

Molina Clinical Policy

Genicular Radiofrequency Ablation and Genicular Nerve Blocks for Chronic Knee Pain: Policy No. 314

Last Approval: 2/9/2022

Next Review Due By: February 2023

OHIO: Do not exclude code 64454 or 64624 as all requests are reviewed for medical necessity on individual basis.

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. References included were accurate at the time of policy approval and publication.

OVERVIEW

Genicular radiofrequency ablation (RFA), also called genicular neurotomy, genicular denervation, cooled radiofrequency therapy and peripheral nerve ablation (PNA) of the knee is performed to relieve chronic pain associated with the knee. During RFA, radiofrequency (RF) energy delivers heat to the genicular nerves surrounding the knee creating a lesion that stops pain input to the central nervous system. Prior to planning the procedure, a diagnostic genicular nerve block is administered to ensure that there is adequate pain relief to indicate the patient is a suitable candidate for therapeutic neurotomy. RFA is performed in an outpatient setting, typically by a pain management specialist using fluoroscopic or ultrasonographic guidance to facilitate localization of the target nerves. After intradermal injection of a local anesthetic, an RF cannula is inserted and advanced until it makes contact with bone. Sensory stimulation is performed to identify the location of each target nerve. At this point, an anesthetic may be applied to the target nerve to relieve pain during the procedure. In conventional RFA, heat is delivered via probe to the target nerve at a temperature of 70°C to 80°C. Newer types of RFA, including pulsed and cooled RFA, deliver heat at lower temperatures and may cover a larger area. The pain relief afforded is temporary, as the peripheral nerves retain the ability to regrow and regenerate over time, thus allowing pain to return (Kidd et al., 2019).

COVERAGE POLICY

Genicular radiofrequency ablation and genicular nerve blocks **are considered experimental, investigational, and unproven** for the treatment of chronic knee pain, including but not limited to **ANY** of the following:

1. Degenerative joint disease or osteoarthritis of the knee; **OR**
2. As a treatment prior to or following a knee replacement; **OR**
3. As a treatment for individuals who are not candidates for knee replacement surgery.

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

Genicular nerve blocks and genicular radiofrequency ablation are under evaluation for the treatment of chronic knee pain for patients that have not been effectively managed by pharmacologic or other therapies. Overall, there is a low-quality body of evidence proposing that genicular nerve blocks and genicular radiofrequency ablation safely relieve pain and improve function in

patients with OA-related knee pain lasting more than 3 months that is refractory to conservative treatment. Currently, there are limitations of these published studies such as small sample size, lack of a control or comparison group, lack of randomization, lack of objective outcome measures, methodology or procedures not clearly reported, and baseline differences in disease severity between groups. Therefore, there is currently insufficient evidence to support the use of genicular nerve blocks and genicular radiofrequency ablation for the treatment of knee pain and OA.

Randomized Controlled Trials (RCTs)

A randomized controlled trial (Choi et al., 2011) examined whether radiofrequency neurotomy applied to genicular nerve branches was effective in providing relief to 38 patients from chronic osteoarthritis knee joint pain. Patients were randomly assigned to receive percutaneous radiofrequency genicular neurotomy under fluoroscopic guidance (radiofrequency group; n=19) or the same procedure without effective neurotomy (control group; n=19). Visual analog scale scores showed that the radiofrequency group had less knee joint pain at 4 (p 0.001) and 12 (p 0.001) weeks compared with the control group. Oxford knee scores showed similar findings (p 0.001). In the radiofrequency group, 10/17 (59%), 11/17 (65%), and 10/17 (59%) achieved at least 50% knee pain relief at 1, 4, and 12 weeks, respectively. Study limitations include small sample size, lack of long-term follow-up, and lack of objective outcome measures.

Another RCT compared RFA with intra-articular steroid injection in 73 patients with chronic OA knee joint pain (Sari et al., 2016). The results suggest that RFA was associated with significantly greater improvements in knee pain, stiffness, and function compared with intra-articular injections of steroid. Benefits began to decline by 3 months for both treatment types across outcomes. There were no adverse events in either treatment group. Study limitations include a lack of power analysis, blinding, long-term follow-up, monitoring of analgesic use, and objective outcome measures; and significant differences in disease severity between groups at baseline.

A fair-quality RCT compared RFA plus intra-articular injection with platelet-rich plasma and sodium hyaluronate with injections alone in 54 patients with chronic OA knee joint pain (Shen et al., 2016). The results suggest that the addition of RFA to intra-articular injection therapy improves knee pain and function in patients with OA compared with intra-articular injections alone. Both treatments were associated with significant improvements from baseline to 3 months for all outcomes. Adverse events were not reported. Study limitations include small sample size, lack of power analysis, randomization method was not reported, assessor blinding unknown, lack of objective outcome measures, no long-term follow-up, and RFA group treatment procedures were not reported thoroughly.

A double-blind, randomized clinical study (Qudsi-Sinclair et al., 2017) compared neurolysis using traditional radiofrequency to local anesthetic and corticosteroid block of the superolateral, superomedial, and inferomedial branches of the knee genicular nerves in patients who had total knee arthroplasty but still experienced pain. 28 patients, 14 on each treatment arm, were followed for over a one-year period. A reduction in pain and significant joint function improvement during the first three to six months was shown, with similar results using both techniques.

A prospective multicenter, randomized, crossover trial by Davis et al. (2018) enrolled 151 subjects with chronic knee pain to compare the safety and efficacy of cooled radiofrequency ablation (CRFA) with intra-articular steroid (IAS) injection in managing pain. Outcomes were measured using the Numeric Rating Scale for knee pain, Oxford Knee Score for function, and the Global Perceived Effect for overall quality of life. At 6 months, the CRFA group had more favorable outcomes in NRS: pain reduction 50% or greater: 74.1% versus 16.2%, $P < 0.0001$ (25.9% and 83.8% of these study cohorts, respectively, were non-responders). Mean NRS score reduction was 4.9 ± 2.4 versus 1.3 ± 2.2 , $P < 0.0001$; mean Oxford Knee Score was 35.7 ± 8.8 vs 22.4 ± 8.5 , $P < 0.0001$; mean improved Global Perceived Effect was 91.4% vs 23.9%, $P < 0.0001$; and mean change in nonopioid medication use was CRFA > IAS ($P = 0.02$). There were no procedure-related serious adverse events. After the 6-month follow up, 82% (58/71) of the IAS patients elected to cross over and receive CRFA treatment. When both groups were then assessed again at 12 months, 65% of the original CRFA group had pain reduction $\geq 50\%$, and the mean overall drop was 4.3 points ($p < 0.0001$) on the numeric rating scale. Seventy-five per cent reported 'improved' effects. The cross-over group demonstrated improvements in pain and functional capacity ($p < 0.0001$). No unanticipated adverse events occurred.

Chen et al. conducted a multicenter, randomized, single-arm crossover trial (2020a) comparing the efficacy and safety of CRFA to a single injection of hyaluronic acid (HA) for treatment of chronic knee pain due to OA. 182 subjects who met the inclusion criteria underwent diagnostic block injections and those with a minimum of 50% pain relief were randomized to receive either CRFA on 4 genicular nerves or a single HA injection. 177 subjects were treated. Outcomes were evaluated at 1, 3, and 6 months using the Numeric Rating Scale (NRS) for pain, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) for function, and Global Perceived Effect (GPE) score and EuroQol-5 Dimensions-5 Level (EQ-5D-5L) questionnaire for quality of life. 158 subjects (76 in the CRFA group and 82 in the HA group) completed the 6-month post-treatment follow-up. Results showed the subjects who were treated with CRFA had a greater reduction in pain and improvement in overall function compared to the subjects treated with a single injection of HA.

Subjects within the HA cohort were then allowed to crossover and receive CRFA treatment, and 68 (82.9%) elected to crossover (Chen et al., 2020b). Outcomes of pain, function and quality of life were then measured at 6 months following the crossover treatment (12-month follow up). Medication usage was also tracked with subjects divided into narcotic and non-narcotic analgesic groups. 73 subjects in the original HA group (62 who elected to crossover and 11 who declined crossover) returned for the 12-month follow up. The crossover group saw improvements in the evaluated outcomes of pain relief, perceived function, and quality of life. There were no statistically significant changes in opioid or non-opioid pain medication usage over time in any group. Of note, 14/87 (16%) subjects in the original HA cohort were not deemed medically appropriate candidates for CRFA and did not elect to crossover. Of the 11 that returned for their 12-month follow-up, 10 (90.9%) reported $\geq 50\%$ pain relief at the 12-month timepoint. Although the study generally shows improved outcomes with CRFA treatment, there are several limitations including lack of blinding, and opportunity for bias due to open label. It should also be noted that the control treatment (hyaluronic acid injection) has not been largely proven effective when managing knee OA pain and is not recommended by the American Academy of Orthopaedic Surgeons for routine use in the treatment of symptomatic osteoarthritis of the knee (AAOS, 2021).

Systematic Reviews

A systematic review (Bhatia et al., 2016) noted 13 reports on ablative or pulsed radiofrequency treatments of innervation of the knee joint. A high success rate of these procedures in relieving chronic pain of the knee joint was reported at 1 to 12 months after the procedures; however, only two of the publications were randomized controlled trials. There was evidence for improvement in function and a lack of serious adverse events of RF treatments. Randomized controlled trials of high methodological quality are required to further elaborate on the role of these interventions in this population.

A systematic review (Gupta et al., 2017) analyzed radiofrequency by conventional, pulsed, or cooled radiofrequency technique to relieve chronic knee pain. Seventeen total publications were included with most of them primarily treating the genicular nerves or alternatively employed in an intra-articular approach. Different therapeutic approaches to targeting the genicular nerve or an intra-articular approach produced no certain advantage. Different therapeutic technologies (conventional, pulsed, or cooled) to targeting the genicular nerve produced no certain advantage. Ongoing concerns on radiofrequency regarding the quality, procedural aspects, and monitoring of outcomes remain.

Chen et al. conducted a systematic review (2020c) to investigate how genicular nerve RFA compared to non-surgical treatments for knee OA in the areas of pain, function, quality of life, composite scores, and adverse events. A search of studies from 1966 to 2019 was conducted and five high-quality and two moderate-quality RCTs met inclusion criteria. While the studies all reported positive outcomes following RFA and no serious adverse effects were reported, there remains a lack of standardization in terms of administration technique and control group treatment. Studied treatments varied, including traditional RFA, RFA with additional platelet-rich plasma (PRP) and hyaluronic acid, and cooled RFA. The control groups also received different treatments (sham, hyaluronic injection, corticosteroid injection) across the studies. Some studies discontinued conventional guideline-directed therapy (e.g., non-steroidal anti-inflammatory drugs, consistent physical therapy). None of the studies reported long-term outcomes, with the longest outcome timeframe being one year. Given the lack of consistency and long-term safety data, the effectiveness of radiofrequency ablation remains questionable.

National and Specialty Organizations

The 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee (Kolasinski, 2020) states that radiofrequency ablation is conditionally recommended for treatment of knee OA. The recommendation remains conditional due to the fact that although some studies have demonstrated potential analgesic benefits with various ablation techniques, the available studies lack a standardized technique and controls were not uniform. There is also a lack of evidence showing long-term safety data.

The American Academy of Orthopaedic Surgeons (2021) Guidelines for treating Osteoarthritis of the Knee classify RFA as “denervation therapy,” along with chemical ablation. The guideline states that “Denervation therapy may reduce pain and improve function in patients with symptomatic osteoarthritis of the knee.” The strength of this recommendation is noted to be limited due to inconsistent evidence and bias. Future research in the area should utilize clinically relevant outcomes and controls for bias.

The Osteoarthritis Research Society International (OARSI) guidelines (Bannuru et al., 2019) do not include RFA in their Level IA, IB, or Level 2 recommendations for treatment of knee osteoarthritis.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed
64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed

HCPCS Codes – N/A

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

02/09/2022	Policy reviewed. Updated ‘Summary of Evidence’ and references.
06/20/2021	IRO Peer Review: Policy reviewed by IRO practicing physician Board certified in Physical Med & Rehab, Pain Management. According to the reviewer: “...There are no CMS LCD's that apply to genicular nerve blocks or RFA. The coverage criteria and exclusions are appropriate. The genicular blocks and RFA are all considered experimental/investigational...”
02/08/2021	Policy reviewed, new literature and guideline found do not change our position, this procedure remains experimental, investigational, and unproven. Added updated literature search to references and one new guideline (Kolasinski et al, 2020).
04/23/2020	Policy reviewed, no changes to criteria; added two new 2020 CPT codes: 64454, 64624; removed old codes 64450, 64640, 64999.
09/18/2019	Policy reviewed, no changes to criteria.
09/13/2018	New policy.

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Government Agencies

- Centers for Disease Control and Prevention (CDC). Arthritis. Osteoarthritis. Updated July 27, 2020. Available from [CDC](https://www.cdc.gov/arthritis/). Accessed January 26, 2022.
- Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: genicular nerve block; nerve block; genicular radiofrequency ablation). Available from [CMS](https://www.cms.gov/medicare-coverage-database/). Accessed January 24, 2022.

Evidence Based Reviews and Publications

- AMR Peer Review. Policy reviewed on July 23, 2018 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the area of Physical Medicine, Rehabilitation and Pain Management.
- Deveza LA, Benell K. Management of knee osteoarthritis. [www.uptodate.com](https://www.uptodate.com/contents/management-of-knee-osteoarthritis). Updated January 11, 2022. Accessed January 24, 2022. Registration and login required.
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Peer Reviewed Publications

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National and Specialty Organizations

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APPENDIX

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

OHIO: Do not exclude code 64454 or 64624 as all requests are reviewed for medical necessity on individual basis.