Neuroablative Techniques for Chronic Pain

**Related Medicare Advantage Medical/Pharmacy Coverage Policies**

- Headache and Occipital Neuralgia Treatments
- Injections for Chronic Pain Conditions
- Physical Therapy and Occupational Therapy

**Related Documents**

Please refer to [CMS website](https://www.cms.gov) for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

<table>
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<th>Type</th>
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<th>Jurisdiction Medicare Administrative Contractors (MACs)</th>
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| NCD     | Induced Lesions of Nerve Tracts | 160.1                                      | J5, J8 - Wisconsin Physicians Service Insurance Corporation | IA, KS, MO, NE  
|         |                                |                                           |                                                            |  
| LCD LCA | Facet Joint Interventions for Pain Management | L38841  
|         |                                | A58477                                     |                                                            | IN, MI  
|         | Sacroiliac Joint Injections and Procedures | L39475  
|         |                                | A59257                                     |                                                            |  
| LCD LCA | Facet Joint Interventions for Pain Management | L35936  
|         |                                | A57826                                     | J6, JK - National Government Services, Inc. (Part A/B MAC) | IL, MN, WI  
|         | Peripheral Nerve Blocks        | L36850  
|         |                                | A57452                                     |                                                            | CT, NY, ME, MA, NH, RI, VT  
|         | Sacroiliac Joint Injections and Procedures | L39455  
|         |                                | A59233                                     |                                                            |  
| LCD LCA | Facet Joint Interventions for Pain Management | L38773  
|         |                                | A58364                                     | J15 - CGS Administrators, LLC (Part A/B MAC) | KY, OH  
|         | Sacroiliac Joint Injections and Procedures | L39383  
|         |                                | A59154                                     |                                                            |  
| LCD LCA | Facet Joint Interventions for Pain Management | L38801  
|         |                                | A58403                                     | JE - Noridian Healthcare Solutions, LLC | CA, HI, NV, American Samoa, Guam, Northern Mariana Islands  
|         | Injections – Tendon, Ligament, Ganglion Cyst, Tunnel Syndromes and Morton’s Neuroma | L34218  
|         |                                | A57079                                     |                                                            |  
|         | Nerve Blockade for Treatment of Chronic Pain and Neuropathy | L35456  
|         |                                | A56034                                     |                                                            |  
|         | Sacroiliac Joint Injections and Procedures | L39462  
|         |                                | A59244                                     |                                                            |  
| LCD LCA | Facet Joint Interventions for Pain Management | L38803  
|         |                                | A58405                                     | JF - Noridian Healthcare Solutions, LLC | AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY  
|         | Injections – Tendon, Ligament, Ganglion Cyst, Tunnel Syndromes and Morton’s Neuroma | L34076  
|         |                                | A57201                                     |                                                            |  
|         | Nerve Blockade for Treatment of Chronic Pain and Neuropathy | L35457  
|         |                                | A52725                                     |                                                            |  
|         |                                | L39464                                     |                                                            |  

Neuroablative techniques in pain management consists of several surgical and non-surgical methods to denervate a nerve. The goal of denervation is to interrupt the pain signals that are sent to the brain from the joints and nerves. An additional objective is to reduce the likelihood of, or to delay, any recurrence by selectively destroying pain fibers without causing excessive sensory loss, motor dysfunction or other complications.

Many techniques accomplish denervation including, but may not be limited to:

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

- **Cooled radiofrequency denervation** is a modification of conventional radiofrequency ablation (RFA), in that it maintains the tissue temperature immediately adjacent to the electrode at 60°C while the target tissue (nerve) is heated to 75°C or higher. This purportedly allows for a larger volume of treated tissue without the risk of damage to the adjacent tissue. Examples of devices used for this procedure include, but may not be limited to, the Accurian RF Platform (when used in the cooled RF mode), COOLIEF Cooled RF Probe and Coolief Sinergy (Coolief Sinergy is specifically for the sacroiliac joint).
• **Cryosurgery** may also be referred to as cryoablation or cryodenervation and is a technique of using extreme cold to destroy tissue, which is cooled to below -20°C by a probe circulating liquid nitrogen.

• **Cryotherapy** is similar to cryosurgery, in that it uses extreme cold to destroy tissue, but is generally used to specifically target cardiac tissue or peripheral nerves. The **CryoNB (cryo nerve block) therapy** is an example of cryotherapy; it is performed with the **CryoICE cryoSPHERE cryoablation probe** and is proposed as a method for blocking postoperative pain by temporarily ablating peripheral nerves.

• **Facet denervation** is one of the most commonly performed neuroablative procedures; it involves the destruction or interruption of a facet joint nerve (medial branch nerve) to relieve chronic pain in the cervical, thoracic or lumbar spine regions.

• **Intratect Intraosseous Nerve Ablation System** is a specialized radiofrequency ablation device, which has been granted US Food & Drug Administration (FDA) approval strictly for destruction of the basivertebral nerve of the L3-S1 vertebrae. It is proposed as a treatment option for low back pain.

• **iovera© System** is similar to cryosurgery, in that it uses cold to ablate a peripheral sensory nerve, but it is done in such a manner that it only produces a temporary denervation and subsequent interruption of the pain signals. It is purported that the nerves will slowly regenerate, and once the function is reestablished, normal nerve conduction resumes. This treatment may also be described as a cold injection or an iovera© injection. It has been suggested as a possible treatment for knee pain associated with osteoarthritis or for postoperative pain management in conjunction with total knee arthroplasty (replacement).

• **Laser ablation** is proposed as a noninvasive treatment which uses laser energy to ablate a peripheral nerve.

• **Pulsed radiofrequency denervation** is another proposed alternative to traditional radiofrequency neurotomy. It delivers short bursts of radiofrequency current instead of a continuous flow, which purportedly allows the needle to remain relatively cool so that the tissue temperature decreases slightly between each burst, reducing the risk of destroying nearby tissue. Examples of devices used for this procedure include, but may not be limited to, the **Accurian RF Platform**, **IonicRF Generator**, **MultiGen 2 RF Generator System** or **NeuroTherm NT2000IX** (when any of these devices are used in pulsed mode).

• **Radiofrequency ablation (RFA)** may also be referred to as nonpulsed radiofrequency ablation, percutaneous radiofrequency neuroablation, radiofrequency coagulation, radiofrequency denervation, radiofrequency lesioning, radiofrequency neuroablation, radiofrequency neurotomy or rhizotomy (articular rhizolysis). This percutaneous procedure utilizes radiofrequency current/energy to heat and ablate/denervate the target nerve. This technique involves the constant application of energy, usually at 80-85°C via an image-guided needle electrode inserted through the skin to the affected nerve. Examples of devices used for RFA include, but may not be limited to, the **Baylis Pain Management Radiofrequency Generator** and **G4 RF Generator**.
This policy addresses neuroablative/denervation (rhizotomy) procedures only, and should be distinguished from *intradiscal* electrothermal procedures, which is a treatment for back pain that applies heat to the *disc* or *disc wall*.

**Coverage Determination**

*iCare follows the CMS requirement that only allows coverage and payment for services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.*

*In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, *iCare may consider the following criteria:*  

**Facet Joint Denervation:**
Please refer to the above CMS guidance for **facet joint denervation**.

**Basivertebral Nerve Denervation**
Denervation of the *intraosseous* basivertebral nerve via radiofrequency ablation *(Intracept Intraosseous Nerve Ablation System)* will be considered medically reasonable and necessary for the treatment of chronic low back pain when **ALL** of the following requirements are met:

- Chronic lumbar back pain of at least 6 months duration that causes functional deficit measured on a **pain or disability scale***; **AND**

- Documented failure to respond to at least 6 months of **non-surgical management****; **AND**

- Absence of nonvertebrogenic pathology per clinical assessment or radiology studies that could explain the source of the individual’s pain including, but not limited to, fracture, tumor, infection or significant deformity; **AND**

- Evidence of Type 1 or Type 2 Modic changes on magnetic resonance imaging *(MRI)*, such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypotensive signals *(Type 1 Modic change)* and changes to the vertebral body marrow including replacement of normal bone marrow by fat and hypertensive signals *(Type 2 Modic change)*, in 1 or more vertebrae from L3-S1; **AND**

- Individual must have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to thermal destruction of the intraosseous BVN *(such screening must include psychological, as well as physical evaluation)*. Documentation of the history and careful screening must be available in the medical chart if requested; **AND**

- Thermal destruction of the intraosseous BVN must only be performed once per vertebral body from L3-S1 per lifetime. Up to 4 vertebral bodies may be treated during one procedure.
*Pain assessment and a disability scale must be obtained at baseline to be used for functional assessment.

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

- Avoidance of activities that aggravate pain;
- Trial of chiropractic manipulation;
- Trial of physical therapy (PT);
- Cognitive support and recovery reassurance;
- Injection therapy – epidural and/or facet;
- Spine biomechanics education;
- Specific lumbar exercise program;
- Home use of heat/cold modalities;
- Low impact aerobic exercise as tolerated;
- Pharmacotherapy (e.g., non-narcotic analgesics, nonsteroidal anti-inflammatory drugs [NSAIDs], muscle relaxants, neuroleptics and narcotics)

**NOTE:** Thermal destruction of the intraosseous BVN must only be performed once per vertebral body from L3-S1 per lifetime. Up to 4 vertebral bodies may be treated during 1 procedure.

**Morton’s Neuroma Denervation**
Denervation of a Morton’s neuroma via a neurolytic agent will be considered reasonable and necessary when ALL of the following requirements are met:

- Diagnosis of a swollen, inflamed nerve in the ball of the foot (e.g., Morton’s neuroma, Heuter’s neuroma, Hauser’s neuroma, or Iselin’s neuroma); AND

- The diagnosis has been confirmed with an injection of local anesthetics and/or steroids

**Trigeminal Nerve Denervation**
Denervation of the trigeminal nerve via nonpulsed radiofrequency ablation will be considered medically reasonable and necessary when ALL of the following requirements are met:

- Diagnosis of trigeminal neuralgia; AND

- Failure of 12 weeks of conservative treatment (pharmacological) under the direction of a healthcare professional, or inability to tolerate side effects of the medication(s)

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.
**Coverage Limitations**

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

Denervation of the intraosseous basivertebral nerve via radiofrequency ablation (Intracept Intraosseous Nerve Ablation System) will not be considered medically reasonable and necessary for the following:

- Active systemic infection or local infection at the intended treatment level;
- Active, untreated substance abuse disorder
- Advanced generalized systemic disease that limits quality-of-life (QOL) improvements would require a statement of the objective of treatment in such cases;
- Bleeding diathesis;
- BMI greater than 40;
- Diagnosed osteoporosis (T-score of -2.5 or less), spine fragility fracture history, trauma/compression fracture at the intended treatment level, or spinal cancer;
- Pregnancy;
- Previous lumbar/lumbosacral spine surgery at the intended treatment level (with the exception of discectomy/laminectomy if performed greater than 6 months prior to BVN nerve ablation and radicular pain resolved);
- Primary radicular pain into the lower extremities (defined as nerve pain following a dermatomal distribution and that correlates with nerve compression on imaging);
- Primary symptomatic lumbar or lumbosacral spinal stenosis (defined as the presence of neurogenic claudication and confirmed by imaging);
- Radiographic evidence of any of the following that correlates with predominant physical complaints:
  - Lumbar/lumbosacral disc extrusion or protrusion greater than 5mm at levels L3-S1;
  - Lumbar/lumbosacral spondylolisthesis at least 2mm at any level;
  - Lumbar/lumbosacral spondyloysis at levels L3-S1;
  - Lumbar/lumbosacral facet arthrosis/effusion correlated with facet-mediated pain at levels L3-S1;
- Skeletally immature patients (18 years of age or older);
- Severe cardiac or pulmonary compromise
The following ablative techniques will not be considered reasonable and necessary:

- Cooled radiofrequency denervation (including, but not limited to, the COOLIEF Cooled RF Probe and Coolief Sinergy); OR

- Endoscopic radiofrequency ablation/rhizotomy for any indication including, but not limited to, the facet joint/nerve; OR

- iovera° System, for any indication including, but not limited to, knee osteoarthritis or before/during/after total knee replacement surgery; OR

- Laser ablation¹⁶⁻²³; OR

- Pulsed radiofrequency denervation, for any indication; OR

- Radiofrequency ablation for the treatment of chronic pain including, but not limited to, the following conditions/areas of the body/nerves regardless of the type of neuroablative technique used:
  - Coccygodynia (coccydynia); OR
  - Dorsal root ganglia; OR
  - Hip, knee or pelvic/pelvis osteoarthritis/pain; OR
  - Nerves innervating the SIJ (the dorsal sacral rami lateral branch); OR
  - Post herniorrhaphy groin pain; OR
  - Sacroiliac joint (SIJ)³⁰⁻³⁵; OR
  - Sural nerve for ankle pain; OR
  - Terminal (peripheral) nerve ending; OR
  - Trigger point(s)

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There remains an absence of randomized blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

Summary of Evidence

Cooled Radiofrequency Denervation

COOLIEF Cooled RF Probe and Coolief Sinergy

Hayes, in their report for use of the Coolief system for osteoarthritis of the knee (KOA) found that the overall quality of the body of evidence for pain associated with KOA that is refractory to conservative measures was rated as very low. While studies generally demonstrated a reduction in pain from baseline up to 6 months, the clinical significance of this reduction was not consistently demonstrated. In addition, the lack of comparison with other minimally invasive techniques limits conclusions that can be drawn. A lack of long-term follow-up further inhibits conclusions that can be drawn regarding the durability of the effect of cooled RFA (CRFA). They also concluded that the overall quality of the body of evidence for the application
of CRFA with the Coolief system prior to TKA was very low. That evidence rating was based on the inclusion of 1 eligible study. An evidence base of 1 moderate-sized study provides an insufficient quantity of evidence to inform evidence-based conclusions.\textsuperscript{71}

ECRI concluded that the evidence is inconclusive due to very-low-quality comparative data when reviewing the Coolief system for KOA, noting study limitations include lack of blinding as well as short follow-up, and lack of studies comparing CRFA with standard RFA.\textsuperscript{45}

Hayes also looked at cooled RF as a treatment option for chronic low back pain arising from the SI joint; they reported an overall low-quality body of evidence evaluating CRFA that suggests it may be safe and potentially effective, though they also noted that it is uncertain whether it is effective in the longer term and what effect it may have on quality of life.\textsuperscript{70}

ECRI, in their report for the Coolief system for treating hip pain, concluded that the evidence is inconclusive due to too few data on the outcomes of interest; they found a small case series that suggests it is safe and reduces pain in chronic hip joint pain, but noted that the evidence is too limited in quantity and quality to permit conclusions. They noted that this puts the study at high risk of bias due to small sample size, retrospective design, single-center focus and lack of control/comparison groups.\textsuperscript{44}

\textit{iovera\textsuperscript{©} System}

Hayes noted, in their report for use of the iovera system for pain associated with total knee arthroplasty (TKA), a minimal level of support in their review of full-text clinical studies, as well as systematic reviews. They identified only 3 clinical studies, all of which, in their opinion, were of poor or very-poor quality, and did not report clear benefits in pain, function or quality of life across all follow-up visits, although they did note lower opioid consumption in at least some of their analysis.\textsuperscript{68} Hayes also reviewed the use of this device for treatment of knee osteoarthritis and, as with use for TKA, found minimal level of support in both the clinical studies and systematic reviews. Here they noted that while there was statistically significant reduction in pain and improvement in function over sham treatment at 90 day follow-up, there was no benefit at 120 and 180 days, suggesting a potential placebo effect. An additional limitation was identified, noting that no studies compared the iovera with active treatment, and none identified potential clinical benefits of repeat administration.\textsuperscript{67}

ECRI found mixed results in their review, noting that it is unclear if the device reduces postoperative pain and opioid use or improves function and quality of life compared with standard care post TKA because available studies (two randomized controlled trials [RCTs] and three nonrandomized controlled studies), are all at high risk of bias and report conflicting results.\textsuperscript{48}

\textit{Pulsed Radiofrequency Denervation}

Hayes, in their report for chronic pain arising from the sacroiliac joint, found an overall very low quality body of evidence that is insufficient to allow conclusions regarding the efficacy and safety of pulsed RF for this indication, as well as a very small and limited body of evidence.\textsuperscript{70} They also performed a review of pulsed RF for chronic cervical spine pain, again noting an overall low quality body of evidence, though those studies did find improved pain for up to 3 to 6 months.\textsuperscript{73} In their review of pulsed RF for chronic shoulder pain they found some positive but low quality evidence suggesting it is safe and may improve pain and function, though they went on to note that substantial uncertainty remains regarding comparative effectiveness versus alternative therapies, long-term outcomes and patient selection criteria.\textsuperscript{75}
Radiofrequency Ablation for Coccygodynia (Coccydynia)
Hayes found the quality of evidence to be very low, citing limitations of the individual studies, a small number of comparative studies and a lack of experimental studies. Overall quality of the evidence was based on the balance of benefits and complications and was assessed taking into consideration the quality of the individual studies and the applicability of the data to general practice. All studies were retrospective and observational. The evidence base comprised 3 poor-quality studies and 1 very poor-quality study. Limitations of the individual studies also included insufficient follow-up time to determine some long-term outcomes.72

Radiofrequency Ablation for Hip, Knee or Pelvic/Pelvis Osteoarthritis/Pain
Hayes reported that the quantity of published, peer-reviewed human clinical data is insufficient to evaluate radiofrequency nerve ablation for the treatment of hip pain, noting a search of peer-reviewed literature yielded a scant amount of evidence pertaining to the use of radiofrequency nerve ablation to treat hip pain.64

In their report for RF nerve ablation for the treatment of KOA, Hayes concluded that a low-quality evidence base suggests that RFA of the genicular nerves may result in improvements in pain and function in patients with treatment-refractory pain associated with KOA; however, substantial uncertainty exists as to the consistency of clinically significant improvements in pain and the duration of effect of RFA on KOA-related pain. In addition, few studies evaluated the effect of RFA of the genicular nerve on QOL, and a standardized treatment protocol is lacking.76

Radiofrequency Ablation for Post Herniorrhaphy Groin Pain
UpToDate reported that the outcomes of nerve ablation are less favorable than surgical nerve excision, as nerve ablation only destroys the offending nerve ending(s), and recurrent pain may develop after subsequent nerve regeneration.107

Radiofrequency Ablation of the Sural Nerve for Ankle Pain
Hayes reported insufficient published evidence to assess the safety and/or impact on health outcomes or patient management using RFA to the sural nerve as a treatment option for ankle pain.86

Radiofrequency Ablation of Trigger Point(s)
A review of the current medical literature shows that there is no evidence to determine that this service is standard medical treatment. There is an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Coding Information
Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.
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<td>Probe/needle, cryoablation</td>
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References


### Change Summary

- 01/01/2024 New Policy.