Medicine (ACOEM) evidence-based practice guidelines on invasive treatments for low back disorders states that there is no quality evidence that automated percutaneous discectomy is an effective treatment for any back or radicular pain problem, and thus is not recommended (Hegmann, et al., 2021).

The North American Spine Society (NASS) published evidence based guidelines for the diagnosis and treatment of lumbar disc herniation (NASS, 2012). Within these guidelines APLD is defined as "a procedure in which a cannula is inserted into the intervertebral disc space, usually with fluoroscopic guidance, and nuclear material is removed without direct visualization by nucleotome, laser or radiofrequency heat. This is an indirect visualization technique using the endoscope and fluoroscopic guidance." NASS recommends APLD as a treatment of lumbar disc herniation with radiculopathy. However, NASS noted the available evidence is poor (C recommendation) and that there is insufficient evidence to recommend for or against APLD compared with open discectomy in the treatment of subjects with lumbar disc herniation and radiculopathy.

The American Society of Interventional Pain Physicians (ASIPP) 2013 Practice Guidelines for the Management of Chronic Spinal Pain, state that the evidence is limited to fair for APLD, and that the procedure is recommended in select cases.

A systematic review published by Manchikanti et al. (2013) evaluated the use of automated percutaneous mechanical lumbar discectomy for treatment of contained herniated lumbar discs. The primary outcome was pain relief; secondary outcome measures were functional improvement, improvement of psychological status, opioid intake, and return to work. Nineteen observation studies were included; of the three randomized trials reviewed, none met inclusion criteria for methodological quality assessment. The evidence is limited for automated percutaneous mechanical lumbar discectomy, but the procedure may provide appropriate relief in properly selected patients with contained lumbar disc herniation.

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 insufficient evidence that APLD is as effective as discectomy/microdiscectomy.

Percutaneous Endoscopic Lumbar Diskectomy (PELD): PELD is a minimally invasive procedure in which indirect access to the herniated disc is made under fluoroscopic guidance using an endoscope and specialized instruments; removal of the disc occurs using laser or other mechanical means. The results of a recent meta-analysis investigating the effect of PELD in

comparison to other surgeries for treatment of lumbar disc herniation supports that similar complications occurred with PELD in comparison, however it was also associated with a significantly higher rate of recurrent disc herniation (Bai, et al., 2021). The author's analysis included 14 studies involving 2528 subjects (ten cohorts, four RCTs), the other surgeries for comparison included open lumbar microdiscectomy, microendoscopic discectomy, minimally invasive transforaminal lumbar interbody fusion, and percutaneous endoscopic lumbar discectomy. Success rates in the PELD and other surgical intervention groups were 90.1% and 88.0%, respectively, recurrence rates in the PELD and other surgical intervention groups were 7.57% and 4.38%, respectively. While numerous outcomes were assessed in the review such success rate, recurrence rate, complication rate, operation time, hospital stay, blood loss, visual analog scale (VAS) score for back pain and leg pain, 12-item Short Form Health Survey (SF12) physical component score, mental component score, Japanese Orthopaedic Association Score, and Oswestry Disability Index, there was either a more favorable clinical outcome for PELD in some (operation time, hospital stay, blood loss, SF-12 mental, and SF-12 physical components) or there were no significant differences between PELD and other surgical groups in terms of success rates, complication rates, Japanese Orthopaedic Association scores, VAS scores for back and leg pain, and ODI scores. The authors acknowledged additional large-scale, well-performed randomized trials are needed to verify their findings.

Percutaneous Endoscopic/Arthroscopic Microdiscectomy: Percutaneous endoscopic/arthroscopic microdiscectomy is a procedure that involves the use of an endoscopic or arthroscopic guided approach to removing herniated disc material. The herniated disc is accessed and removed through small incisions using cannulas and other instruments.

Percutaneous Laminotomy/Laminectomy/Percutaneous Spinal Decompression (e.g., mild® Procedure): The mild® Device Kit (Vertos Medical, Inc., Aliso Viejo, CA) received U.S. Food and Drug Administration (FDA) 510(k) clearance on February 4, 2010 (K093062). The device kit is a 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 (minimally invasive lumbar decompression) procedure. The 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. The mild® procedure has been proposed as a minimally invasive alternative to conservative treatment or surgical decompression for the treatment of lumbar spinal stenosis.

Mekhail and associates (2021) published the results of a retrospective observational cohort study evaluating mild® for treatment of lumbar spinal stenosis, with hypertrophic ligamentum flavum as a contributing factor (n=75). The primary outcome measure was the incidence of open lumbar decompression surgery at the same level (s) as the mild procedure during a five-year follow-up period. Secondary outcome measures included change in patient reported pain levels using the Numeric Rating Scale (NRS), and opioid medication use using the Morphine Milligram Equivalent does per day from baseline to 3, 6, and 12 months post procedure. The mean patient age was 74.4 years, all had continued pain despite conservative management for an average of 6.8 years. Nineteen subjects had mild performed at two levels, all others had single level surgery with the most frequent level treated being L4-L5. No major complications were reported, minor complications included post procedural soreness and ecchymosis, with one case of allergic dermatitis at the surgical site. The authors reported a significant difference in the NRS pain scores from baseline and all three time points, 73.8%, 69.5% and 60.3% respectively for 3, 6 and 12 months post procedure. Within five years nine subjects required open surgical decompression

(2.4% annually), women had an odds ratio of 0.175 of having subsequent surgery compared with men. Only three had surgery at the exact same level as the mild procedure, seven had surgery which involved more levels than the mild. Only two subjects reported improvement in neurogenic claudication following the open procedure, three reported no improvement following open surgery, and three subjects did not have follow-up visits. In the author opinion mild was durable over five years and may allow elderly patients the avoidance of open lumbar surgery. The study is limited by its retrospective design, lack of control group, and small sample population.

Merkow and colleagues (2020) published results of a systematic review evaluating outcomes of both MILD and Superion (intraspinous process device) separately, as treatment of lumbar spinal stenosis. Regarding MILD the authors review included eight studies; two RCTs, three prospective observational trials, and three retrospective observational trials. The authors concluded that MILD is modestly safe and effective for treatment of lumbar spinal stenosis, based primarily on the study by Staats, et al. 2018 showing two year outcomes.

In 2018 Deer and associates published consensus guidelines for minimally invasive spine treatment (MIST) for lumbar spinal stenosis. The United States Preventive Task Force (USPTF) criteria for evidence level and degree of recommendation was used along with strength of consensus for development of the guidelines. Within this guideline regarding percutaneous image guided lumbar decompression, the authors concluded the available evidence is level 1 and is supportive of PILD. In addition to retrospective and prospective studies reviewed by the consensus group, there were two comparative prospective trials that led to reimbursement approval by CMS, noted as being both Level 1 (Brown, et al., 2012; Staats, et al., 2016, detailed below), both compare PILD to lumbar ESI and not to open decompression. The recommendation by the authors is Grade A (good evidence the measure is effective and that benefits outweigh harms), Level 1 (at least 1 controlled and randomized trial, properly designed), Consensus strong (>80% consensus).

In 2018 Staats and colleagues reported the 24 month outcomes of the MiDAS ENCORE trial (6 months outcomes are noted below). Within this trial two year follow-up was reported for the MILD procedure group only. The authors noted of the 149 initial subjects six withdrew prior to treatment, a total of 26 had withdrawn due to receipt of disallowed secondary interventions, eight subjects missed the two year follow-up, five withdrew, and five died, leaving 99 subjects for follow-up at two years. Measured outcomes included ODI, the Numeric Pain Rating Scale, and Zurich Claudication Questionnaire to evaluate function and pain. Incidence of device /procedure-related adverse events were used to assess safety. Using a modified intent to treat analysis, two year results for the MILD group demonstrated improvement in ODI, numeric pain rating scale, and Zurich Claudication Questionnaire (by 22.7 points, 3.6 points, and 1.0 and 0.8 points, respectively), and were clinically meaningful and statistically significant when compared with baseline (P 0<.001). The authors reported that throughout the two year follow-up additional procedures were performed: eight subjects had a subsequent surgical procedure at the index level, 22 received an ESI or nerve block at the index level, (one of these same subjects also received a spinal cord stimulator for pain at the index level), one additional subject received a rhizotomy and one received an intrathecal infusion pump. Overall, no serious device or procedure related adverse events were reported and there was no evidence of spinal instability at two years post procedure. Limitations of this trial include lack of a control group at two year follow-up, lack of comparison to open or other decompressive procedures, and performance of additional procedures throughout the two year follow-up period.

Staats et al. (2016) reported the six month results of a randomized controlled trial comparing the treatment outcomes of the MILD procedure (n=149) and epidural steroid injection (n=153) for lumbar spinal stenosis. Outcomes were measured using ODI, numeric pain rating scale (NPRS), and Zurich Claudication questionnaire. Primary efficacy was the proportion of ODI responders,

tested for statistical superiority of the MILD group versus the active control group with secondary efficacy proportion of NPRS and ZCQ responders using validated MIC thresholds. At 6 months, all primary and secondary efficacy results provided statistically significant evidence that MILD is superior to the active control of epidural steroid injection. The authors are continuing to obtain outcomes extending to two years post procedure. Limitations of the study noted by the authors included lack of blinding and the possibility of a higher non-responder rate versus standard of care in both groups due to restrictions of the study for use of adjunctive therapies.

Kreiner and colleagues (2014) reported their results of a systematic review of evidence evaluating the mild procedure for treatment of lumbar spinal stenosis. The authors used the Grading of Recommendations Assessment, Development and Evaluation Working Group system and compiled outcomes using short- (4-6 weeks), medium- (3-6 months), and long-term (>1 year) measures. The primary outcomes evaluated were pain, measured by the visual analog scale (VAS), and function, measured by the Oswestry Disability Index (ODI). Secondary outcomes included pain and patient satisfaction, measured by the Zurich Claudication Questionnaire, adverse effects/complications, and changes in utilization of co-interventions. The review included one RCT, seven prospective cohorts, four retrospective, and one case series. Compared with preprocedure values, statistically significant improvements were noted in VAS and ODI scores at all time points. The authors reported categorical data was not provided, as a result the proportion of subjects who experienced minimal clinically meaningful outcomes was unknown. Overall the quality of evidence was low and the authors concluded additional high quality data is needed to determine clinical utility.

Chopko (2013) reported two-year outcomes of mild lumbar decompression in the treatment of patients with neurogenic claudication associated lumbar spinal stenosis. The study included 45 of 58 patients included in an earlier analysis of one-year results Of the 13 patients unavailable at two years and not included in the two-year cohort, 3 underwent lumbar spine surgery, one died of unrelated causes, and nine did not respond or withdrew from the study. Outcome measures included the Visual Analog Scale (VAS), Oswestry Disability Index (ODI), and Zurich Claudication Questionnaire (ZCQ). At two years, VAS improved from an average of 7.2 at baseline to a mean of 4.8 ($p<0.0001$); 79% reported an improvement in VAS scores and 29% reported lack of improvement or no improvement. Improvement in physical function and mobility was significant, as measured by the ZCQ and ODI. There were no major adverse events or device-related complications. Limitations of the study include lack of a control group or blinding, and significant numbers of patients lost to follow-up.

Brown (2012) conducted a double-blind randomized study of epidural steroid injections (ESI) vs. the mild procedure in patients with symptomatic lumbar spinal stenosis (n=38). The included patients had painful lower limb neurogenic claudication, with hypertrophic ligamentum flavum as a contributing factor, and had failed conservative treatment. Patients were randomized to the mild procedure (n=21) or ESI (n=17). At six weeks, 76% of the patients in the mild group reported a two point improvement in VAS scores in compared to 35% of patients in the ESI group. There was a significant improvement in Oswestry disability scores in the mild group at six weeks ($p<0.05$), while in the ESI group improvement was not statistically significant. There were no procedure-related or device-related complications in either group. At six weeks, 17 of 21 patients in the ESI group crossed over to the mild procedure. Comparative 12 week outcome data was therefore not available. It is difficult to draw conclusions from this study due to the small number of participants and lack of data on long term outcomes. In addition, patients in the ESI group were treated with a single interlaminar injection; which is generally not typical of ESI treatment.

An observational study conducted by Mekhail et al. (2011) at 11 sites reported one year outcome data on 58 patients treated for spinal stenosis with the mild procedure, with statistically significant

improvement in VAS scores and ODI. A single-site case series conducted by Mekhail et al. in 2012 reported 12-month outcomes for 40 consecutive patients treated for spinal stenosis with the mild procedure. There was significant functional improvement and decreased disability as measured by the Pain Disability Index (PDI), Roland-Morris Disability Questionnaire, walking distance, standing time, and VAS scores.

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 of percutaneous laminotomy/laminectomy approaches, including the mild procedure. Additional well designed trials comparing mild with other decompressive procedures (e.g., standard open laminectomy, minimally invasive decompression) with long-term outcome data are needed to determine how this procedure compares to available alternative treatments for lumbar stenosis.

Percutaneous/Laparoscopic Laser Discectomy/Decompression/ Laser-Assisted 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 cause 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. Targeted percutaneous laser disc decompression (PLDD) has been described as a percutaneous laser disc decompression in which the area of laser evaporated nucleus pulposus is closer to the area of disc herniation (middle zone), in contrast to one-third into the intervertebral space (Luo, et al., 2014).

Updated ASIPP Practice Guidelines for the Management of Chronic Spinal Pain (2013) state that the evidence for percutaneous lumbar laser disc decompression is limited.

The 2021 ACOEM evidence-based practice guidelines on invasive treatments for low back disorders states that there is no quality evidence that laser discectomy is an effective treatment for any back or radicular pain problem, and thus is not recommended (Hegmann, et al., 2021).

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.

A Cochrane systematic review of surgery for lumbar disc prolapse by Gibson and Waddell (2007) 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.

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.

Thermal Intradiscal Procedures

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 90º 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.

Targeted disc decompression is a minimally invasive procedure which involves use of a heat resistant intradiscal catheter. Although similar to IDET in theory, the catheter used in this procedure is a 1.5 cm heating coil, the shrinkage effect and intradiscal pressure changes are generally similar. During targeted disc decompression under fluoroscopic guidance a trocar is inserted to the annulus and advanced to the inner annulus. The intradiscal catheter is pushed forward to the nucleus, and a wire is advanced between the annulus and nucleus. The disc is heated to 90° C. The inner part of the disc reaches a target temperature of 60-65° C causing the disc to shrink, and thereby reducing discal pressure. The epidural space is heated to a lower temperature, approximately 30° C. There is a paucity of evidence evaluating clinical outcomes (Adakli, et al., 2015; Schaufele, et al., 2008) and the effectiveness of this method of treatment remains unknown.

Helm et al (2017) published a systematic review evaluating the efficacy of thermal annular procedures (thermal intradiscal procedures) for treatment of chronic refractory discogenic pain. The main outcome measure was pain relief, a secondary outcome measure was functional improvement of at least 40% following treatment. Short and long term efficacy was defined improvement of less than or greater than six months, respectively. Inclusion criteria was defined as randomized trials with at least six months of follow-up, with statistical analysis, and a sample size of at least 25 subjects. If there were five or more RCTs, other studies were not included. For nonrandomized studies only those with 50 subjects and at least six months follow-up were included. Sixteen studies met inclusion criteria, four RCTs and 12 observational studies. Based upon one high-quality RCT showing efficacy and one moderate-quality RCT interpreted as showing no benefit (Freeman and Pauza studies noted below), the evidence was moderate supporting IDET, there is Level III, or moderate, evidence supporting the use of intradiscal electrothermal therapy (IDET) in treating chronic, refractory discogenic pain. The authors acknowledged quality evidence supports IDET but a countervailing study has been interpreted to show lack of efficacy of the procedure.

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 below) 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 ≥ 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. The author concluded that the evidence for efficacy of IEA remains weak and has not passed the standard of scientific proof.

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.
American Society of Anesthesiologists (ASA) 2010 Practice Guidelines for Chronic Pain Management states: Thermal intradiscal procedures- intervertebral disc annuloplasty (IDET) may be considered for young, active patients with early single-level degenerative disc disease with well-maintained disc height.

Updated American Society of Interventional Pain Physicians (ASIPP) Evidence-Based Practice Guidelines in the Management of Chronic Spinal Pain (Manchikanti, et al., 2013) stated that the evidence for IDET is limited to fair, and that the procedure may be performed in a select group of patients with discogenic pain non-responsive to conservative modalities, including epidural injections.

The 2021 ACOEM evidence-based practice guidelines on invasive treatments for low back disorders states that IDET is not recommended for treatment of acute, subacute, or chronic low back pain or any other back-related disorder (Hegmann, et al., 2021).

NASS evidence based guidelines for diagnosis and treatment of low back pain (2020) indicate intradiscal electrothermal annuloplasty is "suggested" to provide improvements in pain and function at up to two years. This treatment is limited in its effectiveness with roughly 40-50% of patient's receiving a 50% reduction in pain (Grade of Recommendation: B; based on one level I study, one level II study, and one level III study).

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 annular wall of the affected disc, causing annular 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 annular denervation (Davis, 2003). More recently bipolar radiofrequency thermocoagulation has been investigated as treatment of discogenic low back pain (Zhang, et al., 2016). During bipolar radiofrequency thermocoagulation two cannulas are heated simultaneously in contrast to a single cannula as in PIRFT.

NASS evidence based guidelines for diagnosis and treatment of low back pain (2020) indicate there is insufficient evidence to make a recommendation for or against the of percutaneous intradiscal radiofrequency thermocoagulation (Grade of Recommendation: I; based on one level II study).

Updated American Society of Interventional Pain Physicians (ASIPP) Evidence-Based Practice Guidelines in the Management of Chronic Spinal Pain (Manchikanti, et al., 2013) state that the evidence is limited for discTRODE (PIRFT).

The 2021 American College of Occupational and Environmental Medicine (ACOEM) practice guidelines on invasive treatments for low back disorders states that PIRFT is not recommended for treatment of acute, subacute, or chronic low back pain, particularly including discogenic low back pain (Hegmann, et al., 2021).

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.

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 cleared 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.

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of PIRFT. There is insufficient evidence that this procedure is as effective as established alternatives for the treatment of back pain.

Intervertebral Disc Biacuplasty/Cooled Radiofrequency: The Baylis TransDiscal™ system (Baylis Medical Inc., Montreal Canada) is used to perform intervertebral biacuplasty. The TransDiscal system received FDA clearance through the 510(k) process on January 8, 2007. 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.

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.

NASS evidence based guidelines for diagnosis and treatment of low back pain (2020) indicate biacuplasty is an "option" to produce clinically and statistically significant improvement in pain at six months in patients with discogenic low back pain (Grade of Recommendation: C; based on one level I study, three level IV studies).

Within a systematic review published by Helm et al. (2017), (noted above), the authors stated biacuplasty has two high quality studies (Desai et al and Kapural, noted below, one with a placebo control and one with an active comparator), supporting efficacy. Biacuplasty should be considered a treatment option when patients have discogenic back pain refractory to other treatments. Both of the studies reviewed are limited by small sample size and short term outcomes.

Desai et al (2016) conducted a prospective randomized clinical trial to compare outcomes of intradiscal biacuplasty and conventional medical management (n=29) with subjects who received conventional medical management alone (n=34). At six months following treatment, subjects were allowed to cross-over to the experiment group and were subsequently followed for an additional six months. The initial experimental group was followed for 12 months. The primary outcome measured was pain level change using VAS with secondary outcomes that included assessments of function, disability, mental health, quality of life and use of opioids. At 12 months post procedure pain reduction, and improvement in function and disability scores were reported to

be statistically significant and clinically meaningful in the original experimental group. The authors reported 50% of the cross over group responded to the intervention, with mean outcomes similar to the original group. Daily opioid intake was reduced in both the original and cross-over group. In the authors opinion the study demonstrated long-term effectiveness of intradiscal biacuplasty combined with conventional medical management. Limitations of the study included small sample populations, one-year outcomes, and inconsistent follow-up as reported by the authors.

Updated ASIPP guideline referenced above (Manchikanti, et al., 2013) state that the evidence for biacuplasty is limited to fair, and that the procedure may be performed in a select group of patients with discogenic pain non-responsive to conservative modalities, including epidural injections.

Kapural et al. (2013) conducted a randomized controlled trial to evaluate transdiscal radiofrequency biacuplasty (IDB) for discogenic lower back pain (n=59). Twenty nine patients were randomized to IDB and 30 to a sham procedure. All had a history of chronic low back pain for longer than six months. The primary outcome measures were physical function, pain, disability, and opioid usage. At six months, there were statistically significant improvements in the treated group compared to the control group in physical function (p=0.129), pain (p=0.006), and disability (p=0.037). There was no significant difference between groups in opioid usage. Limitations of the study include lack of long-term follow-up and small sample size. Of 1894 patients screened, only 59 were included. Kapural et al. (2015) reported in follow-up that the improvements initially reported at 6 months were maintained at nine and 12 months.

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 tow-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.

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 denaturization 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).

Studies evaluating nucleoplasty consist primarily of uncontrolled case series (Sharp and Isaac, 2002; Singh et al., 2003; Bhagia et al., 2006; Cincu, et al., 2015; Ren, et al., 2015, Adakli, et al., 2015, He, et al, 2021; Pandolfi, et al., 2021). One RCT evaluating percutaneous cervical nucleoplasty (PCN) versus pulsed radiofrequency (PRF) of the dorsal root ganglion for treatment of cervical disc herniation has been published (Halim, et al., 2017). The trial involved 34 patients with radicular pain treated with either PCN (n=17) or PRF (n=17). At three months both groups had significant reduction in pain, although none was superior to other. This study is limited by small sample and short term outcomes; studies evaluating long-term outcomes supporting clinical efficacy are lacking.

Updated ASIPP Practice Guidelines for the Management of Chronic Spinal Pain (2013) state that the evidence is limited to fair for nucleoplasty, and that the procedure is recommended in select cases.

The 2021 American College of Occupational and Environmental Medicine (ACOEM) practice guidelines on invasive treatments for low back disorders state that there is no quality evidence that coblation therapy is an effective treatment for any back or radicular pain problem, and thus is not recommended (Hegmann, et al., 2021).

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.

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.

The safety, efficacy and long-term outcomes of 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.

Other Minimally Invasive Procedures

Hardware Block/Injection/Posterior Element Blockade: Following spinal fusion surgery some patients continue to have pain. Standard clinical practice for diagnosing pseudoarthrosis in the spine is surgical pine exploration. Since surgical exploration is invasive, other modalities such as radiographs and computerized tomography scanning have been used to aid in the diagnosis of post-surgical spine pain. In some cases, a hardware block/injection may be recommended to determine if instrumentation used in the spinal surgery is causing the pain. During the procedure a local anesthetic such as lidocaine is injected into the area of the spine where the instrumentation is located. Theoretically, a reduction in pain confirms the instrumentation as the cause of the pain. At present however, there is insufficient evidence in the peer reviewed scientific literature to support the clinical utility of a hardware block for diagnosis and/or treatment of post-surgical or other spine pain.

Baxano iO-Flex® System: The Baxano iO-Flex® System (Baxano, Inc., San Jose, California) is a method of decompression that employs an "inside-out" approach according to the manufacturer. The system consists of a microblade shaver and several accessories which can be used in either minimally invasive or open procedures and according to the manufacturer instead of cutting through healthy pieces of the spine, the iO-Flex® System uses a fine surgical wire to guide the

thin iO-Flex® shaver instrument to the location of the overgrown bone and tissue to shave away the stenosis from the inside out. Use of this method is purported to preserve facet joint integrity/lamina, thus maintaining stability and minimizing muscle trauma by allowing decompression of up to four nerve roots through a single-point access and unlike traditional rigid instruments used for lumbar decompression the Baxano iO-Flex System utilizes thin flexible instruments. The FDA approvals for these devices suggests the devices are designed for accessing, cutting, and biting soft tissue and bone during surgery involving the spinal column. Nevertheless, evidence in the peer-reviewed scientific literature evaluating these emerging technologies is lacking, therefore evidence based conclusions cannot be made.

Other Intradiscal Injections: Intradiscal oxygen-ozone injection has been proposed as a minimally invasive treatment of lumbar disc herniation. Ozone is reported to be a strong oxidizer that rapidly reacts and oxidizes the proteoglycans in the nucleus pulposus. The procedure is based on the premise that a small reduction in disc volume may result in a significant reduction in pain. The technique is similar to discography and other percutaneous disc procedures. Under image guidance, a needle is positioned into the nucleus pulposus, 1-3 ml of oxygen/ozone from a medical ozone generator is injected into the disc, and 7-9 ml is injected into the paravertebral muscle surrounding the disc. A pain suppressant (e.g., bupivacaine) and/or corticosteroid may also be injected. Oxygen/ozone injection is primarily practiced in Europe and Asia. No medical ozone generators for use in intradiscal injection have received U.S. Food and Drug Administration (FDA) approval.

A meta-analysis of the effectiveness and safety of ozone treatments for herniated lumbar discs conducted by Steppan et al. (2010) reported a mean improvement of 3.9 for Visual Analog Scale (VAS) and 25.7 for Oswestry Disability Index (ODI). The likelihood for showing improvement on the Modified McNab outcome scale was reported as 79.7%, and the likelihood of complications, 0.064%. It is difficult to draw firm conclusions from this analysis due to the quality of included studies. Of 11 included studies, 9 were retrospective, 2 were prospective, and one consisted of unpublished data. In some studies data required for meta-analysis was not reported, and was estimated by the authors.

There is insufficient evidence in the published medical literature to demonstrate the safety and efficacy of ozone injection or to determine how this treatment compares to other available treatment options for disc herniation. In addition, no medical ozone generators have received FDA approval.

Other agents, such as methylene blue, tumor necrosis factor (TNF)-alpha, mesenchymal stem cells, and platelet rich plasma have been investigated as treatment of chronic back pain, however well-designed RCTs are lacking; there is a paucity of evidence in the peer-reviewed published scientific literature (Akeda, et al., 2017; Peng, et al., 2010; Cohen, et al., 2007) and long term outcomes have not yet been evaluated through well-designed studies.

In 2019 a group of authors evaluated intradiscal injection of methylene blue compared with placebo for the treatment of chronic discogenic back pain (Kallewaard, et al., 2019). The study was a multicenter, double blind, RCT involving subjects with chronic lumbar axial pain and replicated a study published in 2010 by Peng, et al, according to the authors. A total of 84 subjects enrolled in the study, 81 were available for follow-up at six months post intervention, 40 from the treatment group who received methylene blue/lidocaine injections and 41 from the control group who received placebo/lidocaine. At six months 35% of the methylene blue intervention group showed treatment success (30% pain intensity reduction) compared with 26.8% in the control group. Participants stated their overall health improved much or very much in 25% of the intervention group and 24.4% of the placebo group. Nine subjects in the

intervention group and 8 subjects in the control group had a pain reduction of at least 30% compared with baseline. The authors concluded their results were in contrast to the study published by Peng et al. and they were unable to confirm intradiscal methylene blue injections were better capable of reducing pain in subjects at six months.

Within evidence based guidelines published by NASS (2020) for diagnosis and treatment of low back pain, the authors concluded there is insufficient evidence to make a recommendation for or against intradiscal platelet rich plasma, methylene blue or intradiscal bone marrow concentrate for patients with discogenic low back pain (NASS, 2020).

Intradiscal injection of gelified ethanol (DiscoGel®) is under investigation as a minimally invasive treatment of disc pain (cervical, lumbar) that fails conservative measures and in the absence of neurological deficit (Hashemi, et al., 2020; Eloqayli, 2019; Kuhelij, et al, 2019; Sayhan, et al., 2018). In contrast to pure alcohol, gelified alcohol (ethanol base with ethyl cellulose) has increased viscosity. The gel is injected into the nucleus pulposus in order to decompress the intradiscal space and reduce intradiscal pressure. The amount injected is dependent upon amplitude of the disc space and the capacity of the disc to accommodate the gel, typically .5 to .8 ml. There is a paucity of evidence in the peer-reviewed literature evaluating gelified ethanol and long term clinical outcomes demonstrating sustained improvement in pain and function have not been reported. A majority of the studies are retrospective or prospective lacking control groups, and involve small sample populations evaluating short to mid-term outcomes, with few reporting outcomes beyond 3 years. Additional randomized studies with long term follow-up are necessary to support safety and efficacy.

Intraosseous Radiofrequency Nerve Ablation: Percutaneous radiofrequency ablation of intraosseous nerves is a technology intended for treatment of chronic low back pain. Intraosseous nerves are reportedly found within the vertebrae, are referred to as basivertebral nerves and are present in the basivertebral foramen. Authors contend the nerves may be a source of intraosseous back pain and that interruption of the nerve pathway using radiofrequency to ablate the nerve will relieve the associated pain. It has been purported that the basivertebral nerve transmits pain signals from the vertebral body to the central nervous system. One device, the INTRACEPT® System (Relievant MedSystems, Inc, Redwood City, CA), received FDA approval for use as a minimally invasive radiofrequency system for treatment of chronic lumbar back pain at one or more levels (i.e., L3 to S1), when back pain is present despite at least six months of conservative care and is accompanied by either Type I or Type 2 Modic changes on MRI (FDA K153272).

Modic changes are vertebral bone marrow signal intensity changes that are seen on magnetic resonance imaging (MRI). It is commonly seen in association with degenerative disc disease. Modic I changes represent bone marrow edema and inflammation, Modic II changes represent fatty marrow replacement, and Modic III represents subchondral bone sclerosis. Type I changes have been more strongly associated with back pain than Type II changes. It is unclear if the presence of Modic changes alone is an indication for treatment in subjects with back pain (Viswanathan, et al., 2020), with aging changes are often an asymptomatic finding.

Evidence in the peer-reviewed scientific literature evaluating intraosseous basivertebral nerve (BVN) ablation consists of randomized controlled trials, retrospective and prospective case series, and systematic reviews (Urits, et al, 2021; Fischgrund, et al., 2019; Khalil, et al., 2019).

In 2022 Conger et al. published an updated systematic review with single arm meta-analysis evaluating intraosseous BVN ablation. The authors included 12 total articles in the updated review (one RCT compared with sham [1, 2, and 5 year outcomes], one RCT compared with standard care, [3, 6, 12, and 24 months outcomes] and four single cohort studies with outcomes reported

between three and 12 months. They calculated the aggregate rates of treatment success defined by clinically important pain and functional improvement observed in the trials. There were no changes to the review methodology, however a ≥ 15 point ODI threshold was used to avoid redundancy; according to the authors the value is considered a robust threshold and exceeds the known minimally clinically important difference for chronic pain. The primary outcome measure was the proportion of individuals with >50% pain reduction. Secondary outcome measures included ≥ 15 point improvement in function using ODI index as well as ≥ 2 point reduction in pain score using the VAS or NRS. The total number of participants in all studies receiving BVN ablation treatment were 414. Most patients reported pain for greater than five years although in one study 74% reported a duration of pain for one to two years. For ≥ 50% pain reduction at six and 12 month the calculated success rates were 65% and 64%, respectively. Rates of ≥ 15 point ODI improvement were 75% and 75%, respectively. Meta-analysis based on intention to treat and worst case scenario demonstrated slightly lower success rates for pain and functional improvement: at six, 12, 24 and 60 months in the RCT 61%, 59%, 49% and 50% of subjects reported ≥ 50% pain improvement. ODI of ≥ 15 point improvement at the same time points were 71%, 70%, 57%, and 57%. The authors concluded that according to GRADE there is moderate quality evidence to support safety and effectiveness of BVN ablation, to reduce pain and disability, in most individuals with vertebrogenic back pain.

DeVivo et al. (2021) published the results of a prospective uncontrolled trial involving 56 subjects who underwent radiofrequency ablation of the basivertebral nerve for chronic vertebrogenic low back pain. The primary aim was to assess pain and reduction in disability, secondary outcomes included feasibility and safety using a CT-guided technique. A one month follow-up MRI was performed to evaluate the area of ablation for target success and a three month follow-up CT study was performed to evaluate bone mineral density related to structural abnormalities resulting from the treatment. Pre and post procedure pain and disability scores were obtained using VAS and ODI with a 2 cm improvement threshold in VAS and 10 point improvement threshold in ODI used to define clinical success. Outcomes demonstrated that at three and 12 months follow-up both VAS and ODI scores decreased significantly when compared to baseline scores. A total of 54 subjects had clinical success (96.5%) for pain as well as disability and 100% of subjects had successful CT- assisted targeting of the ablation zone. Limitations of the study include small sample population and short-term follow-up.

Fischgrund et al. (2020) published the five year results from the treatment arm of their multicenter, prospective RCT evaluating intraosseous basivertebral nerve ablation for chronic low back pain (SMART Trial). Patient reported outcomes of ODI, VAS, post ablation treatments, and patient satisfaction were reported, mean change in ODI was the primary outcome. This study includes the outcomes of 117/133 subjects within the United States centers, 117 subjects were adjudicated as successful for targeting. Subjects in the global population from the original trial were not included. A total of 100 subjects were available for final follow-up, 3 subjects were deceased, 3 withdrew, 1 refused participation, and 10 were lost to follow-up. Long term results for ODI, VAS improvement and responder rates were statistically significant post treatment; ODI was reduced on average by 25.95 ± 18.54 ($p<0.001$), VAS was 4.38 ± 2.35 ($p<0.001$), and responder rate using a 15 point improvement in ODI for a successful response was 77% at 5 years following ablation ($p<0.001$). Using a two point improvement in VAS for a successful response 88% reported a successful response ($p< 0.001$). Improvement in function and pain level seen at one and two year post treatment were sustained at five years and beyond. The authors also reported a 73% reduction in opioid use from baseline at five years, a 55% reduction in subjects who received an injection in the prior 12 months when compared to baseline, and that there were no patient reported complications. In addition to limitations of the initial trial (e.g., large placebo effect) limitations of this continued trial included loss of the control group from the initial trial, lack of outcomes from the global population, and industry funding.

Fischgrund and colleagues published the results of three and twelve month outcomes from a RCT comparing Intracept (n=147) with sham treatment (n=78), as part of the FDA IDE trial (SMART Trial). Inclusion criteria consisted of chronic low back pain for at least six months, nonresponsive to at least six months of conservative treatment, and Modic type I or 2 changes at the vertebral endplate of the level targeted for treatment. Outcomes were measured at 2 and 6 weeks, and at 3, 6, 12, 18 and 24 months postoperative. At 12 months subjects randomized to the sham group were able to crossover to the treatment group. The authors noted due to a high crossover rate (57/78 subjects in the sham group crossed over at 12 months) the subjects treated with RF ablation acted as their own control for 24 month outcomes. ODI scores at three months demonstrated the treatment group had a 20.5 least squares mean improvement vs. 15.2 in the sham group. Using a 10 point improvement in ODI to define "clinically meaningful improvement" in the treatment group 75.6% were successful at 3 mos. and at 24 mos. 76.4% (81/106 subjects) were successful. The authors noted due to a high crossover rate the subjects treated with RF ablation acted as their own control for 24 month outcomes. The authors acknowledged a 17% per protocol patient fallout by month 24 (n=106). The results of these subjects at 24 months were compared to the overall treated population at baseline (n=128) and at 12 months to avoid unintentional bias. Clinical improvements in ODI, VAS, and the Medical Outcomes Trust Short Form Health Survey were statistically significant at all time points during the two years. The mean percent improvements in ODI and VAS compared to baseline at two years were 53.7 and 52.9%, respectively. In the authors' opinion, RF ablation of the basivertebral nerve exhibited sustained clinical benefit in ODI and VAS scores for treatment of chronic low back pain. Limitations of the trial include short term outcomes and a large placebo response to sham treatment (Fischgrund, et al., 2018; Fischgrund, et al., 2019).

Khalil et al. (2019) published the results of a RCT comparing basivertebral nerve ablation to standard care for treatment of chronic low back pain. Inclusion criteria consisted of individuals with chronic pain, isolated to the back for at least 6 months, failure of 6 months of non-operative care, Type I or II Modic changes, and minimum ODI and VAS score of 30 and 4cm, respectively. Primary outcome measures included ODI at baseline, 3, 6, 9, and 12-months post procedure. A 10 point VAS for low back pain, ODI and VAS responder rates, SF-36, and EQ-5D-5L were used as secondary outcome measures. The primary endpoint was a between-arm comparison of the mean change in ODI from baseline to 3 months post-treatment. An interim analysis to determine superiority was conducted when at least 60% of the patients had completed the 3 month primary endpoint visit. Treatment of up to four vertebrae in nonconsecutive levels from L3 to S1 was allowed using the Intracept System; standard care treatment included but was not limited to acupuncture, chiropractic treatment, physical therapy exercise, and spinal injections. The authors reported that at the interim analysis at 3 months showed statistical superiority for all primary and secondary patient reported outcomes in the treatment group (n=51) compared with the standard care group (n=53). As a result, the study enrollment was halted and an early crossover was allowed to the control arm. Twenty-two total adverse events were reported; 15 were reported in 13 of the subjects treated with ablation, seven were procedure related and resulted in back pain of a new location, and either leg pain or paresthesia. Limitations of the study included non-structured standard care among subjects, short term outcomes, and as noted by the authors inability to generalize results due to the strict clinical criteria for chronic low back pain. In 2021 Smuck et al. published results of the subjects who initially received standard care but were able to receive basivertebral nerve ablation following halting of the randomization (n=66, 61 which underwent treatment as five declined). A total of 93% of these subjects had successful targeted treatment, the authors reported six month results were statistically significant and clinically meaningful when using VAS and ODI and furthermore that 65% received 50% reduction in VAS, 36.2% received >75% reduction, and 22.4% had 100% reduction. Twelve month outcomes for the initial treatment arm were also reported within this study and continued to demonstrate VAS and ODI

improvements; 64% received 50% reduction, and 29% were pain free (Smock, et al., 2021). Koreckij et al. (2021) reported the 24 month outcomes of the treatment arm (n=58/66). The authors reported that at two years results were statistically significant for improvement in ODI, VAS, SF-36 PCS, and EQ-5D-5L measures. At 24 months, ODI and VAS improved 28.5 ± 16.2 points (from baseline 44.5; $p < 0.001$) and 4.1 ± 2.7 cm (from baseline 6.6; $p < 0.001$), respectively. A combined responder rate of ODI ≥ 15 and VAS ≥ 2 was 73.7%. A ≥ 50% reduction in pain was reported in 72.4% of patients and 31.0% were pain-free at 2 years. At 24 months, only 3 (5%) of patients had BVNA-level steroid injections, and 62% fewer patients were actively taking opioids. There were no serious device or device-procedure related adverse events reported through 24 months.

Further evidence in the form of a post hoc analysis of the Fischgrund trial noted above (Markman, et al, 2019), and observational case series (Becker, et al., 2017; Kim, et al., 2018; Truumees, et al., 2019, Macadaeg, et al., 2020) have been published and tend to support reduction of opioid use and improvement in pain and function in the short-term.

Professional Societies/Organizations: Professional society recommendations lend support to intraosseous basivertebral nerve ablation as a treatment for a subset of individuals with chronic low back pain (North American Spine Society, [NASS], 2023; International Society for the Advancement of Spine Surgery [ISASS, 2022]; American Society of Pain and Neuroscience [ASPN], 2022).

In 2023 the North American Spine Society published coverage recommendations for Basivertebral Nerve Ablation (NASS, 2023). Within this document NASS reported that "percutaneous interosseous approach has emerged as a possible interventional therapy for this condition. Current BVN ablation evidence demonstrates consistent short- to intermediate-term improvements in function and pain. In addition to two prospective single-arm studies reporting clinically significant improvements in ODI and VAS from baseline, two Level 1 RCTs have demonstrated superiority over standard care at 3 months and 12 months, and over sham control at 12 months.

According to the recommendations BVN ablation is indicated for the following:

- Patients are skeletally mature and have CLBP for at least 6 months, and lower back pain is their main symptom
- Patients have failed to adequately improve despite attempts at nonsurgical management
- Patients have Type 1 or Type 2 Modic changes on MRI — endplate hypointensity (Type 1) or hyperintensity (Type 2) on T1 images plus hyperintensity on T2 images (Type 1) involving in the endplates between L3 and S1.

In 2020 the International Society for the Advancement of Spine Surgery published a guideline "Intraosseous ablation of the basivertebral nerve for relief of chronic low back pain" (Lorio, et al., 2020, updated 2022). Evidence reviewed by the authors included a multicenter, prospective, parallel RCT (INTRACEPT Study), and the FDA IDE trial (SMART Trial, [12 and 24 month outcomes]), seven single arm observational studies, and a prospective single arm study. ISASS concluded the technology is supported as a treatment option for a well-defined subset of patients with chronic low back pain. The procedure is supported by level I evidence demonstrating a statistically significant decrease in pain and improvement in function with outcomes sustained >5 years after a single treatment. based on their findings, patient selection criteria defined by ISASS include individuals with all of the following:

- chronic low back pain for at least 6 months duration
- failure to respond to at least 6 months of nonsurgical management

- magnetic resonance imaging (MRI) demonstrated Modic 1 changes (MC1) or Modic 2 changes (MC2) in at least 1 vertebral endplate at 1 or more levels from L3 to S1 (*Endplate changes, inflammation, edema, disruption, and/or fissuring).
- Fibrovascular bone marrow changes (hypointense signal for Modic type 1)
- Fatty bone marrow changes (hyperintense signal for Modic type 2).

Additional clinical trials evaluating the Intracept system are currently underway. However, in addition to increasing support from professional societies there is some evidence that lends support for a subset of individuals with chronic low back pain, in both industry sponsored studies and non- industry sponsored studies, that BVN ablation may be effective for reducing pain and disability, and for reducing opioid use, with no patient reported complications.

Epiduroscopy/Epidural Myeloscopy/Epidural Spinal Endoscopy: Epiduroscopy, also referred to epidural myeloscopy 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 guidewire 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.

There is insufficient evidence in the published medical literature to support the use of epiduroscopy in the diagnosis or treatment of back pain. There are no published, well-designed, prospective clinical trial of adequate size that evaluates 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 Annular 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 annulus, requiring incision into the annulus to remove it. Sutures may be placed to seal the annular 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 annular repair following discectomy as an alternative method to re-approximate the compromised tissue of the anulus fibrosus. Use of the Xclose system for this indication, however is beyond the scope of the FDA 510(k) clearance, detailed below.

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.

The Barricaid® Annular Closure Device (ACD) (Intrinsic Therapeutics, Washington, DC) received PMA approval in February 2019 and is implanted during surgery following removal of the lumbar disc as treatment for herniation. The device is a permanent implant consisting of a flexible woven polymer fabric component intended to close an annular defect with a bone anchor to affix the device in place. Alternative treatment for herniated disc consists of non-surgical care and/or surgical intervention such as discectomy with fusion or disc replacement. The Barricaid® ACD is indicated for reducing the incidence of reherniation, and reoperation in skeletally mature patients with radiculopathy (with or without back pain) attributed to a posterior or posterolateral herniation, and confirmed by history, physical examination and imaging studies which demonstrate neural compression using MRI to treat a large annular defect (between 4-6 mm tall and between 6-10 mm wide) following a primary discectomy procedure (excision of herniated intervertebral disc) at a single level between L4 and S1.

Authors postulate that a correlation exists between reherniation and the size of the defect in the annulus fibrosis created by discectomy and that implantation of an annular closure device could reduce the risk of reherniation. Thomé and colleagues (2018) reported on a multicenter, randomized clinical trial that evaluated whether the Barricaid Annular Closure Device (ACD) in adjunct to lumbar microdiscectomy would decrease reherniation and reoperation rates compared to lumbar microdiscectomy alone. Inclusion criteria consisted of single-level disc herniation between L1 and S1, posterior disc height at least 5 mm between end plates on sagittal MRI, six weeks of attempted non-surgical management, leg pain severity of at least 40 of 100 using VAS, ODI score of at least 40 of 100, and a large annular defect (4-6 mm tall and 6-10 mm wide) following the discectomy procedure. Subjects were excluded if they had previous surgery at the index level, osteoporosis, or Grade II or higher spondylolisthesis. Individuals were randomly assigned to the ACD group (n=267) or the control group (n=283) which did not include use of the ACD. Clinical follow-up at 2 years (91% compliance) showed symptomatic reherniation at 12% for the ACD group and 25% for the control group ($p<0.001$), and reoperation at 5% for the ACD group and 13% for the control group ($p=0.001$). End plate changes were 84% in the ACD group versus 30% in the control group ($p<0.001$), and ODI scores were comparable between the two groups. Health disparities were not addressed in the study. A limitation to this study is possible bias due to lack of blinding.

In 2018 a group of authors conducted a meta-analysis of outcomes resulting from annular closure devices/annular repair. The authors pooled results using meta-analysis with weighted mean difference and odds ratio as summary statistics. Four studies met inclusion criteria, three reported the use of Barricaid and one reported the use of Anulex (AR); two were RCTs and two were non-randomized comparative cohort studies. Eight hundred eleven subjects underwent discectomy with annular repair compared with 645 subjects who underwent only discectomy. Results demonstrated that 24 symptomatic reherniations were reported among the 811 discectomies in the experiment group compared to 51 of 645 in the control group ($p<0.0001$). There was a lower incidence of durotomies in the annular repair group with only three reported compared to seven in the control group. Both groups had comparable ODI and VAS scores, the authors were not able to determine if superiority of a particular device. Health disparities were not addressed in this study. Limitations noted by the authors include small sample of included studies, inclusion of short term outcomes, and lack of blinding in the studies (Choy, et al., 2018).

Kienzler et al (2019) published results of a multicenter RCT comparing use of a bone-anchored annular closure device (n=272) with lumbar discectomy to lumbar discectomy only (n=278) in subjects deemed to be high risk for reherniation. High risk was defined as a defect 4-6 mm in height and 6-10 mm in width. Subjects had sciatica due to intervertebral disc herniation who failed conservative treatment. Inclusion criteria were posterior or posterolateral disc herniations at one level between L1 and S1, MRI evidence of neural compression, post discectomy annular defects between 4 and 6 mm tall and 6-10 mm wide, six weeks of failed conservative management, minimum posterior disc height of 5 mm at the index level, radiculopathy with or without back pain, with positive straight leg raise, or femoral stretch test, ODI of 40 /100 at baseline, and VAS leg pain score of 40/100 at baseline. Exclusion criteria consisted of several variables as well as Grade II or higher spondylolisthesis, prior surgery at the index level, and clinically compromised vertebral bodies. Follow-up occurred routinely over a three year period and included rate of reherniations, reoperations, and endplate changes, leg and back pain using VAS scores, ODI scores, SF-36 and adverse events. The results at three years were more favorable for the annular closure group using Barricaid for symptomatic reherniation (14.8% vs. 29.5%; $p<0.001$), reoperation (11.0% vs. 19.3%; $p=0.007$), leg pain (21 vs. 30; $p<0.01$), back pain (23 vs. 30; $p=0.01$), ODI (18 vs. 23; $p=0.02$), Physical Component Score (47 vs. 44; $p<0.01$), and Mental Component Score (52 vs. 49; $p<0.01$). The authors noted adverse event neurological function deterioration was noted in 2% of the treatment group compared to 4.3% in the control group at three years, serious adverse events related to the device or procedure occurred in 10.7% of the treatment group compared to 18.7% in the control group and were mainly due to disc reherniation. Serious adverse events occurred in 4.4% of subjects and included mesh migration, mesh detachment, and anchor fracture. Health disparities were not addressed. Limitations of the analysis include lack of blinding, short term follow-up for a young patient population to determine durability.

Results from an RCT published by van den Brink and colleagues (2019) supported that for patients with large annular defects following lumbar discectomy, the annular closure device lowered the risk of symptomatic reherniation and reoperation over a one year period of time when compared to the control group (8.4% vs. 17.3%, and 6.7% vs 12.9%, respectively). This trial involved 554 subjects, 276 who underwent annular closure with the Barricaid device and 278 in the control group. Inclusion criteria were lumbar disc herniation at a single level between L1 and S1, radicular symptoms confirmed by positive straight leg raise or femoral stretch test, MRI confirmation of neural compression, minimum posterior disc height of 5 mm at the index level, ODI 40/100 and at least 40/100 on VAS for leg and back related pain despite conservative treatment for at least six weeks. Exclusion criteria were prior spinal surgery at the index level, spondylolisthesis ≥ 25% slip, and lumbar osteoporosis. Following discectomy subjects were evaluated for Barricaid eligibility using the size of the defect, (4-6 mm tall and 6-10 mm wide) were randomized to either the control group or the Barricaid group. A total of 94% subjects were available for one year follow-up. The cumulative risk of procedure or device serious adverse event over one year was 7.1% and 13.9%, respectively for the Barricaid and control group. Health disparities were not addressed. Limitations noted by the authors include short-term follow-up, performance of limited discectomy in all subjects (the authors noted aggressive disc resection may lower reherniation rates as well), and lack of blinding.

A systematic review and meta-analysis published by Arts and associates (2019) concluded that lumbar discectomy along with a bone-anchored annular repair device lowered the risk of reherniation (OR 0.38; 95% CI 0.24 to 0.61, $p<0.001$) and reoperation (OR 0.33; 95% CI 0.18 to 0.60; $p<0.001$) when compared to lumbar discectomy alone. Lumbar discectomy with annular closure may decrease leg pain, back pain and disability to a greater degree than conservative care. The review included 14 comparative studies, eight of which were RCTS, involving 3947

subjects in total. Eleven of the studies compared discectomy to conservative care (n=3232), three compared discectomy and annular closure to discectomy (n=715); no studies evaluated discectomy and annular closure to conservative care. Leg pain, back pain and disability data were the main outcomes assessed. Conservative care included multimodal nonsurgical treatments, physical therapy, spinal manipulation, and epidural steroid injections. The average follow-up in most studies was two years. Health disparities were not addressed. Authors acknowledged heterogeneity of outcomes among studies in paired meta-analysis, and inclusion of both randomized and nonrandomized results that may have introduced bias.

Thome et al. published five year results from the 2018 trial noted above, a multicenter randomized trial evaluating the effectiveness of annular closure using Barricaid for treatment of disc herniation compared with a control group that included subjects who underwent only lumbar discectomy (Thome, et al., 2021). At five years 404 total subjects were available for follow-up out 550. The authors reported the risk of reherniation and reoperation was lower in the device group (18.8% versus 31.6%, 16% versus 22.6%) compared to the control group, respectively. ODI scores, leg pain severity, and health related quality of life significantly improved over five years with no clinically relevant differences between groups. There was no statistical difference in the risk of serious adverse events between both groups. End plate changes were 20.2% in the ACD group versus 1.4% in the control group ($p<0.001$). Health disparities were not addressed. Limitations noted include the inclusion of only large annular defects, potential bias due to lack of blinding, performance of limited disc removal (aggressive disc resection may result in lower reherniation, although intervertebral instability and /or spondylosis may occur), and only 75% of subjects being available for final follow-up.

Evidence in the peer reviewed scientific literature supports that at five years post procedure the risk of reherniation and reoperation was lower within a group of subjects who underwent annular repair with a bone anchored ACD (18.8% versus 31.6%, 16% versus 22.6%) compared to the control group, respectively. In addition, studies with outcomes of one to three years support improved ODI scores, leg pain severity, and health related quality of life. A 10 year post approval extended study is required by the FDA for the Barricaid device however at this time the evidence is sufficient to support safety and efficacy for individuals undergoing single level discectomy and a resulting large annular defect to reduce the occurrence of reherniation and/or re-operation.

Professional Societies/Organizations: In 2020 the International Society for the Advancement of Spine Surgery (ISASS) published a policy guideline titled: Surgical Treatment of Lumbar Disc Herniation with Radiculopathy (Lorio, et al., 2020). Within this guideline the authors conclude that annular closure using a bone-anchored device has been shown to decrease the rate of recurrent disc herniation and associated reoperation in high-risk patients (i.e., large annular defect).

Several other 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).

Vertebral Body Tethering
Adolescent idiopathic scoliosis is a lateral curvature of the spine of unknown cause with a Cobb angle (a measure of the curvature of the spine) of at least 10° that occurs in children and adolescents 10 to 18 years of age. It is the most common form of scoliosis and usually worsens during adolescence before skeletal maturity. Idiopathic scoliosis is often treated using spinal fusion surgery or bracing. Growing rod instrumentation, also referred to as vertebral body tethering, is a surgical technique involving the use of posterior instrumentation that is sequentially lengthened to allow longitudinal growth of the spine while still attempting to control progressive spinal

deformity. During the surgical procedure, anchors and screws are placed in the selected vertebrae, a flexible cord is inserted through a small incision and placed along the U-shaped head of each screw, the cord is then tightened by a process called "tensioning", screws are used to secure the cord in place and the incision is then closed. It has been purported this procedure will stop progression of the curve while allowing continued growth of the thorax along with development of the pulmonary structures; the overall goal is to create a more normal spinal contour and preserve functional motion. Adverse events following the procedure have been reported and include but are not limited to overcorrection of the curve, risk for disc degeneration within the instrumented spine, risk of fixation failure or cord breakage, and infection.

U.S. Food and Drug Administration (FDA): In 2019 the FDA granted a Humanitarian Device Exemption (HDE) approval of the Tether™-Vertebral Body Tethering System (Zimmer Biomet Holdings, Inc.'s, Warsaw, IN) for treating idiopathic scoliosis in skeletally immature patients considering spinal fusion surgery. The device is indicated for skeletally immature patients that require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, with a major Cobb angle of 30 to 65 degrees whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. Patients should have failed bracing and/or be intolerant to brace wear. The manufacturer claims the device is the only medical device available that treats scoliosis while a person is actively growing and uses their own growth to repair their curve.

Literature Review: Evidence in the published peer-reviewed scientific literature evaluating the safety and efficacy of vertebral body tethering (VBT) for the treatment of adolescent idiopathic scoliosis is insufficient to support clinical safety and efficacy. Most published studies are retrospective or prospective case series with small populations, demonstrating varying clinical outcomes. Overcorrection, tether breakage, pulmonary (e.g., pneumothorax, pulmonary effusion) and other mechanical complications (e.g., screw loosening, screw migration, tether loosening) have been reported in the literature and the effect of tethering on adjacent discs has yet to be established. Meta-analyses have reported VBT complication rates ranging from 23 to 52%, and overall revision rates of 18% to 41% have also been reported (Parent, Shen 2020). Some studies comparing VBT to posterior spinal fusion found that complication and reoperation rates were significantly higher in patients undergoing VBT (Roser, et al., 2023; Zhu, et al., 2022; Shin et al., 2021).

Various approaches have been described in the literature, including thoracoscopic and mini-open techniques. Although to date some results are promising, patient selection criteria has not been firmly established, sample populations remain small, and reported outcomes are short to midterm. Authors generally agree that the timing of surgery, the amount of growth necessary, and magnitude of Cobb angle are yet to be firmly established. At present, published data demonstrating long term clinical outcomes is lacking; additional clinical trials are necessary to support long-term safety and effectiveness before vertebral tethering can be widely accepted (Roser, et al., 2023; Zhu, et al., 2022; Abdullah, et al., 2021; Pehlivanoglu, et al., 2021; Baroncini, et al., 2021; Shin et al., 2021 Szapary, et al., 2021; Alanay, et al., 2020; Pehlivanoglu, et al., 2020; Cheung, et al., 2019).

Roser et al. (2023) conducted a systematic review and meta-analysis of studies to determine the expected curve reduction and potential complications for vertebral body tethering (VBT) in adolescent patients. The review included 19 studies (n=677 patients), and the meta-analysis included 16 of these studies. The mean patient age was 12.2 years, and 84.8% were female. The median Risser score was 0, and the median Sanders was 3. Studies met the inclusion criteria if they evaluated the treatment of adolescent idiopathic scoliosis (AIS) in skeletally immature patients with a main thoracic curve; performed anterior VBT; reported the pre- and post-operative

major curve Cobb angle; and had a minimum two-year follow-up. Studies were excluded if they solely investigated non-idiopathic scoliosis; performed finite element analysis; used non-human models; were a review article, conference abstract, or case report; or only detailed surgical technique. The primary outcome measure was the change in the Cobb angle of the major curvature of the spine. Other outcome measures included surgical details and surgical complications. The mean follow-up of 34.1 months. Most studies used a thoracoscopic approach and the Zimmer Biomet tether. The mean number of vertebral levels treated was 7.6, the mean surgical time was 223 minutes, the mean intra-operative blood loss was 144 ml, and the mean hospital inpatient stay was 4.9 days. The initial mean Cobb angle was 47.8° (confidence interval [CI] 95% 42.9–52.7°) and decreased to 22.2° (CI 95% 19.9–24.5°), with a mean difference of −25.8° (CI 95% − 28.9–22.7) ($p<0.01$). One included study crossed the line of null effect. The overall complication rate was 23% (CI 95% 14.4–31.6%). The mean rate of tether breakage was 21.9% (CI 95% 10.6–33.1%), overcorrection was 11.4% (CI 95% 5.7–17.2%), reoperation was 11.4% (CI 95% 6.2–16.7%), spinal fusion rate was 7.2% (CI 95% 2.3–12.1%), and postoperative pulmonary complications was 6.7% (CI 95% 4–9.5%). Reoperations were most often for removal of the tether due to overcorrection, or replacement of a broken tether. Author-noted limitations of the review included the varied reporting of the final major curve Cobb angles, as some studies excluded patients who had curve progression and required fusion. Additionally, 14 studies had a negative major curve Cobb range due to overcorrection and the effect this had on the true mean result is unknown. Further limitations included the lack of a control group and heterogeneity of the studies. Additional comparative studies with long-term follow-up are needed to evaluate appropriate timing of VBT and the impact of complications.

Zhu et al. (2022) conducted a systematic review and single-arm meta-analysis to evaluate the safety and efficacy of vertebral body tethering (VBT). Twenty-six studies of 1045 patients who had undergone VBT for the treatment of scoliosis were included in the meta-analysis. Excluded from the review were case reports with less than five cases; duplicate reports; and review articles. Most included studies were case series reports (i.e., no comparator group). The primary outcome measure was the number of successful clinical treatments. Clinical success was defined as a residual curve of < 35° or ≤ 30° (depending on the study), and no posterior spinal fusion (PSF) indicated or performed by the latest follow-up. Other outcome measures included complications and revision surgeries. Fourteen studies (n=581 patients) had a mean follow-up time of < 36 months, while 12 studies (n=464 patients) had a mean follow-up time of > 36 months. Sixteen studies reported the pre- and postoperative major curve, and 10 studies reported the pre- and postoperative kyphosis angle. The reported overall clinical success rate was 73.02% (95% confidence interval [CI]: 68.31%–78.05%) (seven studies). The major curve Cobb angle was significantly corrected, with a correction rate of 46.6% ± 13.8% (16%–69%) immediately post-surgery and was 53.2% ± 17.9% (16%–79%) at final follow-up (26 studies). The pooled overall incidence rate of complications was 36.8% (95% CI: 23.9%–49.7%). The incidence rates of the top three complication types were assessed: curve progression with tether breakage (16.79%, 95% CI: 7.43%–26.15%); pulmonary complications (6%, 95% CI: 4.66%–7.68%); and overcorrection (4.55%, 95% CI: 3.4%–6.06%) (24 studies). The subgroup analysis of the incidence rate of complications showed that the rates in patients with follow-up time of < 36 months and those with follow-up time > 36 months were 23.79% (95% CI: 8.67%–38.92%) and 52.17% (95% CI: 33.71%–70.64%), respectively ($p<0.05$). The pooled unplanned reoperation rate was 8.66% (95% CI: 5.53%–13.31%), with the top three being conversion to PSF (3.51%, 95% CI: 2.45%–5.01%), tether removal (2.3%, 95% CI: 1.47%–3.58%), and tether replacement (1.09%, 95% CI: 0.57%–2.08%) (23 studies). Limitations of the review included the small sample sizes in most of the longer-term studies; the lack of uniform criteria for clinically successful treatment; heterogeneity among the studies; and the lack of prospective controlled trials. The authors noted the quality of the included studies was not comprehensive enough to accurately assess the actual effectiveness of VBT.

Clinical trials comparing vertebral body tethering to posterior spinal fusion is limited. Newton et al. (2022) published the results of a retrospective multicenter study that included 237 subjects with thoracic idiopathic scoliosis treated by vertebral body tethering and who had at least two years of follow-up, as well as a matched comparison group of 237 subjects who underwent the posterior spinal fusion. All subjects had Lenke 1 or 2 curve types, one with Lenke 3. Outcomes of interest included comparison of radiographic outcomes, clinical and patient-reported outcomes, complication rates, and revision rates. For the primary outcome of thoracic curve magnitude, changes over three visits (i.e., preoperative, first postoperative, and ≥ 2 years) were compared between groups. Thoracic curve magnitude at the ≥ 2-year visit was categorized as good (<35 degrees), fair (35 to 50 degrees), or poor (>50 degrees) for each patient. For the categorical rankings of the thoracic curve magnitude at ≥ 2 years, 76% of tethered subjects had a good outcome (<35 degrees) compared with 97.4% of spinal fusion subjects. A fair outcome was reported in 22% of tethering subjects and 2.6% of spinal fusion subjects. A residual curve of >50 was present in 7 tethering subjects (3%) and in 0 spinal fusion subjects (0%). Of the 7 subjects, 3 were revised to a spinal fusion at the latest follow-up. This distribution of outcomes across both groups differed significantly ($p<0.001$). A total of 46 revision procedures were performed in 38 of the tethering subjects, compared with four in the spinal fusion group. Overcorrection was the most common reason, followed by continued thoracic curve progression, and distal adding-on or progression of the lumbar curve. A total of 17 underwent a conversion to fusion, four had a residual curve > 50 degrees, seven underwent > two revision procedures, 47 subjects had confirmed or suspected broken tethers. The authors noted greater correction was seen in the spinal fusion group, the average thoracic curve magnitude did not show a significant decrease from the first postoperative radiograph to the follow-up at ≥ 2 years, however many subjects did experience further reduction of scoliosis magnitude. Limitations of the trial include retrospective data, differences in unrestricted propensity matching, and lack of long term follow-up assessing tether failure.

Hoernschemeyer et al. (2020) published the results of retrospective review evaluating vertebral body tethering of subjects with adolescent idiopathic scoliosis with two year follow-up (n=29). Of 31 subjects a total of 29 met inclusion criteria and two subjects were lost to follow-up. The mean patient age at the time of the procedure was 12.7 ± 1.5 years, and most were classified as Risser grade 0 or 1 (52%) and Sanders stage 3 (32%). The average follow-up was 3.2 years, success was defined as Cobb angles of ≤ 30 degrees at skeletal maturity and did not require spinal fusion. A mean of 7.2 v ± 1.4 vertebral levels were tethered with a minimum preoperative Cobb angle of 42 degrees. Successful tethering was reported in 20/27 participants who showed a curve magnitude of less than 30°. A total of 27 subjects had reached skeletal maturity at latest follow-up, two did not reach skeletal maturity. Of those skeletally mature, 20 exhibited a curve of ≤ 30° (success rate of 74%). Fourteen subjects (48%) were found to have broken tethers; 5 occurred during the first 2 years, 8 occurred between 25 and 36 months, and four broke at > 36 months. Of the 14 participants found to have a broken tether, 7 participants were considered clinically successful, 5 were unsuccessful and had not undergone a fusion surgery, and 2 had fusion surgery for continued curve progression. The study is limited by retrospective design and lack of comparison group.

Newton et al (2020) published the results of a retrospective study comparing outcomes of individuals with idiopathic scoliosis who underwent vertebral body tethering (n=23) with a matched cohort who underwent posterior spinal fusion (n=26). Inclusion criteria were defined as primary thoracic idiopathic scoliosis with a curve magnitude between 40° and 67°, Risser stage of ≤1, age of 9 to 15 years, no prior spine surgery, index surgery between 2011 and 2016, and a minimum follow-up of 2 years. The mean main thoracic curve was 53± 8° and 54 ± 7° for the tethering and fusion group, respectively. Mean follow-up was 3.4 years in the tethering group and

3.6 years in the fusion group. The authors reported the tethering group subjects had significantly more residual deformity, with a mean thoracic curve of 33 ± 18° compared with 16± 6° for the fusion group, and required nine revision procedures while the fusion group did not require any. The revisions occurred at a mean postoperative time of 2.3 years. A total of 12 subjects had evidence of broken tethers, four who underwent revision. In the tethering group, 12 (52%) participants were considered to have clinical success as evidenced by thoracic curve less than 35° without a secondary spinal fusion. All of the participants in the spinal fusion group had curves of less than 35°. In the author's opinion two year deformity correction was better maintained in the fusion group, however the tethered group had a delay or prevention of fusion in a majority of subjects. The authors acknowledged larger studies and longer-term follow-up is needed.

Miyanji and colleagues (2020) conducted a retrospective multicenter case series to determine the clinical efficacy of anterior vertebral body tethering (AVBT) in skeletally immature patients with idiopathic scoliosis. A total of 57 subjects were involved in the study, the average age of subjects was 12.7 years, and the average follow-up was 40.4 months. Tethering was offered to subjects with a Risser score of ≤ 3 and a Sanders score of < 5, being skeletally immature, most underwent thoracic tethering while two underwent lumbar tethering. Clinical success was defined as a major coronal Cobb angle of < 35 degrees and was achieved in 44 subjects (77%). The mean preoperative major curve of 51° (SD 10.9°; 31° to 81°) was significantly improved to a mean of 24.6° at the first postoperative visit (mean percentage correction was 45.6%) with further significant correction to a mean of 16.3° at one year and a significant correction to a mean of 23° at the final follow-up. The overall complications rate was 28.1% with a 15.8% rate of unplanned revision surgery. Rationale for unplanned revisions (8 subjects) included tether breakage, overcorrection, insufficient correction, progression of deformity, and need for extension of the tether.

Wong and colleagues (2019) published results of a single center Phase 2A prospective observational study evaluating anterior vertebral body tethering using a braided ultra-high molecular weight polyethylene cord (MIScoli, DePuy Spine) as treatment of idiopathic scoliosis (n=5). Inclusion criteria were age ≥ eight and ≤ 15 years, Risser stage 0, bone age of ≤ 13 years, major right thoracic scoliosis Cobb angle of 35 to 55° and Lenke-1 curve pattern. The mean preoperative main thoracic curve Cobb angle was 40.1° with curve correction of the tethered segment ranging from 0 to 133.3% at 4years. There were 20 adverse events postoperatively, four were considered to be of moderate severity including pneumonia, distal decompensation, curve progression and overcorrection which occurred in three subjects, two required fusion surgery. The remaining 16 adverse events were mild. Overcorrection occurred in 3 of the participants, of which 2 required fusion surgery. The study is limited by small sample, lack of control group, and short term outcomes.

In 2018 Newton et al. published results of a retrospective case series of 17 subjects who underwent thoracic tethering procedures with a mean 2.5 year follow-up for treatment of scoliosis (14 idiopathic, three syndromic). Preoperatively all subjects were at Risser stage 0 and were an average age of 11 +/- two years. The average preoperative curve was 52±10 degrees with correction to 27±20 degrees (51%). The average vertebrae tethered per patient was 6.8 +/- 0.5. The authors noted seven subjects underwent revision; four tether removals were due to overcorrection and three were due to progressive deformity. In addition, three subjects underwent posterior spinal fusion due to progression, eight of the subjects had a suspected broken tether, ten (59%) were considered clinically successful (Newton, et. al., 2018).

Samdani and associates published two trials evaluating vertebral body tethering. Within a retrospective review published in 2014 the authors reported on 11 subjects with thoracic idiopathic scoliosis, these subjects were an average 12.3 years of age, follow-up was reported at

two years post procedure. All subjects underwent tethering of an average of 7.8 levels. Preoperative thoracic Cobb angles corrected on average from 44±9 degrees to 14±12 degrees. The authors reported a revision rate of 18% and no major complications although two subjects returned to the operating room at two years post-operatively for loosening of the tether to prevent overcorrection (Samdani, et al., 2014). In 2015 this same group of authors reported the results of a retrospective review of 32 subjects, mean age of 12 years, noting similar curve correction from 43±8 degrees to 18±11 degrees at one year follow-up. All subjects were considered skeletally immature pre-operatively; mean Risser score 0.42, mean Sanders score 3.2. Patients underwent tethering at an average of 7.7 levels (Samdani, et al., 2015). Both trials involve small sample populations, are retrospective in nature, lack a comparative group, and evaluate only short-term outcomes.

Professional Societies/Organizations: In 2022, the National Institute for Health and Care Excellence (NICE) published guidance on the use of vertebral body tethering for idiopathic scoliosis in children and adolescents. NICE stated that the evidence regarding the safety of vertebral body tethering in this patient group is limited, but raises concerns of serious complications. NICE further noted that evidence on the efficacy of vertebral body tethering is inadequate in quality and quantity, and recommended that the procedure be used only in a research context.

In 2020, the Pediatric Orthopaedic Society of North America (POSNA) and the Scoliosis Research Society (SRS) posted a joint position statement on payor coverage for anterior fusionless scoliosis technologies (i.e., anterior vertebral body tethering). The groups stated "payors should provide coverage for any FDA-approved devices under FDA-stated clinical indications and requirements (limited to surgeons with active IRB approval) at the same level as traditional spinal instrumentation/fusion and growing rod procedures for management of skeletally immature patients (Risser ≤ 2 or Sanders ≤ 5) with idiopathic scoliosis (as defined above, 30 to 65 degrees Cobb angle). For those patients who meet criteria for use of The Tether™ or other similarly FDA approved growth modulation systems, the decision for fusion versus growth modulation is best made between the patient, guardians, and treating physician - accounting for individual needs, values, and perspectives."

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis (150.13)	12/7/2016
NCD	National	Thermal Intradiscal Procedures (TIPs) (150.11)	9/29/2008
LCD	Noridian Healthcare Solutions, LLC	Intraosseous Basivertebral Nerve Ablation (L39642 and L39644)	1/28/2024
LCD	Palmetto GBA	Thermal Destruction of the Intraosseous Basivertebral Nerve (BVN) for Vertebrogenic Lower Back Pain (L39420)	3/5/2023
LCD	Multiple LCDs	Trigger Point Injections	Various

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination.)

Effective 10/15/2024

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Injection Therapy: Trigger Point

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
20552	Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s)
20553	Injection(s); single or multiple trigger point(s), 3 or more muscles

Ultrasound Guidance for Trigger Point Injections

Not Covered or Reimbursable when used for guidance with trigger point injections:

CPT®* Codes	Description
76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation

Injection Therapy: Intradiscal Steroid Injection

Considered Experimental/Investigational/Unproven:

CPT®* Codes	Description
22899	Unlisted procedure, spine
64999	Unlisted procedure, nervous system

Endoscopic Disc/Nerve Root Decompression of the Cervical, Thoracic or Lumbar Spine

Considered Medically Necessary for single level lumbar endoscopic disc and/or nerve root decompression when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar

Considered Experimental/Investigational/Unproven when used to report lumbar endoscopic decompression spinal procedures: Yeung endoscopic spinal system (YESS)/

selective endoscopic discectomy (SED) when combined with ablation, laser or other thermal methods utilized for disc removal; endoscopic disc decompression ablation, or annular modulation using the Disc-FX® System; multilevel endoscopic disc/nerve root decompression of the lumbar spine:

CPT®* Codes	Description
22899	Unlisted procedure, spine
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar
64999	Unlisted procedure, nervous system

Considered Experimental/Investigational/Unproven when used to report cervical and/or thoracic endoscopic disc/nerve root decompression procedures: cervical endoscopic decompression with microforaminotomy (e.g., Jho procedure); endoscopic, anterior cervical disc decompression (e.g., Cervical Deuk Laser Disc Repair):

CPT®* Codes	Description
22899	Unlisted procedure, spine
64999	Unlisted procedure, nervous system

Percutaneous Laminectomy and Disc Decompression Procedures of the Cervical, Thoracic, or Lumbar Spine

Considered Experimental/Investigational/Unproven when used to report automated percutaneous lumbar discectomy (APLD)/automated percutaneous nucleotomy; percutaneous discectomy (PELD); percutaneous laminotomy/laminectomy, percutaneous spinal decompression (e.g., mild® procedure); percutaneous laser discectomy/decompression, laser-assisted disc decompression (LADD), targeted percutaneous laser disc decompression (targeted PLDD):

CPT®* Codes	Description
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar
64999	Unlisted procedure, nervous system
0274T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; cervical or thoracic
0275T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar

HCPCS Codes	Description
C2614	Probe, percutaneous lumbar discectomy

Thermal Intradiscal Procedures

Considered Experimental/Investigational/Unproven when used to report intervertebral disc biacuplasty; intradiscal electrothermal annuloplasty (e.g., intradiscal electrothermal therapy [IDET™]); percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), intradiscal radiofrequency thermomodulation or percutaneous radiofrequency thermomodulation; Coblation® Nucleoplasty™, disc nucleoplasty, decompression nucleoplasty plasma disc decompression, radiofrequency thermocoagulation nucleoplasty (RFTC); targeted disc decompression:

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
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar

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

Other Procedures

Bone-Anchored Annular Device

Considered Medically Necessary for treatment of a large annular defect resulting from a primary discectomy when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
C9757	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar
C1713	Anchor/Screw for opposing bone-to-bone or soft tissue-to-bone (implantable)

Effective 10/15/2024

Intraosseous Radiofrequency Nerve Ablation of the Basivertebral Nerve

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral
64629	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure)

Considered Experimental/Investigational/Unproven when used to report annular repair (Inclose™ Surgical Mesh System, Xclose™ Tissue Repair System [(Anulex Technologies, Inc., Minnetonka, MN]) or any other device); epiduroscopy, epidural myeloscopy, epidural spinal endoscopy; intradiscal injections (e.g., methylene blue, platelet rich plasma, mesenchymal stem cells, bone marrow concentrate, tumor necrosis factor [TNF] alpha), gelified ethanol (e.g., DiscoGel®) and/or paravertebral oxygen/ozone injection; spinal decompression using Baxano iO-Flex® System (e.g., Baxano Device); anterior vertebral body tethering for adolescent idiopathic scoliosis; hardware block/injection:

CPT®* Codes	Description
22836	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments
22837	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments
22838	Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed
22899	Unlisted procedure, spine
64999	Unlisted procedure, nervous system
0232T†	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed
0627T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level
0628T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (List separately in addition to code for primary procedure)
0629T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level
0630T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; each additional level (List separately in addition to code for primary procedure)
0656T	Vertebral body tethering, anterior; up to 7 vertebral segments
0657T	Vertebral body tethering, anterior; 8 or more vertebral segments

Effective 10/15/2024

†**Note: Considered Experimental/Investigational/Unproven when used to report platelet rich plasma used in an intradiscal injection.**

***Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.**

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• Added policy statement for total trigger point injections in a rolling 12-month period. • Added policy statement for ultrasound for trigger point injections.	10/15/2024
Focused review	• Revised policy statement for basivertebral nerve ablation. • Added not medically necessary statement for basivertebral nerve stimulation.	11/15/2023