New York Society of Interventional Pain Physicians

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To
Medical Director
Excellus

Dated: 04/05/2022

We are writing to submit comments for your draft policy 11.01.03, that is set to become effective on May 1, 2022.

NYSIPP promotes the development and practice of safe, high quality, cost effective interventional pain management techniques for the diagnosis and treatment of pain and related disorders and to insure patient access to these interventions.

As you are aware, low back pain is the most expensive occupational disorder in the United States and the leading cause of disability worldwide. We have historically had poor treatment options for a subgroup of patients with chronic, refractory axial low back pain, many of whom traditionally went on to have a spinal fusion with variable results and all of the sequelae that accompany spinal fusion. Thermal destruction of the intraosseous basivertebral nerve (The Intracept Procedure) offers these patients a minimally invasive treatment option with excellent clinical results, minimal recovery time and is much less expensive. This minimally invasive treatment is durable and unlike other ablation procedures it does not need to be repeated. This treatment represents a substantial opportunity to improve pain and function in the most difficult to treat and expensive chronic low back pain patients. The Intracept Procedure is a surgical procedure that provides effective relief for patients suffering from vertebrogenic chronic low back pain (CLBP). Indications for the procedure are clearly defined:

1) Chronic Low Back Pain for > 6 months
2) Failed conservative treatment > 6 months
3) MRI demonstrating Modic changes in the L3 – S1 vertebral bodies. (MRI that demonstrates endplate changes, inflammation, edema, disruption and/or fissuring, fibrovascular bone marrow changes, fatty bone marrow changes)

Basivertebral nerve (BVN) ablation is based on 30 years of basic and clinical research demonstrating that the vertebral endplates are an important source of CLBP that have been ignored. Patients have often been mis-classified as having discogenic pain, leading to many unnecessary procedures and surgeries. Damage to the vertebral endplates create a chronic inflammatory cascade that result in Modic Type 1 and 2 changes on routine MRI. Sensitization of these endplate nerves create vertebrogenic pain signals that are transmitted via the BVN and manifest as back pain. Unlike facet joint and other sources of pain that rely on subjective blocks to make the diagnosis, vertebrogenic pain is diagnosed using objective MRI findings.

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In fact, effective 10-01-2021 vertebrogenic pain is identified by ICD-10CM code M54.51. Additionally, the BVN does not have the ability to regenerate, and the procedure does not need to be repeated as with facet joint ablation. The Intracept procedure is supported by a strong basic and clinical evidence foundation, including a Level I, sham controlled RCT and a second Level I RCT against standard conservative management.

The SMART study demonstrated significant clinical improvements in pain and function that have been sustained through a mean of 6.4 years following treatment. Patients followed long-term demonstrated a 61% improvement in function (Oswestry Disability Index - ODI) and 66% of patients experienced greater than 50% decrease in pain (Visual Analog Scale - VAS) with 34% being completely pain free. Additionally, these patients required significantly fewer injections with a 93% reduction compared to baseline and at the 5 year follow up. The procedure has an excellent safety profile with no serious device-related events.

The second Level I, RCT study, The Intracept Study, was stopped for superiority. Stopping a study for superiority early is a significant accomplishment and rarely achieved in an interim analysis. There has been no other study in spine stopped for superiority. When a study is stopped early for superiority, the results are deemed conclusive of a therapy's effectiveness.

Several of our members have collectively performed the Intracept procedure on hundreds of our patients and have found the results mirrored those in the SMART and Intracept studies. This procedure is reproducible and fills a treatment gap for those patients who previously failed conservative treatment and continued to have unresolved pain.

Patients deserve access to this proven treatment, we urge you to consider adopting positive coverage of thermal destruction of the intraosseous basivertebral nerve (The Intracept procedure). Additionally, other Blue Cross Blue Shield plans have published positive coverage policies:

- BCBS of North Dakota, effective: 1/20/2022: https://www.bcbsnd.com/providers/policies-precertification/medical-policy/b/basivertebral-nerve-ablation
- Highmark BCBS Commercial Medical Policy (Pennsylvania, West Virginia, Delaware, Western New York and Northeastern New York), effective 12/06/2021: https://securecms.highmark.com/content/medpolicy/en/highmark/ny/commercial/policies/Miscellaneous/Z-104/Z-104-003.html
- Blue Cross Blue Shield of Nebraska, effective 3/16/2021: https://medicalpolicy.nebraskablue.com/policy/430/1

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In this era of rising healthcare costs and increasing need for therapies to reduce the use of opioids, the Intracept procedure provides an effective treatment option to fill the gap in the treatment paradigm for patients that fail non-surgical treatment. The evidence supports coverage of the procedure and we request that the policy be updated to allow members access to care.
We welcome the opportunity to schedule a meeting to review clinical evidence in support of coverage for the Intracept procedure. Thank you for your time and consideration of NYSIPP comments.

Sincerely,

1. Fischgrund JS, Rhyne A, Franke J, Sasso R, Kitchel S, Bae H, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: a prospective randomized double-blind sham-controlled multi-center study. Eur Spine J. 2018;27(5):1146-56. DOI: 10.1007/s00586-018-5496-1. Open access.

2. Fischgrund JS, Rhyne A, Franke J, Sasso R, Kitchel S, Bae H, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: two-year results from a prospective randomized double-blind sham-controlled multi-center. Study. Int J Spine Surg 2019;13(2). Open access.

3. Fischgrund JS, Rhyne A, Macadaeg K, Moore G, Kamrava E, Yeung C, et al. Long-term outcomes following intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 5-year treatment arm results from a prospective randomized double-blind sham-controlled multi-center study. Eur Spine J. 2020 Aug;29(8):1925-1934. DOI: 10.1007/s00586-020-06448-x. Open access.

4. Khalil J, Smuck M, Koreckij T, Keel J, Beall D, Goodman B, Kalapos P, Nguyen D, Garfin S. A Prospective, Randomized, Multi-Center Study of Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain. Spine J. 2019 Jun 20. pii: S1529-9430(19)30800-9. doi: 10.1016/j.spinee.2019.05.598. Open access.

5. Kim HS, Adsul N, Yudoyono F, et al. Transforaminal Epiduroscopic Basivertebral Nerve Laser Ablation for Chronic Low Back Pain Associated with Modic Changes: A Preliminary Open-Label Study. Pain Res Manag. 2018;2018:6857983. Published 2018 Aug 14. doi:10.1155/2018/6857983. Open access.

6. Koreckij T, Kreiner S, Khalil JG, Smuck M, Markman J, Garfin S. Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 24-month treatment arm results. NASSJ. Published online October 26, 2021. DOI: https://doi.org/10.1016/j.xnsj.2021.100089. Open access.

7. Macadaeg K, Truumees E, Boody B, Pena E, Arbuckle A., Gentile, J, et al. A

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prospective, open-label, single-arm, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. NASSJ 2020;3(100030). E-pub 18 Sept 2020. https://doi.org/10.1016/j.xnsj.2020.100030. Open access.

8. Michalik A, Conger A, Smuck M, Maus TP, McCormick ZL. Intraosseous Basivertebral Nerve Radiofrequency Ablation for the Treatment of Vertebral Body Endplate Low Back Pain: Current Evidence and Future Directions. Pain Med. 2021 Jul 25;22(Suppl 1):S24-S30. doi: 10.1093/pm/pnab117. PMID: 34308955. Open access.

9. Smuck M, Khalil JG, Barrett K, Hirsch JA, Kreiner S, Koreckij T, et al. A prospective, randomized, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. Reg Anesth Pain Med. 2021;rapm-2020-102259. doi:10.1136/rapm-2020-102259. Open access.

10. Tieppo FV, Sherwood D, Twohey E, Barndt B, Pagan-Rasodo R, Eubanks J, Sayed D. Developments in Minimally Invasive Surgical Options for Vertebral Pain: Basivertebral Nerve Ablation – A Narrative Review. JPR. 2021;14:1887-1907. Open access.

11. Truumees E, Macadaeg K, Pena E, Arbuckle A, Gentile, J, Funk R, et al. A prospective, open-label, single-arm, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. European Spine Journal 2019. https://doi.org/10.1007/s00586-019-05995-2. Open access.

12. Urits I, Noor N, Johal AS, Leider J, Brinkman J, Fackler N, Vij N, An D, Cornett EM, Kaye AD, Viswanath O. Basivertebral Nerve Ablation for the Treatment of Vertebrogenic Pain. Pain Ther. 2021 Jun;10(1):39-53. doi: 10.1007/s40122-020-00211-2. Epub 2020 Oct 31. PMID: 33128702; PMCID: PMC8119576. Open access.

Article Summaries Provided

13. Becker S, Hadjipavlou A, Heggeness MH. Ablation of the basivertebral nerve for treatment of back pain: a clinical study. Spine J 2017;17(2):218-23. DOI: 10.1016/j.spinee.2016.08.032.

A single-arm, open-label pilot study was conducted in the U.S. and Europe and included 16 subjects treated with basivertebral nerve ablation. The study included 12 months of follow-up and demonstrated that the Intracept System was safe and effective for treatment of primary vertebrogenic CLBP within this cohort of subjects with Type 1 and Type 2 Modic changes, with high response rates for improvements in pain and function. There was a statistically significant improvement in Oswestry Disability Index (ODI) at 3 months and this was maintained through 12 months of follow-up. The procedure was demonstrated as safe, with a high degree of targeting and procedural success.There were no device- or procedure-related serious adverse events reported by study sites in this pilot study.

14. Conger A, Schuster NM, Cheng DS, Sperry BP, Joshi AB, Haring RS, Duszynski B, McCormick ZL. The Effectiveness of Intraosseous Basivertebral Nerve Radiofrequency Neurotomy for the Treatment of Chronic Low Back Pain in Patients with Modic Changes: A Systematic Review. Pain Med. 2021 May 21;22(5):1039-1054. doi: 10.1093/pm/pnab040. PMID: 33544851.

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This systematic review by Conger et al found that the relative risk of treatment success for reduction in pain was 4.16 (95% CI 2.12-8.14) and for disability was 2.32 (95% CI 1.52-3.55). The authors concluded that moderate-quality evidence suggests basivertebral nerve ablation is effective in reducing pain and disability in patients with chronic low back pain who are selected based on Type 1 or Type 2 Modic changes.

15. DeVivo AE, D' Agostino G, D' Anna G, Al Qatami H, Gil I, Ventura F, et. al. Intra-osseous basivertebral nerve radiofrequency ablation (BVA) for the treatment of vertebrogenic chronic low back pain. Neuroradiology. 2020;63:809-815. https://doi.org/10.1007/s00234-020-02577-8.

A prospective, uncontrolled level IV case series in Italy evaluated the effectiveness of percutaneous basivertebral nerve ablation in patients with vertebrogenic chronic low back pain using the STAR® Tumor Ablation System. At 3- and 12-month follow-up, VAS and ODI decreased significantly compared to baseline. Clinical success was defined as a ≥ 10-point change in ODI; 96.5% of patients were considered to have clinical success at 12 months. Targeting was deemed successful in 100% of subjects, which consistently included the central portion of the vertebral body along the midline, according to study authors. Study results support previously published safety and efficacy results associated with basivertebral nerve ablation. No immediate or delayed complications were reported.

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