Ablative Procedures to Treat Back and Neck Pain

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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Notice to Medicaid Policy Readers: For comprehensive rules and guidelines pertaining to this policy, readers are advised to consult the Oregon Health Authority. It is essential to ensure full understanding and compliance with the state's regulations and directives. Please refer to OHA's prioritized list for the following coverage guidelines:

Ablative Procedures to Treat Neck and Back Pain: Excluded Services Guideline E1 and Excluded Services Guideline E2

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Notes:

- Frequency limits, including how many treatments may be considered eligible for coverage per rolling 12 months (365 days), are detailed in the Billing Guidelines below.
- Providers should refer to the applicable AMA CPT Manual to assist with proper reporting of these services.

Non-Pulsed Radiofrequency Ablation (RFA) for Facet Pain

Covered Indications

I. Initial non-pulsed radiofrequency ablation of the cervical (C2-3 and below), thoracic, or lumbar spine to the L5-S1 facet joint (L4 and L5 medial branches) may be considered **medically necessary** for the treatment of facet pain when **all** the following criteria (A.-D.) are met:

   A. Pre-procedural documentation must include a complete initial evaluation with history and an appropriately focused musculoskeletal and neurological physical examination. There

should be a summary of the pertinent diagnostic tests or procedures justifying the presence of facet joint pain; **and**

B. Symptoms have failed to improve after 3 months conservative treatment (see Policy Guidelines); **and**

C. Recent radiographic imaging shows one of the following (1.-2.):

1. There is no non-facet pathology (e.g., significant stenosis, fracture, tumor, infection, significant deformity or instability) that might explain the source of the patient's pain; **or**
2. If non-facet pathology is identified on imaging, documentation indicates that provider has ruled out this pathology as the primary source of the patient's pain; **and**

D. Two positive diagnostic facet joint injections and/or medial branch blocks on different days with local anesthetic (no steroids or other drugs) that demonstrate ≥ 80% relief of the primary index pain and duration of relief is consistent with the agent employed. Pain diaries may be requested to ensure this criterion is met.

II. Repeat non-pulsed radiofrequency ablation of cervical, thoracic, or lumbar spine facet joint, previously treated in the initial procedure (see Policy Guidelines), may be considered **medically necessary** when **all** of the following criteria (A. – D.) are met:

A. Criteria for initial treatment (in criterion I. above) was met prior to initial treatment; **and**

B. There is clinical documentation the patient experienced ≥ 50% improvement of pain for at least 12 weeks after the previous ablation; **and**

C. The repeat procedure is performed at a minimum of six months following the initial ablation procedure; **and**

D. Documentation of a formal, in office evaluation including reasons for repeating the ablation.

Note: Repeat diagnostic blocks are required when performing a repeat radiofrequency joint denervation/ablation at the same spinal level(s) as a prior successful ablation procedure if either more than 2 years have passed since the previous RFA, or if there is a question as to the source of the recurrent pain.

Non-Covered Indications

III. Non-pulsed radiofrequency ablation for the treatment of facet pain is considered **not medically necessary** when the above criteria I. or II. are not met, including, but not limited to:

A. Cervical spine at level C0-1 or C1-2

B. Radiofrequency ablation at the level of a prior fusion

Non-Pulsed Radiofrequency Ablation for Non-Facet Pain

IV. Intraosseous radiofrequency nerve ablation of the basivertebral nerve (e.g., Intracept Intraosseous Nerve Ablation System) may be considered medically necessary for treatment of single-level chronic low back pain when ALL of the following criteria are met:

A. Requested procedure is between L3-S1;
B. Member is skeletally mature (closed growth plates);
C. Symptoms have failed to improve after 6 consecutive months of documented, structured, provider-supervised conservative treatment within the last year (see Policy Guidelines)
D. Recent MRI confirm Type 1 or Type 2 Modic changes- 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
E. Other causes of generalized back pain have been treated (e.g., lumbar spinal stenosis, spondylolisthesis, segmental instability, disc herniation, degenerative scoliosis, facet arthropathy or effusion with clinically suspected facet joint pain).

V. Intraosseous radiofrequency nerve ablation of the basivertebral nerve is considered **not medically necessary** when criterion IV. is not met.

VI. Non-pulsed radiofrequency ablation for the treatment of non-facet-related back and/or neck pain is considered r**not medically necessary** for all other indications, including, but not limited to pain related to:

A. The dorsal root ganglion.
B. The ganglion impar (impar of Walther).
C. The sacrum or sacroiliac joint.

VII. Ablation (e.g. cryoablation, pulsed radiofrequency ablation) of the occipital nerve (Greater, Lesser or Third) is considered **not medically necessary** for all indications, including but not limited to occipital neuralgia, cluster headaches or refractory migraine headache.

VIII. Conscious sedation and/or Monitored Anesthesia Care (MAC) is considered **not medically necessary** for intra-articular facet joint injections or medial branch blocks and is not separately reimbursable.

All Other Ablative Procedures

IX. Other ablative procedures (e.g., pulsed RFA, cooled RFA, cryoablation, chemical ablation) are considered **not medically necessary** for the treatment of all types of back pain, neck pain, headaches (e.g., cluster, migraine), and occipital neuralgia.

Link to Evidence Summary

POLICY CROSS REFERENCES

- Intraoperative Monitoring (Company), MP295
- Genicular Nerve Blocks and Nerve Ablation for Knee Pain (Company), MP227

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

The following information must be submitted in order to determine if medical necessity criteria are met:

- Indication for the requested procedure
- Clinical notes documenting that the individual has been evaluated at least once by the requesting physician before submitting a request for procedure.
- Medical records must document that a detailed musculoskeletal/neurological examination has been performed by, or reviewed by the requesting physician, within 3 months prior to procedure.
    - Pre-procedural documentation must include a complete initial evaluation including history and an appropriately focused musculoskeletal and neurological physical examination. There should be a summary of pertinent diagnostic tests or procedures justifying the presence of facet joint pain and the absence of pain from other sources.
- Clinical documentation of extent and response to conservative care (see BACKGROUND for all requirements and exceptions), as applicable to the policy criteria, including outcomes of any procedural interventions, medication use and physical therapy notes
- Evaluation and documentation of the extent and specifics of one or more of the functional impairments or disabilities
- Evaluation and appropriate management of associated cognitive, behavioral or addiction issues if and when present
- Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months or at the time of onset of symptoms
    - 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
- A hard (plain radiograph with conventional film or specialized paper) or digital copy image or images which adequately document the needle position and contrast medium flow (excluding RF ablations and those cases in which using contrast is contra-indicated, such as patients with documented contrast allergies), must be retained and submitted if requested.

DEFINITIONS

Activities of daily living: The activities of daily living (ADLs) is a term used to describe essential skills that are required to independently care for oneself.[1] Examples may include, but are not limited to, the following:

- Ambulating
- Feeding
- Dressing
- Personal hygiene
- Transportation and shopping
- Meal preparation
- Housecleaning and home maintenance

Conservative treatments: Conservative care must be recent (within the last year) and include all of the following:

- Participation in a physical therapy program for the duration of conservative management (i.e., 3 months before surgery depending on the indication for surgery), including at least 3 physical therapy visits
- Oral analgesics (including anti-inflammatory medications, if not contraindicated) or participation in an interdisciplinary pain management program
- Oral corticosteroids (if not contraindicated)

Repeat Procedures: Repeat procedures are procedures performed at the same location as a prior procedure that has occurred within the preceding two years. If more than 2 years have passed since the previous RFA and/or there is a question as to the source of the recurrent pain, then diagnostic procedures must be repeated.

Session: A time period, which includes all procedures (i.e., medial branch blocks (MBB), intraarticular injections (IA), facet cyst ruptures, and RFA ablations) performed during one day.

BACKGROUND

Occipital Nerves

The occipital nerves are a group of nerves that arise from the C2 and C3 spinal nerves, innervating the posterior scalp up as far as the vertex. There are three major occipital nerves in the human body: the greater occipital nerve, the lesser (or small) occipital nerve, and the third (or least) occipital nerve.[2]

Cluster Headache

According to ECRI, "cluster headaches are a primary neurovascular disorder that patients experience as severe to very severe, one-sided head pain. Chronic CHs typically occur every other day, daily, or even several times daily with pain lasting from 15 minutes to a few hours."[3]

Migraine Headache

Migraine headache is defined as recurring headache attacks lasting 4 to 72 hours. "Typical characteristics of the headache are unilateral location, pulsating quality, moderate-to-severe intensity, aggravated by routine physical activity, associated with nausea, and/or photophobia and phonophobia." Migraines can also include an aura or perceptual disturbance. Common treatments of migraines include nonsteroidal anti-inflammatory drugs (NSAIDs), steroids, and triptans (e.g., sumatriptan). Preventative therapies are also available, including calcium channel blockers and corticosteroids.

Occipital Neuralgia

Occipital neuralgia is a rare neurological disorder characterized by piercing, throbbing, or electric-shock-like pain in the upper neck, back of the head, and behind the ears, usually on one side of the head.

Commonly, the cause of occipital neuralgia is unknown; however, it can occur due to irritation or injury to the occipital nerve. Therapies for occipital neuralgia may include pain medications, anesthetic injection, and steroids to reduce inflammation and block the transmission of pain signals.

Ablation of the Occipital Nerve

Ablative procedures (e.g., cryoablation, radiofrequency ablation, rhizotomy) are performed in the attempt to denervate the occipital nerve (greater or lesser), upper cervical nerve (e.g., second cervical nerve, also known as C2), supraorbital, supratrochlear or sphenopalatine ganglion. The proposed goal of denervation is to disrupt pain signals sent from the nerves to the brain without causing excessive sensory loss, motor dysfunction or other complications.

Occipital Nerve Stimulation (ONS)

ONS involves the implantation of subcutaneous electrodes at the base of the skull over the greater, lesser, or third occipital nerves. The electrodes are connected to leads which are tunneled together in a caudal direction to an impulse generator implanted in the chest wall, low back, buttocks, or abdomen. The generators can be controlled by the physician or patient and can provide continuous or intermittent stimulation. Additionally, the generators can be non-rechargeable with a 2 to 5 year lifespan or rechargeable.

Radiofrequency Ablation

Radiofrequency ablation (also known as RFA, RF lesioning, RF nerve ablation, RF neurotomy, RF denervation, RF coagulation or thermocoagulation, or RF rhizotomy), is a minimally invasive (percutaneous) technique used to destroy nerves using heat generated by radiofrequency emissions. It is typically used to treat persistent back and neck pain generated by diseased facets. However, it has also been proposed as a treatment to temporarily reduce other back and neck pain of non-facet origin, including the sacrum and the sacroiliac joint. It has also been proposed as a treatment of back and neck pain by targeting structures other than the facet joint and the medial branch, including the dorsal root ganglion and the intraosseous basivertebral nerve.

<u>Conventional (Non-Pulsed) Radiofrequency Ablation</u>

The conventional form of RFA is referred to as non-pulsed, or continuous RFA. During non-pulsed RFA, a constant application of radiofrequency energy delivers heat to the target nerve thereby creating a lesion that stops pain input to the central nervous system. Prior to planning the procedure, a diagnostic nerve block is conducted to ensure that the patient is a suitable candidate for RFA. The procedure is performed in an outpatient setting, typically by a pain specialist. It is usually performed under fluoroscopic guidance to facilitate localization of the target nerves. After local anesthetic has been injected, an RF cannula is inserted and advanced until it makes contact with bone. Stimulation is performed at 50 hertz to identify the location of each target nerve. Anesthetic may be applied to the target nerve to relieve pain during RFA. During conventional RFA, the RF probe is advanced through the

cannula and the temperature of the tip is typically increased to 70°C to 80°C for 90 to 120 seconds. One lesion is created at each of the target nerves.[4]

Pulsed Radiofrequency Ablation

Pulsed RFA (P-RFA) is another proposed alternative to conventional RFA. P-RFA involves the application of heat applied in short bursts instead of a continuous flow, allowing the tissue to cool between applications and a resulting tissue temperature of approximately 42°C or lower. Lower tissue temperatures and short bursts of application are thought to reduce the risk of destruction to nearby tissue. Examples of devices used for this procedure include, but may not be limited to, the Stryker MultiGen™ 2 RF Generator System (when used on the pulsed mode).

Cooled Radiofrequency Ablation

Cooled radiofrequency ablation/denervation (also known as C-RFA) is a variation on conventional RFA that is also being research. C-RFA maintains the tissue temperature immediately adjacent to the electrode at 60°C while the target nerve is heated to approximately 75°C. This purportedly allows for treatment of a large tissue area without the risk of adjacent tissue damage. Examples of devices used for this procedure include, but may not be limited to, the Coolief Cooled RF Probe.

Chemical Ablation

Chemical ablation may also be referred to as chemical neurolysis, chemical denervation or chemodenervation, and involves the injection of neurolytic agents (e.g., phenol, alcohol, glycerol, saline, and sodium morrhuate). This proposed treatment option for chronic pain generally results in a permanent destruction of the nerve.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

Several radiofrequency and cryosurgery devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Radiofrequency (RF) probes and lesion generators are considered class II devices. The FDA has approved over 60 RF probes (product code: GXI) and over 40 RF lesion generators (product code: GXD). Below are examples of these devices.

- NeuroTherm® NT 2000 (NeuroTherm, Inc.) received 510K clearance in 2011.[5] The FDA determined that this device was substantially equivalent to existing devices for use in lesioning neural tissue in the peripheral nervous system. Existing predicate devices included the NeuroTherm NT 1000 (cleared in 2006), Stryker Interventional Pain RF Generator and RF Electrodes and Cannulae (2004), and Cosman G4 RF Generator (cleared in 2008).

- The Stryker MultiGen™ 2 RF Generator System received 510K clearance in 2017 for "coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications. Examples include, but are not limited to: Facet Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy." This system may be used for both pulsed and non-pulsed/conventional RFA, depending on the setting.[6]
- COOLIEF* Cooled Radiofrequency Kit (Halyard Health, Inc.) received 510K clearance (K163236) in 2016 to be used in combination with the HALYARD* Radiofrequency (RF) Generator (PMG-BASIC/PMG-ADVANCED) for "the creation of Radio-Frequency (RF) heat lesions in nervous tissue for the relief of pain."[7]

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of ablative therapies as potential treatments for chronic back and neck pain of various etiologies. Below is a summary of the available evidence identified through October of 2024.

Because of the subjective nature of outcome measures like pain, randomized clinical trials (RCTs) are needed to determine whether outcomes are truly improved with the use of ablative procedures as opposed to placebo effect. Ideally, trials should be sufficiently powered to avoid spurious results, include homogenous patient populations, longer follow up periods, and report objective outcome measures such as imaging in addition to standardized methods of measuring subjective outcomes like pain severity and functional impairment. Therefore, the evidence review below has primarily focused on RCTs and systematic reviews that have included RCTs.

Despite the limited availability of high-quality evidence for the use of RFA for the treatment of persistent facet pain of the cervical and lumbar regions, RFA has evolved into a standard of care for treatment for these specific areas of the spine. Therefore, the evidence review below does not include conventional RFA for either the cervical or lumbar regions to treat facet pain.

Non-Pulsed Radiofrequency Ablation (RFA) for Facet Pain

Miscellaneous Non-Covered Indications for Facet Pain

There are no radiological findings conclusive for the diagnosis of lumbar facet syndrome. Studies have not been able to show correlation between facet joint pain and degenerative changes noted in radiographs.[8]

No studies were identified which examined the use of RFA at the level of a previous spinal fusion and in many of the available studies identified, these patients were excluded. Therefore, the safety and efficacy regarding the use of RFA to treat facet pain after fusion, has not been determined.

In 2013, Joo et al., compared the use of repeat RFA (n=20) to alcohol ablation (AA) (n=20) in patients with recurrent thoracolumbar facet pain after an initial successful RFA.[9] At the 24-month follow-up only one RFA patient compared to 17 AA patients were without facet joint pain. Authors concluded AA in medial branch block neurotomy provided superior long-term pain relief compared to repeat RFA. This

study is limited by small sample size, which limit conclusions regarding the use of repeat RFA compared to AA. No RCTs were identified regarding the safety and efficacy of initial RFA as a treatment of facet disease of the thoracic spine.

Non-Pulsed Radiofrequency Ablation (RFA) for Non-Facet Pain

Ablation/Denervation of the Dorsal Root Ganglion (DRG)

Systematic Reviews

In 2011, Chua et al. published the results of a systematic review that evaluated pulsed RFA (P-RFA) of spinal structures, including two small RCTs where treatment was directed at the DRG.[10] These two RCT are discussed in detail below.[11,12] Although both of the RCTs included reported a dissipation of the beneficial effects of RFA at 6-8 months, authors considered the evidence for P-RFA of the dorsal root ganglion "compelling" for treatment of cervical radicular pain, but found the evidence for PRF for lumbosacral pain to be of low methodological quality.

In 2013, Pope et al. published a review that included four studies for conventional (non-pulsed) radiofrequency, and 10 for P-RFA of the DRG for chronic radicular pain.[13] Regarding conventional RFA, the reviewers stated that "although prospective observational and retrospective studies have yielded consistent support for DRG treatment in the cervical, thoracic, lumbar, and sacral regions, controlled studies are less compelling, complicated by the challenge of the lurking deafferentation pain potential. Patient selection is vague. Larger, sham-controlled, prospective studies are required to elucidate the place of conventional RFA treatment of the DRG for treatment of chronic pain."

Regarding pulsed RFA, the reviewers stated that there was a paucity of RCTs (only one of the 10 studies included was randomized). Although results were "intriguing", further larger powered, prospective, randomized, sham-controlled studies were needed. The reviewers concluded that "despite a robust understanding of the DRG and its importance in acute nociception, as well as the development and maintenance of chronic pain, relatively poor evidence exists regarding current therapeutic strategies. More prospective studies are required to better qualify the role of the DRG in chronic pain care."

In 2015, Maas et al. published the results of a Cochrane review that assessed the effectiveness of RF denervation procedures for the treatment of patients with chronic low back pain (CLBP) due to various etiologies, including three RCTs for lumbar radicular pain.[14] The review concluded that the effectiveness of RFA on low pain back pain arising from the DRG was inconclusive. These three RCTs were heterogeneous in terms of:

- Diagnostic method: Three separate diagnostic blocks versus, low-volume segmental nerve block versus clinical features plus CT/MRI imaging findings.
- Treatment: Two studies used conventional RFA and one study used pulsed RFA.
- Comparator group: Two studies used placebo, and the other study used P-RFA plus cryodenervation for comparison.

In 2017, Facchini et al. published a review of pulsed RFA in the treatment of pain associated with different spinal conditions.[15] Four RCTs on P-RFA treatment for cervical radicular pain were included.

One study reported significantly better outcome at 3 months compared with sham. The other three studies concluded that P-RFA administered to a DRG might be as effective as transforaminal epidural steroid injection in terms of attenuating lumbar radicular pain caused by disc herniation. Three RCTs and seven observational studies evaluating P-RFA in managing disc herniation and radiculitis were included in the review. Although all studies reported good pain results, different comparator groups were used (placebo, corticosteroids, P-RFA + conventional RFA). In addition, the reviewers felt that the major issues concerning those studies were the lack of standardization of P-RFA parameters, enrolment criteria and heterogeneity in results reporting. There was also concern regarding the invasiveness of the treatment intradiscally.

In 2018, Kwak et al. published a systematic review of the effectiveness of P-RFA treatment on cervical radicular pain, including 4 studies, only one of which was an RCT.[16] The single RCT was published by Lee et al. in 2016 and is summarized below. The other included studies consisted of two small prospective case series (n= 15 and 21) and one small retrospective case series (n=22). All included studies suffer from small sample size and lack of long-term follow-up and all but one study suffer from poor study design and lack of a comparator group. The review not only included heterogeneous studies in terms of study design, but also reported significant heterogeneity between studies with regard to outcomes at multiple follow-up time points.

Randomized Controlled Trials (RCTs)

One small RCT published by Van Zundert et al. in 2007 randomized 23 patients with chronic cervical radicular pain to either P-RFA of the DRG or sham treatment groups.[11] Nine out of 11 patients in the treatment arm and four out of 12 in the three out of 12 in the sham group achieved at least 20% reduction in pain on VAS (P=0.02). At six month follow-up, more patients in the treatment group reduced their use of pain medication, but the difference was not significant. These findings must be confirmed in larger studies before drawing conclusions regarding the efficacy of pulsed RFA.

In 2008, Simopoulos et al. randomized 76 patients with chronic refractory lumbosacral radicular pain to one of two groups who received either P-RFA alone or P-RFA followed immediately by continuous RFA.[12] Two months after the procedure 70% and 82%, respectively, reported successful reduction of pain. These effects were lost by eight months in most patients. The between-group difference was not significant. The authors concluded that additional RCTs are required to determine the effectiveness of P-RFA to the DRG for lumbosacral pain.

In 2012, Fujii et al. reported on the use of P-RFA in a small RCT of 27 patients.[17] P-RFA was performed on the DRG for lumbosacral radicular pain, and control group was treated with nerve root block. VAS pain scores decreased significantly for each group post-treatment, but even at one year, there were no differences in outcomes between the two treatment groups.

In 2015, Koh et al. published the results of a small RCT (n=62 patients with chronic refractory lumbar radicular pain) that assessed the effects of combining P-RFA and transforaminal epidural injection (TFEI).[18] Because this was a combination treatment, compared to sham, the efficacy of RFA alone was not able to be determined. In addition, since this study recruited patients after they had already been treated with TFEI, the results of this study do not provide the efficacy of PRF as a first-line treatment. Lastly, this study had a very short follow-up time of 3 months.

In 2016, Lee et al. evaluated the comparative effectiveness of P-RFA administered to the DRG and transforaminal epidural steroid injections (TFESI) for the treatment of radicular pain due to disc herniation.[19] The RCT included 38 patients who received previous TFESI treatments for spinal radicular pain. The randomized patients (P-RFA group n=19; TFESI group n=19) were treated within 2-6 weeks after the first TFESI and evaluated at two, four, eight, and twelve weeks. No statistically significant differences in effectiveness were noted at any point in the follow-up period between the two treatment groups. One important limitation of this RCT was that the study reported a high attrition rate, losing 13.6% of patients to follow-up.

In 2017, Halim et al. published the results of a small RCT One RCT evaluating percutaneous cervical nucleoplasty (PCN) versus P-RFA of the DRG for treatment of cervical disc herniation. The trial involved 34 patients with radicular pain treated with either PCN (n=17) or PRF (n=17). At three months, both groups had significant reduction in pain, although neither was superior to other. This study is limited by small sample size and short-term outcomes Studies evaluating long-term outcomes supporting clinical efficacy are lacking.

Ablation/Denervation of the Ganglion Impar

Systematic Reviews

In 2024, Hayes published an update of a 2018 Hayes technology assessment of radiofrequency thermocoagulation (RFT) of the ganglion impar for the treatment of chronic coccydynia in adults, including three small (n=10 to 41) retrospective case series that were deemed of very-poor-quality.[20] The review indicated that there is also possible overlap in patients in two of the included studies due to overlap of investigators. All three studies reported improvements in pain from baseline at follow-up ranging from 6-12 months. According to the Hayes review:

> "Individual study limitations include nonrandomized, noncomparative studies, small to very small sample sizes, and absence of power analyses. None of the studies evaluated physical functioning, emotional functioning, or patients' rating of improvement, which are all considered critical outcomes in the assessment of chronic pain in clinical trials"

Hayes reported a rating of "**D2**" for use of ganglion impar RFT for the treatment of chronic coccydynia in adults due to a limited number of studies of very-poor individual study quality.

Nonrandomized Studies

The following nonrandomized study was not included in the Hayes review described above:

In 2014, Gopal and McCrory published the results of a retrospective review of 20 patients with a clinical diagnosis of coccygodynia and failed medical management treated with pulsed radio frequency (P-RFA) applied to the Ganglion of Impar.[21] The authors reported a 50% or greater improvement in pain at six and 12 months follow-up in 15 (75%) patients.

Ablation/Denervation of the Intraosseous Basivertebral Nerve

Systematic Reviews

In 2024, Hayes published an updated evidence review on Intracept intraosseous nerve ablation system (Relievant Medsystems Inc) for treatment of adults with low back pain.[22] Four studies (in eight publications) were included in the study review. Studies included 2 RCTs of fair quality and 2 pre-and post-test prospective studies of poor quality. All studies found improved pain levels and function from baseline. One RCT found improved benefits in pain levels and ODI compared with standard care at 3 months follow up. Another RCT found benefits of pain reduction and ODI compared to sham treatment, but they were not clinically meaningful, and benefit was only found at 3 months, with no difference found at 6 or 12 months follow up. Opioid usage was not clearly improved by Intracept across studies that investigated the outcome. Adverse effects were present but mostly minor. Limitations of the studies were lack of comparator groups for 3 of 6 studies and studies were of generally poor or fair quality. Hayes concluded that there is minimal support for the Intracept Intraosseous Nerve Ablation System for chronic low back pain.

Randomized Controlled Trials (RCTs)

In 2018, Fischgrund et al. evaluated the effectiveness of RF ablation of the basivertebral nerve (BVN), specifically using the Intracept System, for relief of chronic low back pain.[23] A total of 225 patients at 18 sites were enrolled: 147 patients were randomized to the Intracept System group (received treatment) and 78 were randomized to the sham group (received sham surgery). Longest follow-up was 12-months and the only outcomes assessed were subjective, patient-reported ODI and VAS scores. At 3 months the ODI improvement observed in the Intracept group was statistically superior to the sham group (p=0.019). The investigators reported that the improvements were sustained throughout the 12-month follow-up period. Limitations of this study include lack of long-term outcome data for the primary efficacy endpoint (comparative change in ODI from baseline to 3 months) and, as reported by the study investigators:

> "comparison of the difference in outcome score between the sham and treatment groups does not represent the clinical utility of the Intracept Procedure because a sham treatment is not a clinically acceptable treatment for chronic low back pain (CLBP) nor is a sham response likely to occur in an open label setting."

Nonrandomized Study

In 2017, Becker et al. published the results of a single-arm, industry-sponsored study of 17 individuals with chronic low back pain, with a follow-up of 12 months.[24] Outcomes evaluated were self-reported measures: the ODI, VAS score, and SF-36 scores. Statistically significant improvement in ODI observed at three months was maintained through the 12-month follow-up. The mean baseline VAS score decreased from 61 ± 22 to 45 ± 35 at three months follow-up ($p<0.05$), and the mean baseline physical component summary increased from 34.5 ± 6.5 to 41.7 ± 12.4 at three months follow-up (p=0.03). Limitations of this study include the small sample size and the non-randomized, unblinded, single-arm study design.

<u>Ablation/Denervation of the Sacrum and/or Sacroiliac Joint (SIJ)</u>

Systematic Reviews

In 2023, Hayes completed an updated health technology assessment of RFA for sacroiliac joint (SIJ) denervation as a treatment for chronic low back pain.[25] Ten studies met inclusion criteria including four RTCs, four retrospective comparative studies, one prospective pretest-posttest, and one prospective cohort study with historical controls. Follow-up periods ranged from 3 months to 6 years. Studies compared conventional RFA with conservative management (1 study), sham RFA (2 studies), SIJ block with steroid injections (2 studies), cooled RFA (CRFA (4 studies), pulsed RF (PRF) (1 study), and SIJ fusion (1 study), and 1 pretest-posttest study compared RFA treatment with baseline outcomes. Overall, the low quality of evidence suggests that conventional RFA for SIJ denervation may effective for reducing pain in adults with CLBP and has the potential to provide greater short-term pain relief than SIJ injections. The reduction in pain provided by conventional RFA may last up to 6 months, there is conflicting reports of how long these effects last. There is also uncertainty whether conventional RFA is associated with change in pain medication use, disability/function, or quality of life (QoL) as all had a very low-quality body of evidence. Overall very low-quality bodies of evidence result in uncertainty regarding comparative effectiveness of conventional RFA with conservative management, CRFA, PRF, and minimally invasive SIJ fusion.

Hayes assigned nonpulsed RFA a C-rating: "in adult patients with chronic low back pain (LBP) suggestive of lumbar or lumbosacral facet joint origin, with no definitive clinical and/or imaging findings, or proven specific causes of the pain, who have failed conservative treatment, and who demonstrate a positive response to diagnostic medial branch blocks. This Rating reflects some positive but inconsistent evidence of low quality suggesting that nonpulsed RFA is safe, and may improve symptoms of CLBP over the short to intermediate term, as well as remaining questions regarding patient selection criteria, long-term outcomes, and the comparative efficacy versus alternative therapies.

In 2018, Sun et al. published the results of a meta-analysis evaluating the efficacy and safety of C-RFA in treating chronic SIJ pain, including seven studies (N=240 patients).[26] Only two of the included studies were RCTS, which were small in size. The remaining five studies were all observational in nature, and four of them were retrospective in design. The authors noted that the sample size of the included studies was small and heterogeneity existed in terms of patient selection, with some studies including patients with failed back surgery syndrome and/or and previous back surgery while other studies excluded patients with history of spinal surgery. Follow-up times also varied from 3-24 months, with only one study reporting outcomes beyond 12 months. The reviewers concluded that further high-quality, large-scale RCTs were required to validate the findings reported by the review.

In 2015, Maas et al. published the results of a Cochrane review that assessed the effectiveness of RF denervation procedures for the treatment of patients with chronic low back pain (CLBP) due to various etiologies, including two small RCTs for SI joint pain (n < 50 patients).[14] The reviewed stated that low-quality evidence revealed no differences pain (mean difference [MD] of -2.12, 95% CI -5.45 to 1.21) or function (MD -14.06, 95% CI -30.42 to 2.30) over the short term compared to placebo, and one study showed a small effect on both pain and function over the intermediate term (6 months). Quality of evidence for the outcomes assessed in the review ranged from low- to very-low.

Randomized Controlled Trials (RCTs)

In 2017, Juch et al. conducted three multicenter, non-blinded, randomized controlled trials (RCTS) to evaluate the effectiveness of radiofrequency denervation of the facet joints (n=251), sacroiliac joints (n=228), or a combination of both (n=202).[27] Regarding the sacroiliac joint trial, the mean difference

between pain intensity between the RFA and control groups at three months was -0.71 (95% CI: -1.35 to -0.06). The authors concluded, "(t)he findings do not support the use of radiofrequency denervation to treat chronic low back pain from these sources (facet joint, sacroiliac joint, or both)." Limitations of this RCT include lack of blinding, short follow-up, and lack of documentation regarding the use of sedation, which could skew trial results. In addition, based on the diagnostic block protocol and the level of pain relief from the block considered sufficient to proceed to ablation precludes generalizability of the results of this study.

Nonrandomized Studies

In 2017, Tinnirello et al. published the results of a small retrospective study (n=43) comparing two RF devices, Simplicity III (conventional, non-pulsed RFA), and SInergy (cooled RFA, C-RFA), which are specifically designed to denervate the sacroiliac joint (SIJ).[28] There were greater improvements in pain and function, based on self-reported scales, in the patients who were treated with C-RFA at both six and 12 months post-treatment, compared to those treated with conventional RFA. However, the authors concluded that RCTs were needed to confirm the implication made that "Sinergy C-RFA is the preferred RF denervation option for treating SIJ-derived pain and the disability associated with it."

Thoracic Pain

In 2021 (and archived in December 2021), Hayes published the results of a review that evaluated RFA for thoracic spinal indications, including two studies that used nonpulsed RFA and two studies that used pulsed RFA (P-RFA).[29,30] Both studies on nonpulsed RFA were retrospective uncontrolled cohort studies that evaluated nonpulsed RFA for thoracic pain of unknown or mixed etiology. The two P-RFA studies included one RCT (n=96) that treated patients with post-herpetic neuralgia compared to sham treatment, and one retrospective cohort study (n=49) that treated patients with postsurgical thoracic pain with either P-RFA, intercostal nerve RFA, RFA of the DRG, or pharmacologic therapy. Hayes rated the use of both pulsed and non-pulsed RFA for treatment of pain originating from the thoracic spinal region as a "**D2**" due to "conflicting evidence from a limited number of studies." Per the Hayes review:

> "Common individual study limitations resulting in downgrading of study quality included retrospective uncontrolled designs, lack of controls and blinding in some studies, and limited follow-up. Two studies enrolled patients with highly specific indications, limiting the applicability of the findings to broader populations. Substantial uncertainty remains regarding the use of RFA for thoracic pain of broader etiologies, the comparative efficacy of RFA versus alternative therapy, optimal treatment protocols, and long-term efficacy and safety."

Ablation of the Occipital Nerve

Several systematic reviews investigating the use of radiofrequency ablation (RFA) and pulsed radiofrequency ablation (PRFA) for the management of cervicogenic headache (CHA) were identified.[31-33] While numerous studies demonstrated benefit, investigators from each publication concluded that there was a lack of high-quality RCTs and/or strong non-RCTs to support the use of RFA and PRFA in the management of CHA. Limitations included studies' small sample sizes, lack of long-term follow-up, heterogenous treatment parameters, and lack of randomized comparator groups.

All Other Ablative Procedures

Pulsed RFA

Systematic Reviews

In the same review noted above (Hayes 2021) an assessment of RFA for cervical spinal indications was conducted.[29] The authors evaluated four small RCTs (n=23 to 62) and one small retrospective uncontrolled study that evaluated P-RFA. Two studies evaluated treatment of cervical radicular pain, while two studies focused on cervical radiculopathy due to disc herniation. Two RCTs found greater benefits of P-RFA versus sham treatment, one RCT found no difference between P-RFA and percutaneous cervical nucleoplasty (PCN) treatments, and one RCT found that P-RFA combined with nerve blockade was more efficacious than RFA alone. Limitations of the body of evidence include:

- differences across studies in indications and pain etiologies,
- varying P-RFA treatment protocols, outcome measures and definitions of treatment success
- limited long-term follow-up beyond one year
- conflicting results between studies

Limitations of the individual studies included in the review include one or more of the following:

- small sample sizes
- significant loss to follow-up,
- lack of blinding in some studies
- studies statistically underpowered or no power analysis
- uncontrolled study was deemed of poor quality

The review concluded that "uncertainty remains regarding the optimal P-RFA treatment parameters, including lesion temperatures, patient selection criteria, and long-term comparative efficacy and safety. This review also evaluated P-RFA for thoracic spinal pain, which is summarized in the "Miscellaneous Non-Covered Indications for Facet Pain: Thoracic Pain" section above.

In 2016 (updated 2021), Hayes published the results of a review that evaluated RFA for facet joint denervation for low back pain (LBP), including two studies evaluating P-RFA and one study comparing nonpulsed to P-RFA.[34,35] All three studies compared P-RFA to different comparator treatments. Two of the three studies reported no difference in pain relief between P-RFA and comparator treatment. The review stated that there was a small body of low-quality evidence that suggested that P-RFA was equivalent but not superior to sham therapy, steroid injections, and/or combined nonpulsed + P-RFA. Additionally, per the Hayes review:

> "comparison of data among studies was hindered by differences in patient inclusion criteria (e.g., patients with prior surgeries or unoperated patients, patients with varying responses to medial branch blocks), treatment protocols (type of electrodes, varying electrode placement, different ablation temperatures, numbers of procedures), follow-up times, and definitions of response and recurrence (complete or partial pain relief, pain relief duration)."

The review graded the use of P-RFA to treat LBP as a "D2" due to the paucity of evidence and indicated that additional studies were needed before any definitive conclusions can be reached about treatment effect.

Randomized Controlled Trials

A number of small RCTs were not included in the Hayes reviews above.

In 2016, Arsanious et al. published the results of an RCT that evaluated if immediate post-procedural pain scores and post-procedural oral analgesic use were reduced in patients receiving P-RFA via the Neuro-Therm© radiofrequency generator immediately followed by continuous non-pulsed RFA versus non-pulsed RFA alone, for facet joint pain, including 55 patients.[36] The results noted patients receiving P-RFA prior to non-pulsed RFA had less post-procedural pain and reduced analgesic requirements during the first 24 hours. The investigators concluded that long-term follow-up and studies with a larger population were needed to determine the efficacy of P-RFA in this adjunctive setting.

In 2016, Jena et al. published the results of an RCT that evaluated P-RFA for management of low back pain, including 40 patients with chronic discogenic low back pain who received non-pulsed RFA plus intradiscal triamcinolone or P-RFA plus intradiscal triamcinolone.[37] The authors reported that at 6-month follow-up the non-pulsed group had statistically significant improved VAS pain scores and improved function by the straight leg raise test.

Also in 2016, Wang et al. published the results of an RCT that evaluated the efficacy of cervical nerve root block (CNRB), P-RFA, and CNRB plus P-RFA for cervical radicular pain in 62 patients.[38] The patients were randomized into three groups and received either CNRB, P-RFA, or CNRB plus P-RFA. At 6-months follow-up, the combination therapy yielded statistically significant lower pain intensity numeric rating scale (NRS) scores and higher global perceived effect (GPE) overall improvement scores, than either CNRB or P-RFA alone. There were no statistically significant differences in NRS or GPE between the CNRB and P-RFA groups. The investigators concluded that follow-up of 6 months "is still too short to determine the long-term effects of this combined procedure. A study with a larger sample size and longer duration of follow-up may help to confirm the safety and efficacy of this combined approach."

In 2017, Chang et al. compared the effectiveness of bipolar P-RFA and monopolar P-RFA in patients with chronic lumbosacral radicular pain, including 50 patients.[39] Patients in both groups showed significant improvement in pain intensity NRS scores at 3-month follow-up compared to baseline scores. Reductions in the NRS scores over time were significantly larger in the bipolar P-RFA group. Three months after treatment, 19 patients (76.0%) in the bipolar group and 12 patients (48.0%) in the monopolar group reported pain relief of ≥50%.

Most recently in 2017, Do et al. published the results of an RCT comparing intra-articular lumbar facet joint P-RFA and intra-articular lumbar facet joint corticosteroid injections (CI) in 60 patients with lumbar facet joint pain.[40] Changes in pain intensity NRS scores for pain were assessed at baseline and three additional time points. Both groups had significantly reduced NRS scores for pain at each time point compared to baseline scores. At six months of follow-up, there was no significant difference in pain scores between the groups.

Of note, most of the RCTs described above evaluated P-RFA as an adjunctive treatment. This limits the ability to draw definitive conclusions regarding the efficacy of P-RFA as a stand-alone treatment for back pain originating from any source. All of the identified RCTs suffered from small sample size and lack of reporting of long-term outcomes.

Cooled RFA

Systematic Reviews

In 2014, Leggett et al. published a systematic review evaluating RCTs on RFA for chronic low back pain of various etiologies including pain associated with SI joints.[41] This review included two small RCTs (n=14 and 34) that evaluated continuous cooled RFA (C-RFA). One RCT was found to have high risk of bias with regards to blinding of both the participants and the providers, and the other RCT had an unclear risk of bias in terms of blinding. The reviewers reported that although the two studies suggested that continuous C-RFA was "efficacious in reducing SI joint pain, with only two available RCTs, more data on the efficacy of RFA for sacroiliac joint pain would strengthen this conclusion".

In 2021, Hayes published the results of a review that evaluated RFA for sacroiliac joint (SIJ) denervation as a treatment for chronic low back pain, four studies (two RCTs) evaluating cooled RFA (C-RFA), and one study evaluating comparing non-pulsed RFA to C-RFA.[42] Overall the body of evidence was considered to be of low quality. The review reported that consistently better functional outcomes and decreased use of analgesics with C-RFA compared to either baseline or comparator treatments. However, the evidence regarding overall success of the treatment and pain relief were conflicting. In addition, the review stated that there was "insufficient evidence to establish definitive patient selection criteria for cooled RFA as a treatment for SIJ-mediated chronic LBP."

Limitations of the body of evidence:

- a large proportion of the studies were observational and non-comparative in design
- follow-up times were generally short (between 3-6 months)
- comparator groups differed between studies (e.g., sham, another type of RFA)
- inconsistent/conflicting outcomes between studies

The review concluded the following:

- Longer-term studies are needed to determine the duration of pain relief associated with C-RFA and to evaluate the efficacy and safety of repeated treatments.
- "Good-quality studies comparing the effectiveness of conventional RFA with cooled RFA for chronic LBP are lacking. Therefore, questions remain as to the comparative efficacy and safety of these treatments."

Cryoablation

Nonrandomized Studies

In 2007, Birkenmaier et al., published the results of a small case series of 46 patients treated with medial branch cryoablation in the treatment of lumbar facet joint pain.[43] At 6-weeks follow-up, only 72% of

patients were self-reportedly pain free or had major improvement of pain. However, those with reduced pain reported improvement up to 12-month follow-up. Similar results have been reported in two other small prospective case series (n=50 and 76), with reductions in pain reported at 6- to 12-months follow-up in 40%-50% of patients.[44,45] These results have also been confirmed in a more recent retrospective observational study (n=91).[46] However, this retrospective study relied on a patient-completed questionnaire, which were initiated at a median of 1.7 years after the intervention.

All of the studies identified evaluating cryoablation where limited to treatment of lumbar facet pain and suffer from small sample size, heterogeneity in diagnostic parameters and ablation targeting techniques between studies, and lack of control groups.

CLINICAL PRACTICE GUIDELINES

American Society of Interventional Pain Physicians (ASIPP)

The 2020 ASIPP guidelines (an update of the 2013 guidelines) for facet joint interventions for the management of chronic spinal pain recommend the following:[47,48]

Lumbar Spine

- The level of evidence is II with moderate strength of recommendation for lumbar radiofrequency ablation with inclusion of 11 relevant randomized controlled trials (RCTs) with 2 negative studies and 4 studies with long-term improvement.
- The level of evidence is II with moderate strength of recommendation for therapeutic lumbar facet joint nerve blocks with inclusion of 3 relevant randomized controlled trials, with long-term improvement.
- The level of evidence is IV with weak strength of recommendation for lumbar facet joint intraarticular injections with inclusion of 9 relevant randomized controlled trials, with majority of them showing lack of effectiveness without the use of local anesthetic.

Cervical Spine

- The level of evidence is II with moderate strength of recommendation for cervical radiofrequency ablation with inclusion of one randomized controlled trial with positive results and 2 observational studies with long-term improvement.
- The level of evidence is II with moderate strength of recommendation for therapeutic cervical facet joint nerve blocks with inclusion of one relevant randomized controlled trial and 3 observational studies, with long-term improvement.
- The level of evidence is V with weak strength of recommendation for cervical intraarticular facet joint injections with inclusion of 3 relevant randomized controlled trials, with 2 observational studies, the majority showing lack of effectiveness, whereas one study with 6-month follow-up, showed lack of long-term improvement.

Thoracic Spine

- The level of evidence is III with weak to moderate strength of recommendation with emerging evidence for thoracic radiofrequency ablation with inclusion of one relevant randomized controlled trial and 3 observational studies.
- The level of evidence is II with moderate strength of recommendation for thoracic therapeutic facet joint nerve blocks with inclusion of 2 randomized controlled trials and 2 observational studies with long-term improvement.
- The level of evidence is III with weak to moderate strength of recommendation for thoracic intraarticular facet joint injections with inclusion of one randomized controlled trial with 6 month follow-up, with emerging evidence.

American Association of Neurological Surgeons and Congress of Neurological Surgeons (AANS/CNS)

In 2014, the AANS and CNS published joint guidelines on the treatment of degenerative disease of the lumbar spine, recommending the following:[49]

- "Lumbar medial nerve ablation is suggested for the short-term (3- to 6-month) relief of facet-mediated pain in patients who have chronic lower-back pain without radiculopathy from degenerative disease of the lumbar spine." This was a grade "B" recommendation, based on four RCTs.

- "Diagnostic facet blocks by the double-injection technique with an improvement threshold of 80% are an option for predicting a favorable response to facet medial nerve ablation by thermocoagulation for facet-mediated chronic low-back pain without radiculopathy in patients with degenerative disease of the lumbar spine." This was a grade "C", based on a single RCT.

National Institute for Health and Care Excellence (NICE)

In 2020, NICE updated a guideline on the management of low back pain in patients over 16 years old, recommending the following with regards to conventional (non-pulsed) RFA.[50]

- "Consider referral for assessment for radiofrequency denervation for people with chronic low back pain when:
    - non-surgical treatment has not worked for them **and**
    - the <u>main source of pain is thought to come from structures supplied by the medial branch nerve</u> **and**
    - they have moderate or severe levels of localised back pain (rated as 5 or more on a visual analogue scale, or equivalent) at the time of referral.
- Only perform radiofrequency denervation in people with chronic low back pain after a positive response to a diagnostic medial branch block."

This guidance is unchanged from the original 2016 publication and subsequent 2018 review/update.

North American Spine Society (NASS)

In 2023, NASS published a defining appropriate coverage position on Basivertebral Nerve Ablation, recommending BVN based on evidence showing short- to intermiediate-term improvements with function and pain.

They recommend the following:
"BVN ablation is indicated when:

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

BVN ablation is **NOT** indicated in ANY of the following scenarios:

- Evidence on imaging (MRI, flexion/extension radiographs, etc.) suggests another obvious etiology for the patient's LBP symptoms, including but not limited to lumbar stenosis, spondylolisthesis, segmental instability, disc herniation, degenerative scoliosis or facet arthropathy or effusion with clinically suspected facet joint pain
- Metabolic bone disease (eg, osteoporosis), treatment of spine fragility fracture, trauma/compression fracture or spinal cancer
- Spine infection or active systemic infection
- Neurogenic claudication, lumbar radiculopathy or radicular pain due to neurocompression (eg, HNP, stenosis), as primary symptoms
- Patients with severe cardiac or pulmonary compromise
- Patients with implantable pulse generators (eg, pacemakers, defibrillators) or other electronic implants unless specific precautions are taken to maintain patient safety."[51]

EVIDENCE SUMMARY

Non-Pulsed Radiofrequency Ablation (RFA) for Facet Pain

There is sufficient evidence regarding the safety and efficacy of non-pulsed RFA for facet pain in the cervical, thoracic, and lumbar regions. Evidence shows improvement to short and intermediate term pain and function and clinical guidelines recommend the procedure.

Non-Pulsed Radiofrequency Ablation (RFA) for Non-Facet Pain

Dorsal Root Ganglion Pain

There is insufficient evidence regarding the safety and efficacy of non-pulsed RFA for pain related to the dorsal root ganglion. The body of evidence consists mainly of observational studies, with only a small number of RCTs identified. RCTs evaluating RFA of the DRG are heterogeneous in terms of the diagnostic methods, types of RFA, and comparator groups used. In addition, no clinical practice guidelines were identified that addressed the use of non-pulsed RFA of the DRG to alleviate back or neck pain.

Ganglion impar Pain

There is a paucity of evidence regarding the safety and efficacy of non-pulsed RFA for pain related to the ganglion impar. The body of evidence consisted of four small retrospective case series. In addition, no clinical practice guidelines were identified that addressed the use of non-pulsed RFA of the ganglion impar to alleviate back pain.

Intraosseous Basivertebral Nerve Pain (e.g., Intracept Procedure)

There is enough evidence to support the use of intraosseous basivertebral nerve ablation (Intracept procedure) for a select population suffering from back pain. Evidence from randomized and observational studies shows improvement to short and intermediate term pain and function and clinical guidelines such as the North American Spine Society recommend the procedure.

Sacroiliac Joint Pain

There is insufficient evidence regarding the safety and efficacy of any type of ablative treatment for facet or non-facet pain in the sacroiliac joint region. The small number of RCTs that were identified compared non-pulsed RFA to were heterogeneous in terms of comparator groups and whether the treatment consistently led to improved outcomes. Most studies identified only reported short-term follow-up of 3-6 months. In addition, no clinical practice guidelines were identified that strongly supported the use of non-pulsed RFA to alleviate sacroiliac-related back pain.

Occipital Nerve Ablation

There is insufficient evidence to support the safety and efficacy of occipital nerve ablation for refractory migraine headaches or occipital neuralgia. Evidence addressing ablation of the occipital nerve is limited, with no demonstrated clinical utility reported in high-quality studies. Furthermore, no clinical practice guidelines recommend ablation for treating migraines or neuralgia. Therefore, ablation of the occipital nerve is considered not medically necessary.

All Other Ablative Procedures

Pulsed RFA

There is insufficient evidence regarding the safety and efficacy of pulsed RFA for facet or non-facet pain of the back or neck. The small number of RCTs that were identified for any given pain generator were typically small in sample size, reported short-term follow-up, were heterogeneous in terms of comparator groups and whether the treatment consistently led to improved outcomes. In addition, no clinical practice guidelines were identified that strongly supported the use of pulsed RFA to alleviate back or neck pain of any origin. Therefore, cooled RFA for facet or non-facet pain of the back or neck is considered not medically necessary.

Cooled RFA

There is insufficient evidence regarding the safety and efficacy of cooled RFA for facet or non-facet pain of the back or neck. The small number of RCTs that were identified for any given pain generator were typically small in sample size, reported short-term follow-up, were heterogeneous in terms of comparator groups and whether the treatment consistently led to improved outcomes. In addition, no clinical practice guidelines were identified that strongly supported the use of cooled RFA to alleviate back or neck pain of any origin. Therefore, pulsed RFA for facet or non-facet pain of the back or neck is considered not medically necessary.

Cryoablation

There is insufficient evidence regarding the safety and efficacy of cryoablation for facet or non-facet pain of the back or neck. All of the studies identified evaluating cryoablation were limited to treatment of lumbar facet pain and suffer from small sample size, heterogeneity in diagnostic parameters and ablation protocol, and lack of control groups. In addition, no clinical practice guidelines were identified that addressed the use of cryoablation to alleviate back or neck pain of any origin. Therefore, cryoablation for facet or non-facet pain of the back or neck are considered not medically necessary.

HEALTH EQUITY CONSIDERATIONS

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.

The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online here.

BILLING GUIDELINES AND CODING

Frequency Limits

Facet Joint Interventions generally consist of three types of procedures: Intraarticular (IA) Facet Joint Injections, Medial Branch Blocks (MBB) and Radiofrequency Ablations (RFA)

- Facet Joint Procedures (IA or MBB): For each covered spinal region no more than four (4) joint sessions will be reimbursed per rolling 12 months.
- Facet joint denervation: For each covered spinal region no more than two (2) radiofrequency sessions will be reimbursed per rolling 12 months. If member meets criteria for repeat ablation, an additional two (2) radiofrequency sessions (for a total a four) per rolling 12 months will be allowed.

Coding Guidance

Diagnostic and Therapeutic injections:

- Each facet level in the spinal region is composed of bilateral facet joints (i.e., there are two facet joints per level, one on the right side and one on the left). Unilateral or bilateral facet interventions may be performed during the facet joint procedure (a diagnostic nerve block), a therapeutic facet joint (intraarticular) injection, a medial branch block injection, or the medial branch radiofrequency ablation (neurotomy) in one session. A bilateral intervention is still considered a single level intervention.
- Each unilateral or bilateral intervention at any level should be reported as one unit, with bilateral intervention signified by appending the modifier -50.
- One medial branch block is counted as two (2) facet joint injections.

Regions:
An anatomic spinal region for paravertebral facet joint block (diagnostic or therapeutic), is defined as cervical\thoracic (CPT codes 64490, 64491, 64492) or lumbar\sacral (CPT codes 64493, 64494, 64495) per the AMA CPT Manual.

Levels:
- 64490 (cervical or thoracic) or 64493 (lumbar or sacral) reports a single level injection performed with image guidance (fluoroscopy or CT).
- 64491 or 64494 describes a second level which should be reported separately in addition to the code for the primary procedure. 64491 should be reported in conjunction with 64490 and 64494 should be reported in conjunction with 64493.
- 64492 or 64495 describes a third and additional levels and should be listed separately in addition to the code for the primary procedure and the second level procedure and cannot be reported more than once per day. 64492 should be reported in conjunction with 64490/64491 and 64495 should be reported in conjunction with 64493/64494.

Laterality:
- Bilateral paravertebral facet injection procedures 64490 through 64495 should be reported with modifier 50.
- For services performed in the ASC, do not use modifier 50. Report the applicable procedure code on two separate lines, with one unit each and append the -RT and -LT modifiers to each line.

Therapeutic injections:
Documentation of why patient is not a candidate for RFA must be submitted for therapeutic treatment.

Chemodenervation of nerve:

- Codes 64633, 64634, 64635, 64636 are reported per joint, not per nerve. Although two nerves innervate each facet joint, only one unit per code may be reported for each joint denervated, regardless of the number of nerves treated (AMA CPT Manual 2020).
- Each unilateral or bilateral intervention at any level should be reported as one unit, with bilateral intervention signified by appending the modifier -50.

Region:

- An anatomic spinal region for thermal facet joint denervation is defined as cervical/thoracic (CPT codes 64633 and 64634) or lumbar/sacral (CPT codes 64635 and 64636) per the AMA CPT Manual.
- For neurolytic destruction of the nerves innervating the T12-L1 paravertebral facet joint, use 64633.

Levels:

- 64633 or 64635 describes a single level destruction by neurolytic agent performed with image guidance (fluoroscopy or CT).
- 64634 or 64636 describes each additional level which should be reported separately in addition to the code for the primary procedure. 64634 should be used in conjunction with 64633 and 64636 should be used in conjunction with 64635.

Laterality:

- For bilateral procedures report modifier 50 on each line in which the intervention was of a bilateral nature.
- For services performed in the ASC, do not use modifier 50. Report the applicable procedure code on two separate lines, with one unit each and append the -RT and -LT modifiers to each line.
- Non-thermal facet joint denervation (including chemical, low grade thermal energy (<80 degrees Celsius or any other form of pulsed radiofrequency) should not be reported with CPT codes 64633, 64634, 64635 or 64636. These services should be reported with CPT code 64999. Code 64999 is non-covered when used to report non-thermal facet joint denervation.

<u>Intraoperative Monitoring</u>

Intraoperative neurophysiological testing and monitoring (CPT: 95940; HCPCS: G0453) will deny as not medically necessary when billed with radiofrequency ablation codes. See the Intraoperative Monitoring (Company) policy for criteria.

<u>Facet Joint Injections and Medial Branch Blocks</u>

The following codes for monitored anesthesia and moderate sedation will deny when billed with CPT codes for intra-articular facet joint injections or medial branch blocks (64490-64495):

- 00300
- 00600
- 00620

- 00630
- 00640
- 01992
- 99152
- 99153
- 99156
- 99157

Sacroiliac Joint Pain

The CPT code 64640, which is appropriate for destruction by neurolysis for sacroiliac joint pain, is not specific to the procedures and/or indications addressed in this policy. Code 64640 will be considered not medically necessary for the therapies addressed in this policy when the request is for any of the following ICD-10 diagnosis codes:

Code or Code Range	**Description**
G57.00 - G57.03	Lesion of sciatic nerve
M25.751 - M25.759	Osteophyte, hip
M43.08	Spondylolysis, sacral and sacrococcygeal region
M43.18	Spondylolisthesis, sacral and sacrococcygeal region
M43.28	Fusion of spine, sacral and sacrococcygeal region
M46.1	Sacroiliitis, not elsewhere specified
M46.98	Unspecified inflammatory spondylopathy, sacral and sacrococcygeal region
M47.28	Other spondylosis with radiculopathy, sacral and sacrococcygeal region
M47.818	Spondylosis without myelopathy or radiculopathy, sacral and sacrococcygeal region
M47.898	Other spondylosis, sacral and sacrococcygeal region
M48.08	Spinal stenosis, sacral and sacrococcygeal region
M48.8X8	Other specified spondylopathies, sacral and sacrococcygeal region
M51.17	Intervertebral disc disorders with radiculopathy, lumbosacral region
M53.2X8	Spinal instabilities, sacral and sacrococcygeal region
M53.3	Sacrococcygeal disorders, not elsewhere classified
M53.88	Other specified dorsopathies, sacral and sacrococcygeal region
M54.14 - M54.17	Radiculopathy, thoracic or lumbosacral region

M54.30 - M54.5	Sciatica and lumbago
M70.60 - M70.72	Trochanteric and other bursitis
M72.9	Neuralgia and neuritis, unspecified
M76.00 - M76.22	Enthesopathies, hip

CODES*		
CPT	01937	Anesthesia for percutaneous image-guided injection, drainage or aspiration procedures on the spine or spinal cord; cervical or thoracic
	01938	Anesthesia for percutaneous image-guided injection, drainage or aspiration procedures on the spine or spinal cord; lumbar or sacral
	01939	Anesthesia for percutaneous image-guided destruction procedures by neurolytic agent on the spine or spinal cord; cervical or thoracic
	01940	Anesthesia for percutaneous image-guided destruction procedures by neurolytic agent on the spine or spinal cord; lumbar or sacral
	01941	Anesthesia for percutaneous image-guided neuromodulation or intravertebral procedures (eg, kyphoplasty, vertebroplasty) on the spine or spinal cord; cervical or thoracic
	01942	Anesthesia for percutaneous image-guided neuromodulation or intravertebral procedures (eg, kyphoplasty, vertebroplasty) on the spine or spinal cord; lumbar or sacral
	64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
	64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)
	64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
	64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure)
	64640	Destruction by neurolytic agent; other peripheral nerve or branch
	64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
	64491	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level (List separately in addition to code for primary procedure)
	64492	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure)

	64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
	64494	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level (List separately in addition to code for primary procedure)
	64495	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure)
	64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)
	64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral
	64629	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure)
	20999	Unlisted procedure, musculoskeletal system, general
	22899	Unlisted procedure, spine
	27299	Unlisted procedure, pelvis or hip joint
	64999	Unlisted procedure, nervous system
HCPCS	None	

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY

2/2023	Converted to new policy template.
3/2023	Interim update. Combined with Occipital Nerve Ablation policy. Updated neck pain to include C2-3 and below.
6/2023	Interim update. Changed denial from investigational to not medically necessary.
1/2024	Annual update. Medical necessity criteria added for thoracic spine levels and intraosseous radiofrequency ablation of the basivertebral nerve.
5/2024	Interim update. Updated criteria wording and added “Policy Guideline” addressing repeat procedures.
12/2024	Annual review. No changes.
7/2025	Interim update. Clarified note regarding repeat diagnostic blocks.