

Policy: MP329

Section: Medical Benefit Policy

Subject: Genicular Nerve Ablation

I. Policy: Genicular Nerve Ablation

II. Purpose/Objective:

To provide a policy of coverage regarding Genicular Nerve Ablation

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION: Genicular Nerve Ablation (e.g., radiofrequency {RFA}, pulsed radiofrequency, cooled radiofrequency {COOLIEF} cryoablation, cryoneurolysis, cryoanalgesia, or chemical neurolysis {chemodenervation}) has been proposed as a treatment for chronic knee pain due to osteoarthritis that have not been effectively managed by pharmacologic or other standard therapies or as a treatment to control pain pre or post knee replacement.

INDICATIONS:

Genicular nerve ablation and cryoanalgesia is considered to be medically necessary to treat chronic knee pain secondary to osteoarthritis when all of the following criteria are met:

- Chronic knee pain secondary to osteoarthritic degeneration; and
- Inadequate response to or contraindication to pharmacologic analgesia; and
- Member is not yet considered a surgical candidate or has comorbidities that preclude surgical intervention

EXCLUSIONS: The Plan does **NOT** provide coverage for genicular nerve ablation for chronic knee pain caused by degenerative changes secondary to conditions other than osteoarthritis because it is considered **experimental, investigational or unproven** and therefore **NOT COVERED**. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Genicular Nerve Ablation

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- 64450 Injection, anesthetic agent; other peripheral nerve or branch [when specified as genicular nerve block]
- 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
- 64640 Destruction by neurolytic agent; other peripheral nerve or branch [when specified as ablation of genicular nerve(s)]
- 64999 Unlisted procedure, nervous system [when specified as cooled or pulsed RF therapy (not destruction) to genicular nerve(s)]

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Geisinger Technology Assessment Committee Triage Group. Genicular Nerve Ablation for Chronic Knee Pain. August 2019

Choi WJ, Hwang SJ, Song JG, et al. Radiofrequency treatment relieves chronic knee osteoarthritis pain: a double-blind randomized controlled trial. Pain. 2011; 152(3):481-487.

Davis T, Loudermilk E, DePalma M et al. Prospective, multicenter, randomized, crossover clinical trial comparing the safety and effectiveness of cooled radiofrequency ablation with corticosteroid injection in the management of knee pain from osteoarthritis. Reg Anesth Pain Med. 2018; 43(1):84-91.

Davis T, et al. Twelve-month analgesia and rescue, by cooled radiofrequency ablation treatment of osteoarthritic knee pain: results from a prospective, multicenter, randomized, cross-over trial. Reg Anesth Pain Med 2019 Feb 16.

Gupta A, Huettner DP, Dukewich M. Comparative effectiveness review of cooled versus pulsed radiofrequency ablation for the treatment of knee osteoarthritis: a systematic review. *Pain Physician*. 2017; 20(3):155-171.

Iannaccone F, Dixon S, Kaufman A. A review of long-term pain relief after genicular nerve radiofrequency ablation in chronic knee osteoarthritis. *Pain Physician*. 2017; 20(3):E437-E444.

McCormick ZL, Korn M, Reddy R, et al. Cooled radiofrequency ablation of the genicular nerves for chronic pain due to knee osteoarthritis: six-month outcomes. *Pain Med*. 2017; 18(9):1631-1641.

Qudsi-Sinclair S, Borrás-Rubio E, Abellan-Guillén JF, et al. A comparison of genicular nerve treatment using either radiofrequency or analgesic block with corticosteroid for pain after a total knee arthroplasty: a double-blind, randomized clinical study. *Pain Pract*. 2017; 17(5):578-588.

Santana Pineda MM, Vanlinthout LE, Moreno Martín A, et al. Analgesic effect and functional improvement caused by radiofrequency treatment of genicular nerves in patients with advanced osteoarthritis of the knee until 1 year following treatment. *Reg Anesth Pain Med*. 2017; 42(1):62-68.

Bhatia A, Peng P, Cohen SP. Radiofrequency Procedures to Relieve Chronic Knee Pain: An Evidence Based Narrative Review. *Reg Anesth Pain Med*. 2016;41(4):501-10

Sari S, Aydin ON, Turan Y, Ozlulerden P, Efe U, Kurt Omurlu I. Which one is more effective for the clinical treatment of chronic pain in knee osteoarthritis: radiofrequency neurotomy of the genicular nerves or intra-articular injection? *Int J Rheum Dis*. 2016.

Shen WS, Xu XQ, Zhai NN, Zhou ZS, Shao J, Yu YH. Radiofrequency thermocoagulation in relieving refractory pain of knee osteoarthritis. *Am J Ther*. 2016.

El-Hakeim EH, Elawamy A, Kamel EZ, et al. Fluoroscopic guided radiofrequency of genicular nerves for pain alleviation in chronic knee osteoarthritis: a single-blind randomized controlled trial. *Pain Physician* 2018;21(2):169–177

Hayes, Inc. Search and Summary. Coolief Cooled RF (Halyard Health, Inc) for Knee and Hip Pain. Lansdale, PA: Hayes, Inc. May 2018a.

Hayes, Inc. Technology Brief. Peripheral Nerve Ablation for Treatment of Osteoarthritic Knee Pain. Lansdale, PA: Hayes, Inc. 2017e. Reviewed September 2018b.

Ikeuchi M, Ushida T, Izumi M, et al. Percutaneous radiofrequency treatment for refractory anteromedial pain of osteoarthritic knees. *Pain Med*. Apr 2011;12(4):546-551

Radnovich R, Scott D, Patel AT, et. al. Cryoneurolysis to treat the pain and symptoms of knee osteoarthritis: a multicenter, randomized, double-blind, sham-controlled trial. *Osteoarthritis and Cartilage* 25 (2017) 1247-1256. PMID 28336454

Dasa V, Bliss R, Lensing G, et. al. Clinical Report Cryoneurolysis nerve block for total knee arthroplasty. *Myosience Clinical Reports* 2016 1(1): 1-4

Erdem Y, Sir E. The Efficacy of Ultrasound-Guided Pulsed Radiofrequency of Genicular Nerves in the Treatment of Chronic Knee Pain Due to Severe Degenerative Disease or Previous Total Knee Arthroplasty. *Med Sci Monit*, 2019; 25: 1857-1863

Kim SY, Le PU, et al. Is Genicular Nerve Radiofrequency Ablation Safe? A Literature Review and Anatomical Study. *Pain Physician* 2016; 19:E697-E705

Kirdmir P, Catay S, Alkaya-Solmaz F. The genicular nerve: radiofrequency lesion application for chronic knee pain. *Turk J Med Sci*. 2017 Feb 27;47(1):268-272

Kim DH, Lee MS, et al. A Prospective Randomized Comparison of the Efficacy of Ultrasound- vs Fluoroscopy-Guided Genicular Nerve Block for Chronic Knee Osteoarthritis. *Pain Physician* 2019; 22:139-146.

Bellini M, Barbieri M. Cooled radiofrequency system relieves chronic knee osteoarthritis pain: the first case-series. *Anaesthesiol Intensive Ther* 2015;47(1):30-33.

Rojhani S, Qureshi Z, Chhatre A. Water-cooled radiofrequency provides pain relief, decreases disability, and improves quality of life in chronic knee osteoarthritis. *Am J Phys Med Rehabil* 2017;96(1):e5-e8.

Best Doctors. Independent Technology Review. July 3, 2020

Geisinger Technology Assessment Committee Triage Group. Genicular Nerve Ablation and Cryoanalgesia for Chronic Knee Pain. August 2020

Mihalko WM. Cryoneurolysis Prior to Total Knee Arthroplasty Reduces Postoperative Pain and Opioid Use. The 2019 Members Meeting of the Knee Society; 2019; Cape Neddick, ME.

Plessl D, Salomon B, Haydel A, Leonardi C, Bronstone A, Dasa V. Rapid Versus Standard Recovery Protocol Is Associated With Improved Recovery of Range of Motion 12 Weeks After Total Knee Arthroplasty. *JAAOS - Journal of the American Academy of Orthopaedic Surgeons*. 2020

Dasa V, Lensing G, Parsons M, Harris J, Volaufova J, Bliss R. Percutaneous freezing of sensory nerves prior to total knee arthroplasty. *Knee*. 2016;23(3):523-528

Iffeld BM, Gabriel RA, Trescot AM. Ultrasound-guided percutaneous cryoneurolysis for treatment of acute pain: could cryoanalgesia replace continuous peripheral nerve blocks? *Br J Anaesth*. 2017;119(4):703-706.

Iffeld BM, Preciado J, Trescot AM. Novel cryoneurolysis device for the treatment of sensory and motor peripheral nerves. *Expert Rev Med Devices*. 2016;13(8):713-725.

Hsu M, Stevenson FF. Wallerian degeneration and recovery of motor nerves after multiple focused cold therapies. *Muscle Nerve*. 2015;51(2):268-275.

Hsu M, Stevenson FF. Reduction in muscular motility by selective focused cold therapy: a preclinical study. *J Neural Transm* 2014;121(1):15-20

McClean BC, Nguyen CD, Newman DP. Cryoablation of the Infrapatellar Branch of the Saphenous Nerve Identified by Non-Invasive Peripheral Nerve Stimulator for the Treatment of Non-Surgical Anterior Knee Pain: A Case Series and Review of the Literature. *Cureus*. 2020;12(6):e8747.

Iffeld BM, Gabriel RA, Trescot AM. Ultrasound-guided percutaneous cryoneurolysis providing postoperative analgesia lasting many weeks following a single administration: a replacement for continuous peripheral nerve blocks?: a case report. *Korean Journal of Anesthesiology*. 2017;70(5):567-570.

Gabriel RA, Iffeld BM. Novel methodologies in regional anesthesia for knee arthroplasty. *Anesthesiol Clin*. 2018;36(3):387-401.

Hsu M, Stevenson FF. Wallerian degeneration and recovery of motor nerves after multiple focused cold therapies. *Muscle & nerve*. 2015;51(2):268-275.

Evans PJ, Lloyd JW, Green CJ. Cryoanalgesia: the response to alterations in freeze cycle and temperature. *British journal of anaesthesia*. 1981;53(11):1121-1127.

Walega D, McCormick, Manning D, et. al. Radiofrequency ablation of genicular nerves prior to total knee replacement has no effect on postoperative pain outcomes: a prospective randomized sham-controlled trial with 6-month follow-up. *Reg Anesth Pain Med* 2019 Apr 25.

Chen A, Khalouf F, Zora K, et. al. Cooled radiofrequency ablation provides extended clinical utility in the management of knee osteoarthritis: 12 month results from a prospective, multi-center, randomized, cross-over trial comparing cooled radiofrequency ablation to a single hyaluronic acid injection. *BMC Musculoskelet Disord* 2020 Jun 9;21(1):363

Hunter C, Davis T, Loudermilk E. et. al. Cooled radiofrequency ablation treatment of the genicular nerves in the treatment of osteoarthritic kneed pain: 18 and 24 month results. *Pain Pract* 2020 Mar;20(3):238-246.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 8/19

Revised: 8/20 (add coverage provision)

Reviewed: 8/21

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.