Subject: Genicular Radiofrequency Ablation and Genicular Nerve Blocks for Chronic Knee Pain		Original Effective Date: 9/13/2018
Policy Number: MCP-314	**Revision Date(s):**	
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Contents

DISCLAIMER

This Molina clinical policy 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 policy document and provide the directive for all Medicare members. [1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [29]

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. The nerves supplying the knee are called the genicular nerves that include the articular branches of the obturator, femoral, saphenous, common peroneal, and tibial nerves. During PNA, radiofrequency (RF) energy delivers heat to the target nerve thereby creating a lesion that stops pain input to the central nervous system. Prior to planning the procedure, a diagnostic genicular nerve block is conducted to ensure that the patient is a suitable candidate for PNA. Patients are awake during PNA, which is performed in

an outpatient setting and typically by a pain management specialist. It is usually performed with 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 at 50 hertz to identify the location of each target nerve. At this point, an anesthetic may be applied to the target nerve to relieve pain during RFA. Next, the RF probe is advanced through the cannula and the temperature of the tip is increased to 70°C to 80°C for 90 to 120 seconds. One lesion is created at each of the target nerves. PNA takes less than 1 hour.

POSITION STATEMENT

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: [ALL]

- ❑ Degenerative joint disease or osteoarthritis of the knee; or
- ❑ As a treatment prior to or following a knee replacement; or
- ❑ As a treatment for individuals who are not candidates for knee replacement surgery

SUMMARY OF MEDICAL EVIDENCE [5-28]

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, retrospective design, methodology or procedures not clearly reported, and baseline differences in disease severity between groups. Therefore, based on paucity of data 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. A summary of the relevant studies are outlined below.

RCT's

A randomized controlled trial (Choi 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. [6]

Another RCT compared PNA with intra-articular steroid injection in 73 patients with chronic OA knee joint pain (Sari et al., 2016). The results suggest that PNA 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. [18]

A fair-quality RCT compared PNA 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 PNA 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 PNA group treatment procedures were not reported thoroughly. [20]

A double-blind, randomized clinical study (Qudsi-Sinclair 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. [16]

Systematic Reviews

A systematic review (Bhatia 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 role of these interventions in this population. [5]

A systematic review (Gupta 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. [8]

Professional Society Guidelines

At the current time, there are no guidelines by any professional society that include genicular nerve blocks and genicular radiofrequency ablation as a possible treatment approach for chronic knee pain and OA. [2-5]

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed [New 2020 Code]
64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed [New 2020 Code]

HCPCS	Description
	N/A

ICD-10	Description: [For dates of service on or after 10/01/2015]
M17.0-M17.9	Osteoarthritis of Knee
M25.561-M25.569	Pain in the knee

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Professional Society Guidelines

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REVIEW/REVISION HISTORY

9/13/2018: New Policy
9/18/2019: Policy reviewed, no changes to criteria.
4/23/2020: Policy reviewed, no changes to criteria. Two new 2020 CPT codes added: 64454 & 64624. Removed the old codes 64450, 64640 & 64999.

2/8/2021: Policy reviewed, new literature and guideline found does not change our position, this procedure remains experimental, investigational and unproven. Added updated literature search to references and one new guideline under reference #4