November 19, 2018

Blue Cross and Blue Shield of Kansas City
2301 Main Street
Kansas City, MO 64108

Re: Radiofrequency Ablation of Peripheral Nerves to Treat Pain, Policy Number 7.01.154

To Whom It May Concern:

The Spine Intervention Society, a multi-specialty association of over 2,800 physicians dedicated to the development and promotion of the highest standards for the practice of interventional procedures in the diagnosis and treatment of spine pain, would like to take this opportunity to comment on your coverage policy for radiofrequency ablation (RFA) of peripheral nerves to treat pain associated with knee osteoarthritis (OA).

The Society's membership includes many of the clinicians and academicians whose published literature provides the seminal references upon which the practice of evidence-informed interventional spine care, as well as interventional pain management for musculoskeletal care, is based. Our organization has a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved so that patients do not have to suffer or undergo more invasive and often unnecessary surgical procedures.

We would specifically like to comment on the **current policy's classification of RFA of peripheral nerves to treat pain associated with knee OA as investigational. We are most concerned that this policy is not consistent with current evidence**, which shows that for patients suffering with chronic knee pain (≥ 3 months) due to knee OA and/or after total knee arthroplasty not improved with standard conservative management, RFA of the corresponding genicular nerves is an effective, non-surgical treatment that will improve patient's function and quality of life. Patients treated with RFA experience decreased dependence on oral pain medications, reduced physical therapy utilization, and many are spared future costly and unnecessary surgical interventions.

Choi *et al,* in a 2010 double-blinded, randomized controlled trial (RCT) investigated the efficacy of thermal RFA in patients greater than 50 years old with persistent arthritic knee pain (≥ 3 months) not improved with physical therapy, oral analgesics, and intra-articular knee injections (either corticosteroid or hyaluronic acid) [1]. Nineteen patients who had positive diagnostic, fluoroscopically-guided genicular nerve blocks underwent subsequent standard, thermal RFA. The patients in this group reported significant decreased joint pain on the Visual Analog scale (VAS) and Oxford knee scores at 1-, 3-, and 6-month follow-up

intervals compared with 19 patients with similar demographics and knee OA severity, who underwent the sham procedure.

Similar results were found in a 2016 RCT by Qudsi-Sinclair *et al*; however, this study assessed the effectiveness of RFA in a population of patients with continued knee pain at least 6 months after knee replacement [2]. Prior to RFA, patients underwent fluoroscopically-guided genicular nerve blocks with lidocaine. Of the 28 patients included in the study, 14 were randomized to thermal RFA and 14 to therapeutic peripheral nerve injection with corticosteroid. Both groups' pain and function improved, with decreased use of pain medications at months 3 and 6, with similar results approaching 1 year for both groups. Besides some localized post-injection discomfort, no major adverse events were noted with the above studies.

The 2018 trial by Davis *et al* is the largest study and was also the first to employ cooled radiofrequency ablation (CRFA) [3]. Patients meeting inclusion criteria had at least grade 2 Kellgren–Lawrence radiographic OA, refractory knee pain of ≥6 month duration, pain of at least 6 of 10 on a Numeric Rating Scale (NRS), an Oxford Knee Score (OKS) of at least 35, and at least 50% improvement with genicular nerve blocks. The 151 patients who met the inclusion criteria were randomized to receive either CRFA or intra-articular steroid (IAS) injection. CRFA was performed under fluoroscopic guidance with 17-gauge introducers at 60°C for 150 seconds. The primary outcome measure was the percentage of patients achieving at least 50% pain reduction at 6 month follow-up as measured by the NRS. Secondary outcome measures included function measured on OKS, patient's overall perception of the treatment, and analgesic usage. Pain relief with CRFA was superior to that obtained with IAS at all time periods, and at 6 month follow-up, 74% of the CRFA group had at least 50% relief compared with just 16% of the IAS group. Function and global perception were also superior in the CRFA cohort, although there was no statistically significant difference between the groups in terms of oral opioid use. The longer duration of relief noted in this study, compared with duration of relief reported for traditional RFA, provides evidence for the theoretical increased benefit of CRFA -- namely the creation of larger lesions to reduce the technical failure rate of the procedure (*i.e.,* failure to effectively ablate the target nerves).

The most recent 2018 RCT by El-Hakeim *et al* compared RFA to conservative management consisting of oral acetaminophen, diclofenac, and physical therapy, as needed [4]. Sixty patients with grade 3 or 4 Kellgren–Lawrence OA were randomized to receive either RFA or conservative treatment. RFA was accomplished with three 90 seconds cycles at 90°C per site, which is a substantially longer duration of RFA than that employed by any other RCT. Patients were evaluated at baseline, 2 weeks, 3 months, and 6 months. Results showed statistically significant, superior pain relief with RFA at all follow-up intervals. Function, as assessed by the WOMAC Index, was improved in both groups at 6 months, but was superior with RFA. Lastly, patient satisfaction as measured on a Likert scale was significantly higher at 3- and 6-month follow-up in the RFA group. However, the study is limited by the failure to select patients based on response to diagnostic blocks and the absence of patient blinding.

The 2017 RCT by McCormick *et al* also employed CRFA, but the study was designed to determine the predictive value of prognostic nerve blocks, not to compare RFA to other modalities [5]. Fifty-four patients with chronic knee pain due to OA received CRFA. The study included patients between 30 and 80 years of age, with >6 months of refractory knee pain, NRS pain score of at least four, and at least grade 2 radiographic OA. Prior to RFA, the 32 patients in the nerve block group received prognostic blocks, of which 29 had positive blocks and proceeded to RFA. Notably, only three of 32 (9.3%) patients had a negative block, defined as <50% pain relief. Twenty-five patients were randomized to the non-nerve block RFA group. Follow-up was conducted at 1, 3, and 6 months, but the primary outcome measure was attainment of at least 50% pain relief at the 6-month mark. Results showed significant improvements in both groups at 6 months, with 58.6% of the nerve block group and 64% of the non-nerve block group achieving at least 50% relief at 6 months. There were no significant differences between groups in terms of pain and function at any of the time periods.

Prospective observational evidence outside of RCTs can also be used to demonstrate the effectiveness of a procedure. In fact, when the outcomes of well-performed, prospective trials demonstrate dramatic and sustainable results that are reproducible across studies, one could argue that the need to demonstrate that the effects of the procedure are not due to placebo effects alone are seriously minimized.

One such prospective cohort study published by Iannaccone *et al* presents results of 31 patients treated with genicular RFA [6]. The patients were assessed at both 3 and 6 months after RFA. At 3 months the average pain relief was 67% improvement from baseline and at 6 months those that received pain relief at 3 months continued to have durable pain relief of 95%.

Another study by Pineda *et al* in 2017 presented evidence that RFA of the genicular nerves significantly reduced perceived pain and disability in the majority of participants, without adverse events [7]. This single-center, prospective, observational study included patients with grade 3 to 4 arthrosis suffering from intractable knee pain of at least 6 months and scoring 5 or more on the visual analog scale (VAS). The proportion of participants with improvement of at least 50% in pretreatment VAS scores at 1, 6, and 12 months following intervention were 88% (22/25), 64% (16/25), and 32% (8/25), respectively.

Due to the robust nature of the evidence, RFA of the genicular nerves is a valuable treatment for patients suffering from chronic knee pain and for patients with residual pain after total knee arthroplasty. Further, the procedure is indicated and may be the only option for patients that are not surgical candidates or who choose not to have surgical treatment. Acknowledging the strength and quality of the evidence in support of the safety and effectiveness of genicular nerve RFA, **the American Medical Association's Current Procedural Terminology (CPT®) Editorial Panel has approved a Category I code that will go into effect on January 1, 2020.**

We hope that this information, as well as any dialogue and collaboration between Blue Cross and Blue Shield of Kansas City and the Spine Intervention Society, will lead to the establishment of a reasonable coverage policy that will eliminate inappropriate utilization while preserving access in appropriately selected patients. We offer our ongoing input and expertise in this matter. If we may answer any questions or provide any assistance, please feel free to contact Belinda Duszynski, Senior Director of Policy and Practice at bduszynski@SpineIntervention.org.

Sincerely,

Timothy P. Maus, MD
President
Spine Intervention Society

References:

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