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Claudia Campos, MD, FACP
Juan Schaening-Perez, MD
Denise Nachodsky, MD
1717 W. Broadway
Madison, WI 53701-1787

Submitted via: policycomments@wpsic.com

Re: Public Comment for Proposed LCD - Peripheral Nerve Blocks and Procedures for Chronic Pain (DL40300)

Dear Drs. Campos, Schaening-Perez, and Nachodsky,

The Society of Interventional Radiology (SIR)[1] and the American College of Radiology (ACR)[2] appreciate the opportunity to provide comments on the proposed Local Coverage Determination (LCD) related to peripheral nerve block procedures. We are committed to advancing high-quality, image-guided, minimally invasive care that reduces reliance on opioids and improves patient outcomes.

Opioid Crisis

The United States continues to face a severe opioid epidemic, which remains a leading cause of preventable death and disability. According to the Centers for Disease Control and Prevention (CDC), over 75% of the nearly 110,000 drug overdose deaths in 2022 involved opioids. In response, national clinical guidance, including the CDC's 2022 Clinical Practice Guideline for Prescribing Opioids for Pain, has emphasized the importance of non-opioid and non-pharmacologic therapies, including interventional procedures, in the management of chronic pain.

In light of this guidance, we urge the Medicare Administrative Contractor (MAC) to ensure that the final LCD supports access to evidence-based, opioid-sparing interventional procedures. Overly restrictive coverage policies risk limiting effective treatment options for Medicare beneficiaries and may inadvertently contribute to ongoing opioid use, increased expense due to increased physician visits and prescriptions, and associated harms. Interventional radiologists, as specialists in image-guided pain management, play a critical role in delivering safe and effective alternatives to systemic pharmacologic therapy.

Peripheral Nerve Ablation Procedures

SIR and ACR urge the MAC to consider a more nuanced, evidence-based approach to coverage for peripheral nerve ablation procedures, particularly in cases of non-spinal, non-cancer-related pain. As

[1] SIR is a professional medical society representing over 8,000 members, including U.S. physicians practicing in vascular and interventional radiology.
[2] ACR is a professional medical society representing over 41,000 physicians practicing diagnostic radiology, interventional radiology, radiation oncology, and nuclear medicine, as well as medical physicists.

outlined in clinical practice, the epicenter of the diagnostic and treatment algorithm for these patients is an image-guided peri-neural injection. The use of advanced imaging modalities ensures accurate needle placement, avoids diagnostic ambiguity, and enhances the predictive value of the injection.

This approach enables two key outcomes:

1. Identification of patients who are likely to benefit from targeted nerve ablation (e.g., radiofrequency ablation, cryoneurolysis, or other neuroablative therapies) based on a positive, albeit temporary, response to the diagnostic block.

2. Reduction in unnecessary procedures by eliminating patients who do not respond to diagnostic nerve blocks, thus aligning with both clinical appropriateness and cost-effectiveness.

This clinical model mirrors long-standing practices in cancer pain management, in which a successful diagnostic block is the threshold for proceeding to ablation for more durable relief. In the context of peripheral somatic nerve pain, such as genicular, suprascapular, occipital neuralgias, etc., this paradigm supports safe, selective, and opioid-sparing intervention.

We respectfully recommend that the LCD recognize this diagnostic-therapeutic continuum and allow coverage for peripheral nerve ablation procedures when preceded by a positive response to a diagnostic image-guided block. Such an approach ensures that these services are applied judiciously, in alignment with clinical evidence and public health imperatives to reduce opioid reliance.

Diagnostic Blocks, Nerve Ablation, and Procedural Pain Management

SIR and ACR respectfully request the withdrawal of the proposed non-coverage of peripheral nerve blocks and denervation procedures beyond the narrow scope currently outlined in the draft LCD. As interventional radiologists, we emphasize a patient-centered, evidence-informed model of care that balances diagnostic clarity with procedural precision, while prioritizing opioid-sparing alternatives.

In clinical practice, our general approach to peripheral somatic pain (outside the spine and unrelated to malignancy) centers around the use of **image-guided peri-neural injections**. This approach serves three critical functions:

1. **Interruption of Nociceptive Conduction**: Peripheral nerve blocks interrupt nerve conduction along clearly defined pain pathways, providing temporary pain relief that may be diagnostic or therapeutic depending on the indication.

2. **Periprocedural Analgesia**: Peripheral nerve blocks are frequently used to reduce procedural pain for interventional therapies. For example, **hepatic hilar nerve blocks (HHNB)** are commonly performed prior to percutaneous transhepatic cholangiography (PTC) or thermal ablation of hepatic tumors. This use aligns with the LCD's exception for "acute surgical pain," and we recommend that such scenarios be explicitly recognized and preserved within any final policy.

3. **Target Testing Prior to Ablation**: A **diagnostic block with local anesthetic ± corticosteroid** (e.g., 0.25% bupivacaine, 40 mg triamcinolone) allows for confirmation of the target nerve's role in

pain generation. A positive response, albeit short-acting (lasting hours to days), provides non-ambiguous diagnostic information and enables **predictive patient selection for nerve ablation** (e.g., radiofrequency ablation or cryoneurolysis) for longer-term relief. This diagnostic-therapeutic paradigm mirrors long-standing practices in cancer pain management. It is equally applicable to conditions such as occipital neuralgia, genicular nerve pain, or suprascapular nerve-mediated shoulder pain.

The current LCD permits this pathway only for trigeminal neuralgia, while broadly excluding it for other anatomically and physiologically analogous nerves, even when supported by diagnostic efficacy and published evidence. This exclusion is overly restrictive and will unintentionally prevent Medicare beneficiaries from accessing effective, opioid-sparing interventions that are both clinically and economically justified.

ASA-Endorsed Use of Medial Branch Radiofrequency Ablation for Chronic Spine Pain

SIR and ACR support the continued Medicare coverage of **radiofrequency ablation (RFA) of the medial branch nerves** for the treatment of chronic neck and low back pain. This procedure is a well-established and evidence-based component of interventional pain management for facet-mediated axial spine pain.

Specifically highlighted in the **American Society of Anesthesiologists (ASA) 2022 Practice Guidelines**, the use of medial branch RFA for patients with chronic spinal pain unresponsive to conservative therapies is endorsed. The guidelines cite **Category A1 evidence**, supported by **meta-analyses of randomized controlled trials**, demonstrating that RFA provides **statistically and clinically significant pain relief for 2 to 6 months** in appropriately selected patients.

This recommendation reflects the highest level of evidence available for interventional spine procedures and aligns with real-world clinical outcomes. As interventional radiologists who routinely perform these procedures using image guidance and standardized protocols, we emphasize that medial branch RFA:

- Offers a targeted, minimally invasive alternative to systemic pharmacologic therapy, including opioids;
- Supports functional improvement and reduces reliance on repeat injections; and
- Demonstrates a favorable risk-benefit profile when preceded by a positive diagnostic medial branch block.

Given the consistency of evidence and national guideline support, **we urge the MAC to ensure that RFA of the medial branch nerves remains a covered service under the LCD.**

Genicular Nerve Neurolysis for Chronic Knee Pain

SIR and ACR urge the MAC to reconsider the non-coverage position for all neurolysis procedures, especially genicular nerve neurolysis procedures, including radiofrequency ablation (RFA) and cryoneurolysis, for chronic knee pain, particularly in patients who are not candidates for surgery or who have persistent pain following total knee arthroplasty (TKA).

A 2025 systematic review and meta-analysis of sham-controlled randomized controlled trials (RCTs) provides high-level evidence supporting the safety and efficacy of genicular neurolysis. The pooled results demonstrated:

- A mean pain reduction of –1.65 on a 0–10 numeric rating scale at 12 weeks,
- A significant improvement in function, with a WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) mean difference of –11.37, and
- No serious adverse events reported across included studies.

Importantly, trial sequential analysis confirmed that the evidence is conclusive for both pain reduction at 12 weeks and functional improvement at 24 weeks, minimizing concerns about random error or false-positive findings.

Additionally, subgroup analysis favored conventional monopolar RFA over other modalities, providing further guidance on optimal technique selection.

These findings meet the threshold of medical reasonableness and necessity and should inform Medicare coverage policy. Denying coverage for these procedures—despite robust evidence from sham-controlled RCTs- unnecessarily restricts access to effective, opioid-sparing, minimally invasive treatments for a growing population of patients with chronic knee pain who have exhausted conservative therapy.

Another 2025 systematic review reported pooled success rates for genicular neurolysis of 51% at 6 months and 43% at 12 months for achieving ≥50% pain reduction, with higher success rates observed when larger lesioning techniques were employed, supporting the durability and technique-dependent efficacy of this intervention.

We respectfully request that an updated LCD will allow coverage of genicular nerve neurolysis when:

- The patient has chronic knee pain unresponsive to conservative therapy,
- A diagnostic genicular nerve block demonstrates ≥50% pain relief, and
- Neurolysis is performed using validated techniques such as conventional monopolar RFA or cryoneurolysis.

This evidence-based approach aligns with the goals of Medicare to support high-value care while minimizing the use of low-evidence or high-risk therapies, such as chronic opioid use or repeat surgical intervention.

<u>Pudendal Neurolysis</u>

SIR and ACR strongly encourage the MAC to reconsider its current non-coverage position on pudendal nerve interventions, including pulsed radiofrequency (PRF) and pulsed dose radiofrequency (PDRF), for the treatment of pudendal neuralgia.

A growing body of high-quality evidence, including multiple prospective and retrospective studies and a recent randomized controlled trial, demonstrates that PRF and PDRF targeting the pudendal nerve can

result in significant reductions in pain scores and improvements in quality of life for up to 6–12 months. These interventions are particularly impactful for patients with pudendal neuralgia who are refractory to conservative measures and pharmacologic therapy.

Reported remission rates of 88–89% and minimal adverse events across published data highlight the safety and clinical utility of these procedures. The evidence base supports their use as effective, minimally invasive, and opioid-sparing alternatives in this challenging patient population.

We respectfully request that the LCD be revised to allow coverage of image-guided PRF or PDRF of the pudendal nerve when:

1. The diagnosis of pudendal neuralgia has been clearly established,
2. Conservative therapies have failed or are contraindicated, and
3. The procedure is performed using image guidance and appropriate clinical protocols.

Peripheral nerve ablation aligns with CMS's "Roadmap to Address the Opioid Crisis" by expanding access to evidence-based, non-opioid pain management strategies for individuals with chronic pain, supporting safer, more sustainable treatment pathways for Medicare beneficiaries. Excluding coverage for these procedures not only conflicts with evolving clinical evidence but also deprives patients of access to safe and effective pain-relief strategies. Recognizing these procedures under Medicare would support a more comprehensive, evidence-aligned approach to managing chronic pelvic pain.

We respectfully and firmly request that the MAC adopt a **more evidence-aligned and clinically flexible coverage policy** that includes:

- Recognition of diagnostic blocks as a gateway to targeted ablation;
- Coverage for image-guided neurolysis procedures where supported by published evidence;
- Preservation of coverage for medial branch RFA;
- Inclusion of genicular and pudendal nerve ablation for appropriately selected patients.

This approach reflects clinical best practices, safeguards patient access to effective therapies, and supports national efforts to combat opioid overuse.

We appreciate the opportunity to provide meaningful feedback on the CMS proposed LCD for Peripheral Nerve Blocks and Procedures for Chronic Pain. If you have any questions, please do not hesitate to contact SIR's Senior Manager of Health Policy and Economics, Ashley Maleki, at amaleki@sirweb.org or (703) 844-0378.

Sincerely,

Robert A. Lookstein, MD, FSIR
President, Society of Interventional Radiology

Dana Smetherman, MD, MPH, MBA, FACR, FSBI
Chief Executive Officer
American College of Radiology

cc: Eve Lee, MBA, CAE
Chief Executive Officer, Society of Interventional Radiology

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