Molina Clinical Policy
Radiofrequency Ablation (RFA) for Chronic Back Pain Associated with the Facet Joint: Policy No. 085

Last Approval: 4/5/2021
Next Review Due By: April 2022

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members.[1] References included were accurate at the time of policy approval and publication.

OVERVIEW

The **facet joints (zygapophyseal joints or z-joints)** are paired synovial joints located in the posterior compartment of the spine and innervated by the dorsal medial rami of the spinal nerves. The role of the facet joints is to limit hyperflexion, extension, lateral flexion, and axial rotation. In some patients, facet joints have been identified as the source of neck, thoracic, and lower back pain, particularly facetogenic back pain. The synovial membrane that surrounds the facet joint can be stretched, strained, or trapped, causing facet joint pain (Falco et al., 2012; Manchikanti et al., 2013a; Manchikanti et al., 2015; Allegri et al., 2016; Manchikanti et al., 2016). Diagnostic medial branch block (MBB) requires injecting a local anesthetic, such as lidocaine or bupivacaine, near the medial branch that supplies the facet joint with the intent of guiding facet treatment by eliminating pain associated with the affected joint for the duration of the anesthetic effect, whereas blocking a non-painful joint with an anesthetic has no effect on pain. Patient selection for RF neurotomy should be based on response to controlled diagnostic blocks, according to guidelines (ASIPP, 2013).

Radiofrequency facet joint ablation/denervation (RFA) (alternatively referred to as percutaneous RFA, radiofrequency facet neurotomy, radiofrequency facet rhizotomy, or radiofrequency articular rhizolysis) is a percutaneous procedure involving the use of RF energy to heat tissue to the point of ablation (Manchikanti et al., 2016). Facet denervation is intended to provide long-term pain alleviation. However, nerves regenerate, thus repeat treatments may be necessary (Cohen et al. 2020).

- Conventional RFA, also known as nonpulsed or thermal RFA, involves applying steady heat to the afflicted nerve using an image-guided needle electrode percutaneously. This procedure causes denervation providing pain relief for chronic (longer than 3 months) neck and back pain; however, higher temperatures can lead to larger lesions that compromise adjacent tissues (Qaseem et al. 2017).
- Pulsed RFA (PRFA) has been proposed as a non-ablative alternative to conventional RFA (also referred to as cool RFA). Instead of the continuous flow of RF current produced by continuous RF generators, PRFA delivers short bursts of radiofrequency current, allowing the tissue to cool between bursts, resulting in significantly lower maximum temperatures when compared to the continuous mode and reducing the risk of neighboring tissue destruction. It does not compromise the target nerve and surrounding tissue, hence requiring less accurate electrode placement.

Both RFA (nonpulsed) and PFRA (pulsed) are performed in the outpatient setting and appear safe for persistent lower back pain (LBP), with minimal safety issues reported. *Nonpulsed RFA* has a moderate-quality but conflicting evidence for its efficacy, while pulsed RFA lacks published peer-reviewed scientific literature supporting its efficacy in adult patients with chronic LBP.

Regulatory Status

RFA for spinal pain is a procedure, it is not regulated by the FDA. However, the FDA oversees RFA equipment, and there are various devices approved for use in conducting RFA for neurosurgical operations that are listed in the FDA 510(k) database. These devices are classified according to two product codes: radiofrequency lesion generators (GXD) and radiofrequency lesion probes (GXI).

RELATED POLICIES

Sacroiliac Injections and Radiofrequency Ablation (RFA) for Sacroiliac Joint Pain: Policy No. MCP-033

COVERAGE POLICY

Non-pulsed, Conventional radiofrequency ablation (RFA) **may be considered medically necessary** for chronic cervical or lumbar neck or back pain in adults who are age 18 years or older as part of a comprehensive pain management treatment program when **ALL** of the following criteria are met:

1. Diagnosis of chronic severe somatic, non-radicular back pain (cervical or lumbar) defined as persisting beyond three (3) months and affecting activity of daily living functional ability (> 6 on NRS Pain Rating Scale*); **AND**

2. Inadequate response to a minimum of three (3) months of conservative therapy that includes **ALL** of the following:

    a. Physical therapy for a minimum of four (4) weeks (3-4 times per week for a total of 12 sessions); **OR** Documentation of the basis for physical therapy contraindication. If ANY of the following conditions exist, PT may be contraindicated:
        - Pain worsened with physical therapy, **OR**
        - Physical therapy tried but was not able to be tolerated

    AND

    b. Activity or exercise modification; **AND**

    c. Drug therapy (e.g., NSAIDS, muscle relaxants, corticosteroids, antidepressants, anticonvulsants, or opiates)

    * The Numeric Rating Scale (NRS-11): Rating Pain Level
    0: No Pain
    1-3: Mild Pain (nagging, annoying, interfering little with ADLs)
    4-6: Moderate Pain (interferes significantly with ADLs)
    7-10: Severe Pain (disabling; unable to perform ADLs)

AND

3. Documentation of a positive response to diagnostic facet injection or MBB trial** as evidenced by:

    a. Dual injections performed in the same anatomic location(s) at two (2) separate points in time, at least one week apart; **AND**

    b. Significant functional pain relief of 70% measured by a decrease in pain medications and increase in physical function for the duration of the anesthetic administered; **AND**

    c. Initial diagnostic facet joint injection produced a successful response

    ** Refer to *MCP-30: Facet Joint/MBB Diagnostic Injections for Chronic Spinal Pain* for complete definition of a successful diagnostic trial.

AND

4. For each covered spinal region (cervical or lumbar), RFA should be performed at no more than four (4) joints per session (e.g., two [2] bilateral levels or four [4] unilateral levels).

Continuation of Therapy

Repeat radiofrequency ablation therapy **is considered medically necessary** when **ALL** of the following is met:

1. At least six (6) months have elapsed since the previous radiofrequency ablation treatment AND maximum of two (2) procedures over a 12-month period per side and level; **AND**
2. For each covered spinal region (cervical or lumbar), RFA should be performed at no more than four (4) joints per session (e.g., two [2] bilateral levels or four [4] unilateral levels); **AND**
3. RFA may be performed at the same level no more than twice annually and only if the initial radiofrequency ablation results in significant pain relief (at least 50%) and improvement in patient specific ADLs for at least six (6) months.

Limitations and Exclusions

1. All other requests that do not meet the criteria above are considered not medically necessary.

2. All other methods of ablation/denervation for the treatment of chronic neck and spinal/back pain are considered experimental/investigational (not an all-inclusive list):
   a. Chemodenervation: (e.g., alcohol, phenol, glycerol or hypertonic saline)
   b. Cryodenervation (cryoablation) (NASS 2020)
   c. Cooled RFA for facet denervation (e.g., COOLIEF)
   d. Endoscopic RFA/denervation/rhizotomy procedures
   e. Pulsed RFA for treatment of facet-mediated pain (64999)
   Refer to the 'Summary of Evidence' section for further discussion on the lack of published peer-reviewed scientific literature on the efficacy of this method of ablation.
   f. Laser RFA/denervation/rhizotomy procedures

3. The following procedures are considered experimental, investigational and unproven due to insufficient evidence in the peer-reviewed medical literature that have not established long-term safety, efficacy and effect on net health outcomes:
   a. Therapeutic MBB
   b. Thoracic radiofrequency denervation

4. Relative or absolute contraindications to RFA include:
   a. Neurologic abnormalities
   b. Definitive clinical and/or imaging findings
   c. Proven specific causes of low back pain, including disc herniation, spondylolisthesis, spondylosis ankylopoietica, spinal stenosis, discogenic or stenotic compression, malignancy, infection, and trauma
   d. Allergy to radiopaque contrast or local anesthetic
   e. Presence of more than one pain syndrome
   f. Lack of response to diagnostic nerve blocks
   g. Unstable medical conditions or psychiatric illness

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Conventional (non-pulsed) RFA / Pulsed RFA

Nonpulsed, conventional RFA has a larger body of randomized controlled trials (RCTs) for the treatment of chronic low back pain (LBP) associated with facet joint syndrome in the lumbar and lumbosacral regions, but these studies have produced inconsistent results, whereas pulsed RFA has a significantly smaller body of evidence with a range of comparison groups. The body of evidence supporting nonpulsed RFA in the treatment of chronic LBP is rated as

moderate due to limitations in the quality of some individual studies and inconsistency in findings, whereas the body of evidence supporting pulsed RFA in the treatment of chronic LBP is rated as low due to a lack of evidence (Hayes; 2021). There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management for pulsed RFA at this time.

- In a Health Technology Assessment (*Radiofrequency Ablation For Facet Joint Denervation For Chronic Low Back Pain*), the majority of the studies evaluated were for nonpulsed RFA as the primary intervention (10 studies), in comparison to a limited number (3 studies) that specifically assessed pulsed RFA (Hayes; annual review April 23, 2021). Nonpulsed RFA appears to be similar or superior to sham and active therapies for chronic LBP associated with facet joint pain, according to a moderately large body of moderate-quality evidence identified a (Hayes HTA, 2021). Two RCTs examining overall treatment success for nonpulsed RFA against sham therapy, including 1 good-quality research (Moussa and Khedr, 2016) and 1 fair-quality trial (Moussa and Khedr, 2016), preferred RFA versus sham therapy (Nath et al., 2008). There were no significant differences noted in nonpulsed RFA versus sham therapy in 2 high-quality studies (Geurts et al., 2003; van Wijk et al., 2005) and superior to steroid injections in 1 high-quality trial (Zhou et al (2016).
- A modest body of low-quality evidence suggests that percutaneous pulsed RFA is comparable, but not superior to, sham therapy (1 study), steroid injections (1 study), and nonpulsed and pulsed RFA combined (1 study) in terms of chronic LBP resolution.
- Treatment efficacy following non-pulsed RFA was evaluated as a primary outcome in 3 studies (Geurts et al., 2003; Nath et al., 2008; Moussa & Khedr, 2016) and as a secondary outcome in 2 studies (van Wijk et al., 2005; Zhou et al., 2016). While overall treatment success was not evaluated in the pulsed RFA studies (Hayes 2021) but LBP relief was reported in 3 studies: 1 good-quality study found no significant benefits from pulsed RFA compared to sham therapy (Tekin et al., 2007); 1 poor-quality study found that pulsed RFA significantly reduced pain compared to steroid injections (Hashemi et al., 2014); and 1 poor-quality study found no difference between pulsed RFA and combined pulsed and nonpulsed RFA (Hashemi et al., 2014). (Simopoulos et al., 2008).

Conventional (non-pulsed) RFA

The evidence for conventional (non-pulsed) RF includes systematic reviews and RCTs for those with facet joint pain who receive RFA. Symptoms, functional results, quality of life, and medication use are relevant outcomes. Definitive patient selection criteria for RFA as a treatment for chronic spinal pain and a standard RF denervation technique for RFA have not been established which affects definitive conclusions regarding the efficacy and safety of the procedure. The literature reports minor safety risks, although it is unclear whether safety outcomes were consistently collected and recorded. A summary of the more recent peer-reviews and systematic reviews is outlined below.

In an UpToDate peer-review on nonsurgical interventional treatment for LBP, Chou (2021) noted that small clinical trials testing radiofrequency denervation for facet joint pain found no efficacy or only modest, generally short-term, improvement (van Wijk et al. 2005; Tekin et al. 2007; Nath et al. 2008; Leclaire et al. 2001; van Kleef et al. 1999; Bogduk et al. 2006; Gofeld et al. 2006). Discogenic LBP (Oh et al. 2004), radicular pain (Geurts et al. 2003), and chronic sacroiliac joint pain (Cohen et al. 2008) have also shown limited effect.

Janapala et al. (2021) performed a systematic review and meta-analysis of randomized trials to determine the efficacy of radiofrequency neurotomy in the treatment of chronic LBP originating in the facet joints. Six of the 12 studies included in this analysis exhibited both short- and long-term effectiveness, 4 trials demonstrated just short-term effectiveness, and two trials demonstrated lack of effectiveness. The authors observed that additional systematic studies (not included in the analysis) provided contradictory results. Maas et al. (2015) found a lack of efficacy in radiofrequency denervation, which reduced pain in the short-term compared to placebo but did not improve long-term pain or function, in a meta-analysis of 23 randomized studies of patients with facet joint discomfort. Schneider et al. (2020) demonstrated efficacy in patients with complete pain alleviation and in roughly 57% of patients with parallel needle implantation. In a meta-analysis, Lee et al. (2017) concluded that conventional radiofrequency denervation led in a significant reduction in LBP with favorable outcomes when compared to sham operations over a one-year period. The analysis included 231 participants enrolled in several studies who underwent denervation treatments. Leggett et al. (2014) reviewed six sham-controlled RCTs conducted between 1994 and 2008 and discovered systematic diversity in selection criteria and outcomes, as well as unclear effectiveness. In comparison, Poetscher et al. (2014) analyzed nine RCTs comparing radiofrequency denervation to various forms of treatment and placebo, concluding that radiofrequency denervation was more efficacious than placebo and steroid injection; nonetheless, this evidence should be interpreted cautiously.

Chen et al. (2019) conducted a meta-analysis of 15 randomized controlled studies comparing the clinical effectiveness of radiofrequency neurotomy (n=528) vs nonsurgical conservative treatment (n=457) for persistent lumbar and sacroiliac joint pain. Patients with a minimum of six months' history of persistent function-limiting lumbar and sacroiliac joint pain were included. The Oswestry Disability Index (ODI), pain scales, and measures of quality of life were used as primary outcomes. When compared to controls, patients treated with radiofrequency neurotomy improved much more on the ODI, pain, and quality of life. The authors concluded that radiofrequency neurotomy enhanced function following treatment of persistent lumbar facet joint pain.

Manchikanti et al. (2015) assessed the clinical utility of facet joint interventions in the treatment of chronic spinal pain in a systematic review. A comprehensive search identified 26 publications for inclusion, with the majority (n=17) specifically evaluating interventions in the lumbar spine. Meta-analysis was not possible due to heterogeneity; however, the investigators found level I and II evidence, respectively, for short- and long-term effectiveness of RF neurotomy in the lumbar spine.

National and Specialty Organizations

The **American Society of Anesthesiologists (ASA)** (2010) notes that literature supports the efficacy of RFA, according to their Task Force on Pain Management's Chronic Pain Section (2010). The Task Force recommends the use of conventional RFA for the treatment of neck discomfort. Neuroablative treatments should be used in conjunction with other forms of pain management and only as a last option when other forms of pain control are inadequate.

The **American Society of Regional Anesthesia and Pain Medicine** (Cohen et al., 2020) issued the following recommendations in a consensus practice guideline on interventions for lumbar facet joint pain from a multispecialty, international working group:

- Prior to lumbar facet RFA, MBB should be used as a prognostic screening test.
- In patients who had a positive success from their initial RFA surgery, which is commonly characterized as at least 50% pain reduction after three months, repeat RFA procedures are indicated for recurrence of pain.
- Due to the low success rates and short duration of benefit observed in some studies, it is recommended to repeat the procedure no more than two times per year.

The **American Society of Interventional Pain Physicians (ASIPP)** updated 2020 guideline states the following regarding the evidence for facet joint treatments for chronic spine pain; the guideline was reviewed in the ASIIP clinical practice guidelines. Manchikanti et al. (2020) made the following recommendations:

- Cervical and lumbar RFA: The level of evidence is II with moderate strength of recommendation (for lumbar RFA with inclusion of 11 relevant RCTs with 2 negative studies and 4 studies with long-term improvement; for cervical RFA with inclusion of one RCT with positive results and 2 observational studies with long-term improvement.
- Thoracic radiofrequency ablation: The level of evidence is III with weak to moderate strength of recommendation with emerging evidence for with inclusion of one relevant RCT and 3 observational studies.
- For facet joint nerve ablation, the suggested interval between procedures is 6 months or longer (a maximum of two times per year), given that 50% or better pain reduction is attained for 5-6 months. If interventional procedures are applied to multiple locations, they should be performed at intervals of no less than one week and ideally two weeks for the majority of treatments unless they are permitted or contraindicated in one setting.
- The therapy frequency for medial branch neurotomy should be maintained at at least 6-month intervals for each region when multiple regions are involved. It is also proposed that all regions be treated at the same time, providing that all treatments are carried out safely.
- Interventional operations should only be repeated as needed during the treatment or therapeutic phase, based on medical necessity criteria.

NOTE: Level II is moderate evidence obtained from at least one relevant high quality RCT or multiple relevant moderate or low quality RCTs or Evidence obtained from at least one high quality diagnostic accuracy study or multiple moderate or low-quality diagnostic accuracy studies. Level III is evidence obtained from at least one relevant moderate or low quality randomized controlled trial study or evidence obtained from at least one relevant high quality non-randomized trial or observational study with multiple moderate or low-quality observational studies or evidence obtained from at least one moderate quality diagnostic accuracy study in addition to low quality studies.

According to the ASIPP Interventional Pain Management practice guidelines (2013), the evidence for treatment of cervical facet joint pain in the short- and long-term is adequate. This assessment was based on 1 RCT and 5 observational studies. (Manchikanti et al., 2013a; Manchikanti et al., 2013b).:

- The therapeutic frequency for medial branch neurotomy should remain at intervals of at least 6 months or longer per each region (maximum of 2 times per year) between each procedure, provided that 50% or greater relief is obtained for 10 to 12 weeks.
- All regions be treated at the same time, provided all procedures are performed safely.
- "Based on the available evidence, it appears that the best response is obtained after confirmation of the diagnosis of facet joint pain with controlled diagnostic blocks, preferably with 75% pain relief as the criterion standard with dual blocks."

The **American Pain Society (APS)** published updated evidence-based guidelines on management of LBP in 2009 *(Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain)*. The guidelines determined that there was poor-quality evidence to support the efficacy of RF denervation of the medial branch nerves in patients with presumed facet joint pain. Interpretation of the evidence was deemed to be difficult and controversial due to the uncontrolled facet joint blocks for patient selection and suboptimal RFA techniques in certain studies. The guideline recognized a reasonable safety profile with no reporting of serious adverse events but generally highlights poor reporting of AEs throughout the literature (Chou et al. 2009).

The **Institute for Clinical Systems Improvement (ICSI)** *Health Care Guideline Assessment and Management of Chronic Pain* notes that percutaneous RFA is a safe procedure for patients who are correctly diagnosed with facet joint pain. This assessment recommends that RFA may be an effective alternative for patients with cervical facet joint pain who have failed conservative treatment, including therapeutic exercise, activity modification, medical therapy, joint injections, and nerve blocks. Properly selected candidates for this procedure should experience complete or nearly complete relief of their pain following fluoroscopically guided, low-volume local anesthetic blocks of the medial or lateral branch nerves that innervate the targeted joints (ICSI 2018, 2013).

The **National Institute for Health and Care Excellence (NICE)** issued the following recommendations for the management of LBP and sciatica (2016; revised 2020):

- Consider referral for assessment for radiofrequency denervation for people with chronic LBP when:
  - Non-surgical treatment has not worked for them; and
  - The main source of pain is thought to come from structures supplied by the medial branch nerve; and
  - They have moderate or severe levels of localized back pain (rated as 5 or more on a visual analog scale, or equivalent) at the time of referral.
- Denervation with radiofrequency should be performed only in patients with chronic LBP have a favorable response to a diagnostic MBB.
- Do not offer imaging for people with LBP with specific facet joint pain as a prerequisite for radiofrequency denervation. Imaging should not be used as a prerequisite for radiofrequency denervation in patients with LBP with specific facet joint pain.

The **North American Spine Society (NASS)** clinical guidelines offer evidence-based recommendations for the diagnosis and management for the diagnosis and treatment of adults with LBP (Kreiner et al., 2020). The following RFA recommendations are made by the guidelines:

- Thermal RFA is recommended as a therapy option for patients suffering from zygapophyseal joint pain in the low back. When more rigorous diagnostic criteria are utilized, the outcome of this process becomes more dependable. These ablations provide relief for at least six months after the treatment. Grade of recommendation: B (Fair evidence, Level II or III studies with consistent findings, for or against recommending intervention).
- In patients with sacroiliac joint discomfort detected by dual diagnostic blocks, cooled RFA of the sacral lateral branch nerves and dorsal ramus of L5 may be considered. Grade of recommendation: C (Poor quality evidence (Level IV or V studies) for or against recommending intervention).
- Cryodenervation for the treatment of zygapophyseal joint pain has inadequate evidence to make a recommendation for or against it. Grade of recommendation: I (Insufficient or conflicting evidence not allowing a recommendation for or against intervention).

SUPPLEMENTAL INFORMATION

Zygapophyseal (facet) joint level: The zygapophyseal joint or the two medial branch (MB) nerves that innervate that zygapophyseal joint.

Session: All injections / blocks procedures performed on one day and includes medial branch blocks (MBB), and intraarticular injections (IA).

Region: All injections performed in cervical / thoracic or all injections performed in lumbar (not sacral) spinal areas.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
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	Unlisted procedure, nervous system

HCPCS Codes – None.

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

4/13/2022 Policy reviewed and updated; no changes in coverage criteria (revised verbiage and language for clarity with no changes in intent); updated Overview, Summary of Evidence and References sections.
4/5/2021 Policy reviewed, no changes. One new guideline found reference #40 American Society of Interventional Pain Physicians (ASIPP).
9/16/2020 Updated definition successful diagnostic facet injection/MBB trial to: dual injections performed in the same anatomic location(s) at 2 separate points in time, at least one week apart; and significant functional pain relief of 70% measured by a decrease in pain medications and increase in physical function for the duration of the anesthetic administered; and initial diagnostic facet joint injection produced a successful response." Updated definition of Pulsed RFA to include the following: an alternative to conventional RFA, sometimes referred to as cool RFA.
4/23/2020 Policy reviewed, criteria updated based on current standard of care medical guidelines that include ODG and InterQual; eviCore and other guidelines. Changed facet diagnostic block improvement scale from 50% to 70% to be consistent with Facet Injection MCR, changed the level restriction criteria for RFN to no more than four (4) joints per session (e.g., two [2] bilateral levels or four [4] unilateral levels to be consistent with Facet Injection MCR. RFA may be performed at the same level no more than twice annually and only if the initial radiofrequency lesion results in significant pain relief (at least 50%) and improvement in patient specific ADLs for at least 6 months. Revised conservative therapy to tried and failed a minimum of 3 months that includes PT for a minimum of 4 weeks. These changes are consistent with ODG. eviCore and other current guidelines and vetted by IRO reviewer, practicing board-certified physician in the areas of Pain Management and Physical Medicine and Rehabilitation (1/13/2020).
9/2019 Clarified under the exclusion section that radiofrequency ablation for thoracic spinal pain is considered E/I or unproven.
3/8/2018 Policy reviewed, no changes to criteria.
6/19/2019 Policy reviewed, no changes to criteria.
7/2017 Reduced PT requirement from 20 sessions to 10-12 sessions over 8 weeks, changed improvement scales from significant functional improvement of 80% to significant functional pain relief of 50% measured by a decrease in pain medication and increase in functional

ability, moved and added additional relative or absolute contraindications to RFA to exclusions section, removed the neuroimaging requirement and added that thoracic region RFA are considered experimental, investigational and unproven. Changes are based on 2017 ODG Guidelines. Policy reviewed by an IRO peer reviewer, practicing, board-certified physician in the areas of Pain Management and Physical Medicine and Rehabilitation (5/22/2013).

12/2008, 9/2010, 6/2013, 12/11/2013, 6/12/2014, 12/16/2015, 6/15/2016 Policy reviewed.

7/5/2007 New policy.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: radiofrequency or facet or denervation or 64635). No NCDs located. Available from CMS.
2. United States Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). Search 510(k) database. Available from FDA.

Peer Reviewed Publications

1. Allegri M, Montella S, Salici F, et al. Mechanisms of low back pain: A guide for diagnosis and therapy. F1000Res. 2016 Jun 28;5:F1000 Faculty Rev-1530. doi: 10.12688/f1000research.8105.2. PMID: 27408698; PMCID: PMC4926733.
2. Chen CH, Weng PW, Wu LC, et al. Radiofrequency neurotomy in chronic lumbar and sacroiliac joint pain: A meta-analysis. Medicine (Baltimore). 2019 Jun;98(26):e16230.
3. Chou R. Atlas SJ, Stanos SP, Rosenquist RW. Nonsurgical interventional therapies for low back pain: A review of the evidence for an American Pain Society Clinical Practice Guideline. Spine (Phila Pa 1976). 2009 May 1;34(10):1078-93.
4. Chou R, Huffman LH. Guideline for the evaluation and management of low back pain: Evidence review. Glenview, IL: American Pain Society; 2009. Available from APS.
5. Falco FJ, Manchikanti L, Datta S, et al. Systematic review of the therapeutic effectiveness of cervical facet joint interventions: An update. Pain Physician. 2012 Nov;15(6):E839-68.
6. Hashemi M, Hashemian M, Mohajerani SA, Sharifi G. Effect of pulsed radiofrequency in treatment of facet-joint origin back pain in patients with degenerative spondylolisthesis. Eur Spine J. 2014;23(9):1927-1932.
7. Janapala RN, Manchikanti L, Sanapati MR, Thota S, Abd-Elsayed A, Kaye AD, Hirsch JA. Efficacy of radiofrequency neurotomy in chronic low back pain: A systematic review and meta-analysis. J Pain Res. 2021;14:2859-2891 https://doi.org/10.2147/JPR.S323362.
8. Lee CH, Chung CK, Kim CH. The efficacy of conventional radiofrequency denervation in patients with chronic low back pain originating from the facet joints: A meta-analysis of randomized controlled trials. Spine J. 2017;17(11):1770–1780. doi:10.1016/j.spinee.2017.05.006.
9. 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.
10. Maas ET, Ostelo RW, Niemisto L, et al. Radiofrequency denervation for chronic low back pain. Cochrane Database Syst Rev. 2015;(10):CD008572.
11. Manchikanti L, Kaye AD, Boswell MV, et al. A systematic review and best evidence synthesis of effectiveness of therapeutic facet joint interventions in managing chronic spinal pain. Pain Physician. 2015;18(4):E535–E582. doi:10.36076/ppj.2015/18/E535.
12. Manchikanti L, Hirsch JA, Falco FJ, Boswell MV. Management of lumbar zygapophysial (facet) joint pain. World J Orthop. 2016;7(5):315-337.
13. Moussa WM, Khedr W. Percutaneous radiofrequency facet capsule denervation as an alternative target in lumbar facet syndrome. Clin Neurol Neurosurg. 2016;150:96-104.
14. Poetscher AW, Gentil AF, Lenza M, Ferretti M. Radiofrequency denervation for facet joint low back pain: a systematic review. Spine. 2014;39(14):E842-E849.
15. Schneider BJ, Doan L, Maes MK, et al. Systematic review of the effectiveness of lumbar medial branch thermal radiofrequency neurotomy, stratified for diagnostic methods and procedural technique. Pain Med. 2020;21(6):1122–1141. doi:10.1093/pm/pnz349.
16. Simopoulos TT, Kraemer J, Nagda JV, Aner M, Bajwa ZH. Response to pulsed and continuous radiofrequency lesioning of the dorsal root ganglion and segmental nerves in patients with chronic lumbar radicular pain. Pain Physician. 2008;11(2):137-144.
17. Zhou Q, Zhou F, Wang L, Liu K. An investigation on the effect of improved x-rays-guided radiofrequency thermocoagulation denervation on lumbar facet joint syndrome. Clin Neurol Neurosurg. 2016;148:115-120.

National and Specialty Organizations

1. American College of Physicians.
   - Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive treatments for acute, subacute, and chronic low back pain: A clinical practice guideline from the American College of Physicians. Clinical Guidelines. Published April 2017. https://doi.org/10.7326/M16-2367.
2. American Pain Society.
   - Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: An evidence-based clinical practice guideline from the American Pain Society. Spine. 2009;34(10):1066-1077.
   - Chou R, Huffman LH. Guideline for the evaluation and management of low back pain: Evidence review. Glenview, IL: American Pain Society (APS); 2009.
3. American Society of Regional Anesthesia and Pain Medicine.
   - Cohen SP, Bhaskar A, Bhatia A, et al. Consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group. Regional Anesthesia & Pain Medicine. Published Online April 3, 2020. doi: 10.1136/rapm-2019-101243.
4. American Society of Anesthesiologists (ASA) Task Force and American Society of Regional Anesthesia (ASRA). Practice guidelines for chronic pain management: an updated report by the ASA Task Force on Chronic Pain Management and the ASRA and Pain Medicine. Anesthesiology. 2010;112(4):810-833. https://doi.org/10.1097/ALN.0b013e3181c43103.
5. American Society of Interventional Pain Physicians (ASIPP)

- Manchikanti L, et al. Comprehensive evidence-based guidelines for facet joint interventions in the management of chronic spinal pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines. J Pain Physician: May/June 2020;23(3S):S1-S127. Available from ASIPP.
- Manchikanti L, Abdi S, Atluri S, et al. An Update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: Guidance and recommendations. Pain Physician. 2013a;16(2 Suppl):S49-S283. Available here.
- Manchikanti L, Falco FJ, Singh V, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part I: Introduction and general considerations. Pain Physician. 2013b;16(2 Suppl):S1-S48. Available here.

6. Institute for Clinical Systems Improvement (ICSI). Assessment and management of chronic pain. Available from ICSI. Published Nov. 2013.
7. Institute for Clinical Systems Improvement (ICSI). Low back pain, adult acute and subacute. Available from ICSI. Published March 2018.
8. Summers J. Spine Intervention Society recommendations for treatment of cervical and lumbar spine. Pain. Nov. 14, 2013. Available here.
9. National Institute for Health and Clinical Excellence (NICE). Low back pain and sciatica in over 16s: Assessment and management [NG59]. Available from NICE. Published November 2016. Updated December 2020.
10. North American Spine Society (NASS). Kreiner DS, Matz P, Bono CM, et al. Guideline summary review: An evidence-based clinical guideline for the diagnosis and treatment of low back pain. Spine J. 2020 Jul;20(7):998-1024. doi: 10.1016/j.spinee.2020.04.006. Erratum in: Spine J. 2021 Feb 24; PMID: 32333996.

Other Peer Reviewed and National Organization Publications (used in the development of this policy)

1. AIM Specialty Health. Clinical appropriateness guideline: Appropriate use criteria – interventional pain management. Available from AIM. Accessed March 22, 2022.
2. Cohen SP, Huang JH, Brummett C. Facet joint pain – advances in patient selection and treatment. Nat Rev Rheumatol. 2013 Feb;9(2):101-16. doi: 10.1038/nrrheum.2012.198.
3. Cohen SP, Strassels SA, Kurihara C, Crooks MT, Forsythe A, Marcuson M. Outcome predictors for sacroiliac joint (lateral branch) radiofrequency denervation. Reg Anesth Pain Med. 2009 May-Jun;34(3):206-14.
4. Cohen SP, Strassels SA, Kurihara C, Lesnick IK, et al. Does sensory stimulation threshold affect lumbar facet radiofrequency denervation outcomes? A prospective clinical correlational study. Anesth Analg. Nov 2011; 113(5); 1233-41.
5. Cohen SP, Williams KA, Kurihara C, et al. Multicenter, randomized, comparative cost-effectiveness study comparing 0, 1, and 2 diagnostic medial branch (facet joint nerve) block treatment paradigms before lumbar facet radiofrequency denervation. Anesthesiology. 2010 Aug;113(2):395-405.
6. DynaMed. Chronic low back pain (record no. T116935). Available from DynaMed. Updated November 30, 2018. Accessed March 2022. Registration and login required.
7. Hayes. https://evidence.hayesinc.com. Accessed March 2022. Registration and login required.
   a. Radiofrequency ablation for facet joint denervation for chronic low back pain. Published December 1, 2016. Archived January 1, 2022. Updated March 2020.
   b. Percutaneous radiofrequency ablation for cervical and thoracic spinal indications. Published November 3, 2016. Updated Published January 2020. Archived December 3, 2021.
   c. Radiofrequency ablation of the dorsal root ganglion for treatment of back pain. Published January 2019. Archived May 2019.
   d. Pulsed radiofrequency treatment of complex regional pain syndrome of the lumbar region. Updated Oct. 2020. Archived Nov 27, 2021.
8. MCG. Facet neurotomy (ACG: A-0218 AC), 25th ed. https://www.mcg.com/. Updated June 2021.
9. UpToDate. http://www.uptodate.com. Registration and login required.
   a. Wheeler, SG. Evaluation of chronic pain in adults. Updated June 21, 2021.
   b. Chou R. Subacute and chronic low back pain: Nonsurgical interventional treatment. Updated June 10, 2021.
      - Cohen SP, Hurley RW, Buckenmaier CC 3rd, et al. Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain. Anesthesiology 2008; 109:279.
      - Oh WS, Shim JC. A randomized controlled trial of radiofrequency denervation of the ramus communicans nerve for chronic discogenic low back pain. Clin J Pain 2004; 20:55.
      - van Wijk RM, Geurts JW, Wynne HJ, et al. Radiofrequency denervation of lumbar facet joints in the treatment of chronic low back pain: a randomized, double-blind, sham lesion-controlled trial. Clin J Pain 2005; 21:335.
      - Geurts JW, van Wijk RM, Wynne HJ, et al. Radiofrequency lesioning of dorsal root ganglia for chronic lumbosacral radicular pain: a randomised, double-blind, controlled trial. Lancet 2003; 361:21.
      - Gofeld, M. Radiofrequency facet denervation: A randomized control placebo versus sham procedure. Clin J Pain 2006; 22:410.
      - Nath S, Nath CA, Peterson K. Percutaneous lumbar zygapophysial (Facet) joint neurotomy using radiofrequency current, in the management of chronic low back pain: A randomized double-blind trial. Spine. 2008; 33 (12):1291-1297.
      - Leclaire R, Fortin L, Lambert R, et al. Radiofrequency facet joint denervation in the treatment of low back pain: A placebo-controlled clinical trial to assess efficacy. Spine (Phila Pa 1976) 2001; 26:1411.
      - van Kleef M, Barendse GA, Kessels A, et al. Randomized trial of radiofrequency lumbar facet denervation for chronic low back pain. Spine (Phila Pa 1976) 1999; 24:1937.
      - Bogduk N. Lumbar radiofrequency neurotomy. Clin J Pain 2006; 22:409.
      - Tekin I, Mirzai H, et al. A comparison of conventional and pulsed radiofrequency denervation in the treatment of chronic facet joint pain. Clinical Journal of pain, 2007;23:524-529.
   c. Zacharia I. Management of non-radicular neck pain in adults. Updated November 16, 2021.

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*