April 3, 2025

Via email: NGSnewlcdrequest@anthem.com
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National Government Services, Inc.
Medical Policy Unit
Attention: New LCD Request
P.O. Box 7108
Indianapolis, IN 46207-7108

Re: NEW LCD REQUEST- Thermal Destruction of Intraosseous Basivertebral Nerve (BVN)

Dear Dr. Medical Directors and Medical Policy Team,

In October 2023 I was involved in a pre-LCD meeting to discuss the Intracept procedure with NGS Medical Directors in the JK jursidication. Since that time there has been significant newly published evidence which further supports the effectiveness of the Intracept procedure, and therefore, I am submitting a formal request for LCD development.

As specified in the Medicare Program Integrity Manual, Chapter 13, Local Coverage Determinations, attached is a complete and formal request that meets all the requirements to be considered for a new Local Coverage Determination (LCD) for thermal destruction of intraosseous basivertebral nerve (BVN).

1. This request is complete and is being sent via email.
2. This request clearly identifies the statutorily defined Medicare benefit category and a rationale justifying the category assignment (see page 2-3).
3. This request includes information that addresses the relevance, usefulness, clinical health outcomes, and medical benefits of the procedure/service (see pages 3-9).
4. This request includes information that fully explains the design, purpose, and/or method, as appropriate, of performing the procedure/service (see pages 9-11).
5. The proposed language for the LCD is included (see pages 12-24).
6. This request is supported by Level I peer-reviewed evidence. Full copies of the published evidence are included (please see attached).

Thank you for your consideration of this request for a new LCD, and please contact me if you have any questions.

REQUEST FOR NEW LOCAL COVERAGE DETERMINATION (LCD)

Thermal Destruction of the Intraosseous Basivertebral Nerve (the Intracept™ Procedure)

Thermal destruction (i.e., radiofrequency ablation) of the intraosseous basivertebral nerve (BVN) (the Intracept™ Procedure) is a medically necessary therapeutic minimally invasive procedure that is used to treat a specific subtype of chronic low back pain, known as vertebrogenic pain or vertebral endplate pain. The procedure may be performed in an inpatient, outpatient, or ambulatory surgery center setting. The procedure falls under the following statutorily defined Medicare benefit categories found in the Social Security Act:

Part A – Hospital Insurance Benefits for the Aged and Disabled

Section 1812 – Inpatient hospital services

Rationale justifying assignment: Thermal destruction (i.e., radiofrequency ablation) of the intraosseous BVN is a medically necessary surgical procedure to treat a specific subtype of chronic low back pain, known as vertebrogenic pain or vertebral endplate pain. The procedure may be performed in an inpatient setting.

Part B – Supplementary Medical Insurance Benefits for the Aged and Disabled.

Section 1832 – Physician services

Rationale justifying assignment: Thermal destruction (i.e., radiofrequency ablation) of the intraosseous BVN is a medically necessary surgical procedure to treat a specific subtype of chronic low back pain, known as vertebrogenic pain or vertebral endplate pain, that is performed by a physician.

Section 1833 – Outpatient hospital facility services furnished in connection with surgical procedures

Rationale justifying assignment: Thermal destruction (i.e., radiofrequency ablation) of the intraosseous BVN is a medically necessary surgical procedure to treat a specific subtype of chronic low back pain known as vertebrogenic pain, or vertebral endplate pain that may be performed in the hospital outpatient setting or ambulatory surgery center.

Information that addresses the relevance, usefulness, clinical health outcomes, and the medical benefits of the item or service:

Approved for commercial use in 2018, intraosseous basivertebral nerve ablation (BVNA) fills a critical need for patients who previously had no effective treatment option to improve their low back pain (LBP) and related disability. The Intracept™ Procedure is the first targeted treatment option for patients with vertebrogenic pain, which affects an estimated 1 in 6

patients with chronic low back pain (CLBP).[1] Intraosseous BVNA differentiates itself from other CLBP therapies in several ways – it specifically targets the transmission of a proven source of LBP – the basivertebral nerve; a single effective treatment can result in 5+ years of durable improvement in pain and function, and it is supported by a notable depth and breadth of scientific evidence.

Before the discovery of the BVN and the advent of intraosseous BVNA, patients with vertebrogenic pain fell into a longstanding chasm of non-specific LBP, with early studies reporting the vast majority of LBP cases to have an unclear source.[2] The lack of differentiation in pain sources led to large variations in treatment and outcomes. It is now recognized that CLBP is a common symptom for a heterogenous group of causative conditions. Subgrouping individuals with CLBP, based on anatomy of pain generation, is critical for the application of more targeted and effective treatments.[3]

Decades of advances in scientific understanding of spine biochemistry and the pathophysiology of LBP fostered identification of vertebral endplate damage as an important source of CLBP that is visible with MRI. A substantial body of evidence dating back to the 1990s demonstrate vertebral endplates are richly innervated.[4-6] In fact, vertebral endplates have a much higher incidence and density of pain receptors than the adjacent intervertebral disc.[7] When vertebral endplates are damaged, an inflammatory cascade ensues leading to nerve sensitization and pain.[8-10] Pain from the endplates is transmitted via the basivertebral nerve (BVN) located within the vertebral body to the sinuvertebral nerve and ultimately to the brain.[11] Damaged endplates with resulting chronic inflammation are readily visible as Type 1 and/or Type 2 Modic changes (MC) on routine MRI and are a highly specific biomarker for CLBP.[12-22]

The location of the BVN within the vertebral body presented an opportunity to eliminate or reduce vertebrogenic pain by ablating the nerve close to its origin. Additionally, histological studies and long-term outcomes data support that the unmyelinated BVN does not regenerate, unlike facet medial branch nerves or other peripheral nerves treated with ablation. A minimally invasive, outpatient procedure, the Intracept™ Procedure, was developed using a transpedicular approach to access the vertebral body and radiofrequency energy to ablate the BVN. Unlike other radiofrequency ablation procedures for low back pain that select patients using subjective responses to various therapies and often require additional treatments, BVN ablation patients are selected using an objective MRI biomarker, Modic changes, that correlates with long-term pain relief after a single treatment. Recognizing this body of evidence and the need for greater granularity in differentiating various types of LBP, the CDC approved a specific diagnosis code, effective October 1, 2021, for patients with vertebrogenic low back pain (M54.51). There are currently no other FDA cleared or approved treatments for vertebrogenic pain. Disc-based therapies target a different etiology and vary in strength of supporting evidence and efficacy outcomes.

Treatment of vertebrogenic low back pain with intraosseous BVN is a safe, effective, durable and minimally invasive procedure that has been shown in clinical trials to meaningfully reduce

pain and function for out to five years post-procedure, improving quality of life and leading to patient satisfaction, improved activity levels, and reduced utilization of treatments for low back pain, benefitting patients, physician and healthcare systems alike. Furthermore, identification of patients is scientific, based on objective MRI characteristics, patient presentation and their clinical workup, allowing for studious application of this novel and unique therapy for patients.

Clinical health outcomes and medical benefits demonstrate effectiveness, and a new LCD is justified and supported by peer-reviewed evidence. Full copies of published evidence are included.

The safety, efficacy, durability, reproducibility of thermal destruction (i.e., ablation) of the intraosseous BVN is supported by a notable foundation of clinical evidence, including two level 1 randomized controlled clinical trials (RCTs), meta-analyses, single-arm studies, systematic reviews, book chapters, societal guidelines and independent studies. Please see BVNA bibliography for reference.

- **Safety:**
  - Across sponsored clinical trials, the serious adverse event (SAE) rate for intraosseous BVNA was less than 0.3%, representing only 1 SAE (a vertebral compression fracture) in a patient receiving hormone therapy.
- **Efficacy:**
  - More than 40 publications support the positive impact on clinical health outcomes and medical benefits of intraosseous BVNA.
  - Two well-designed RCTs (SMART and INTRACEPT) establish BVNA as superior compared to a sham control and standard care, respectively.
- **Durability:**
  - The results of intraosseous BVNA have been durable out to 5 years post-procedure in three separate clinical trials:
    - SMART FDA randomized controlled trial[23-25, 30]
    - INTRACEPT trial[26-30]
    - CLBP single-arm study[30-32]
- **Reproducibility:**
  - Early sponsored clinical trial results have been replicated in several independent studies in the United States and internationally.[33-37] Even with variation in study design, investigators, practice cites and evolution of the therapy, similar results are observed post-BVNA.
- **Impact on Healthcare Utilization and Cost-Effectiveness:**
  - Intraosseous BVNA decreases utilization of healthcare resources for low back pain – specifically therapeutic injections, pain interventions and surgeries, as well as opioid consumption[38-39]
  - The cost-effectiveness analysis published earlier this year by leading researchers in health economics demonstrated a >99% probability that BVNA was cost-effective in the US, based on the willingness-to-pay threshold.[39]

Summary of Clinical Evidence:

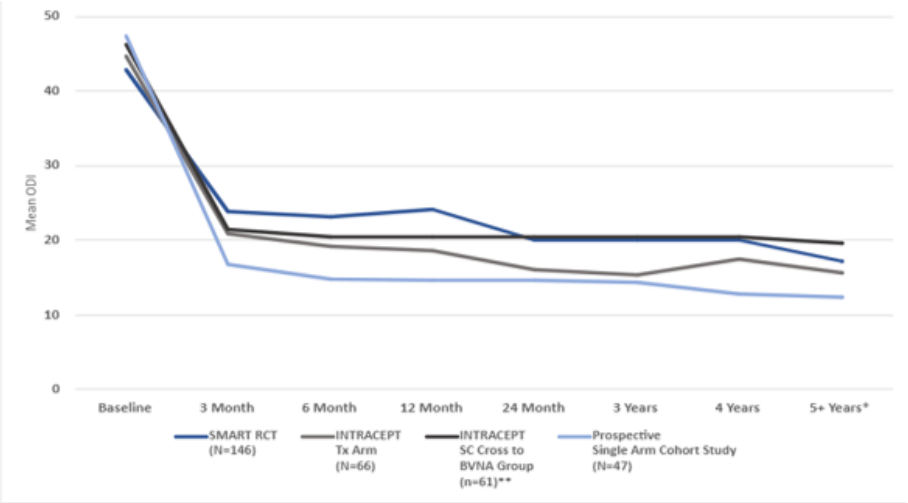
Clinical Studies

After a successful Pilot Study of 16 patients in 2007,[40] an international randomized double-blind sham-controlled trial of 225 patients was developed in collaboration with the FDA (SMART RCT) and demonstrated statistically and clinically significant differences, leading to FDA clearance for intraosseous BVNA.[23] After 12 months, patients randomized to the sham control arm were given the option to cross to the treatment arm, and 73% elected to receive BVNA.[24] The original treatment arm was followed out to more than 5 years for clinical and safety outcomes. Pain and functional improvements demonstrated in the BVNA arm of this RCT were sustained at 24 months and a mean of 6.4 years demonstrating the durability of results.[25,30]

A second randomized controlled trial (INTRACEPT RCT) was conducted to compare BVNA to nonsurgical standard care in 140 patients.[26-30] Enrollment was stopped early for clear statistical superiority of BVNA for the primary endpoint and all secondary endpoints by an independent data management committee who conducted a prespecified interim analysis.[26-27] As all endpoints showed significant benefits over standard care, and per informed consent regulatory requirements requiring patients to be notified when new data becomes available in a clinical trial that may impact their consent to participate, the data management committee recommended the control arm be re-baselined and then offered early cross to active treatment. Ninety-two percent (92%) of control patients opted to receive BVNA. Significant differences between the study arms in pain, function, and quality of life were demonstrated through 6 months (the point of stopping enrollment and offering control arm crossover).[27] Control patients that had not shown improvement prior to cross to active treatment, reported the same significant improvements from re-baseline to 6-months post ablation as the original BVNA arm. Treatment effects were durable for the BVNA arm and cross-over arm through 5 years.[26-30]

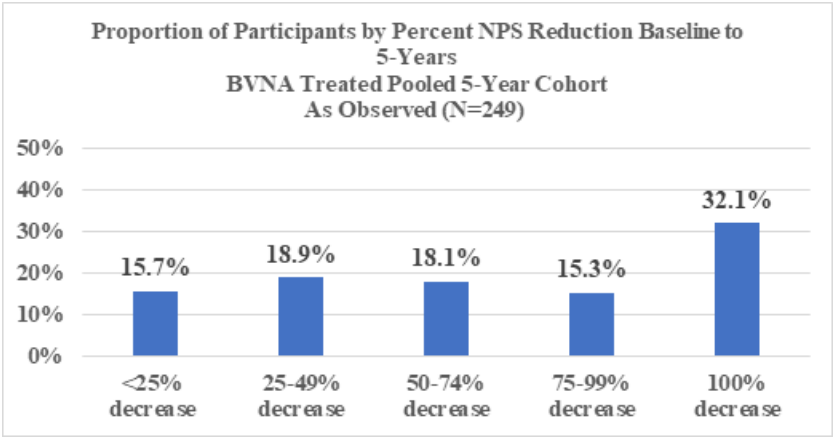
Pain and functional improvements reported in the randomized controlled trials (RCTs) have been reproduced in a prospective single arm cohort study of 47 patients from two typical community spine practices with durability of treatment effect at five years.[31-32] Pooled results for SMART, INTRACEPT and CLBP-Single Arm long-term follow-up studies show significant improvements in pain (pain score) and function (ODI) out beyond 5-years.[30] See Figures 3 and 4.

Figure 3 - Multi-Study Comparison of Functional Improvement – Comparison of mean ODI over time for the two Level I RCTs and the CLBP single arm study.



**Standard arm re-baselined and offered active treatment at a median of 5.8 months

Figure 4 – Pain Response by Quadrant – Pooled 5-Year Results (SMART, INTRACEPT, Single-Arm)



BVNA has an excellent safety profile with no serious device-related events and only one serious device procedure-related event (vertebral compression fracture in one patient on hormonal replacement therapy) in more than 473 clinical study procedures performed (<0.3% serious event rate). No adverse events were reported in the 5-year post-BVNA long-term follow-up period of the recent aggregate analysis.[30] Since commercialization in 2018, the device or device-procedure-related serious adverse events remain low overall.

Independent Data

Independent literature reviews,[41-49] independent studies (globally),[33-37] and three independent meta-analysis support the effectiveness and safety of BVNA for the treatment of vertebrogenic pain.[56-58] Independent reviews concluded that anatomic, histologic, and

clinical evidence supports the concept of vertebral pain and the nociceptive role of the BVN in the pathogenesis of CLBP and that BVNA appears to be an effective and durable treatment option when applied to a select patient population based on defined clinical and radiographic criteria.

The single-arm study by Schnapp et al is the first U.S. study to be independently funded.[35-36] Thirty-five patients were treated with BVNA and 31 completed 12 month visits post-procedure (89% retention rate). The real-world study cohort patients were older, and the inclusion/exclusion criteria less stringent, than prior clinical trials. The mean age of patients was 73.0 ± 6.34 years, 64.5% had LBP > 5 years, and patients were not excluded for radicular pain or screened for osteoporosis. Five patients had prior spinal fusion surgeries and 15 had prior lumbar medial branch radiofrequency ablation procedures. Study results showed statistically and clinically meaningful improvements in ODI and VAS at 1-, 3-, 6- and 12-months post-BVNA compared to baseline. A reduction of 25.2 points (95% CI 16.3, 34.0) in ODI was reported at 12-months post-BVNA ($p<0.001$). Additionally at 12-months, 67.7 % of patients demonstrated ODI improvements above the MCID (decrease of 15 points) and 77.4 % of patients demonstrated a decrease on VAS above the MCID (at least 2 cm reduction). No adverse events or symptoms of compression fracture were reported in the study.[35-36]A single arm meta-analysis of both sponsored and independent literature demonstrated that at 6 and 12 months after BVNA, approximately 65% and 75% of patients respectively, report clinically significant pain and functional improvements; calculated proportions of responders remained stable at 24 and 60-months.[50]

In a meta-analysis of RCTs comparing pain interventions, BVNA was found to provide significant improvements in VAS and ODI scores for 6-, 12- and 24-months follow-up ($p \leq 0.05$).[52] BVNA was significantly more effective based on improvements in pain and function compared to intradiscal steroid injections, pulsed RFA, and annuloplasty interventions at 6- and 12-months following treatment. While pain improvements for biologic therapy and multifidus muscle stimulation were not statistically different from BVNA at 6-, 12- and 24-months, BVNA had fewer serious adverse events (statistically significant) than intradiscal biologic therapy and multifidus muscle stimulation, specifically at 6-months follow-up. In comparison, one study examining multifidus stimulation reported a 23.5% rate of surgical revisions, removals or re-implantations in the two years of follow-up. BVNA, biologic therapy and multifidus stimulation all provided significant, durable improvements in both pain and function compared to other interventions, which provided only short-term pain relief. Studies on BVNA reported no SAEs, a significantly better result than for studies of biologic therapy and multifidus stimulation. BVNA, biologic therapy and multifidus stimulation each represent different, yet effective, approaches to relief of chronic low back pain suggests that they may be addressing different, specific pathological sources of pain. Authors state that, “such distinctions, when applied to clinical practice, promise to deliver more effective and economical care path for the CLBP population.”[52]

Predictive Analyses of Response to BVNA

An independent analysis of 296 patients diagnosed with VEP and treated with BVNA from three clinical trials was conducted to clinically describe vertebrogenic pain and to identify clinical and imaging characteristics that were predictive of a positive response to BVNA. Results of these predictive analyses were published in a series of articles and demonstrated that pain stemming from VEP, (vertebrogenic pain) correlated with a clinical presentation of midline LBP, typically without radiation, that is exacerbated by forward flexion, sitting, and driving; these clinical findings are consistent with anterior column pain.[53-55] Stepwise regression analyses of clinical characteristics showed that Type 1 and/or Type 2 Modic changes were predictive of response to BVNA.[53] Pain and functional response was similar for both Type 1 or Type 2 Modic changes as well as for differing volumes of intensity changes within the vertebral body.[55] Modic changes that were localized to the endplate responded similarly to those with Modic > 50% of the vertebral height or endplate area demonstrating that Modic changes are binary.[55] The degree of disc degeneration nor the presence/size of endplate defects impacted treatment success rates. The authors concluded that clinical assessment characteristics that are consistent with VEP, combined with the binary presence of Type 1 or Type 2 Modic changes are currently the best methods of diagnosing vertebrogenic pain and identifying patients that are likely to respond to BVNA.[3,53-55]

Societal Guidelines

The International Society for the Advancement of Spine Surgery (ISASS) performed a systematic review including independent studies and concluded that "the utilization of intraosseous basivertebral nerve ablation to address vertebrogenic low back pain has become a recognized safe, predictable, and durable surgical method for the management of chronic axial low back pain identified using well-established clinical and MRI findings, Modic type 1 and/or type 2 changes. The procedure is supported by Level I evidence including a systematic review and 2 RCTs demonstrating a statistically significant decrease in pain and an improvement in function with outcomes sustained > 5 years after a single treatment."[47]

Likewise, the American Society for Pain and Neuroscience (ASPN) released treatment guidelines on vertebrogenic pain and BVNA in 2022.[56] In a systematic review conducted using the United States Preventive Services Task Force Criteria (USPSTF) Modified for Interventional Spine Procedures[57] a Grade A rating of the quality of evidence for BVNA for the treatment of vertebrogenic pain was provided indicating "there is high certainty that the net benefit is substantial in appropriately selected individuals" with a practice recommendation of "should offer or provide this service".[56] In December 2022, ASPN released evidence-based clinical guidelines (the ASPN Back Guideline) to rate the literature and provide therapy grades for the most commonly available interventional treatments for LBP, including BVNA.[58] The guidelines assigned Grade A to the quality of evidence for

basivertebral nerve ablation and the level of certainty around net benefit of the procedure was rated as "High".[58]

Healthcare Utilization and Cost-Effectiveness

Two publications explore the healthcare economics of BVNA. The first study explored the impact of BVNA on healthcare utilization - McCormick published long-term data from a pooled analysis of three prospective clinical trials (SMART, INTRACEPT, CLBP Single-Arm), demonstrating that BVNA significantly reduces the long-term utilization of additional treatments for LBP.[38] Through five years post-Intracept Procedure, patients with vertebrogenic pain experienced significant reductions in their use of opioids and therapeutic lumbosacral spinal injections following treatment. This includes a 70% reduction in active opioid use compared to baseline as well as a 65% reduction in therapeutic lumbosacral spine injections. The rate of fusion surgery was low (6.5%) and less than half the published rate of 14% at 6 months[59] in patients with CLBP and degenerative disc disease. Interestingly, 65% of additional pain interventions and surgeries over the 5-year follow-up were performed for treatment of pain sources outside of the index vertebrogenic pain.[38]

In September 2024, a cost-effectiveness analysis using a base case model for BVNA (the Intracept™ Procedure) was published, showing BVNA is cost-effective compared to standard care (with > 99% probability).[39] Data from SMART, INTRACEPT and the CLBP single-arm studies were utilized for the cost-effectiveness modeling. Quality of life measures were based on the EuroQol 5-Dimension 5-Level (EQ-5D-5L) and SF36v2®. Alternative scenario analyses and probabilistic sensitivity analyses were also conducted to assess the robustness of the model results and decrease potential bias. Findings showed the incremental cost-effectiveness ratio (ICER) of $11,376 per quality-adjusted life year (QALY) at a 5-year time horizon fell below the willingness-to-pay threshold of US$100,000-US$150,000 per QALY. These findings represent a conservative assumption, as the model considered the cost of BVNA only and excluded the reduction of downstream healthcare utilization.[39] The health economic studies of BVNA expand our understanding beyond compelling clinical outcomes to include cost-effectiveness.[38-39]

Information that fully explains the design, purpose, and/or method, as appropriate, of performing thermal destruction of intraosseous BVN for which this request is made.

Design

Treating a specific target (BVN) along with a well-understood pathophysiology, and a well-defined radiographic biomarker are all critical to successful patient selection and strong treatment outcomes observed in patients treated with the IntraceptTM Procedure. Intracept is the only FDA cleared system specifically designed to effectively and safely access the basivertebral nerve with a transpedicular approach and apply radiofrequency ablation intraosseously. The ablation parameters for the IntraceptTM Procedure system were meticulously designed to optimize treatment effectiveness and safety.

Purpose
The Intracept Procedure Intraosseous Nerve Ablation System is intended to be used in conjunction with radiofrequency (RF) generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change).

Method/Procedure
The procedure is performed with the FDA 510(k) cleared Intracept Intraosseous Nerve Ablation System which consists of:

Relievant Medsystems RF Generator is intended to be used with the Intracept RF probes FDA cleared as part of the Intracept Intraosseous Nerve Ablation System.

Intracept Intraosseous Nerve Ablation System consists of sterile, single use components including:

- **Two-Level Vertebral Body Intracept Access Instrument Kit** includes introducers (bevel and diamond tip configurations), cannulas and stylets that provide access to the intended site of RF ablation.
- **Additional Level Intracept Access Instrument Kit** also includes additional cannulas required to provide access to the intended site of RF ablation on subsequent vertebral bodies. These are used with the introducers and stylets provided in the initial kit.
- **Three-Level Vertebral Body Intracept Access Instrument Kit** includes introducers (bevel and diamond tip configurations), cannulas and stylets that provide access to the intended site of RF ablation.
- **Drill Intracept Access Instrument Kit** includes a drill that can be used to provide access to the intended site of RF ablation prior to use of other Access Instruments.
- **Intracept RF Probe** conducts RF energy to the target location. It is temperature controlled and maintains 85 degrees for 15 minutes per vertebral body treated.

The procedure is performed under general anesthesia or moderate sedation. MRI imaging is used to identify the vertebral bodies to be treated while fluoroscopic imaging is used intraoperatively to ensure accurate placement of the radiofrequency probe. A small incision is made to insert an introducer cannula to the surface of the vertebral body. The introducer cannula is malleted to access the vertebral body via a transpedicular approach. Upon reaching the junction of the pedicle and vertebral body, a curved cannula assembly is deployed to penetrate the vertebral body and navigate towards the BVNA target, located in the posterior 1/2 of the vertebral body. A straight channeling stylet is utilized if the channel needs to be extended to the midline location of the basivertebral nerve. A bipolar radiofrequency probe is

connected to a radiofrequency generator and inserted into the vertebral body. Radiofrequency energy is applied for 15 minutes at 85 degrees Celsius to ablate the basivertebral nerve. The next vertebral body is accessed using the same technique with additional instrumentation. Energy is again applied for 15 minutes to ablate the basivertebral nerve in this adjacent vertebral body. At the completion of the procedure, all instruments are removed, and the incisions are closed.

REQUESTED LANGUAGE FOR INCLUSION IN THE LCD

LCD Title: DLXXXX: Thermal destruction of intraosseous basivertebral nerve (BVN) for vertebrogenic lower back pain

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this LCD may be monitored and addressed through post-payment data analysis and subsequent medical review audits.

History/Background and/or General Information

Thermal destruction (i.e., ablation) of the intraosseous basivertebral nerve (BVN) (the Intracept Procedure) is a medically necessary therapeutic, interventional surgical procedure this is used to treat certain types of chronic low back pain.

The procedure is performed using fluoroscopic imaging under moderate/conscious sedation or general anesthesia. At a minimum, the basivertebral nerve is ablated in at least one vertebral body.

Covered Indications

Thermal destruction of the intraosseous BVN (Intracept Procedure) will be considered medically reasonable and necessary when the following three (3) requirements as outlined by the FDA (Food & Drug Administration) are met:

- CLBP of at least 6 months duration, and
- Failure to respond to at least 6 months of conservative care*, and
- Imaging (e.g., MRI) features consistent with Type 1 or Type 2 Modic changes such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change), in one or more vertebrae from L3-S1.

*Non-surgical management may include but is not limited to:

- Avoidance of activities that aggravate pain
- Trial of Chiropractic manipulation
- Trial of physical therapy
- Cognitive support and recovery reassurance
- Therapeutic spinal injections

- Spine biomechanics education
- Specific lumbar exercise program
- Home use of heat/cold modalities
- Low impact aerobic exercise as tolerated
- Pharmacotherapy (e.g., non-narcotic analgesics, NSAIDs, muscle relaxants, neuroleptics and narcotics)

Documentation of Pain and Disability

It is appropriate that scales used to measure pain and/or disability are documented in the medical record. Acceptable scales include but are not limited to: verbal pain rating scale, Numerical Rating Scale (NRS), Numeric Pain Score (NPS), and Visual Analog Scale (VAS) for pain assessment, and Pain Disability Assessment Scale (PDAS), Oswestry Disability Index (ODI), Oswestry Low Back Pain Disability Questionnaire (OSW), Quebec Back Pain Disability Scale (QUE), Roland Morris Pain Scale, Back Pain Functional Scale (BPFS), and the PROMIS profile domains to assess function.

Contraindications

- Skeletally immature patients ($\leq$ 18 years old)
- Severe cardiac or pulmonary compromise
- Active systemic infection or local infection in the area to be treated
- Patients who are pregnant
- Patients with active implantable pulse generators (e.g. pacemakers, defibrillators)
- Patients where the targeted ablation zone is < 10 mm away from a sensitive structure not intended to be ablated, including the vertebral foramen (spinal canal)
- Situations where unintended tissue damage may result based on clinical assessment by the physician
- Application with electrosurgical instruments NOT tested and specified for USE with Relievant RFG

Provider Qualifications

Medicare Program Integrity Manual states services will be considered medically reasonable and necessary only if performed by appropriately trained providers.
Patient safety and quality of care mandate that healthcare professionals who perform thermal destruction of intraosseous BVN are appropriately trained and/ or credentialed by a formal residency/fellowship program and/or are certified by either an accredited and nationally recognized organization or by a post-graduate training course accredited by an established national accrediting body or accredited professional training program whose core curriculum includes the performance and management of the procedures addressed in this policy. Credentialing or privileges are required for procedures performed in inpatient, outpatient and ambulatory surgery center settings.

All aspects of care must be within the provider's medical licensure and scope of practice.

Summary of Evidence

Clinical Studies

After a successful Pilot Study of 16 patients in 2007,[40] an international randomized double-blind sham-controlled trial of 225 patients was developed in collaboration with the FDA (SMART RCT) and demonstrated statistically and clinically significant differences, leading to FDA clearance for intraosseous BVNA.[23] After 12 months, patients randomized to the sham control arm were given the option to cross to the treatment arm, and 73% elected to receive BVNA.[24] The original treatment arm was followed out to more than 5 years for clinical and safety outcomes. Pain and functional improvements demonstrated in the BVNA arm of this RCT were sustained at 24 months and a mean of 6.4 years demonstrating the durability of results.[25,30]

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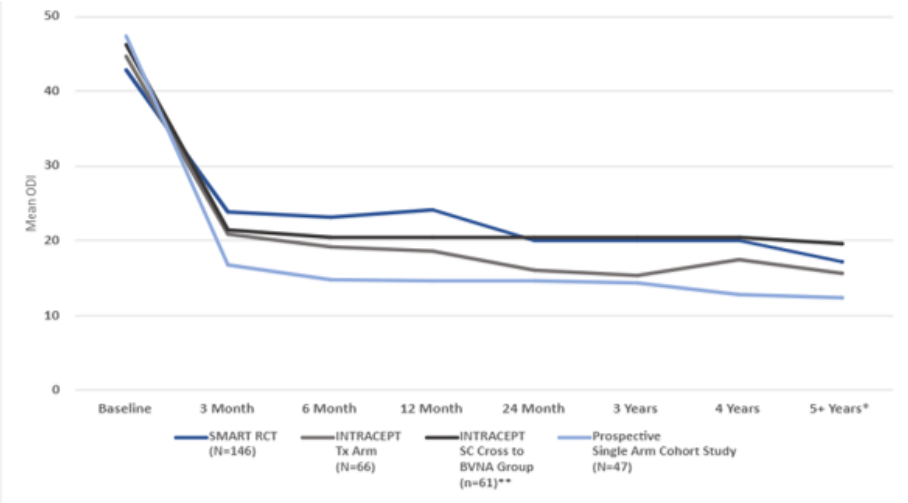
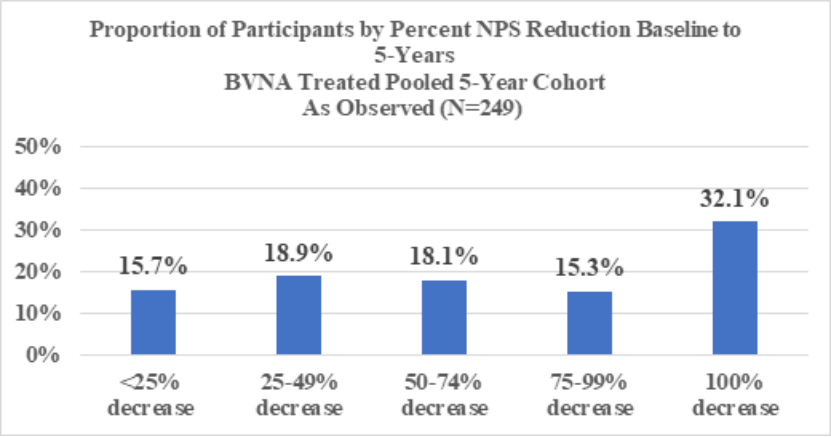
Figure 3 - Multi-Study Comparison of Functional Improvement – Comparison of mean ODI over time for the two Level I RCTs and the CLBP single arm study.



**Standard arm re-baselined and offered active treatment at a median of 5.8 months

Figure 4 – Pain Response by Quadrant – Pooled 5-Year Results (SMART, INTRACEPT, Single-Arm)



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Independent Data

Independent literature reviews,[41-49] independent studies (globally),[33-37] and three independent meta-analysis support the effectiveness and safety of BVNA for the treatment of vertebrogenic pain.[56-58] Independent reviews concluded that anatomic, histologic, and clinical evidence supports the concept of vertebral pain and the nociceptive role of the BVN in the pathogenesis of CLBP and that BVNA appears to be an effective and durable treatment option when applied to a select patient population based on defined clinical and radiographic criteria.

The single-arm study by Schnapp et al is the first U.S. study to be independently funded.[35-36] Thirty-five patients were treated with BVNA and 31 completed 12 month visits post-procedure (89% retention rate). The real-world study cohort patients were older, and the inclusion/exclusion criteria less stringent, than prior clinical trials. The mean age of patients was 73.0 ± 6.34 years, 64.5% had LBP > 5 years, and patients were not excluded for radicular pain or screened for osteoporosis. Five patients had prior spinal fusion surgeries and 15 had prior lumbar medial branch radiofrequency ablation procedures. Study results showed statistically and clinically meaningful improvements in ODI and VAS at 1-, 3-, 6- and 12-months post-BVNA compared to baseline. A reduction of 25.2 points (95% CI 16.3, 34.0) in ODI was reported at 12-months post-BVNA ($p<0.001$). Additionally at 12-months, 67.7 % of patients demonstrated ODI improvements above the MCID (decrease of 15 points) and 77.4 % of patients demonstrated a decrease on VAS above the MCID (at least 2 cm reduction). No adverse events or symptoms of compression fracture were reported in the study.[35-36]A single arm meta-analysis of both sponsored and independent literature demonstrated that at 6 and 12 months after BVNA, approximately 65% and 75% of patients respectively, report clinically significant pain and functional improvements; calculated proportions of responders remained stable at 24 and 60-months.[50]

In a meta-analysis of RCTs comparing pain interventions, BVNA was found to provide significant improvements in VAS and ODI scores for 6-, 12- and 24-months follow-up ($p \leq 0.05$).[52] BVNA was significantly more effective based on improvements in pain and function compared to intradiscal steroid injections, pulsed RFA, and annuloplasty interventions at 6- and 12-months following treatment. While pain improvements for biologic therapy and multifidus muscle stimulation were not statistically different from BVNA at 6-, 12- and 24-months, BVNA had fewer serious adverse events (statistically significant) than intradiscal biologic therapy and multifidus muscle stimulation, specifically at 6-months follow-up. In comparison, one study examining multifidus stimulation reported a 23.5% rate of surgical revisions, removals or re-implantations in the two years of follow-up. BVNA, biologic therapy and multifidus stimulation all provided significant, durable improvements in both pain and function compared to other interventions, which provided only short-term pain relief. Studies on BVNA reported no SAEs, a significantly better result than for studies of biologic therapy and multifidus stimulation. BVNA, biologic therapy and multifidus stimulation each represent different, yet effective, approaches to relief of chronic low back pain suggests that they may be addressing different, specific pathological sources of pain. Authors state that, “such distinctions, when applied to clinical practice, promise to deliver

more effective and economical care path for the CLBP population."[52]

Predictive Analyses of Response to BVNA

An independent analysis of 296 patients diagnosed with VEP and treated with BVNA from three clinical trials was conducted to clinically describe vertebrogenic pain and to identify clinical and imaging characteristics that were predictive of a positive response to BVNA. Results of these predictive analyses were published in a series of articles and demonstrated that pain stemming from VEP, (vertebrogenic pain) correlated with a clinical presentation of midline LBP, typically without radiation, that is exacerbated by forward flexion, sitting, and driving; these clinical findings are consistent with anterior column pain.[53-55] Stepwise regression analyses of clinical characteristics showed that Type 1 and/or Type 2 Modic changes were predictive of response to BVNA.[53] Pain and functional response was similar for both Type 1 or Type 2 Modic changes as well as for differing volumes of intensity changes within the vertebral body.[55] Modic changes that were localized to the endplate responded similarly to those with Modic > 50% of the vertebral height or endplate area demonstrating that Modic changes are binary.[55] The degree of disc degeneration nor the presence/size of endplate defects impacted treatment success rates. The authors concluded that clinical assessment characteristics that are consistent with VEP, combined with the binary presence of Type 1 or Type 2 Modic changes are currently the best methods of diagnosing vertebrogenic pain and identifying patients that are likely to respond to BVNA.[3,53-55]

Societal Guidelines

The International Society for the Advancement of Spine Surgery (ISASS) performed a systematic review including independent studies and concluded that "the utilization of intraosseous basivertebral nerve ablation to address vertebrogenic low back pain has become a recognized safe, predictable, and durable surgical method for the management of chronic axial low back pain identified using well-established clinical and MRI findings, Modic type 1 and/or type 2 changes. The procedure is supported by Level I evidence including a systematic review and 2 RCTs demonstrating a statistically significant decrease in pain and an improvement in function with outcomes sustained > 5 years after a single treatment."[47]

Likewise, the American Society for Pain and Neuroscience (ASPN) released treatment guidelines on vertebrogenic pain and BVNA in 2022.[56] In a systematic review conducted using the United States Preventive Services Task Force Criteria (USPSTF) Modified for Interventional Spine Procedures[57] a Grade A rating of the quality of evidence for BVNA for the treatment of vertebrogenic pain was provided indicating "there is high certainty that the net benefit is substantial in appropriately selected individuals" with a practice recommendation of "should offer or provide this service".[56] In December 2022, ASPN released evidence-based clinical guidelines (the ASPN Back Guideline) to rate the literature and provide therapy grades for the most commonly available interventional treatments for LBP, including BVNA.[58] The guidelines assigned Grade A to the quality of evidence for basivertebral nerve ablation and the level of certainty around net benefit of the procedure

was rated as “High”.[58]

Healthcare Utilization and Cost-Effectiveness

Two publications explore the healthcare economics of BVNA. The first study explored the impact of BVNA on healthcare utilization - McCormick published long-term data from a pooled analysis of three prospective clinical trials (SMART, INTRACEPT, CLBP Single-Arm), demonstrating that BVNA significantly reduces the long-term utilization of additional treatments for LBP.[38] Through five years post-Intracept Procedure, patients with vertebrogenic pain experienced significant reductions in their use of opioids and therapeutic lumbosacral spinal injections following treatment. This includes a 70% reduction in active opioid use compared to baseline as well as a 65% reduction in therapeutic lumbosacral spine injections. The rate of fusion surgery was low (6.5%) and less than half the published rate of 14% at 6 months[59] in patients with CLBP and degenerative disc disease. Interestingly, 65% of additional pain interventions and surgeries over the 5-year follow-up were performed for treatment of pain sources outside of the index vertebrogenic pain.[38]

In September 2024, a cost-effectiveness analysis using a base case model for BVNA (the Intracept™ Procedure) was published, showing BVNA is cost-effective compared to standard care (with > 99% probability).[39] Data from SMART, INTRACEPT and the CLBP single-arm studies were utilized for the cost-effectiveness modeling. Quality of life measures were based on the EuroQol 5-Dimension 5-Level (EQ-5D-5L) and SF36v2®. Alternative scenario analyses and probabilistic sensitivity analyses were also conducted to assess the robustness of the model results and decrease potential bias. Findings showed the incremental cost-effectiveness ratio (ICER) of $11,376 per quality-adjusted life year (QALY) at a 5-year time horizon fell below the willingness-to-pay threshold of US$100,000-US$150,000 per QALY. These findings represent a conservative assumption, as the model considered the cost of BVNA only and excluded the reduction of downstream healthcare utilization.[39] The health economic studies of BVNA expand our understanding beyond compelling clinical outcomes to include cost-effectiveness.[38-39]

Regulatory Status

- K153272 – FDA Clearance July 9, 2016

http://www.accessdata.fda.gov/cdrh_docs/pdf15/K153272.pdf

- K170827 – FDA Clearance August 9, 2017

http://www.accessdata.fda.gov/cdrh_docs/pdf17/K170827.pdf

Relievant Medsystems RF Generator

- K171143 – FDA Clearance August 18, 2017

http://www.accessdata.fda.gov/cdrh_docs/pdf17/K171143.pdf

Intracept System - RF Probe

- K180369 - FDA Clearance September 14, 2018

https://www.accessdata.fda.gov/cdrh_docs/pdf18/K180369.pdf

Intracept Intraosseous Nerve Ablation System

- K190504 – FDA Clearance May 3, 2019

https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190504.pdf

- K213836 – FDA Clearance March 11, 2022
- K222281 – FDA Clearance October 26, 2022

FDA indications for use:
The Intracept Intraosseous Nerve Ablation System is intended to be used in conjunction with radiofrequency (RF) generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change).

Coding

ICD-10-CM Diagnosis Codes:

M54.51	Vertebrogenic low back pain; low back vertebral endplate pain
M46.86	Other specified inflammatory spondyloarthropathies, lumbar
M46.87	Other specified inflammatory spondyloarthropathies, lumbosacral
M47.816	Spondylosis w/o myelopathy or radiculopathy, lumbar
M46.817	Spondylosis w/o myelopathy or radiculopathy, lumbosacral
M51.36	Other intervertebral disc degeneration, lumbar
M51.37	Other intervertebral disc degeneration, lumbosacral

CPT Codes:

64628 Thermal destruction of intraosseous basivertebral nerve, inclusive of all imaging guidance; first two vertebral bodies, lumbar or sacral

64629+ Thermal destruction of intraosseous basivertebral nerve, inclusive of all imaging guidance; each additional vertebral body, lumbar or sacral

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