

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 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

Trigger points are hypersensitive areas of skeletal muscle that are associated with palpable nodules in taut bands of muscle fibers. Stimulation or compression of a trigger point may result in localized tenderness, referred pain, or a local twitch response. Trigger point pain most commonly occurs in muscles that maintain body posture such as the neck, shoulder, and pelvic girdle. Muscle injury or repetitive muscle stress may result in the formation of trigger points. This causes in regional persistent pain and a reduction in range of motion in the affected muscles. Trigger points can be active or spontaneously painful, or latent, causing pain only when stimulated by digital pressure. Physical examination may reveal a nodule of muscle fiber. Palpation of this nodule may result in pain over the trigger point or pain radiating to another area with a local twitch response. Trigger point pain is frequently associated with myofascial pain syndrome. Conservative management of trigger point pain may include activity modification combined with oral medication such as NSAIDS, analgesics, steroids, and muscle relaxants for pain relief. Physical and chiropractic therapy may be utilized to increase range of motion. Injections of anesthetics, with or without corticosteroids, have been used to relieve pain when conservative treatment has failed.

Radiofrequency (RF) ablation and **pulsed radiofrequency (PRF)** ablation are ablative techniques which utilize a high frequency alternating current to denervate specific areas and are proposed treatments for trigger point pain. RF energy is a form of continuous heat source that is transmitted to the tip of a needle probe which is inserted through the skin and guided by x-ray or ultrasound to ablate targeted tissues. PRF, also known as cooled RF, differs from RF in that it employs pulsed heat energy, allowing tissue cooling between energy pulses. It is hypothesized that PRF minimizes the possibility of tissue being ablated, and that exposure to a rapidly changing electrical field alone generates sufficient cellular change to produce a therapeutic effect.

COVERAGE POLICY

Radiofrequency and pulsed radiofrequency ablation treatment of trigger points are considered **experimental**, **investigational**, **and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

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

There is limited published evidence in the peer-reviewed scientific literature about RF and PRF as treatment options for trigger point pain. Most published literature includes prospective case series and individual case reports. Large

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randomized controlled trials that compare RF and PRF to other treatments such as injections are lacking. The majority of the published literature on the use of RF and PRF for the treatment of trigger-point pain is limited by small sample sizes, lack of a control group and an uncertainty regarding the safety and effectiveness of long-term follow-up.

Randomized Controlled Trials

Ashtiani et al. (2023) completed a pilot randomized trial to compare the effectiveness of RF modulation therapy to tailored physiotherapy for participants with myofascial pelvic pain syndrome. A total of 46 female participants were randomized on a 1:1 basis to the RF group (n = 22) or the physiotherapy group (n = 24). Participants in the physiotherapy group received 10 treatment sessions while those in the RF group received six treatment sessions. The primary outcome measured during the study "was reduction in pelvic pain [measured using the visual analog score] after the final session and in the follow-up period 3 months after the final intervention session." Other outcomes measured included 1) abdominal, levator ani, piriformis, and obturator internus trigger points, 2) pelvic floor muscle endurance, 3) pelvic floor muscle strength, and 4) perineometry measurements. The mean age of all participants was 48.89±11.50 years (RF = 48.13±12.83 years; physiotherapy = 49.58±10.35 years). The mean body mass index for the RF group was 27.52±4.53 and 25.55±2.06 for the physiotherapy group. Results showed similar reductions "in reducing pain and improving [pelvic floor muscle] endurance after the final intervention session in each group, whereas perineometer readings and [pelvic floor muscle] strength were associated with greater improvements in the physiotherapy group." The presence of trigger points in the abdominal region was reduced by 76% from baseline to follow-up in both groups (p < 0.001). Additionally, the presence of trigger points in the obturator internus was decreased by 88% from baseline to follow-up for both groups (p < 0.001). No difference was noted in trigger points for the pirformis muscle between baseline and follow-up for either group (p = 0.148). Limitations of this study included an "insufficient sample size to account for borderline significant differences and trends observed in the current results." Researchers noted "this study demonstrated the comparable effectiveness of a radiofrequency-based therapy plan and conventional physiotherapy programs in reducing pelvic pain and improving [pelvic floor muscle] function." However, additional large, well-controlled trials are needed to validate these results.

Diego et al. (2019) published the results of a small (n=24) prospective, randomized, double-blind, and placebocontrolled trial that examined the feasibility of radiofrequency in patients with myofascial chronic neck pain. There was a total of 24 participants in the study, 14 of whom were randomly assigned to the radiofrequency group and 10 to the control group. The radiofrequency group received 12 minutes of radiofrequency twice per week for 4 weeks, for a total of 8 sessions. The control group was treated for the same duration with the same device, but without an energy source. The following outcomes were assessed: reduction of neck pain intensity at myofascial trigger points using the visual analog scale (VAS), improvement in cervical range of motion (CROM) using a CROM measurement device, and reduction of neck disability using the neck disability index (NDI). The evaluator who recorded the pre- and posttreatment measurements was blind to treatment allocation. In the radiofrequency group, there was a significant difference between baseline VAS and all measurement periods (p<0.001), but not in the control group (p>0.05). The NDI improved significantly in both groups (p<0.05), but there was no significant difference when comparing results between groups (p=0.254). There was no difference in CROM time between the two groups. The study found no significant difference between RF and no treatment in patients with myofascial chronic neck pain.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Niraj (2018) enrolled 120 participants with abdominal myofascial pain syndrome (AMPS) over a 3-year period in a prospective study. Participants were assigned to a structured pain management pathway and their pain-related outcomes were audited prospectively. The treatment plan started with medical management, which included a trial with amitriptyline, pregabalin, and tramadol. For localized pain, a 5% lidocaine plaster was prescribed, as well as a TENS machine trial and a course of acupuncture. Participants were advanced to the second treatment modality, trigger point injection with a local anesthetic agent, if their pain returned to baseline within 3 months. Trigger point injections with a depot steroid added to the local anesthetic were tried if injection with local anesthetic failed (no improvement at 3 months). Participants were offered PRF of the trigger points if the pain management techniques failed to provide pain relief for at least 3 months. There were 43 participants in total who received PRF, 12 (28%) did not respond to treatment, 5 (12%) responded but their responses were not sustained, and 26 (60%) had a durable response (relief lasting more than 6 months). In the 26 participants who received PRF and had a durable response, there was a reported complications with PRF (flare-up lasting at least 1 week). The authors concluded that, "While this study was designed to evaluate the use of a pain management pathway to treat AMPS, it provides evidence that PRF as a treatment option may hold promise for this pain syndrome. Further research, in the setting of a randomized controlled

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trial, may provide additional evidence that PRF is an effective and durable treatment option for AMPS.

Cho et al. (2017) published a comparative study of 36 patients with myofascial pain syndrome (MPS) of the trapezius muscle (TM) in which participants were randomly assigned to one of two groups to investigate the effects of ultrasound (US)-guided PRF stimulation on the interfascial area of the TM. In addition, its effect on the interfascial area of the TM was compared to that of interfascial block (IFB) with 10 mL of 0.6% lidocaine. Eighteen patients received PRF stimulation on the interfascial area of the TM (PRF group), while 18 patients underwent IFB with lidocaine on the same area (IFB group). Using a numerical rating scale (NRS), pain intensity was assessed at pretreatment, 2, 4, and 8 weeks after treatment. The Short Form-36 Health Survey (SF-36), which includes the physical component score (PCS) and the mental component score (MCS), was used to assess guality of life at pretreatment and 8 weeks after treatment. One patient was lost to follow-up in the PRF group. Both groups showed a significant decrease in NRS scores 2, 4, and 8 weeks after treatments and an increase in PCS and MCS of the SF-36 at 8 weeks. The decrements of NRS scores two weeks after each treatment were not significantly different between the two groups. However, 4 and 8 weeks after the procedures, the NRS score in the PRF group was significantly lower than in the IFB group. The PCS and MCS of the SF-36 in the PRF group were significantly higher than those in the IFB group at 8 weeks after the treatments. US-guided interfascial PRF had a greater long-term effect on reducing pain and quality of life for the treatment of MPS of the TM than US-guided IFB. In conclusion, US-guided PRF stimulation on the interfascial area of the TM can be a beneficial alternative for pain management after MPS of the TM. However, the authors noted that the study had several limitations that required additional research to address these limitations, including a small sample size (n=36), short-term follow-up (the effects of PRF and IFB were evaluated in only 8 weeks), the inability to explain the mechanism of action of PRF in reducing MPS-induced pain, and the absence of a placebo group.

National and Specialty Organizations

The American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine published *Practice Guidelines for Chronic Pain Management:* An Updated Report (2010) outlining the expert consensus/recommendations on various treatments and procedures for chronic pain. The report supports the use of conventional radiofrequency ablation for neck pain, with a variety of recommendations pertaining to low back pain; but does not specifically address trigger point pain in general or in respect to a specific body location.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
20999	Unlisted procedure, musculoskeletal system, general [when specified as radiofrequency or pulsed
	radiofrequency treatment of trigger points]

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 needed.

APPROVAL HISTORY

10/09/2024	Policy reviewed, no changes to coverage position. Updated references. IRO Peer Review on August 29, 2024, by a practicing physician board certified in Anesthesiology and Pain Management.
10/12/2023	Policy reviewed, no changes to coverage position. Updated references.
10/12/2022	Policy reviewed, no changes to coverage position. Updated references.
10/13/2021	Policy reviewed, no changes to coverage position. Updated references.
09/16/2020	New policy. IRO Peer Review June 28, 2020, by a practicing, board-certified physician(s) in the areas of Pain Management and
	Physical Medicine and Rehabilitation.

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