Subject: Radiofrequency Ablation (RFA) for Chronic Back Pain associated with the Facet Joint ***NOTE:*** *RFA is also called percutaneous radiofrequency facet denervation, percutaneous facet coagulation, percutaneous radiofrequency neurotomy, radiofrequency facet rhizotomy, and radiofrequency articular rhizolysis.*	**Original Effective Date:** 7/5/07
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MCPC Approval Date: 7/25/17, 3/8/18, 6/19/19, 4/23/20, 9/16/20, 4/5/21	

Contents

DISCLAIMER

This Molina Clinical Review (MCR) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Review (MCR) document and provide the directive for all Medicare members.[1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [45]

Radiofrequency ablation (RFA)

Radiofrequency ablation (RFA) is a percutaneous treatment for chronic spinal pain using radiowave-induced heat to create a lesion in a spinal sensory nerve. RFA is also called percutaneous radiofrequency facet denervation, percutaneous facet coagulation, percutaneous radiofrequency neurotomy, radiofrequency facet rhizotomy, and radiofrequency articular rhizolysis. The RF probe is inserted, and the target nerves are generally targeted unilaterally or bilaterally for 40 to 90 seconds using an electrode temperature of 60°C to 90°C. The goal of RFA is to relieve pain by interrupting the transmission of pain signals from the sensory nerve to the brain. RFA may be offered to patients if dual diagnostic facet injection/medial branch block (MBB) injections each produce ≥ 70% relief of the primary (index) pain and the onset and minimum duration of relief is consistent with the anesthetic agent employed.

Pulsed Radiofrequency Denervation (PRFD) [45]

Pulsed RFA (PRFA) an alternative to conventional RFA, sometimes referred to as cool RFA, [45] has been introduced as a nonablative alternative to RFA. PRFA delivers short bursts of radiofrequency (RF) current, instead of the continuous flow of RF current produced by continuous RF generators. This allows the tissue to cool between bursts, resulting in considerably lower maximum temperatures as compared with the continuous mode, and reduces the risk of neighboring tissue destruction. It does not destroy targeted nerves and surrounding tissue and therefore requires less precise electrodes placement. During PRFA, intermittent low temperature electric currents of 2 Hz at temperatures not exceeding 42°C are transmitted to the nerve.

Both RFA and PFRA are performed in the outpatient setting.

CRITERIA RECOMMENDATION [45- 52]

- ❑ 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: [ALL]
- ❑ Diagnosis of chronic severe somatic, **nonradicular** back pain (cervical, or lumbar) defined as persisting beyond 3 months and affecting activity of daily living functional ability: > 6 on the NRS Pain Rating Scale*

- ❑ Has tried and failed a minimum of 3 months of conservative therapy that includes: [ALL]
    - o Physical therapy (PT) for a minimum of 4 weeks (3-4x per week for a total of 12 sessions); or
    - o There must be documentation submitted that explains why physical therapy is contraindicated: *<u>*Note:*</u> PT may be contraindicated if any of the following are present:
        - ➢ pain worsened with PT;
        - ➢ PT tried but was not able to be tolerated

        AND
    - o Activity or exercise modification; and
    - o Drug therapy (i.e. NSAIDS, muscle relaxants, corticosteroids, antidepressants, anticonvulsants, or opiates); and

***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)

- ❑ Documentation of a successful diagnostic facet injection/MBB trial* as evidenced by:
  - 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; and

  *Please see MCR-30 Facet Joint/MBB Diagnostic Injections for Chronic Spinal Pain for complete definition of a successful diagnostic trial.

- ❑ 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). [51]

CONTINUATION OF THERAPY [45-52]

Repeat radiofrequency ablation therapy is considered medically necessary when the following criteria is met: **[ALL]**

- ❑ At least six months have elapsed since the previous radiofrequency ablation treatment (maximum of 2 procedures per region annually; **and**

- ❑ 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). [51]

- ❑ 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 6 months.

Definitions:

- ❑ A zygapophyseal (facet) joint level is defined as the zygapophyseal joint or the two medial branch (MB) nerves that innervate that zygapophyseal joint.
- ❑ A session is defined as all injections/blocks procedures performed on one day and includes medial branch blocks (MBB), and intraarticular injections (IA)
- ❑ A region is defined as all injections performed in cervical/thoracic or all injections performed in lumbar (not sacral) spinal areas.

Note: Criteria recommendations are mainly obtained from the Official Disability Guidelines, AMR peer review and other professional society guidelines. [46 48 50-52]

LIMITATIONS [45-52]

- ❑ All other requests that do not meet the criteria above are considered **not medically necessary**
- ❑ Radiofrequency ablation for thoracic spinal pain is considered **experimental/investigational or unproven** [45]
- ❑ Lateral branch nerve radiofrequency ablation of the sacroiliac joint is considered an e**xperimental/investigational procedure** as there is insufficient evidence from clinical trials to support its safety and effectiveness.

- Pulsed radiofrequency ablation also known as cooled RFA is considered an experimental/investigational procedure as there is insufficient evidence from clinical trials to support its safety and effectiveness. [45]
- Relative or absolute contraindications to RFA include:
  - Neurologic abnormalities
  - Definitive clinical and/or imaging findings
  - Proven specific causes of low back pain, including disc herniation, spondylolisthesis, spondylosis ankylopoietica, spinal stenosis, discogenic or stenotic compression, malignancy, infection, and trauma
  - Allergy to radiopaque contrast or local anesthetic
  - Presence of more than one pain syndrome
  - Lack of response to diagnostic nerve blocks
  - Unstable medical conditions or psychiatric illness

SUMMARY OF MEDICAL EVIDENCE [3-39]

The published literature includes moderate quality evidence that percutaneous RFA of spinal nerve branches is safe and may have some efficacy for patients with pain and symptoms originating in the cervical and lumbar spine. Evidence from uncontrolled and a few controlled studies that show RFA may provide short-term pain relief in selected patients with chronic low back pain (LBP), however the majority of patients did not experience complete pain relief, the durability of effect remains unclear and the results are conflicting. Most complications reported in the reviewed studies were transient, and consisted primarily of pain or discomfort during or subsequent to treatment. There is a less substantial and smaller body of evidence of low quality that pulsed RFA is safe and has some benefits for adult patients with chronic LBP, but additional studies are needed before any definitive conclusions can be reached. Patients included in the studies were adults presenting with chronic LBP without a definitive cause that did not respond adequately to conservative therapies. All studies required that patients undergo diagnostic medial nerve branch blocks prior to RFA treatment, and to be candidates for RFA, to have a positive response to at least 1 diagnostic block. Generally, the mean age of the populations was > 40 years old. The primary outcomes, as well as the tools used to measure those outcomes, varied across the literature. Commonly reported secondary outcome measures included pain intensity, duration of relief, physical function, use of analgesics, quality of life (QOL), patient satisfaction, complications, and treatment-related costs. Patients were treated with nonpulsed or pulsed RFA of the medial branch nerves innervating the lumbar or lumbosacral facet joints (zygapophyseal joints) at the spinal level deemed to be associated with pain as determined by the diagnostic nerve branch blocks. Generally, treatments were performed as outpatient procedures and application of RFA was consistent within studies, with most populations treated within a single center by the same treating physician. Across studies, however, there were wide variations in treatment parameters, with temperatures ranging from 67°C to 90°C and RF energy application times ranging from 60 to 120 seconds in the nonpulsed RFA groups; and in the pulsed RFA group, temperatures of up to 42°C were applied for highly variable intervals and durations. Overall, evidence from randomized, double-blind, sham-controlled trials demonstrated a significant placebo effect, and conflicting results were obtained from RCTs investigating conventional nonpulsed RFA for treating chronic LBP associated with lumbar and lumbosacral facet joint syndrome.

Evidence regarding the efficacy of pulsed RFA as the primary intervention was limited to 3 studies with several different comparator groups. As a result, the data regarding pulsed RFA are insufficient to support conclusions about treatment effect. There is insufficient published evidence to reassess the safety and/or impact on health outcomes or patient management of RFA for the treatment of thoracic back pain.

A summary of the more recent systematic reviews are outlined below.

A 2014 systematic review sought to determine the efficacy of RFA for chronic LBP associated with lumbar facet joints, sacroiliac joints, discogenic LBP, and the coccyx. Searches of several databases identified 11 studies for inclusion, 6 of which were conducted in populations with lumbar facet joint pain diagnosed via medial branch nerve blocks. Conventional nonpulsed RFA was utilized in 5 of the studies, while the remaining study employed a combination treatment of pulsed and nonpulsed RFA. Pain reduction was the primary outcome of interest; however, meta-analysis of the data could not be performed due to inconsistent and poor reporting of mean differences and SDs. In any case, the evidence was supportive of the effectiveness of RFA for LBP associated with the lumbar facet joints (Leggett et al., 2014). [22]

Poetscher and colleagues (2014) evaluated the treatment effects of RF denervation for patients with facet joint-related chronic LBP and the investigators identified 9 publications from several sources meeting inclusion criteria. The investigators suggest that there is low- to moderate-quality evidence to support the effectiveness of RF denervation over sham treatment for treatment of LBP associated with lumbar facet joints. There was insufficient evidence to draw conclusions relating to cost-effectiveness and complications (Poetscher et al., 2014). [30]

A Cochrane review by Maas et al. (2015) had the primary aim of assessing the effectiveness of RF denervation for the treatment of patients with chronic LBP. A total of 23 RCTs were identified via searches of several databases through to May 2014, and by manual searching. Overall, the investigators rated the quality of evidence as low to moderate, with just over half of the included studies (56%) determined to have a low risk of bias. The investigators concluded that while there was low- to moderate-quality evidence to suggest that RF denervation provides pain relief for patients with chronic LBP, the same could not be said for improving function. The authors recognized selective reporting and the avoidance or similarity of cointerventions as the primary issues contributing to bias across the body of evidence. In addition, the authors cite the need for high-quality studies with standardized outcomes, long-term follow-up, and including large samples of carefully selected patients. [25]

Another systematic review (2015) sought to evaluate the clinical utility of facet joint interventions in the treatment of chronic spinal pain. 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. [24]

PROFESSIONAL SOCIETY GUIDELINES

American Society of Interventional Pain Physicians (ASIPP): An updated 2020 practice guideline states the following:

- The level of evidence is II with moderate strength of recommendation for lumbar radiofrequency ablation with inclusion of 11 relevant randomized controlled trials (RCTs) with 2 negative studies and 4 studies with long-term improvement.
- The level of evidence is II with moderate strength of recommendation for cervical radiofrequency ablation with inclusion of one randomized controlled trial with positive results and 2 observational studies with long-term improvement..
- The level of evidence is III with weak to moderate strength of recommendation with emerging evidence for thoracic radiofrequency ablation with inclusion of one relevant randomized controlled trial and 3 observational studies.

*Note: Level II is moderate evidence obtained from at least one relevant high quality randomized controlled trial or multiple relevant moderate or low quality randomized controlled trials 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.

An updated 2013 practice guideline states that the suggested 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. It is further suggested that all regions be treated at the same time, provided all procedures are performed safely. [40]

American Pain Society (APS): The APS guidelines in 2009 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. Generally, the guideline recognized a reasonable safety profile, with no reporting of serious adverse events (AEs), but generally highlights poor reporting of AEs throughout the literature. [41]

Institute for Clinical Systems Improvement (ICSI): According to an ICSI chronic pain assessment and management guideline, 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. [44]

CODING INFORMATION: THE CODES LISTED IN THIS CLINICAL POLICY ARE FOR INFORMATIONAL PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE AND INCLUSION OR EXCLUSION OF ANY CODES DOES NOT GUARANTEE COVERAGE. PROVIDERS SHOULD REFERENCE THE MOST UP-TO-DATE SOURCES OF PROFESSIONAL CODING GUIDANCE PRIOR TO THE SUBMISSION OF CLAIMS FOR REIMBURSEMENT OF COVERED SERVICES.

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)

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REVISION/REVIEW HISTORY

7/17: 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 per AMR review.
3/8/18 & 6/19/19: Policy reviewed, no changes to criteria.
9/19: Clarified under the exclusion section that radiofrequency ablation for thoracic spinal pain is considered experimental/investigational or unproven.
4/23/20: 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 AMR reviewer.
9/16/20: Updated the definition successful diagnostic facet injection/MBB trial to the following: 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.*
4/5/21: Policy reviewed, no changes to criteria. One new guideline found reference #40 American Society of Interventional Pain Physicians (ASIPP).