

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 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 Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. 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 low back pain (LBP), particularly facetogenic back pain. The synovial membrane that surrounds the facet joint can be stretched, strained, or trapped, causing facet joint pain (Allegri et al. 2016; Manchikanti et al. 2015; ¹Manchikanti et al. 2013; Falco et al. 2012). 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 non-pulsed 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.
- 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 (non-pulsed) and PFRA (pulsed) are performed in the outpatient setting and appear safe for persistent LBP, with minimal safety issues reported. Non-pulsed RFA has a moderate-quality but conflicting evidence for 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).

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RELATED POLICIES

MCP-030: Facet Joint/MBB Diagnostic Injections for Chronic Spinal Pain MCP-033: Sacroiliac Injections and Radiofrequency Ablation (RFA) for Sacroiliac Joint Pain

COVERAGE POLICY

Non-pulsed, conventional radiofrequency ablation (RFA) **may be considered medically necessary** for chronic cervical or lumbar pain in adults who are age 18 years or older as part of a comprehensive pain management treatment program when **ALL** 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*).
- 2. Inadequate response to a minimum of three (3) months of conservative therapy that includes ALL the following:
 - a. Physical therapy for a minimum of four (4) weeks (3-4 times per week for a total of 12 sessions) Physical therapy may be contraindicated for **ANY** of the following conditions:
 - Pain worsened with physical therapy
 - Physical therapy tried but was not able to be tolerated
 - Documentation of the contraindication is required
 - b. Activity or exercise modification
 - 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)
- 3. Documentation of a positive response to diagnostic facet injection or MBB trial** as evidenced by **ALL** the following:
 - a. Dual injections performed in the same anatomic location(s) at two (2) separate points in time, at least one week apart
 - 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
 - c. Initial diagnostic facet joint injection produced a successful response

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

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 RFA therapy **is considered medically necessary** when <u>ALL</u> the following is met:

- 1. At least six (6) months have elapsed since the previous RFA treatment AND maximum of two (2) procedures over a 12-month period per side and level.
- 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).
- 3. RFA may be performed at the same level no more than twice annually <u>and</u> only if the initial RFA results in significant pain relief (at least 50%) <u>and</u> 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 Medical 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 LBP, 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

Non-pulsed, conventional RFA has a larger body of randomized controlled trials (RCTs) for the treatment of chronic 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 non-pulsed 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 currently.

In a Health Technology Assessment (Radiofrequency Ablation For Facet Joint Denervation For Chronic Low Back Pain), most of the studies evaluated were for non-pulsed RFA as the primary intervention (10 studies), in comparison to a limited number (3 studies) that specifically assessed pulsed RFA (Hayes 2021). Non-pulsed 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, 2021). Two RCTs examining overall treatment success for non-pulsed RFA against sham therapy, including 1 good-quality research (Moussa et al.2016) and 1 fair-quality trial (Moussa et al.2016), preferred RFA versus sham therapy (Nath et al. 2008). There were no significant differences noted in non-pulsed RFA versus sham therapy in 2 high-

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quality studies (van Wijk et al. 2005; Geurts et al. 2003) 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 non-pulsed 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 (Moussa, 2016; Nath et al. 2008; Geurts et al. 2003) and as a secondary outcome in 2 studies. (Zhou et al. 2016; van Wijk et al. 2005). 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 non-pulsed RFA (Hashemi et al. 2014; (Simopoulos et al. 2008).

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. Discogenic LBP radicular pain and chronic sacroiliac joint pain 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. 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.

Akgul et al. (2022) conducted the first comparative review of RFA involving the cervical, thoracic, and lumbar spinal regions to understand the long-term efficacy of RFA. The review included 1275 patients aged 18 years and older who had a clinical follow-up for at least one year and had more than six months of back pain. The total included patients with pain in these regions, without radicular pain and without primary and/or metastatic disease in the spinal region. A

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total of 774 patients underwent RFA (156 – cervical, 184 – thoracic, 434 – lumbar and lumbosacral). No significant differences were found in any of the baseline demographic variables. Improvements were found in visual analogue scale and quality-of-life scores as compared prior to and after RFA application within the groups. Significant improvements were also found in the RFA group versus the control group.

Li et al. (2022) performed a systematic review and network meta-analysis to analyze and compare the efficacy and RF denervation treatments for facet joint derived LBP. The authors performed searches using the Cochrane Library, Embase, PubMed, and China Biology Medicine for eligible RCTs (January 1966 – December 2021). Interventions analyzed included conventional radiofrequency denervation (CRF), pulsed radiofrequency denervation (PRF), pulsed radiofrequency treatment of the dorsal root ganglia (PRF-DRG), radiofrequency facet capsule denervation (RF-FC), and radiofrequency ablation under endoscopic guidance (ERFA). Ten 10 RCTs (n = 715 patients) were included in the review. There was moderate evidence demonstrating greater effect with CRF denervation on pain relief than sham control in the short term and the long term. Evidence was fair for PRF denervation – it was more effective than sham control for pain over the long term. Fair evidence demonstrated that ERFA denervation was more effective for pain relief than sham control in the short term and the sham control in the long term). Fair evidence demonstrated that ERFA denervation was more effective for pain relief than sham control in the long term. Fair evidence demonstrated that ERFA denervation was more effective for pain relief than sham control in the short term. The authors concluded that PRF-DRG denervation was more effective for pain relief than sham control in the short term. The authors concluded that RF is an effective treatment for patients with chronic LBP that is derived from the facet joint.

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. The Task Force recommends the use of conventional RFA for the treatment of neck discomfort. Conventional (e.g., 80°C) or thermal (e.g., 67°C) radiofrequency ablation of the medial branch nerves to the facet joint should be performed for low back (medial branch) pain when previous diagnostic or therapeutic injections of the joint or medial branch nerve have provided temporary relief. 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 multispeciality, 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 ASIPP 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 RFA: 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 most treatments unless they are permitted or contraindicated in one setting.
- The therapy frequency for medial branch neurotomy should be maintained 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

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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.

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

- Consider referral for assessment for radiofrequency denervation for people with chronic LBP when:
 - Non-surgical treatment has not worked for them; and
 - o 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/block procedures performed on one day, including MBBs, and intraarticular injections.

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

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

Code	Description
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or

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	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

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 not 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 need

APPROVAL HISTORY

04/10/2024	Policy reviewed, updated Summary of Medical Evidence and References. No changes to Coverage Criteria.
04/13/2023 04/13/2022	Policy reviewed and updated; no changes in coverage criteria; updated Summary of Medical Evidence section. 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.
04/05/2021 09/16/2020	Policy reviewed, no changes. One new guideline found reference #40 American Society of Interventional Pain Physicians (ASIPP). Updated definition successful diagnostic facet injection/MBB trial to: <u>dual</u> 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.
04/23/2020	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).
09/2019 06/19/2019	Clarified under the exclusion section that radiofrequency ablation for thoracic spinal pain is considered E/I or unproven. Policy reviewed, no changes to criteria.
03/08/2018	Policy reviewed, no changes to criteria.
07/2017	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).
06/15/2016	Policy reviewed.
12/16/2015 06/12/2014	Policy reviewed. Policy reviewed.
12/11/2013	Policy reviewed.
06/2013	Policy reviewed.
09/2010 12/2008	Policy reviewed. Policy reviewed.
07/05/2007	New policy.

REFERENCES

- 1. Akgul MH, Akgun MY. Effect of radiofrequency denervation on pain severity among patients with cervical, thoracic or lumbar spinal pain: A clinical retrospective study. Heliyon. 2022 Sep 26;8(9):e10755. doi: 10.1016/j.heliyon.2022.e10755. PMID: 36193536; PMCID: PMC9526146.
- 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.

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- 3. American Society of Anesthesiologists Task Force on chronic pain management; American Society of Regional Anesthesia and Pain Medicine. 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 Apr;112(4):810-33. doi: 10.1097/ALN.0b013e3181c43103. PMID: 20124882.
- 4. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database: Local coverage determination facet joint interventions for paint management (L35936). Effective October 1. 1015. Revision date February 10, 2022. Accessed March 15, 20204. https://www.cms.gov/medicare-coverage-database/search.aspx
- 5. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. (Search: facet joint, radiofrequency, chronic low back pain, denervation). Accessed March 15, 2024. https://www.cms.gov/medicare-coverage-database/search.aspx
- 6. 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. doi: 10.1097/MD.00000000016230. PMID: 31261580; PMCID: PMC6617467.
- 7. Chou R. Subacute and chronic low back pain: Nonsurgical interventional treatment. Updated June 10, 2021. Accessed March 15, 2024. http://www.uptodate.com
- Chou R, Loeser JD, Owens DK, et al. American Pain Society Low Back Pain Guideline Panel. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: An evidence-based clinical practice guideline from the American Pain Society. Spine (Phila Pa 1976). 2009 May 1;34(10):1066-77. doi: 10.1097/BRS.0b013e3181a1390d. PMID: 19363457.
- Cohen SP, Bhaskar A, Bhatia A, et al. Consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group. Reg Anesth Pain Med. 2020 Jun;45(6):424-467. doi: 10.1136/rapm-2019-101243. Epub 2020 Apr 3. PMID: 32245841; PMCID: PMC7362874.
- 10. 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-Dec;15(6):E839-68. PMID: 23159978.
- 11. 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 Jan 4;361(9351):21-6. doi: 10.1016/s0140-6736(03)12115-0. PMID: 12517462.
- 12. Hashemi M, Hashemian M, Mohajerani SA, et al. Effect of pulsed radiofrequency in treatment of facet-joint origin back pain in patients with degenerative spondylolisthesis. Eur Spine J. 2014 Sep;23(9):1927-32. doi: 10.1007/s00586-014-3412-x. Epub 2014 Jul 6. PMID: 24997616.
- 13. Hayes. Radiofrequency ablation for facet joint denervation for chronic low back pain. Published December 1, 2016. Updated April 23, 2021. Accessed March 14, 2024. https://evidence.hayesinc.com/.
- 14. Hooten WM, Timming R, Belgrade M, et al. Institute for Clinical Systems Improvement. Assessment and Management of Chronic Pain. Updated November 2013.
- 15. Janapala RN, Manchikanti L, Sanapati MR, et al. Efficacy of radiofrequency neurotomy in chronic low back pain: A systematic review and meta-analysis. J Pain Res. 2021 Sep 10;14:2859-2891. doi: 10.2147/JPR.S323362. PMID: 34531682; PMCID: PMC8439627.
- 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. Epub 2020 Apr 22. Erratum in: Spine J. 2021 Feb 24;: PMID: 32333996.
- 17. 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 Nov;17(11):1770-1780. doi: 10.1016/j.spinee.2017.05.006. Epub 2017 May 30. PMID: 28576500.
- 18. Li H, An J, Zhang J, et al. Comparative efficacy of radiofrequency denervation in chronic low back pain: A systematic review and network meta-analysis. Front Surg. 2022 Aug 5;9:899538. doi: 10.3389/fsurg.2022.899538. PMID: 35990102; PMCID: PMC9388860.
- 19. MCG. Facet neurotomy (ACG: A-0218 AC). Updated September 21,2023.
- 20. Manchikanti L, Kaye AD, Boswell MV, et al. A systematic review and best evidence synthesis of the effectiveness of therapeutic facet joint interventions in managing chronic spinal pain. Pain Physician. 2015 Jul-Aug;18(4):E535-82. PMID: 26218948.
- Manchikanti L, Kaye AD, Soin A, 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 facet joint interventions 2020 guidelines. Pain Physician. 2020 May;23(3S):S1-S127. PMID: 32503359.
- 22. ²Manchikanti 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. 2013 Apr;16(2 Suppl):S1-48. PMID: 23615882.
- 23. ¹Manchikanti 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. 2013 Apr;16(2 Suppl):S49-283. PMID: 23615883.
- 24. Manchikanti L, Hirsch JA, Falco FJ, et al. Management of lumbar zygapophysial (facet) joint pain. World J Orthop. 2016 May 18;7(5):315-37. doi: 10.5312/wjo.v7.i5.315. PMID: 27190760; PMCID: PMC4865722.
- Maas ET, Ostelo RW, Niemisto L, et al. Radiofrequency denervation for chronic low back pain. Cochrane Database Syst Rev. 2015 Oct 23;2015(10):CD008572. doi: 10.1002/14651858.CD008572.pub2. PMID: 26495910; PMCID: PMC8782593.
- 26. Moussa WM, Khedr W. Percutaneous radiofrequency facet capsule denervation as an alternative target in lumbar facet syndrome. Clin Neurol Neurosurg. 2016 Nov;150:96-104. doi: 10.1016/j.clineuro.2016.09.004. Epub 2016 Sep 5. PMID: 27618781.
- Nath S, Nath CA, Pettersson K. Percutaneous lumbar zygapophysial (Facet) joint neurotomy using radiofrequency current, in the management of chronic low back pain: a randomized double-blind trial. Spine (Phila Pa 1976). 2008 May 20;33(12):1291-7; discussion 1298. doi: 10.1097/BRS.0b013e31817329f0. PMID: 18496338.
- 28. National Institute for Health and Care Excellence (NICE). Low back pain and sciatica in over 16s: assessment and management [NG59]. Published November 30, 2016. Updated December 2020. Accessed March 14, 2024. https://www.nice.org.uk/guidance/ng59
- 29. Poetscher AW, Gentil AF, Lenza M, et al. Radiofrequency denervation for facet joint low back pain: A systematic review. Spine (Phila Pa 1976). 2014 Jun 15;39(14):E842-9. doi: 10.1097/BRS.0000000000337. PMID: 24732848.
- Schneider BJ, Doan L, Maes MK, et al. Standards Division of the Spine Intervention Society. Systematic Review of the Effectiveness of Lumbar Medial Branch Thermal Radiofrequency Neurotomy, Stratified for Diagnostic Methods and Procedural Technique. Pain Med. 2020 Jun 1;21(6):1122-1141. doi: 10.1093/pm/pnz349. PMID: 32040149.
- 31. Simopoulos TT, Kraemer J, Nagda JV, et al. 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 Mar-Apr;11(2):137-44. PMID: 18354708.
- 32. Tekin I, Mirzai H, Ok G, et al. A comparison of conventional and pulsed radiofrequency denervation in the treatment of chronic facet joint pain. Clin J Pain. 2007 Jul-Aug;23(6):524-9. doi: 10.1097/AJP.0b013e318074c99c. PMID: 17575493.
- 33. United States Food and Drug Administration (FDA). Generator, lesion radiofrequency and Probe, radiofrequency lesion. Classification

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



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> product codes GXD and GXI. Premarket Notification 510(k). Rockville, MD. Accessed March 15, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

34. 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 Jul-Aug;21(4):335-44. doi: 10.1097/01.ajp.0000120792.69705.c9. Erratum in: Clin J Pain. 2005 Sep-Oct;21(5):462. PMID: 15951652.

APPENDIX

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

Washington

For Medicaid reviews, consider and apply the following state-specific criteria: Health Technology Assessment (HTA) "Facet Neurotomy" Washington State Healthcare Authority, May 16, 2014.