

Clinical Policy Title: Radiofrequency ablation for spine pain

Clinical Policy Number: CCP.1010

Effective Date:	June 1, 2013
Initial Review Date:	March 21, 2013
Most Recent Review Date:	February 5, 2019
Next Review Date:	February 2020

Policy contains:

- Low back pain.
- Neck pain.
- Non-pulsed radiofrequency ablation.

Related policies:

CCP.1030	Spine pain — facet joint injections
CCP.1043	Chiropractic care
CCP.1063	Spinal surgeries
CCP.1098	Spinal cord stimulators for chronic pain
CCP.1113	Cervical artificial total disc replacement
CCP.1213	Interspinous dynamic stabilization devices

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of non-pulsed radiofrequency ablation to be clinically proven and, therefore, medically necessary for members with chronic cervical or lumbar spine pain when all of the following criteria are met (InterQual[®], 2018a, 2018b; Manchikanti, 2013b):

- Pain has persisted for \geq three months.
- Conservative treatment has failed to alleviate pain, defined as:
 - \circ Nonsteroidal anti-inflammatory drugs or acetaminophen \geq three weeks.
 - Activity modification \geq six weeks.
 - Physical therapy \ge six weeks.
- Pain is nonradicular by physical examination.

- Pain is aggravated by hyperextension, rotation, or lateral bending of the spine, depending on the orientation of the facet joint at that level.
- No neurologic deficits exist.
- Imaging is nondiagnostic for pain etiology.
- Facet joint origin of pain is suspected with a documented pain reduction ≥ 80 percent using a dual diagnostic medial branch block.

AmeriHealth Caritas considers the use of additional non-pulsed radiofrequency ablation to be clinically proven and, therefore, medically necessary for members who require (InterQual, 2018a, 2018b):

- A second neuroablation ≤ two levels different than the first neuroablation (unilateral or bilateral) and meet the above medical necessity criteria, provided that at least one week has passed since the first neuroablation.
- Repeat neuroablation to the same side(s) and same level(s) as the initial neuroablation series and meet all of the following criteria:
 - Return of original pain.
 - Documented pain reduction \ge 50 percent after initial neuroablation.
 - \circ At least six months have elapsed since the last treatment per level, per side.
 - Documented pain relief lasts \geq six months.
 - No prior spinal fusion, infection, or malignancy at level selected for neuroablation.

AmeriHealth Caritas considers the use of pulsed radiofrequency ablation to be investigational and therefore, not medically necessary for treatment of spine pain (Itz, 2016; Manchikanti, 2009).

Limitations:

All other uses of non-pulsed radiofrequency ablation therapies are not medically necessary, including, but not limited to, the following:

- Pain of thoracic spine, sacroiliac joint, or coccyx origin (Aydin, 2010; Legget, 2014; Manchikanti, 2009, 2012a).
- Instances of no improvement in pain after a medial branch blockade (InterQual, 2018a, 2018b).
- Less than a six-month interval has elapsed between treatments at the same anatomical site (InterQual, 2018a, 2018b).
- Ablation performed without fluoroscopic guidance (Watters, 2014).
- Ablation not performed at the medial branch of the spinal nerve innervating the facet joint.

Radiofrequency ablation of the paravertebral facet joints must be performed by physicians who are board-certified in the diagnosis and treatment of members with chronic and acute spine pain.

For Medicare members only:

AmeriHealth Caritas considers the use of non-pulsed radiofrequency ablation to be clinically proven and, therefore, medically necessary for Medicare members with intractable spine pain when all of the above medical necessity criteria are met, with the following exceptions (National Coverage Determination 160.1; Local Coverage Determinations L33814; L34974; L36471; L35996; L34892; L33930):

- For initial radiofrequency ablation:
 - Facet joint origin of pain is suspected with a documented pain reduction ≥ 50 percent using the dual diagnostic nerve block technique.
 - Pain relief is maintained for \geq three months.
- Subsequent radiofrequency ablation involving the same joints within 12 months:
 - Documented pain reduction \geq 50 percent after previous radiofrequency ablation.
 - Documented improvement in activities of daily living for \geq six months.

For each covered spinal region (cervical/thoracic or lumbar), no more than two thermal radiofrequency sessions are considered medically necessary in any rolling 12-month year, involving no more than four joints per session (e.g., two bilateral levels or four unilateral levels).

Alternative covered services:

- Pharmaceutical therapy (e.g., analgesics, non-steroidal anti-inflammatory drugs, and antidepressants).
- Psychological and behavioral health services.
- Physical and occupational therapy.
- Chiropractic care.
- Surgery.
- Interventional procedures (e.g., nerve blocks, spinal injections) for administering local anesthesia.

Background

Chronic, persistent low back and neck pain is seen in 25 percent and 60 percent of patients, respectively, one year or longer after the initial episode (Manchikanti, 2013a). From 1999 to 2008, mean inflationadjusted annual ambulatory expenditures on medical care for patients with chronic spine pain increased by 95 percent (Davis, 2012). Management of chronic spine pain in the era of the opioid epidemic challenges providers to explore alternative, cost-effective pain relief options.

Effective treatment may be difficult to achieve without a clear cause of the pain, yet a definitive diagnosis is often difficult given the complexity of chronic spine pain. Minimally invasive interventional techniques identify and modulate the neurophysiologic origin of pain, when present (Manchikanti, 2013b). Diagnostic techniques such as diagnostic facet joint nerve blocks, sacroiliac joint injections, and provocation discography are used to identify the origin of pain. Pain relief consistent with the expected duration of action of the agent used suggests a genuine, physiologic response. Moderate-quality

evidence from 13 studies supports 75 percent to 100 percent pain relief with dual diagnostic facet joint nerve blocks as the criterion standard (Falco, 2012b).

Radiofrequency ablation:

Interventional treatments provide neuromodulation of spine pain at various pain origins. Radiofrequency ablation (or neurotomy) is a nonsurgical approach that applies electrocautery to denature (or injure) the nerve (Manchikanti, 2013b). There are two types of radiofrequency ablation. Non-pulsed radiofrequency ablation applies an electrode and undisrupted high-voltage, high-frequency electrical current at 80°C to 85°C for a predetermined amount of time to disrupt pain signals that are sent to the brain from a specific body area. The current produces heat and coagulation, causing denervation in the targeted tissue sites. Treatment should be directed to at least two levels of a single joint for successful denervation. Destruction of nerve fibers may be temporary or permanent. When the axons regenerate, the pain may return, requiring repeated procedures.

Pulsed radiofrequency ablation delivers short bursts of radiofrequency current to the tissue surrounding the electrode (Manchikanti, 2013b). The interrupted, short bursts of high-voltage electrical current do not exceed 42°C, allowing the surrounding tissue to cool without causing tissue coagulation.

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.
- The Cochrane Library.

We conducted searches on January 8, 2019. Search terms were: "radiofrequency ablation" (MeSH), "low back pain" (MeSH), "neck pain" (MeSH), "spine pain" (MeSH), and "treatment back pain."

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- Guidelines based on systematic reviews.
- Economic analyses, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes sometimes referred to as efficiency studies which also rank near the top of evidence hierarchies.

Findings

Guidelines from medical professional societies (American Society of Anesthesiologists, 2010; Itz, 2016; Manchikanti, 2009) and systematic reviews (Falco, 2012a; Leggett, 2014; Manchikanti, 2012b) indicate that non-pulsed radiofrequency ablation therapy provides effective pain relief of cervical and lumbar facet joint origin by interruption or denervation. For facet joint pain, radiofrequency ablation of the innervating medial branches of the rami dorsalis of the affected segmental nerves can be performed with the expectation of pain control for three to 12 months and functional improvement for three to six months (Itz, 2016).

However the evidence of effectiveness is derived from studies with significant methodological limitations that may impact data interpretation (Falco, 2012a; Leggett, 2014; Manchikanti, 2012b). Few randomized controlled or comparative trials of radiofrequency ablation with adequate sample size and follow-up duration have been published, and the majority of evidence is taken from small randomized controlled trials, prospective uncontrolled studies, case series, and retrospective chart analyses.

The success rate will depend on careful patient selection. Non-pulsed radiofrequency ablation should be considered a second-line treatment option after conservative treatments have failed to provide pain relief (Itz, 2016; Manchikanti, 2009) and when previous diagnostic or therapeutic injections of the joint or medial branch nerve have provided temporary relief (American Society of Anesthesiologists, 2010).

There was insufficient evidence supporting the effectiveness of non-pulsed radiofrequency ablation as treatment for lumbar discogenic pain, coccyx pain, sacroiliac joint pain, or thoracic spine pain (Aydin, 2010; Legget, 2014; Manchikanti, 2009, 2012a). The effectiveness of pulsed radiofrequency for any spine pain indication is inconclusive (Itz, 2016; Manchikanti, 2009).

The American Society of Interventional Pain Physicians suggests treatment intervals of at least six months per each region treated (maximum of two times per year), provided that 50 percent or greater relief is obtained for 10 to 12 weeks (Manchikanti, 2009). They further suggest treating all regions at the same time, provided all procedures are performed safely.

Policy updates:

In 2017, we identified a systematic review (Engel, 2016) from the International Spine Intervention Society that examined cervical radiofrequency ablation in treatment of chronic neck pain of zygapophysial joint origin. The endpoints were 100 percent relief of pain at six and 12 months after treatment. A majority of patients were pain-free at six months after treatment, and more than one-third were pain-free at one year. Two treatments were required for complete pain relief at six months. The authors noted few side effects and concluded that fluoroscopically guided cervical radiofrequency ablation is effective for abolishing zygapophysial joint pain and carries only minor risks.

In the 2018 update, we did not identify any relevant, newly published literature.

In 2019, we added two evidence-based guidelines (Manchikanti, 2013b; Watters, 2014), InterQual criteria (2018a, 2018b) for percutaneous neuroablative procedures, one National Coverage Determination (160.1), and six Local Coverage Determinations to the policy. Manchikanti (2013b), Watters (2014), and InterQual criteria recommend using the dual diagnostic medial branch block technique with a pain-reduction threshold of at least 80 percent to minimize the high false positive rate associated with the previous 50 percent threshold. However, Medicare Local Coverage Determinations still apply the 50 percent pain relief threshold for diagnosing facet nerve etiology (Medicare Local Coverage Determinations L33814; L34974; L36471; L35996; L34892; L33930). Therefore, we modified the medical necessity criteria to align with InterQual criteria and guideline recommendations, and added a separate Medicare section to the policy to reflect differences in recommendations between Medicaid and Medicare members.

The policy ID was changed from CP# 03.02.02 to CCP.1010.

References

Professional society guidelines/other:

American Society of Anesthesiologists. Practice guidelines for chronic pain management. An updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. *Anesthesiology* 2010;112:810-833. Doi: 10.1097/ALN.0b013e3181c43103.

Engel A, Rappard G, King W, Kennedy D. Standards Division of the International Spine Intervention Society. The effectiveness and risks of fluoroscopically-guided cervical medial branch thermal radiofrequency neurotomy: A systematic review with comprehensive analysis of the published data. *Pain Med*. 2016 Apr;17(4):658-669. Doi: 10.1111/pme.12928.

InterQual 2018.1 Procedures Criteria. Neuroablation, Percutaneous. Cervical facet joint pain. Change Healthcare LLC. Philadelphia, Pennsylvania.(a)

InterQual 2018.1 Procedures Criteria. Neuroablation, Percutaneous. Lumbar facet joint pain. Change Healthcare LLC. Philadelphia, Pennsylvania.(b)

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Watters WC, 3rd, Resnick DK, Eck JC, et al. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 13: Injection therapies, low-back pain, and lumbar fusion. *J Neurosurg Spine*. 2014;21(1):79-90. Doi: 10.3171/2014.4.spine14281.

Peer-reviewed references:

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Davis MA, Onega T, Weeks WB, Lurie JD. Where the United States spends its spine dollars: Expenditures on different ambulatory services for the management of back and neck conditions. *Spine (Phila Pa 1976).* 2012;37(19):1693-1701. Doi: 10.1097/BRS.0b013e3182541f45.

Falco FJ, Manchikanti L, Datta S, et al. An update of the systematic assessment of the diagnostic accuracy of lumbar facet joint nerve blocks. *Pain Physician*. 2012;15(6):E869-E907. <u>http://www.painphysicianjournal.com/current/pdf?article=MTc4NQ%3D%3D&journal=71</u>. Accessed January 9, 2019.(a)

Falco F, Manchikanti L, Datta S, et al. Systematic review of the therapeutic effectiveness of cervical facet joint interventions: an update. *Pain Physician* 2012;15(6):E839-E868. <u>http://www.painphysicianjournal.com/current/pdf?article=MTc4NA%3D%3D&journal=71</u>. Accessed January 9, 2019.(b)

Leggett LE, Soril LJ, Lorenzetti DL, et al. Radiofrequency ablation for chronic low back pain: a systematic review of randomized controlled trials. *Pain Res Manag.* 2014;19(5):e146-e153. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4197759/. Accessed January 9, 2019. Manchikanti KN, Atluri S, Singh V, et al. An update of evaluation of therapeutic thoracic facet joint interventions. *Pain Physician*. 2012;15(4):E463-E481.

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Centers for Medicare & Medicaid Services National Coverage Determinations:

NCD 160.1 Induced Lesions of Nerve Tracts.

Local Coverage Determinations:

L33814 Destruction of Paravertebral Facet Joint Nerve(s).

L34974 Facet Joint Injections.

L36471 Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy.

L35996 Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy.

L34892 Facet Joint Interventions for Pain Management.

L33930 Paravertebral Facet Joint Blocks.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

CPT Code	Description	Comments
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)	
64999	Pulsed radiofrequency ablation	

ICD-10 Code	Description	Comments
M54.2	Cervalgia	

M54.4	Low back pain	
M54.9	Dorsalgia unspecified	

HCPCS Code	Description	Comments
N/A		