Anthem

Medical Policy

Subject: Percutaneous Vertebral Disc and Vertebral Endplate Procedures
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Description/Scope

This document addresses several minimally invasive surgical procedures designed to destroy nociceptive nerve fibers with or without structural changes to the intervertebral discs. The following percutaneous vertebral disc and vertebral endplate procedures have been explored as a treatment of chronic low back pain secondary to disc disease:

- intradiscal electrothermal therapy (IDET) (also referred to as intradiscal electrothermal annuloplasty)
- percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)
- intraosseous basivertebral nerve ablation
- intradiscal biacuplasty (IDB)

Note: Please see the following document for percutaneous and endoscopic spinal procedures designed to remove or ablate disc material and decompress the disc (for example, percutaneous lumbar discectomy, laser discectomy, and disc decompression using radiofrequency energy):

- SURG.00071 Percutaneous and Endoscopic Spinal Surgery

Position Statement

Medically Necessary:

Intraosseous basivertebral nerve ablation (BVNA) is considered **medically necessary** when all of the following criteria are met:

1. Individual is skeletally mature; **and**
2. Chronic unremitting low back pain of at least 6 months duration is present;**and**
3. Has failed to respond to at least 6 months of supervised conservative medical management (for example, exercise, nonsteroidal and/or steroidal medication [unless contraindicated], physical therapy, including passive and active treatment modalities, and activity/lifestyle modification); **and**
4. Diagnosis of vertebrogenic pain meeting the following criteria:
    a. Documented by history and physical examination;**and**
    b. Magnetic resonance imaging (MRI)-demonstrated Modic Type 1 or 2 changes in at least one vertebral endplate, at one or more levels from L3 to S1, including the following:
        i. Fibrovascular bone marrow changes are present (hypointense MRI signal for Modic Type 1);**or**
        ii. Fatty bone marrow changes are present (hyperintense MRI signal for Modic Type 2);
        and
5. Qualifying Modic changes have been confirmed by two independent physicians*;**and**
6. Qualifying Modic changes are exhibited at each level to be treated;**and**
7. There is no previous history of lumbar spine surgery;**and**
8. There is no previous history of BVNA at the planned level of treatment;**and**
9. No evidence on imaging (MRI, flexion/extension radiographs, CT) of other causes of low back pain (including, but not limited to: lumbar stenosis, degenerative scoliosis, spondylolisthesis, segmental instability, facet arthropathy and disc disease); **and**
10. No evidence of lumbar radiculopathy or radicular pain;**and**
11. No evidence of metabolic bone disease (for example, osteoporosis with T score ≤ -2.5).

*Note: All imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede. The results of all imaging studies should correlate with the clinical findings in support of the requested procedure.

Not Medically Necessary:

BVNA is considered **not medically necessary** when the criteria above are not met, and for all other indications.

Investigational and Not Medically Necessary:

The following procedures are considered **investigational and not medically necessary:**

1. Percutaneous intradiscal electrothermal therapy; **or**
2. Percutaneous intradiscal radiofrequency thermocoagulation; **or**
3. Intradiscal biacuplasty.

Rationale

Intradiscal Electrothermal Therapy (IDET)

IDET with the SpineCath® IntraDiscal ElectroThermal Therapy (IDET™) System (Smith & Nephew, Inc., Andover, MA, USA) is a percutaneous intradiscal electrothermal annuloplasty procedure used to treat chronic low back pain related to degenerative disc disease. The procedure involves applying targeted thermal energy to the posterior disc annulus, which causes contraction of collagen fibers and destruction of afferent nociceptors. The intradiscal catheter system received U.S. Food and Drug Administration (FDA) 510(k) clearance in February 2008.

A randomized controlled trial (RCT) evaluating IDET published by Pauza and colleagues (2004) included 64 individuals with discogenic low back pain lasting more than 6 months. Of these, 37 participants were randomized to undergo the IDET procedure and 27 to a sham procedure. Principal outcome measures included pain and disability assessed using a visual analog scale (VAS), the 36-

Item Health Short Form Survey (SF-36), and the Oswestry Disability Index (ODI) scale. A total of 56 participants (88%) were included in the per protocol analysis. Mean change at 6 months in the VAS was significantly higher in the IDET group (2.4) than the sham group (1.1), p=0.045. However, mean change in the SF-36 bodily pain scale, the SF-36 physical functioning scale and the ODI did not differ significantly between groups.

Freeman and colleagues (2005) conducted a sham-controlled RCT study on individuals with discogenic back pain and annular tears who failed to improve despite conservative treatment. The study was carried out with 38 participants undergoing IDET and 19 receiving the sham procedure. Several subjective outcomes were measured utilizing the Low Back Outcome Score (LBOS), the ODI, and the SF-36. A successful outcome was defined as: 1) no neurological deficit; 2) improvement in the LBOS of greater than 7 points; and 3) improvement in the physical function and bodily pain section of the SF-36 form of at least greater than one standard deviation. No participant in either arm of the study met the criteria for a successful outcome. The findings of this study suggest that while IDET appears to be a safe procedure with no permanent complications, there is no significant benefit of IDET over sham treatment.

An industry funded meta-analysis by Appleby and colleagues (2006) analyzed the peer-reviewed published literature on IDET from 1998 to 2005, both controlled and uncontrolled studies. The authors identified 17 unique publications, only 1 of which was an RCT (the Pauza, 2004 study, discussed above). While the authors concluded that the pooled results of the literature provided evidence of the safety and efficacy of the IDET procedure, 16 of the 17 studies reviewed were case series and lacked control or comparison groups.

Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)

The PIRFT procedure is a minimally invasive surgical technique in which radiofrequency (RF) energy is directly applied to disc material. Similar to IDET, this procedure does not ablate the disc material, but alters the biomechanics of the disc or destroys the nociceptive pain fibers.

The Radionics® discTRODE™ (probe) system (Radionics, Inc., Burlington, MA) received 510(k) clearance from the FDA in October 2000 to reduce pain, physical impairment and functional disability due to annular disruption of contained herniated discs. Two published double-blind sham-controlled RCTs on the Radionics device were identified. In 2001, Barendse and colleagues published an RCT with 24 individuals who had chronic discogenic low back pain. Participants in the radiofrequency treatment group (n=13) received a 90-second 70°C treatment of the intervertebral disc. Individuals in the control group (n=15) underwent the same procedure, but without use of RF current. Both the treating physician and the participants were blinded to the group assignment. Physical impairment, rating of pain, the degree of disability, and quality of life were assessed by a blinded investigator prior to the beginning of treatment. At the end of 8 weeks, the VAS, global perceived effect, and ODI scores did not differ significantly between the 2 groups, suggesting that PIRFT is not effective in reducing chronic discogenic low back pain.

Kvarstein and colleagues (2009) reported on 20 individuals with chronic discogenic low back pain. Individuals were assigned to active treatment with the discTRODE probe or a sham control group. Both study groups underwent insertion of the RF probe by the treating physician while a separate operator controlled delivery of the RF therapy, thus blinding the participants as well as the treating physician to treatment or sham. The primary outcome measure was change in pain intensity. Secondary outcome measures were the individual's categorical impression of change in experienced pain, health-related quality of life, and functional ability. The primary outcome, change in pain intensity, was not statistically significant between groups and, with the exception of subject's impression of pain, other outcomes were similar between groups. The authors found that, at 12 months, mean change in pain intensity in the active treatment group was small and not clinically meaningful. Taking into consideration that 40% (4 of 10) of the treated individuals had increased pain 12 months after treatment, the authors concluded that the benefit of PIRFT was inconsistent and would not recommend intra-annular thermal therapy with the discTRODE probe as a treatment for chronic low back pain.

Intraosseous Basivertebral Nerve Ablation

The Intracept® Intraosseous Nerve Ablation System (Relievant Medsystems, Inc, Redwood City, CA) received 510(k) clearance in August 2017 as an RF ablation system for use in ablation of the basivertebral nerves (BVN) of the L3 through S1 vertebrae. Two RCTs have evaluated the Intracept system for treatment of chronic low back pain. Fischgrund (2018; 2019; 2020) compared Intracept treatment to sham treatment and Khalil (2019) compared it to usual care.

In 2018, Fischgrund and colleagues published a double-blind, sham-controlled RCT evaluating the Intracept system and RF ablation of the BVN for the treatment of chronic low back pain. A total of 225 skeletally mature participants with chronic (≥ 6 months) isolated lumbar pain who had not responded to at least 6 months of non-operative management were randomized to either a sham (n=78) or treatment (n=147) intervention. Skeletal maturity is determined by x-ray of the ends of long bones. In immature bones, growth plates appear as dark lines at the ends of the bones. At the end of growth, when the cartilage completely hardens into bone, the dark line is no longer visible and growth plates are considered closed. Type 1 or Type 2 Modic changes were required at each treatment level and treatment was limited to a minimum of two and a maximum of three consecutive vertebral body levels from L3–S1. Modic changes were determined on MRI images by identification of vertebral endplate hypointensity (Type 1) or hyperintensity (Type 2) on T1 images plus hyperintensity on T2 images (Type 1). Radiographic evaluations were performed by a blinded independent radiologist. In the active treatment group, the RF probe was activated and the temperature at the tip was maintained at 85°C for 15 minutes. The duration of the session in the sham group was the same but the RF treatment was only simulated. Study participants had a minimum ODI of 30 points (on 100 point scale) and a minimum VAS of 4 cm (10 cm scale). The primary efficacy endpoint was the comparative change in ODI from baseline to 3 months. Both intention-to-treat (ITT) and per protocol (PP) analysis were pre-planned. A total of 19 of 147 (13%) participants in the treatment group were excluded from the PP analysis; 16 for a targeting failure, 1 for procedural failure and 2 for protocol non-compliance. One participant in the sham group was excluded from the PP analysis and this was for protocol non-compliance.

At 3 months, in the ITT analysis, there was no statistically significant difference between groups in the primary outcome, mean ODI. ODI improved a mean of 19.0 points in the treatment group and 15.4 points in the sham group, p=0.107. However, there was a difference between groups in the 3-month PP analysis: the mean ODI in the treatment arm improved 20.5 points and 15.2 points in the sham arm, p=0.019. In the 12-month PP analysis, the difference between the treatment and sham groups in mean ODI was no longer statistically significant (22.6 points versus 25.3 points, p=0.153). PP analyses of pain severity (assessed by VAS) found no significant difference between groups in VAS improvement at 3 months (p=0.083) but significantly greater improvement in the treatment compared with the control group at 6 and 12 months. Eight procedure-related events (2.7%) were reported in 6 participants following the 225 procedures; 2 of these 6 participants were in the sham arm. The events included nerve root injury (n=1), lumbar radiculopathy (n=2), retroperitoneal hemorrhage (n=1), and transient motor or sensory deficits (n=4).

Additional data from the intervention group have been published; 24-month data in 2019 and 5-year data in 2020. Data beyond 12 months on pain and function outcomes in the sham-treated group were not available as unblinding occurred at that time and most individuals crossed over to treatment with the Intracept system. Thus, long-term comparative outcomes are not known.

At 24 months, 106 of 128 (83%) of individuals in the 3-month PP analysis of active treatment completed 24-month follow-up

(Fischgrund, 2019). Mean improvement in ODI, which was 20.8 points at 3 months, was 23.4 points at 24 months. A total of 100 individuals were available for analysis at the 5-year follow-up (Fischgrund, 2020). There was a significant mean reduction in ODI at 5 years compared with baseline (42.8 and 25.95, respectively, p<0.001). Mean VAS score was also significantly lower at 5 years (4.38) compared with baseline (6.74), p<0.001. In addition, 66% of individuals reported at least a 50% reduction in VAS at 5 years compared with baseline and 34% reported complete pain resolution. It is unclear whether the reduction in ODI is related to treatment, or other factors, given the absence of a comparison group.

A second RCT evaluating the Intracept system, known as the INTRACEPT trial, was published by Khalil and colleagues in 2019. The trial was open label and compared intraosseous RF treatment to standard care in skeletally mature individuals with at least 6 months of chronic low back pain who had not responded to at least 6 months of conservative care. Eligibility was determined by an independent medical monitor based on each individual's medical, clinical, and radiographic presentation. Intervention with the Intracept system consisted of treatment of up to four vertebrae in non-consecutive levels from L3 to S1. Individuals in the standard care continued treatment with conservative therapy. The primary study endpoint was difference in the ODI at 3 months. A pre-planned interim analysis was undertaken when 60% of participants reached the 3-month follow-up (n=51 in the Intracept group and n=53 in the standard care group). The interim analysis found statistically significant differences between groups on all patient-reported outcomes measures, favoring the Intracept group. For the primary outcome, the mean change in the ODI at 3 months in the interim analysis was -25.3 points in the Intracept group and -4.4 points in the standard care group, p<0.001. Mean change in VAS was -3.46 points in the Intracept group and -0.01 in the standard care group, p<0.001. As specified in the study protocol, the study was halted and individuals in the standard care group were allowed to cross over to treatment with the Intracept system. Limitations of this study include the lack of a sham control and limited duration of follow-up.

Between-arm comparisons of the full randomized INTRACEPT trial were conducted at 3 and 6 months by Smuck and colleagues (2021). A total of 140 participants were randomized to either BVN ablation (n=66) or standard of care (n=74). In the BVN ablation group, treatment was at each level from L3 to S1 that exhibited qualifying Modic Type 1 or Type 2 changes. Results from BVN ablation were superior to standard of care at 3 and 6 months for the primary endpoints (6-month results: mean ODI reduction, difference between arms of −24.5 (confidence interval [CI], −29.4 to −19.6 points; p<0.001), and VAS pain improvement, difference of −3.3 cm between arms (CI, −4.0 to −2.6, p<0.001). Despite the improvements in pain and disability index, no significant differences in opioid use were observed at 6-month follow-up (p=0.56). The results in the treatment arm at 12 months were also evaluated. BVN ablation showed a 25.7 ± 18.5 point reduction in mean ODI (p<0.001), and a 3.8 ± 2.7 cm VAS reduction (p<0.001) from baseline, with 64% demonstrating at least a 50% reduction and 29% pain free. Likewise, Koreckij and colleagues (2021) reported treatment arm follow-up data at 24 months. VAS and ODI improved 4.1 ± 2.7 cm (from baseline 6.6; p<0.001) and 28.5 ± 16.2 points (from baseline 44.5; p<0.001), respectively. These studies were limited by a short period of follow-up, especially for the direct comparison of treatment to standard of care through only 6 months, calling into question the durability of the results. Additional limitations include the open label design and industry funding which may be sources of bias.

No additional RCTs were identified. Macadaeg and colleagues (2020) published the 12-month results of a prospective cohort study, but it was limited by a lack of a comparison group.

In 2020, De Vivo and colleagues published the results of a prospective experimental uncontrolled trial in which BVN ablation was performed on 56 consecutive individuals with vertebrogenic chronic low back pain. An articulating bipolar radiofrequency electrode (STAR™ Tumor Ablation System, Merit Medical Systems) was used for BVN ablation. Pain and disability levels were measured pre-procedure and at 3- and 12-month follow-up using VAS and ODI. The authors reported that at follow-up, VAS and ODI scores decreased significantly compared to baseline, however no statistical analysis was provided. Predetermined improvement threshold VAS and ODI scores corresponding to the minimum clinically important differences were set to measure clinical success. According to these thresholds, clinical success for pain and disability was reached in 96.5% of individuals. There are several limitations to this study including lack of statistical analysis, short duration of follow-up and lack of a control group.

The studies described above are all in agreement that in individuals with suspected vertebrogenic low back pain, other potential causes of low back pain must be excluded before treatment with BVNA can be considered. There must be no radiographic evidence of other pain etiology such as disc extrusion or protrusion > 5 mm, spondylolisthesis > 2 mm at any level, spondylolysis at any level, segmental instability, degenerative scoliosis or facet arthrosis or effusion correlated with facet-mediated low back pain. Symptomatic spinal stenosis, metabolic bone disease, spine infection, spinal fracture or cancer must also be ruled out.

In 2021, Conger and colleagues published a systematic review of the effectiveness of BVN neurotomy for the treatment of chronic low back pain. A total of seven publications with 321 participants were included. The success rate for at least 50% pain reduction ranged from 45% to 63% at 3 months. Functional improvement (determined by an increase of at least 10 points on the ODI) ranged from 75% to 93%. Compared to sham controls, the relative risk of treatment success was 1.25 (95% CI: 0.88-1.77) and 1.38 (95% CI: 1.10-1.73) for pain reduction and ODI improvement, respectively. The authors concluded that there is moderate-quality evidence suggesting that BVN ablation is effective in reducing pain and disability. However, it is problematic that all existing RCTs of BVN ablation have been directly supported by industry funding, increasing the risk of publication bias. Non-industry funded, high-quality, large prospective studies with long term follow-up are needed to confirm the findings of this analysis.

In 2022, Conger and colleagues reported results of an updated systematic review with single-arm meta-analysis of the effectiveness of intraosseous BVN radiofrequency ablation for the treatment of vertebrogenic low back pain. A total of 12 publications representing 6 unique study populations with 414 participants receiving BVN ablation were included. The primary outcome was the proportion of participants treated with BVN ablation who reported at least 50% pain score improvement on a VAS or numeric rating scale. Results showed a success rate of 65% and 64% for pain relief at 6 and 12 months, respectively. An increase of at least 15 points on the ODI indicating functional improvement was 75% at both 6 and 12 months. The overall quality of evidence was evaluated with the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) system. The authors concluded that, according to GRADE, there is moderate-quality evidence that BVN ablation effectively reduces pain and disability. It is important to note that the authors found no new RCTs comparing BVN ablation with sham and the majority of studies included in the analysis were supported by industry funding.

Smuck and colleagues (2023) performed an analysis of pooled 3-year outcomes from two prospective clinical trials described above (Macadaeg, 2020; Smuck, 2021). Primary outcomes were the mean changes in numeric pain scores and ODI between baseline and 3 years. There were 95 individuals who completed a 3-year evaluation. There were significant improvements in pain and function at 3 years with a mean reduction in numeric pain score of 4.3 points from 6.7 at baseline (95% CI, 3.8, 4.8; p<0.0001) and a mean reduction in ODI of 31.2 points from 46.1 at baseline (95% CI, 28.4, 34.0; p<0.0001). Opioid use was reduced by 74% at 3 years. It was concluded that intraosseous BVN ablation produces statistically significant, clinically meaningful and durable improvements in pain and function through 3 years post-procedure. However, as the authors noted, "limitations of this study are the open-label design, industry sponsorship, and the lack of a long-term comparator group within the two studies."

In all published BVNA studies, data are from individuals treated once at each planned vertebral level of treatment. No data on repeat interventions have been published.

Intradiscal Biacuplasty (IDB)

In December 2006, the TransDiscal™ System (Baylis Medical Company Inc., Montreal, QC Canada) received FDA 510(k) clearance as an IDB device proposed to reduce chronic intervertebral disc-related back pain by using cooled radiofrequency probes to ablate the neurons that generate pain sensations.

A sham-controlled RCT evaluating IDB was published by Kapural and colleagues in 2013. The study included 64 individuals with chronic discogenic low back pain (6 months duration or longer) and evaluated outcome measures of SF-36 physical functioning subscore (0-100), the numerical rating scale (NRS) for pain (0-10), and the ODI (0-100) at 1, 3, and 6 months. The investigators reported that there were no significant differences between the groups at 1 or 3 months. At 6 months, the IDB group showed a significantly greater change from baseline for the SF-36 (15.0 vs. 2.63), NRS (-2.19 vs. -0.64) and ODI (-7.43 vs. 0.53). Mean SF-36 and NRS scores were considered to be clinically significant, but mean ODI scores did not achieve the minimally important difference of 10 points. With clinical success defined post-hoc as a 15-point increase in physical function together with a greater than 2-point decrease in pain, 30% of IDB participants and 3% of sham-treated participants were considered successful. There was no significant difference in opioid use between the 2 groups. Limitations of this study include the lack of a formal assessment of blinding effectiveness among participants, the relatively short follow-up time of 6 months, and the limited number of participants evaluated in the sample and subgroup analysis.

A total of 22 of 27 participants in the original active treatment group were followed for 12 months and reported clinically significant improvements in physical function and NRS scores; although, the magnitude of the decrease was modest and the final NRS score of 4.4 remained high (Kapural, 2015). Participants were unblinded at 6 months, and those initially randomized to sham procedure were given the option to cross over to IDB. Out of 30 participants in the sham group, 24 chose to cross over with only 20 of 24 participants followed to 6 months. In this group, improvements in physical function and pain did not differ statistically from those participants originally randomized to IDB treatment. No complications or adverse events were reported that related to the procedure.

Desai and colleagues (2016) published an open-label RCT of 63 individuals with lumbar discogenic pain diagnosed by provocation discography. Participants were randomized to IDB plus conservative medical management (IDB plus CMM; n=29) or CMM alone (n=34). At 6 months, participants in the CMM group were eligible for crossover if desired. The primary outcome measure was defined as the change in VAS from baseline to 6 months. Secondary outcome measures included treatment “responders,” defined as the proportion of participants with a 2-point or 30% decrease in VAS scores. For the primary outcome measure, the mean VAS score reduction was significantly greater in the IDB plus CMM group compared to the CMM group alone (-2.4 vs. -0.56; p=0.02). For the secondary outcome measure, the proportion of responders was greater in the IDB plus CMM group compared to the CMM (50% vs. 18%); however, the rate was not statistically significant. Limitations of this industry-sponsored study include all enrolled individuals were required to fail an initial 6 months of CMM, and the lack of a sham control group and participant blinding.

Of the 29 participants originally randomized to IDB, 22 (76%) were available for 12-month follow-up (Desai, 2017). The mean 12-month change in VAS score was -2.2 (from 6.7 at baseline to 4.4 at 12 months, p=0.001). After 6 months, participants randomized to CMM alone were allowed to choose to receive IDB and were followed for another 6 months; 25 of 34 participants crossed over to IDB plus CMM. VAS score improved from 7.0 to 4.7 (p<0.001) in the crossover group, and 55% were considered to be responders. However, only 27% of crossover participants achieved at least 50% improvement in pain, compared with 41% of participants in the original IDB plus CMM group. An important limitation of this study was that it was not statistically powered to evaluate reduction in opioid use, as the sample size was not adequate to detect statistically different changes between the study groups. It was reported that not every eligible participant in the IDB plus CMM and crossover study groups provided data at each respective follow-up time-point. Finally, CMM protocols were not standardized from clinic to clinic and participant to participant, and the physicians were permitted to treat study participants based on personal clinical preferences.

Other Considerations

The Centers for Medicare and Medicaid Services (CMS) determined for services on or after September 29, 2008, that thermal intradiscal procedures (TIPs) are not reasonable and necessary for the treatment of low back pain.

Chou and colleagues (2009) published an evidence-based guideline for the American Pain Society (APS). Their recommendations on IDET and PIRFT were:

- There is good or fair evidence from randomized trials that PIRFT thermocoagulation is not effective.
- There is insufficient (poor) evidence from randomized trials (conflicting trials, sparse and lower quality data, or no randomized trials) to reliably evaluate other interventional therapies, which include IDET.

An American Society of Interventional Pain Physicians (ASIPP) (Manchikanti, 2013) evidence-based practice guideline in the management of chronic spinal pain for thermal annular procedures states:

- The evidence for intradiscal electrothermal therapy (IDET) and biacuplasty is limited to fair and is limited for discTRODE.
- IDET and biacuplasty may be performed in a select group of patients with discogenic pain nonresponsive to conservative modalities including epidural injections.

A 2020 guideline from the International Society for the Advancement of Spine Surgery (ISASS) (Lorio, 2020) recommended the use of intraosseous ablation of the BVN from L3 through S1 vertebrae for individuals with chronic low back pain who meet the following criteria:

- Chronic low back pain of at least 6 months duration;
- Failed to respond to at least 6 months of nonsurgical management; and
- MRI-demonstrated Modic Type 1 or 2 changes in at least 1 vertebral endplate at 1 or more levels from L3 to S1.

The quality of the ISASS guideline is unclear. Two of the four authors had potential conflicts of interest. The authors did not describe the methodology used in guideline creation such as literature search methods, methods for evaluating the validity of studies, and the methods for formulating recommendations.

In a follow up to the 2020 guideline, the ISASS published a policy statement and literature review concerning intraosseous BVN ablation (Lorio, 2022). The guideline states that intraosseous BVN ablation from the L3 through S1 vertebrae may be considered medically indicated for individuals when all the following criteria are met:

- Chronic low back pain of at least 6 months duration; and
- Failure to respond to at least 6 months of nonsurgical management; and
- MRI-demonstrated Modic Type 1 or 2 changes in at least 1 vertebral endplate at 1 or more levels from L3 to S1; and
- Fibrovascular bone marrow changes (hypointense signal for Modic type 1); and
- Fatty bone marrow changes (hyperintense signal for Modic type 2).

As in the 2020 ISASS guideline, the authors did not describe the methodology used in the 2022 guideline creation such as literature search methods, methods for evaluating the validity of studies, and the methods for formulating recommendations.

In 2022, the American Society of Pain and Neuroscience (ASPN) published guidelines on the treatment of vertebrogenic pain with BVN ablation (Sayed, 2022b). The guidelines state that BVN ablation is an effective tool to treat vertebrogenic pain with strong evidence to support long-term improvement in pain and function. Based on the United States Preventive Services Task Force (USPSTF) criteria for grading evidence, ASPN gives BVN ablation Level A grade evidence with high certainty that the net benefit is substantial in appropriately selected individuals. Those who would be candidates for BVN ablation have had at least 6 months of chronic low back pain with the anterior column primarily contributing, failed conservative measures, and have Modic 1 or 2 changes on MRI at L3-S1.

ASPN published an additional guideline in 2022 on interventional treatments for low back pain (Sayed, 2022a). Based on the USPSTF criteria for quality of evidence, BVN ablation is recommended with a Grade A and Level of Certainty 1a. BVN ablation at the L3 through S1 vertebrae is indicated when individuals meet the following criteria:

- Chronic axial low back pain (greater than 6 months of duration).
- Pain refractory to conservative nonsurgical treatment for at least 6 months of duration.
- Evidence of vertebral endplate changes on MRI as below:
    - Modic Type I and/or Modic type II changes.
    - Vertebral endplate changes with inflammation, edema, disruption and/or fissuring.
    - Fibrovascular bone marrow changes (hypointensive signal for Modic type I changes).
    - Fatty bone marrow replacement (hyperintensive signal for Modic type II changes).

In 2023 the North American Spine Society (NASS) published coverage recommendations for BVN ablation (NASS, 2023). NASS asserts that two level 1 RCTs have demonstrated superiority of BVN ablation over standard care at 3 months and 12 months, and over sham control at 12 months (Fischgrund, 2018; Khalil, 2019). NASS recommends coverage of BVN ablation when:

- Individuals are skeletally mature and have chronic low back pain for at least 6 months, and lower back pain is their main symptom.
- Individuals have failed to adequately improve despite attempts at nonsurgical management.
- Individuals 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.

The Spine Intervention Society has endorsed these coverage recommendations for BVN ablation developed by NASS.

A 2020 guideline from NASS on the diagnosis and treatment of low back pain made the following recommendations:

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

While the NASS guideline states that biacuplasty produces clinically and statistically significant improvements in pain, three of the four studies reviewed for the recommendation were rated as poor quality (Level IV).

Summary
There is insufficient evidence in the published medical literature to support the use of percutaneous vertebral disc and vertebral endplate procedures, other than BVNA, in the treatment of individuals with chronic discogenic or vertebrogenic low back pain. In sham-controlled RCTs, the procedures were either not found to result in better short-term outcomes or outcomes were mixed and did not clearly support the efficacy of active treatment. There is a lack of long-term comparative data on the efficacy and safety of percutaneous vertebral disc and vertebral endplate procedures.

Background/Overview

The intervertebral disc is a combination of strong connective tissues which hold one vertebra to the next and acts as a cushion between the vertebrae. It is made of a tough outer layer called the annulus fibrosus and a gel-like center called the nucleus pulposus. Discs are basically shock absorbers, whose content is 70%-90% water. The center of the disc may start to lose water content, making the disc less effective as a cushion, causing displacement of the disc's center (herniation or rupture) through a crack in the outer layer. Pain may be from the disc itself (discogenic pain) or from disc herniation or prolapse resulting in pressure on nearby nerve roots. Most disc herniations occur in the bottom two discs of the lumbar spine, at and just below the waist. A herniated disc can press on a nerve root in the spine and may cause back pain or pain, numbness, tingling or weakness of the leg called sciatica (pain radiating down the leg). Disc problems may occur as a result of injury, wear and tear, or with aging.

The IDET procedure using the Smith & Nephew SpineCath System describes a minimally invasive procedure that has been proposed as an alternative to spinal fusion for the treatment of chronic low back pain related to disc disease. In an initial step, the pathogenic disc is identified using pressure-based discography. A navigable catheter with an embedded thermal resistive coil is inserted posterolaterally into the disc annulus or nucleus. The catheter is advanced through the disc circuitously to return posteriorly. Electrothermal heat is then generated with the thermal resistive coil; the disc material is heated for up to 20 minutes. This outpatient procedure typically requires less than 30 to 40 minutes of recovery time. The mechanism of action of pain relief is unknown, but it is thought to be related to shrinkage of the collagen fibers within the annulus, or destruction of the adjacent nociceptive pain fibers.

The PIRFT procedure differs from the IDET procedure in that radiofrequency energy is applied directly to the involved disc. The radiofrequency probe is placed into the center of the disc instead of around the annulus. The practitioner activates the probe and delivers radiofrequency energy into the center of the disc for 90 seconds at a temperature of 70°C. As in IDET, the mechanism of action of pain relief is not precisely understood, but is thought to be related to a reduction of the pain receptor input by destroying the pain receptor fibers.

The Intracept intraosseous nerve ablation procedure targets the BVN with radiofrequency energy. Treatment occurs with the individual in a prone position; either general anesthesia or conscious sedation is used. For the procedure, the radiofrequency probe is inserted into a channel leading to the trunk of the BVN. A radiofrequency generator is used to ablate the BVN, with the temperature at the tip of the probe maintained at 85°C for 15 minutes.

The IDB procedure uses two internally cooled radiofrequency probes placed on the posterolateral sides of the intervertebral annulus fibrosus to heat nerve tissue while circulating water to cool the tissue that is adjacent to the disc. During the procedure, the individual is mildly sedated and the area to be treated anesthetized. After approximately 15 minutes, the probes and needles are removed and a bandage is placed over the treatment site. IDB is similar to PIRFT in that it uses radiofrequency energy and similar to IDET and PIRFT in that it is not designed to coagulate, burn or destroy the disc material.

Definitions

Annulus: The hard, tough outer layer of the vertebral disc surrounding the center portion called the*nucleus,* which is a softer gel-like substance.

Basivertebral nerve: an intraosseous nerve that weaves through the vertebral bodies entering posteriorly at the basivertebral foramen and branches out to innervate the superior and inferior endplates.

Biomechanics: The study of the effects of internal and external forces on the human body in movement and rest.

Discogenic pain: Pain generated by the disc itself which is externally intact, as opposed to disc prolapse or herniation which put pressure on nearby nerve roots.

Epiphyseal plate: A thin layer of cartilage at the end of a long bone where new bone growth takes place, also known as the growth plate.

Intraosseous: Occurring within a bone or administered by entering a bone.

Modic changes: Bone marrow lesions seen within a vertebral body on MRI. Changes appear as vertebral endplate hypointensity (Type 1) or hyperintensity (Type 2) on T1 images plus hyperintensity on T2 images (Type 1).

Percutaneous: Through the skin (puncture as opposed to "open" surgical incision).

Percutaneous thermal intradiscal procedures (TIPS): Procedures that involve the insertion of a catheter or probe in the spinal disc under fluoroscopic guidance for the purpose of producing or applying heat or disruption within the disc to relieve low back pain.

Radiofrequency: The use of electrodes to generate heat to alter tissue structure.

Skeletal maturity: The state of full development of the skeleton when the epiphyseal plates close, a process beginning in childhood and usually complete by 25 years of age.

Spine anatomy: The spine is divided into three major sections: the cervical (neck), the thoracic (mid-back) and lumbar spine (lower back). These sections are made up of individual bones called *vertebrae,* which are the primary area of weight bearing and provide a resting-place for the *discs,* which act as shock absorbers between the vertebrae.

Vertebral endplate: The transition region where a vertebral body and intervertebral disc interface with each other.

Vertebrogenic pain: Back pain caused by damage to vertebral endplates.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

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

ICD-10 Procedure

	For the following codes **when specified as intraosseous basivertebral nerve ablation**:
015B3ZZ	Destruction of lumbar nerve, percutaneous approach
015B4ZZ	Destruction of lumbar nerve, percutaneous endoscopic approach

ICD-10 Diagnosis

	All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

22526	Percutaneous intradiscal electrothermal annuloplasty [IDET], unilateral or bilateral including fluoroscopic guidance; single level
22527	Percutaneous intradiscal electrothermal annuloplasty [IDET], unilateral or bilateral including fluoroscopic guidance; 1 or more additional levels
22899	Unlisted procedure, spine [when specified as percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) or intradiscal biacuplasty (IDB)] [CPT coding instructions specify use of 22899 Unlisted procedure, spine for percutaneous intradiscal annuloplasty, any method other than electrothermal]

ICD-10 Procedure

	For the following codes **when specified as percutaneous intradiscal electrothermal annuloplasty (IDET), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) or intradiscal biacuplasty (IDB)**:
0RQ33ZZ	Repair cervical vertebral disc, percutaneous approach
0RQ34ZZ	Repair cervical vertebral disc, percutaneous endoscopic approach
0RQ53ZZ	Repair cervicothoracic vertebral disc, percutaneous approach
0RQ54ZZ	Repair cervicothoracic vertebral disc, percutaneous endoscopic approach
0RQ93ZZ	Repair thoracic vertebral disc, percutaneous approach
0RQ94ZZ	Repair thoracic vertebral disc, percutaneous endoscopic approach
0RQB3ZZ	Repair thoracolumbar vertebral disc, percutaneous approach
0RQB4ZZ	Repair thoracolumbar vertebral disc, percutaneous endoscopic approach
0SQ23ZZ	Repair lumbar vertebral disc, percutaneous approach
0SQ24ZZ	Repair lumbar vertebral disc, percutaneous endoscopic approach
0SQ43ZZ	Repair lumbosacral disc, percutaneous approach
0SQ44ZZ	Repair lumbosacral disc, percutaneous endoscopic approach

ICD-10 Diagnosis

All diagnoses

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Revised	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised MN criteria for basivertebral nerve ablation (BVNA). Revised Rationale and References sections.
	10/25/2023	Revised MN statement to correct spelling of arthropathy. Updated references.
Revised	08/10/2023	MPTAC review. Added MN and NMN criteria for BVNA. Updated Rationale, Definitions, Coding and References sections.
Reviewed	08/11/2022	MPTAC review. Rationale and References sections updated.
	12/29/2021	Updated Coding section with 01/01/2022 CPT and HCPCS changes; added 64628, 64629 effective 01/01/2022, replacing C9752, C9753 deleted 12/31/2021 and NOC code.
Reviewed	08/12/2021	MPTAC review. Rationale, Definitions, and References sections updated.
Reviewed	08/13/2020	MPTAC review. Rationale and References sections updated.
Revised	08/22/2019	MPTAC review. Title changed to Percutaneous Vertebral Disc and Vertebral Endplate Procedures. The three investigational and not medically necessary statements combined into single statement with bullet points. Intraosseous basivertebral nerve ablation added to the investigational and not medically necessary statement. Updated Description, Rationale, Background, Definitions and References sections. Updated Coding section; added 64999, C9752, C9753, 015B3ZZ, 015B4ZZ.
Reviewed	11/08/2018	MPTAC review. Updated Rationale and References sections.
Reviewed	02/27/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale, References, and Index sections.
Reviewed	02/02/2017	MPTAC review. Updated formatting in Position Statement section. Updated Rationale and References sections.
Reviewed	02/04/2016	MPTAC review. Updated Rationale and References sections. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review. Format changes throughout document. Updated Rationale, Background, and Reference sections.
Reviewed	02/13/2014	MPTAC review. Updated Rationale, Background, and References sections.
Revised	02/14/2013	MPTAC review. Added IDB acronym to the Subject. Clarified Position Statements. Clarified and updated the Description, Rationale, Background, Definitions, References, and Index sections.
Reviewed	02/16/2012	MPTAC review. References updated.
Reviewed	02/17/2011	MPTAC review. References updated.
Reviewed	02/25/2010	MPTAC review. References updated.
	01/01/2010	Updated Coding section with 01/01/2010 CPT changes; removed CPT 0062T, 0063T deleted 12/31/2009.
Revised	02/26/2009	MPTAC review. Scope of document expanded to address intradiscal biacuplasty. Title, position statement, rationale and background/overview section revised to address intradiscal biacuplasty. Updated review date, coding, index, history sections and references.
Reviewed	02/21/2008	MPTAC review. Updated review date, rationale, references and history sections. No change to position statement. The phrase “investigational/not medically necessary” was clarified to read “investigational and not medically necessary.” This change was approved at the November 29, 2007 MPTAC meeting.
Revised	03/08/2007	MPTAC review. Updated the Description, Position Statement, Rationale, Coding and Reference sections of the document to address percutaneous intradiscal radiofrequency thermocoagulation. Document formerly titled Percutaneous Intradiscal Electrothermal Coagulation (IDET Procedure).
	01/01/2007	Updated Coding section with 01/01/2007 CPT/HCPCS changes; removed HCPCS codes S2370, S2371 deleted 09/30/2004.

Reviewed	03/23/2006	MPTAC review. Updated the Rationale, Coding and Reference sections of the document.
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	07/27/2004	SURG.00052	Chronic Spine Pain Treatments/Procedures (Minimally Invasive)
WellPoint Health Networks, Inc.	09/23/2004	3.07.06	Percutaneous Intradiscal Electrothermal Coagulation (IDET Procedure)

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.