JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Medical Policy Manual** **Medical Policy**	*Policy Number*	CMS24.16
		Effective Date	11/01/2023
		Approval Date	08/15/2023
	Subject **Genicular Nerve Treatments for Chronic Knee Pain**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

Johns Hopkins Advantage MD | Johns Hopkins Health Plan of Virginia Inc. (JHHPVA) | Priority Partners

Keywords: Genicular, Knee, Nerve Block

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I. ACTION

X	New Policy	
	Revising Policy Number	
	Superseding Policy Number	
	Retiring Policy Number	

II. POLICY DISCLAIMER

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

III. POLICY

For Advantage MD refer to: Medicare Coverage Database

- No Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) identified, (Accessed 7/27/2023)

For Johns Hopkins Health Plan of Virginia (JHHPVA) refer to: Medicare Coverage Database

- No Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) identified, (Accessed 7/27/2023)

For Priority Partners refer to: Code of Maryland Regulations

- Code of Maryland Regulations (COMAR) 10.67.06.27 Benefits - Limitations

- For additional regulatory information, refer to Professional Services Fee Schedule

For US Family Health Plan refer to: Tricare Policy Manuals

- TRICARE Policy Manual 6010.63-M, April 2021, Chapter 4, Section 20.1 Nervous System
- For additional regulatory information, refer to No Government Pay Procedure Code List

IV. POLICY CRITERION

A. Genicular Nerve Block (GNB)
   1. Unless benefits are provided under the member's contract, JHHP considers genicular nerve blocks for the treatment of knee pain attributed to Osteoarthritis investigational. It does not meet the Technological Evaluation Criteria (TEC) as defined in CMS01.00 Medical Policy Introduction
   2. When GNBs are covered under the members contract, ALL of the following criteria must be met: (*Applicable to PPMCO only*)
      a. Knee pain characterized as chronic or > 6 months, AND;
      b. Knee pain that interferes with ADLs, AND;
      c. Limited range of motion in knee with crepitus or effusion on physical examination, AND
      d. Radiologic evidence of Osteoarthritis that is Grade 2 or more on the Kellgren-Lawrence Classification Scale, AND;
      e. Documentation of unsuccessful conservative therapy (non-surgical management) for 12 weeks of ALL of the following unless adequate documentation is provided as to why conservative management is contraindicated.
         i. Trial and insufficient response to pharmacological therapy such as oral nonsteroidal anti-inflammatory medication (NSAID) and/or acetaminophen unless contraindicated
         ii. Trial and insufficient response to Observed Physical Therapy for >12 weeks with adequate documentation from therapist
         iii. Trial and insufficient response to Therapeutic intra-articular injections into knee

B. Genicular Radiofrequency Ablation (RFA) (*Applicable to Advantage MD and PPMCO) & (Applicable to JHHPVA effective 1/1/2024)*
   1. When benefits are provided under the member's contract, JHHP considers RFA for the treatment of knee pain attributed to Osteoarthritis medically necessary for patients who meet ALL of the following criteria:
      a. Knee Pain characterized as chronic or >6 months, AND;
      b. Knee Pain that interferes with ADLs, AND;
      c. Limited range of motion in Knee with Crepitus or Effusion (swelling) on Examination, AND;
      d. Radiologic evidence of Osteoarthritis that is Grade 2 or more on the Kellgren-Lawrence Classification Scale, AND;
      e. Documentation of unsuccessful conservative therapy (non-surgical management) for 12 weeks of ALL of the following unless adequate documentation is provided as to why conservative management is contraindicated.
         i. Trial and insufficient response to pharmacological therapy such as oral nonsteroidal anti-inflammatory medication (NSAID) and/or acetaminophen unless contraindicated
         ii. Trial and insufficient response to observed Physical Therapy for >12 weeks with adequate documentation from therapist
         iii. Trial and insufficient response to therapeutic intra-articular injections into the knee
   2. Unless benefits are provided under the member's contract, JHHP considers RFA investigational for the following conditions. It does not meet the Technological Evaluation Criteria (TEC) as defined in CMS01.00 Medical Policy Introduction
      a. Rheumatoid Arthritis

b. Status Post Total Knee Arthroplasty (TKA)

C. Unless benefits are provided under the member's contract, JHHP considers general anesthesia and monitored anesthesia for the majority of minor pain procedures not medically necessary in the absence of medical documentation of unusual medical circumstances.

V. DEFINITIONS

Genicular: Of or relating to the knee joint

Genicular Nerve Block (GNB): Minimally invasive procedure involving the injection of medication (local anesthetic such as bupivacaine or lidocaine, glucocorticoid, alcohol) to sensory non motor nerves in the knee after visualization of anatomic markers by ultrasound or fluoroscopy.

Radiofrequency Ablation (RFA): Minimally invasive procedure involving the insertion of a radiofrequency probe to anatomic landmarks using imaging (fluoroscopic or ultrasound). An electrode at the end of the probe delivers a pre-prescribed amount of current that disrupts/burns a selected non motor nerve.

Visual Analog Score (VAS): A validated unidimensional tool used to measure a persons' pain on a scale from 0 to 10 (Katz, 1999).

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC): A validated self-administered tool to measure pain, disability and joint stiffness of a person using a battery of 24 questions (McConnell, 2001).

Kellgren & Lawrence Osteoarthritis Scale: A radiological classification system commonly used in research to classify Osteoarthritis as well as for clinical decision making (Kohn, 2016).

Grade	Description
0	No radiologic features of osteoarthritis
1	Doubtful narrowing of joint space, possible osteophylic lipping
2	Possible narrowing of joint space, definitive osteophytes
3	Definite narrowing of joint space, multiple osteophytes, some subcondral sclerosis, possible bony deformity
4	Marked narrowing of joint space, large osteophyte, severe subcondral sclerosis, definite bony deformity

VI. BACKGROUND

In the United States, arthritis is a fairly common and disabling diagnosis affecting approximately 1 in 4 Americans daily (Centers for Disease Control and Prevention, 2023) with knee osteoarthritis accounting for 80% of the total disease burden by some accounts (Wallace, 2017). The cause of knee osteoarthritis is multifactorial though treatment goals are the same – pain control, improved function. As the population continues to age, the prevalence of this diagnosis will only grow with the need for new treatments.

At present, the gold standard for treatment for severe knee pain secondary to osteoarthritis is total arthroplasty. However, over 1 in 5 persons still have chronic knee pain after this procedure (Wylde, 2018). One in 7 persons will require revision surgery in

15 years (Shmerling, 2021). Bridge therapies range from non-pharmacologic therapy like physical therapy to pharmacological therapy like oral NSAIDS or intra-articular glucocorticoid.

Genicular Nerve Blocks (GNB) and Genicular Nerve Radiofrequency Ablation (RFA) are emerging as new therapies to offer pain relief to patients with chronic pain from knee osteoarthritis.

GNB are a minimally invasive procedure which involves the injection of the genicular nerve with medication to block the transmission of pain. The evidence base for this procedure is lacking with only 4 randomized clinical trials (Guler 2022, Kim 2018, Shanahan 2023, Yilmaz 2021) found in a review of literature evaluating GNB versus standard therapy such as an intra-articular (IA) corticosteroid or physical therapy. These studies were limited by their sample sizes (24-51 in the treatment arm) as well as their time to follow up (8-12 weeks). Although studies showed statistical significance, their clinical significance is questionable. Though pain was shown to be reduced in all four RCTs, the effects were not long standing and often returning to baseline by 8 weeks (Kim, 2018). Further, Yilmaz et.al (Yilmaz, 2021) determined that quality of life was not shown to be significantly different between the groups receiving GNB with IA steroid compared to those who received IA steroid alone. GNB are often done before RFA to provide predictive value, though no differences in outcomes have been observed between studies that preselected patients with GNB vs. those whose patients underwent RFA without GNB. This was shown in a randomized trial in which no differences were observed in genicular nerve RFA outcomes comparing patients who underwent a screening GNB before treatment to those who did not (McCormick, 2018). Due to the lack of a stronger body of published, adequately designed randomized control trials, GNB as a stand-alone treatment remains an investigational therapy with unclear clinical significance. Clinical criteria are provided when benefit plans dictate coverage of this service.

RFA is a minimally invasive procedure that involves the destruction of the genicular nerve to interrupt pain signaling. The evidence base for this modality is growing in the past 10 years, with more articles published about this procedure in 2020 compared to lumbar or cervical facet procedures (Kim P. C., 2021). The traditional technique was introduced by Choi et.al. (Choi, 2011) in a randomized trial comparing RFA to a sham procedure. Of the 17 patients that received RFA, there was a >50% reduction in pain as noted by Visual Analog Score (VAS) for up to 12 weeks. This study was limited by its small size and its lack of long-term follow-up. Since this trial, multiple randomized trials have been performed that have used a variety of techniques (cooled versus pulsed RFA, bipolar versus unipolar, need for prognostic GNB prior to procedure). Three large meta-analyses (Liu 2022, Sajan 2022, Wu 2022) reviewing numerous RCTs (15-48 trials evaluating 1009-3171 patients) have been done which compare the efficacy of RFA treatment to other pain control modalities or alone. Each noted improvement of knee pain and function for individuals with knee osteoarthritis for up to 12 weeks minimally and Wu noted pain control extending to 6 months. These meta-analyses help to overcome the limitations of the RCTs (e.g. methodology, population, sample size, follow up) and continue to show that despite these challenges, RFA does reduce pain, improve function and QOL. Further subgroup analysis in Liu et.al meta-analysis (2022) showed that there was no benefit to performing a prognostic GNB prior to RFA. A large multicenter prospective RCT is pending to look aggressive targeting of multiple sensory nerve targets in the knee (Cohen, 2023).

Due to the limited number of RCTs thus far with individual's s/p TKA or with inflammatory autoimmune conditions, these groups were not included in subgroup analysis. Therefore, RFA will continue to be considered investigational for this group.

VII. CODING DISCLAIMER

Note: The following CPT/HCPCS codes are included below for informational purposes and may not be all inclusive. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply that the service described by the code is a covered or

non-covered health service. Benefit coverage for health services is determined by the member's specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply.

Note: All inpatient admissions require preauthorization.

Adherence to the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits
Advantage MD: Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Johns Hopkins Health Plan of Virginia Inc. (JHHPVA): Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Priority Partners (PPMCO): Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria.

VIII. CODING INFORMATION

CPT® CODES ARE FOR INFORMATIONAL PURPOSES ONLY	
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

IX. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins Health Plans (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

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XI. APPROVALS

Historical Effective Dates: 11/01/2023