

October 14, 2022

Part A Policy
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Re: Proposed LCD on Sacroiliac Joint Injections and Procedures (DL39402)

To Whom It May Concern:

The undersigned medical specialty societies, comprising physicians who utilize and/or perform interventional spine procedures to accurately diagnose and treat patients suffering from spine pathologies, would like to take this opportunity to express our strong support for coverage of sacroiliac interventions for pain management, and provide a detailed explanation of their importance to patients' quality of life.

Our societies have a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved.

Significant relief of pain, improved quality of life, restoration of function, and decreased utilization of other healthcare resources are outcomes that should be readily available to patients covered by Medicare. When sacroiliac interventions are performed in a disciplined, responsible manner, they achieve outcomes that are clinically, socially, and economically worthwhile.

We commend the Medicare Administrative Contractors for inviting comments and presentations from physicians and experts earlier this year and giving appropriate and careful consideration to the evidence available about the important role these procedures play in treating patients with back pain. The result is a proposed local coverage determination that preserves and promotes access to sacroiliac joint injections but precludes coverage of radiofrequency ablation – a procedure proven to be safe and effective in providing pain relief and functional improvement in appropriately selected patients. We would like to offer the following comments to provide clarification and ensure that the procedures are made available to patients in a manner that will result in improved outcomes and quality of life.

NEUROANATOMICAL CONSIDERATIONS OF SIJ PAIN

The SIJ has both anterior and posterior innervation. The joint itself is innervated anteriorly by the lumbosacral trunks, obturator nerve, and gluteal nerves. The posterior sacroiliac joint complex (PSIJC) is innervated by the posterior sacral network (PSN), which consists of primarily the S1–S3 dorsal rami and, in some cases, fibers of the L5 dorsal ramus. **It is important to note that the intraarticular joint and the PSIJC are two different pain generators with different innervations. It logically follows that they should require different treatments to appropriately target the structures responsible for their respective generation of pain [1-4]. Intraarticular injections target anterior**

innervation. If pain is originating from the PSIJC, intraarticular injections will not result in significant improvements in pain or function. As currently proposed, patients with pain originating from the PSIJC have no interventional treatment options. *Intraarticular SIJ injections do not diagnose or treat pain originating from the PSIJC.*

L5 DORSAL RAMUS AND SACRAL LATERAL BRANCH PROCEDURES

Diagnostic L5 Dorsal Ramus and Sacral Lateral Branch Blocks

Diagnostic L5 dorsal ramus and sacral lateral branch blocks involve injecting a small amount of local anesthetic onto the L5 primary dorsal ramus and S1-S3 dorsal rami lateral branches. These injections are used to evaluate whether anesthetizing the PSIJC mediates the patient's pain and to what degree. *They do not diagnose pain originating from within the SIJ.*

Indications

Small volume (≤ 0.5 mL per nerve) image-guided anesthetic blockade of the L5 primary dorsal ramus and per target for 1st-3rd sacral dorsal rami lateral branches are indicated to aid in the diagnostic work-up of LBP and must be considered prior to radiofrequency lesioning of these nerves. A positive response is at least 75% reduction of pain for the expected duration of the anesthetic, observed on 2 separate occasions. These blocks are appropriate when ALL of the listed criteria are met:

- a) The patient reports primarily non-radicular, typically unilateral pain that is maximal below the L5 vertebrae, localized over the posterior SIJ, and consistent with SIJ pain.
- b) A physical examination typically demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, *i.e.*, at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) or the absence of tenderness elsewhere (*e.g.*, greater trochanter, lumbar spine, coccyx) that would explain the patient's symptoms.
- c) Positive response to a cluster of at least 3 provocative tests (1. Patrick's or FABER, 2. Gaenslen, 3. Thigh thrust, 4. Sacral thrust, 5. Distraction, 6. Compression). Note that the thrust tests may not be recommended in pregnant patients or those with connective tissue disorders.

L5 Dorsal Ramus and Sacral Lateral Branch Radiofrequency Neurotomy

L5 dorsal ramus and sacral lateral branch radiofrequency neurotomy (LBRFN) involves applying thermal radiofrequency energy to generate lesions along the L5 dorsal ramus and S1-S3 lateral branches aimed at coagulating the nerves responsible for PSIJC pain. *They do not treat pain originating from within the SIJ.*

Indications

Image-guided thermal radiofrequency neurotomy of the L5 primary dorsal ramus and sacral dorsal rami lateral branches at S1, S2, and S3 are indicated for the treatment of sacroiliac pain when either of the listed criteria are met:

- a) Clinical criteria for positive diagnostic anesthetic blocks of the L5 primary dorsal ramus and sacral dorsal rami lateral branches (as above) are met AND pain has been

present for at least 3 months AND pain is severe enough to cause some degree of functional deficit despite other conservative treatment.

- b) Posterior sacroiliac ligament complex pain has recurred after $\geq 50\%$ improvement for ≥ 6 months from prior radiofrequency neurotomy of the L5 primary dorsal ramus and sacral dorsal rami lateral branches.

Evidence in Support of LBRFN

Sacroiliac interventions are validated treatments for sacroiliac joint pain. Several high-quality systematic reviews have been published related to intraarticular sacroiliac joint injections [1] and PSIJC procedures [2-4]. These reviews are attached and present the outcomes reported in the literature, concluding that these procedures are effective for a substantial proportion of patients who are diagnosed accurately and treated with the procedure targeting the appropriate pain generator(s) as identified by diagnostic blocks.

The best available evidence on radiofrequency neurotomy of the L5 dorsal ramus and sacral lateral branches are two randomized controlled trials (RCT) that have demonstrated the efficacy of the procedure [6,7]. A pooled, between-group analysis of these RCTs revealed that those treated with radiofrequency neurotomy were four times more likely to achieve $\geq 50\%$ pain reduction at three months compared with sham (proportion rate ratio/relative risk [4.84 (95% CI 1.19–19.73)]) [2]. Despite the level of benefit shown in the pooled analysis, both these studies used patient selection criteria which is less than ideal for identifying PSIJC-mediated pain. Thus, the true benefit of radiofrequency neurotomy is likely superior in a properly selected patient population. Ultimately, there appears to be a therapeutic effect with treatment responder rates ranging from 32–89%, which is likely attributable to wide ranging variability in patient selection in the available studies for review [4]. Additionally, LBRFN has been shown to provide long-term pain relief, with studies reporting that 50-70% of patients achieved $\geq 50\%$ pain reduction at up to 18-24 months [8,9], and pain relief can be reinstated with a repeat procedure [10]. It is also important to highlight during the current opioid crisis that LBRFN has been shown to reduce opioid dependency [11].

To date, there are three high-quality comprehensive reviews of the literature on LBRFN [2-4]. In 2015, King *et al.* concluded that there was “moderate” quality evidence for LBRFN, yet admittedly felt the current research base was limited by heterogeneity in the patient selection criteria. In 2019, Yang *et al.* reaffirmed that there exists “moderate” evidence to support efficacy and effectiveness of LBRFN for the treatment of PSIJC pain. Both King *et al.* and Yang *et al.* further delineated that PSIJC was a unique pain generator from the intra-articular SIJ, and both reviews conclude that radiofrequency neurotomy can provide relief for PSIJC pain.

In addition, a multidisciplinary, multi-society effort to develop appropriate use criteria for sacroiliac interventions concluded that intraarticular sacroiliac injections and thermal lateral branch radiofrequency neurotomy are appropriate treatments for appropriately selected patients. The multi-society expert rating panel consisted of members representing the American Academy of Orthopaedic Surgeons, American Society of Anesthesiologists, American College of Radiology, American Academy of Physical Medicine and Rehabilitation, American Academy of Pain Medicine, North American Spine Society, and Spine Intervention

Society. Panel members weighed the evidence and their clinical expertise in determining appropriateness of sacroiliac interventions for specific clinical scenarios [12].

Acknowledging the strength and quality of the evidence in support of the safety and effectiveness of LBRFN, the American Medical Association's Current Procedural Terminology (CPT®) Editorial Panel approved a Category I code that went into effect on January 1, 2020.

SACROILIAC JOINT INJECTIONS

The proposed LCD states under "Limitations" that sacroiliac joint injections to treat "axial spine pain" are investigational, and therefore, not considered medically reasonable and necessary. As written, the language could possibly be construed as excluding pain over the sacrum. Therefore, we recommend the language be revised to "axial spine pain primarily above the level of L5".

The undersigned societies appreciate the opportunity to provide these comments and would welcome the opportunity to again work with the Medicare Administrative Contractors to revise the coverage criteria included in the LCDs to ensure appropriate access to sacroiliac interventions for Medicare patients. If you have any questions or wish to discuss any of our suggestions, please contact Sarah Cartagena, Director of Health Policy at the Spine Intervention Society, at scartagena@spineintervention.org.

Sincerely,

American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
American Society of Anesthesiologists
American Society of Neuroradiology
American Society of Regional Anesthesia and Pain Medicine
Georgia Society of Interventional Pain Physicians
North American Neuromodulation Society
North American Spine Society
Society of Interventional Radiology
Spine Intervention Society

Attachments:

- North American Spine Society. Coverage Policy Recommendations: Sacroiliac Joint Injections and Radiofrequency Ablation. 2020.
- MacVicar J, Kreiner DS, Duszynski B, Kennedy DJ. Appropriate use criteria for fluoroscopically guided diagnostic and therapeutic sacroiliac interventions: results from the Spine Intervention Society convened multispecialty collaborative. *Pain Med* 2017;18:2081-2095.
- Yang AJ, Wagner G, Burnham T, McCormick ZL, Schneider BJ. Radiofrequency ablation for chronic posterior sacroiliac joint complex pain: a comprehensive review. *Pain Med* 2021;22(Suppl 1):S9-S13. <https://doi.org/10.1093/pm/pnab021>
- King W, Ahmed SU, Baisden J, Patel N, Kennedy DJ, Duszynski B, MacVicar J. Diagnosis

and treatment of posterior sacroiliac complex pain: a systematic review with comprehensive analysis of the published data. *Pain Med* 2015;16(2):257-65. <https://doi.org/10.1111/pme.12630>

- Yang AJ, McCormick ZL, Zheng PZ, Schneider BJ. Radiofrequency ablation for posterior sacroiliac joint complex pain: a narrative review. *PM R* 2019;11 Suppl 1:S105-S113. doi: 10.1002/pmrj.12200. Epub 2019 Jul 25. PMID: 31169356.

References:

1. Kennedy DJ, Engel A, Kreiner DS, Nampiaparampil D, Duszynski B, MacVicar J. Fluoroscopically Guided Diagnostic and Therapeutic Intra-Articular Sacroiliac Joint Injections: A Systematic Review. *Pain Med*. 2015;16:1500-1518.
2. Yang AJ, Wagner G, Burnham T, McCormick ZL, Schneider BJ. Radiofrequency ablation for chronic posterior sacroiliac joint complex pain: a comprehensive review. *Pain Med*. 2021;22:S9-S13.
3. King W, Ahmed SU, Baisden J, Patel N, Kennedy DJ, Duszynski B, MacVicar J. Diagnosis and treatment of posterior sacroiliac complex pain: a systematic review with comprehensive analysis of the published data. *Pain Med*. 2015;16:257-65.
4. Yang AJ, McCormick ZL, Zheng PZ, Schneider BJ. Radiofrequency ablation for posterior sacroiliac joint complex pain: a narrative review. *PM R*. 2019;11 Suppl 1:S105-S113.
5. North American Spine Society. Coverage Policy Recommendations: Sacroiliac Joint Injections and Radiofrequency Ablation. 2020.
6. Cohen SP, Hurley RW, Buckenmaier CC, et al. Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain. *Anesthesiology*. 2008;109:279-88.
7. Patel N, Gross A, Brown L, Gekht G. A randomized, placebo controlled study to assess the efficacy of lateral branch denervation for chronic sacroiliac joint pain. *Pain Med*. 2012;13:383-98.
8. Ho KY, Hadi MA, Pasutharnchat K, Tan KH. Cooled radiofrequency denervation for treatment of sacroiliac joint pain: two-year results from 20 cases. *J Pain Res*. 2013;6:505-511.
9. Romero FR, Vital RB, Zanini MA, Ducati LG, Gabarra RC. Long-term follow-up in sacroiliac joint pain patients treated with radiofrequency ablative therapy. *Arq Neuropsiquiatr*. 2015;73(6):476-479.
10. Kurklinsky S, Boone MK, Candler SA, Schwab A, Ghazi S. Repeat Cooled Radiofrequency Ablation Is Beneficial for Chronic Posterior Sacroiliac Joint Pain. *Pain Med*. 2020;21(8):1532-1537.
11. Tinnirello A. Reduction of opioid intake after cooled radiofrequency denervation for sacroiliac joint pain: a retrospective evaluation up to 1 year. *Korean J Pain*. 2020;33(2):183-191.
12. MacVicar J, Kreiner DS, Duszynski B, Kennedy DJ. Appropriate Use Criteria for Fluoroscopically Guided Diagnostic and Therapeutic Sacroiliac Interventions: Results from the Spine Intervention Society Convened Multispecialty Collaborative. *Pain Med*. 2017;18:2081-2095.