November 7, 2025

Noridian Healthcare Solutions, LLC
Attention: Draft LCD Comments
4510 13th Ave. S, STE1
Fargo, ND 58103-6646

via Email: policydraft@noridian.com

RE: Request for Postponement and Collaborative Development of Evidence-Based LCDs

On behalf of the undersigned societies representing >100,000 physicians dedicated to the safe, evidence-based care of individuals living with chronic pain, we respectfully submit this joint consensus comment regarding the proposed non-coverage determination for peripheral nerve blocks (PNBs), peripheral nerve radiofrequency ablation (RFA), and related interventional procedures used to treat pain conditions.

We strongly urge Noridian to:

1. **Rescind this LCD** as it oversteps the Federal Agency goals outlined by the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services (DHHS), and Multisociety Guidelines.
2. **If not rescinded immediately, postpone the issuance of the proposed LCD to collaborate with the undersigned societies** to develop evidence-based LCDs that reflect the most current research and important clinical considerations to establish **appropriate coverage criteria** for these procedures.

We appreciate the opportunity for alignment with the latest scientific evidence, uphold Medicare's commitment to patient access, advance the Centers for Medicare & Medicaid Services' (CMS) opioid reduction goals, and avoid unintended harm to patients with chronic pain.

POPULATION PLACED AT RISK BY THIS LCD PROPOSAL AND CURRENT TREATMENT LANDSCAPE

Chronic pain (i.e., pain lasting ≥3 months) is a debilitating condition that affects daily work and life activities for a very large number of Medicare beneficiaries and has been linked with depression [1], Alzheimer's Disease and related dementias [2], higher suicide risk [3], and substance use and misuse [4]. Studies also confirm the high costs associated with chronic high-impact pain [5]. The CDC analyzed data from 2019–2021 to provide updated estimates of the prevalence of chronic pain and high-impact chronic pain among adults in the United States, as well as within population groups defined by demographic, geographic, socioeconomic, and health status characteristics. During 2021, an estimated 20.9% of U.S. adults (51.6 million people) experienced chronic pain, and 6.9% (17.1 million people) experienced high-impact chronic pain (i.e., chronic pain that results in substantial restriction to daily activities) [5].

Therefore, the CDC has called explicitly on clinicians, practices, health systems, and payers to vigilantly address health inequities and ensure access to appropriate, affordable, diversified, coordinated, and effective pain management care for all patients. The CDC's 2022 Clinical Practice Guideline for Prescribing Opioids for Pain provides recommendations to promote a multimodal and multidisciplinary approach to pain management and implementation strategies to reduce disparities in pain management care, inclusive of radiofrequency ablation, epidural steroid injections, nerve blocks, and neuromodulation [6]. These guidelines state, "Clinicians should maximize use of nonpharmacologic and nonopioid pharmacologic therapies" to prevent and/or reduce opioid use. Furthermore, the DHHS Pain Management Best Practices Interagency Task Force Report (2019), following extensive input from multiple stakeholders, called for a multidisciplinary evaluation and access to non-opioid therapies, including neural blockade and radiofrequency ablation [7].

Conservative options alone are frequently ineffective for managing chronic pain conditions [8,9]. In an analysis of 96 randomized controlled trials (RCTs) including 26,169 participants, Busse *et al*. demonstrated that conservative options are rarely effective, and even opioids are associated with minimal benefit [8]. Likewise, Finnerup *et al*. conducted an exhaustive systematic review of chronic pain medications and found that the drugs typically used for chronic pain indications (e.g., gabapantenoids, selective norepinephrine reuptake inhibitors, topical agents) are associated with a very high number needed to treat (NNT) in placebo controlled RCTs, ranging from 6 to 11; in other words, only every 6^{th} to 11^{th} patient benefited from these medications beyond placebo leaving the vast majority in pain [9].

Alternatively, nerve block and radiofrequency ablation treatments provide powerful, target-specific diagnostic information and therapeutic effects, founded in principles of precision medicine. Nerve blocks are used to confirm the underlying diagnosis or diagnoses contributing to a given patient's chronic pain presentation. Nerve blocks are also used to accurately prognosticate the outcomes of subsequent curative procedures or procedures that provide greater durability of treatment effect in patients who have failed to respond to conservative care.

While this is intuitive to practicing Pain, Spine, and Musculoskeletal physicians, the utility of nerve blocks and radiofrequency ablation procedures has clearly been overlooked in the proposed LCD. When patients with chronic pain have access to Pain, Spine, and Musculoskeletal specialists for lower back pain, neuropathy, and headaches, there is a decrease in opioid initiation and use [10]. Therefore, Medicare beneficiaries must continue to have access to effective non-opioid pain management options.

BACKGROUND AND RATIONALE FOR RESCINDING THIS LCD

The proposed policy would broadly eliminate coverage for procedures integral to the practice of Pain Medicine, Physical Medicine and Rehabilitation, Anesthesiology, Neurology, Radiology, Neurosurgery, Orthopedic Surgery, and Sports Medicine, specifically for the treatment of chronic musculoskeletal and neuropathic pain. These interventions have decades of clinical use, are supported by peer-reviewed literature,

demonstrate well-established mechanisms of action and favorable safety profiles, and provide substantial real-world value when used appropriately.

Of note, some of the more unique PNB and peripheral nerve RFA procedures are used to treat conditions that are too rare to realistically study in well-powered RCTs (e.g., treatment refractory sphenopalatine neuralgia, auriculotemporal neuralgia, supraorbital neuralgia, supratrochlear neuralgia, spinal accessory neuralgia, Complex Regional Pain Syndrome (CRPS) of the upper extremity, superficial radial sensory neuralgia phantom limb pain, cluneal neuralgia, isolated infrapatellar branch of saphenous neuralgia, CRPS of the lower extremity, Baxter's neuralgia, among many others). In such cases, conducting multiple sham-controlled and pragmatic trials is simply unrealistic, and it is unreasonable to maintain the same evidence development standards as for prevalent pain conditions like osteoarthritis of the knee. Eliminating access to these procedures will likely worsen disability and diminish quality of life, while increasing reliance on costly surgical and opioid prescriptions. These downstream effects would raise, rather than reduce, overall healthcare utilization and spending. Moreover, restricting access would be inconsistent with CMS's Roadmap for Addressing the Opioid Crisis, which explicitly encourages coverage of evidence-based, interventional, non-pharmacologic pain management strategies [11].

PERIPHERAL NERVE BLOCKS AND RFA (EXCLUDING TRIGEMINAL AND GENICULAR NERVE)

LCD Evidence Summary

The proposed LCD does not meet the evidentiary standards necessary to justify a non-coverage determination for all PNB procedures, which must consider the clinical and policy implications of offering versus withholding a given treatment, including the risks of the treatment compared to alternatives, as captured by systems like the United States Preventive Services Task Force (USPSTF) Grades and Levels of Certainty Regarding Net Benefit. Using occipital nerve blocks as an example, the LCD's evidence assessment acknowledges generally favorable systematic reviews and highlights a study by Malekian et al (2022), but omits key findings – namely, that patients treated with occipital nerve blocks experienced a significant reduction in migraine episodes [12] – as well as established clinical practice guidelines supporting their use for other complex headache types [13]. Chronic headache and migraine are leading causes of absenteeism and disability, and occipital nerve blocks are a relatively inexpensive and safe intervention for these extremely challenging conditions [14-19]. Even the CDC 2022 opioid guidelines specifically cited two publications that attest to the utility of the occipital blocks in acute migraine treatment [6,17,20]. Limiting access will likely lead to an increase in expensive medications, ER and urgent care visits for migraine and other complex headache attacks, and more expensive and invasive procedures.

Stellate ganglion blocks (SGBs) are used to treat CRPS, a rare, incompletely understood, but debilitatingly painful condition with limited treatment options in cases where conservative care has failed to provide meaningful pain relief and restoration of function. It involves phases of intense pain mediated by autonomic, immune, and inflammatory

alterations [21]. The proposed LCD describes two systematic reviews and acknowledges high heterogeneity, unclear allocation concealment, and high risk of bias without evaluating individual RCTs. The highest-quality RCT [22] found significant improvement in pain and depression scores for patients treated with SGBs versus controls at 12 months. Clinical guidelines for treatment of CRPS define sympathetic nerve blocks (SGBs) as a minimally invasive, first-line intervention [23]. Eliminating access to SGBs will increase utilization of more costly interventions, such as neuromodulation, intrathecal drug infusions, and sympathectomy.

As mentioned above, several of the conditions for which PNBs and RFA are utilized are rare, yet these procedures have been relied on as standard of care for decades and have demonstrated effectiveness in reducing pain and improving quality of life for many patients.

Evidence-Based Multidisciplinary Guideline Recommendations

For many of the peripheral nerve block procedures proposed for non-coverage, the LCD does not adequately account for key recommendations from recently published multisociety guidelines endorsed by the American Society of Regional Anesthesia and Pain Medicine, the American Academy of Pain Medicine, the American Society of Interventional Pain Physicians, and the International Pain and Spine Intervention Society [24]. Developed through a rigorous, multidisciplinary consensus process, these guidelines reflect best practices grounded in current evidence and clinical experience. They accurately synthesize the literature in the context of procedural safety, available alternative treatments, and overall value to the healthcare system. Importantly, they evaluate not only the strength of the evidence (e.g., GRADE methodology) but also the clinical and policy implications of offering versus withholding a given treatment. Maintaining this comprehensive perspective is essential for sound medical decision-making and responsible healthcare policy.

Multiple studies and clinical experience demonstrate that these procedures are both effective and safe when used according to established guidelines. PNBs and ablations can provide rapid, durable pain relief, improve function and quality of life, and reduce reliance on systemic analgesics, including opioids. Restricting access to these interventions would have direct negative consequences for patients with chronic pain.

Key recommendations from the multisociety guidelines [24] include, but are not limited to:

- Greater occipital nerve blocks for occipital neuralgia, migraine, post-traumatic headache, and cluster headaches are recommended (moderate level of certainty).
- SGB with either ultrasound or fluoroscopic guidance for facial pain due to herpes zoster infection and for upper extremity CRPS is recommended (moderate level of certainty).
- Sympathetic blocks for CRPS and certain visceral pain syndromes, and coccydynia with or without the addition of corticosteroid are recommended (moderate level of certainty).

- Ilioinguinal and iliohypogastric nerve blocks with ultrasound guidance are recommended (moderate level of certainty).
- Trigeminal and pudendal nerve blocks: Conditionally recommended for neuralgia and pelvic neuropathic pain syndromes.

For context, the above recommendations (and others contained in the clinical practice guideline) are based on the USPSTF Grades and Levels of Certainty Regarding Net Benefit. As above, the level of evidence must be interpreted within the broader context of safety, alternative treatments, and the implications of offering versus not offering a given treatment. A "moderate level of certainty" under USPSTF criteria indicates that benefits likely outweigh harms, though additional evidence may refine effect size—thus supporting continued coverage pending further study.

Terminology/Nomenclature

The proposed LCD includes confusing terminology, which raises some questions regarding coverage. Specifically, the term "thoracic nerve blocks" is non-specific. Thoracic nerve blocks could be interpreted to include diagnostic procedures targeting multiple structures in the thoracic spine. The data described in the LCD are specific to intercostal and erector spinae plane blocks. This should be clarified before finalization. Additionally, "any other peripheral nerve blocks or denervations not listed above" is also confusing and could be interpreted to include all nerves distal to the spinal cord, including selective nerve root blocks and medial branch blocks.

Additionally, the proposed LCD does not distinguish between pulsed RFA and thermal RFA (standard, bipolar, and cooled RFA). Thermal RFA uses heat to coagulate or ablate target nerve tissue, impairing its ability to transmit pain signals. This is not the case with pulsed RFA, so these procedures must be evaluated separately.

Non-Coverage: Unintended Consequences

Although we agree with and applaud attempts to reduce wasteful healthcare expenditure, the proposed LCD is unlikely to achieve this. Many of the specified PNBs and ablations (excluding genicular nerve block and ablation) represent relatively uncommon procedures for relatively rare conditions. Patients with many of these uncommon conditions are limited to few, if any, other options, a prime example being refractory complex regional pain syndrome (CRPS) that has not responded to conservative and non-invasive care. Based on the 2024 Medicare Part B National Summary Data file, annual expenditure for peripheral nerve blocks/ablation procedures totaled $25,842,067, excluding genicular nerve blocks and ablations (described below) [25]. Alternative treatment strategies for these conditions include proprietary (and often expensive) medications, which similarly lack consistent, non-industry-funded clinical evidence, generic opioid medications (which contradict Medicare's initiatives at reducing opioids), and more invasive, costlier implants and procedures.

To ensure responsible and evidence-based utilization, we propose a coverage framework that emphasizes appropriate patient selection, standardized procedural parameters, and robust quality assurance measures such as procedure registries,

outcomes monitoring, and reporting tools to support continuous improvement in care delivery. We would welcome the opportunity to develop this in partnership with the MACs.

TRIGEMINAL NERVE BLOCKS AND RFA

Trigeminal neuralgia (TN) is an extremely disabling facial pain condition that can lead to significant functional disability, inability to talk, brush teeth, and perform other activities. Pain can be triggered by innocuous factors, such as wind or facial contact. Patients often lose significant weight due to the inability to eat. Given this, individuals with this disease must receive prompt treatment. Unfortunately, the proposed LCD regarding radiofrequency ablation of the gasserian ganglion for TN relies on incorrect information about TN surgery, in general, and the utility of trigeminal nerve blocks, and will only serve to hinder care.

The criteria for coverage of TN RFA in the proposed LCD have significant issues:

- Criterion 1. People with TN are severely disabled. While medical therapy is effective for some, it is often not tolerated well due to side effects, such as hyponatremia or drowsiness. It is inappropriate to require an arbitrary six-month waiting period before proceeding to surgery. Criterion 2 even acknowledges the limitations of medical therapy. These patients often undergo evaluations by specialists, such as dentists and ENT physicians, before receiving a formal diagnosis of TN.
- Criterion 3. This states that patients may be candidates for RFA if they are "not a good surgical candidate" or "decline surgical intervention". This phraseology reveals a misunderstanding of trigeminal RFA. This is indeed a surgical procedure and should be appropriately considered as such. Moreover, this criterion also seems to specify a set progression of surgical procedures (*i.e.,* not a candidate for another procedure that is considered first-line, with RFA as a fallback). When surgeons discuss TN procedures with those suffering from the disease, five procedures are often discussed: microvascular decompression (MVD), stereotactic radiosurgery, RFA, percutaneous balloon compression (PBC) rhizotomy, and percutaneous glycerol rhizotomy. There is no set order for considering these procedures. The principle of patient-centered care dictates that it is ultimately up to the patient and their physician which procedure they undergo, after a thorough discussion of the risks and benefits of each procedure for which the patient is eligible.
- Criterion 5. We do not know of any high-level, peer-reviewed publication that proves that response to a trigeminal nerve block can differentiate those patients with TN from those with other facial pain syndromes. Therefore, there is no significant published literature or guidelines indicating that the response to a trigeminal nerve block predicts response to surgical procedures for trigeminal neuralgia. While we support coverage of trigeminal nerve blocks in general, as they may be helpful for some patients with TN and other facial pain conditions, this requirement before TN RFA significantly delays or outright denies care for patients with TN. We also note that the rest of the LCD rules trigeminal nerve

blocks as not medically necessary, which does not comport with this requirement for coverage of TN RFA.

Subsequently, the proposed LCD states that other procedures are deemed "not reasonable and necessary." This list includes multiple types of PNBs (including trigeminal blocks) and RFA, as well as "percutaneous strategies such as balloon compression, glycerol rhizotomy, and microvascular decompression". This wording is both confusing and incorrect.

- Including MVD in this list of percutaneous procedures demonstrates a lack of understanding of this procedure, which is not a percutaneous procedure at all, but instead, an open craniotomy for direct manipulation of the trigeminal nerve and the surrounding vasculature. This procedure should be deemed medically necessary for patients with radiographic evidence of vascular compression of the trigeminal nerve. *This procedure is not appropriate for inclusion in a proposed LCD regarding percutaneous procedures for TN.*
- We are uncertain why percutaneous trigeminal glycerol rhizotomy, a procedure in use for decades, is deemed "not reasonable and necessary." This procedure has decades of documented safety and efficacy [26-28]. *This procedure should be listed specifically as medically necessary in any proposed LCD.*
- PBC rhizotomy is also listed as "not reasonable and necessary" in the proposed LCD without justification. This procedure is currently one of the more common percutaneous surgical procedures for TN due to its minimally invasive nature, the lack of requirement for patient cooperation (see section below regarding procedural anesthesia), and its ability to treat multiple divisions of the trigeminal nerve simultaneously. Importantly, PBC rhizotomy effectively treats pain in the V1 region that is contraindicated for treatment with RFA due to the risk of production of corneal anesthesia with the latter technique. Multiple peer-reviewed studies attest to the immediate and long-term efficacy of this procedure [28-32]. *This procedure should be listed specifically as medically necessary in any proposed LCD.*
- Another paragraph in the proposed LCD states that, "Moderate or Deep Sedation, General Anesthesia, and Monitored Anesthesia Care (MAC) is usually unnecessary or rarely indicated for these procedures and therefore not considered medically reasonable and necessary." This is another incorrect statement. The vast majority of TN RFA are performed under MAC and PBC rhizotomies under general anesthesia due to the significant pain when inserting a needle into the gasserian ganglion through the foramen ovale in a patient with active TN. Moreover, the actual process of lesioning the ganglion (either via PBC rhizotomy or RFA) is extremely painful, and it would be inhumane to perform these lesions without anesthesia. PBC rhizotomy is most often performed under general anesthesia due to the absence of a requirement for patient cooperation during the procedure. In select cases, trigeminal RFA may also be performed under general anesthesia. *Both MAC and general anesthesia should be deemed medically necessary for these procedures in any proposed LCD, with the choice of anesthesia left to the discretion of the treating physician and anesthesia team.*

In summary, the proposed LCD contains numerous incorrect statements and errors related to TN. The six-month waiting period, explicit exclusion of PBC rhizotomy as medically necessary, the contradictory nerve block requirements, the misclassification of MVD, and the prohibition of MAC and general anesthesia for these procedures all warrant revision. Taken together, these errors will lead to inappropriate denial of care for Medicare beneficiaries suffering from TN, a disorder so severe that it is termed "suicide pain."

GENICULAR NERVE BLOCKS AND RFA

LCD Evidence Summary

The proposed LCD does not meet the evidentiary standards necessary to justify a non-coverage determination. Notably, the LCD failed to include important Level 1 studies in the literature review and did not recognize flaws in prior systematic reviews relied upon in their analysis of the evidence. As such, the LCD's evidence review does not reflect the totality of high-quality data supporting genicular nerve RFA (GNRFA) or appropriately analyze the literature contained. A recent systematic review (Kanjanapanang et al.) appropriately stratifies GNRFA outcomes by procedural factors (lesion size and lesion number), a new sham-controlled RCT demonstrates the efficacy of GNRFA (Makkar et. al), and a new pragmatic RCT (Das et al.) demonstrates greater effectiveness of a large lesion compared to small lesion GNRFA technique (similar to the findings of the Kanjanapanang et al. systematic review):

- Kanjanapanang et al. (2025): 43-65% of patients achieved ≥50% pain relief at 6–24 months [33].
- Makkar et al. (2024) and Das et al. (2025): High-quality RCTs showing significant improvements in pain, function, and quality of life [34,35].

The Almeida meta-analysis pooled heterogeneous techniques without adjusting for lesion size or nerve target, potentially underestimating efficacy [36].

The most rigorous and current systematic review presented moderate-certainty evidence supporting the effectiveness of GNRFA for knee osteoarthritis (KOA) [33]. Across 28 studies, 51% of patients receiving GNRFA achieved ≥50% pain relief at six months and 58% at twenty-four months. Additionally, 69% reported clinically meaningful pain relief, defined as a ≥2-point reduction on NRS, at six months. These findings demonstrate a robust, durable, and clinically meaningful benefit, with parallel improvements in function, quality of life, and patient global assessment across studies. Furthermore, this review found that techniques generating large lesions demonstrated higher pooled success rates compared to small lesions at 12 months [55% (95% CI: 51%-59%) vs 34% (95% CI: 26%-43%)], highlighting the importance of stratifying study results by critical technical considerations.

Further support for these findings comes from two recent high-quality RCTs [34,35] published after the Kanjanapanang review period. Makkar et al. (2024) conducted a well-designed RCT, which similarly demonstrated significant improvements in pain, function,

and quality of life following GNRFA, with a substantially higher proportion of responders compared with the sham group [34]. Das et al. (2025) reported results from a non-industry-sponsored pragmatic RCT in which patients similarly experienced significant improvements in pain and function at 6 and 12 months post-GNRFA [35].

The LCD relies heavily on Almeida *et al.*, a review with substantial methodological and interpretive limitations [36]. Specifically, the authors pooled trials with differing procedural targets and lesion strategies, obscuring clinically meaningful distinctions. The review also failed to stratify outcomes by key procedural factors, such as the number of nerves treated or lesion size – both of which have been shown to significantly affect outcomes. Finally, Almeida *et al.* downgraded nearly all included evidence to "very low certainty" without transparent application of the GRADE methodology.

In contrast, Kanjanapanang *et al.* systematically evaluated these procedural variables [33]. Their pooled data demonstrated higher success rates when three or more nerves were treated, particularly the superomedial, superolateral, and inferomedial branches, and when larger lesions were created using an 18G cannula, bipolar lesioning technique, or internally-cooled thermal RFA, compared with monopolar 22G RFA needles or other small RFA lesion sizes. These procedural factors are critical determinants of efficacy and should be incorporated into any valid assessment of the clinical evidence. Omitting these variables, as was done in the Almeida review, produces misleading conclusions. Based on this careful evaluation of the evidence, procedural techniques continue to be refined to maximize effectiveness.

In the past five years alone, at least 10 systematic reviews and meta-analyses, including more than 25 RCTs, have evaluated GNRFA [33,36-44]. The overwhelming majority of these studies demonstrate clinically significant short- to medium-term improvements in pain and function compared to sham procedures or other treatments currently covered by CMS. Notably, all reviews except Almeida et al. concluded that GNRFA is an effective treatment for knee osteoarthritis. Selectively relying on a single, methodologically flawed outlier review to justify non-coverage disregards the broader, more contemporary body of evidence and risks creating a policy misaligned with the clear scientific consensus.

Evidence-Based Multidisciplinary Guideline Support

Several guidelines have been published in recent years, transparently assessing the evidence and formulating evidence-based recommendations for GNRFA [45,46]. The ASPN guideline was published in 2022, included in the LCD, and concluded that GNRFA of the superomedial, superolateral, and inferomedial branches is safe and effective for treating KOA as well as pain that is refractory to total knee arthroplasty (TKA) (Level of Evidence: I, Grade of Recommendation: A, Strong Consensus) [45]. The second guideline, published by the Indian Society for the Study of Pain in 2022, was not included in the LCD. The guideline concluded that GNRFA for KOA provides significant pain relief and mid- to long-term functional improvement (Level of Evidence: I, Grade of Recommendation: A, Strong Consensus). Both conventional and cooled RFA may yield meaningful pain relief and improved performance in patients with post-TKA pain and dysfunction (Level of Evidence: I, Grade of Recommendation: A, Strong Consensus) [46].

A forthcoming multisociety guideline [47] from pain medicine, musculoskeletal, and radiology organizations, expected to be published in the next 3 months, recommends treating three or more genicular nerves using an 18G cannula, bipolar lesioning technique, or internally-cooled thermal RFA, which all produce larger ablation zones, and adhering to appropriate diagnostic and imaging criteria for patient selection. This multisociety consensus reflects the maturity of the field and establishes a reproducible, high-value standard of care.

Non-Coverage: Unintended Consequences

GNRFA is a non-opioid, minimally invasive therapy that has been shown to reduce pain, improve function, and decrease the need for analgesics, including opioids. Multiple studies demonstrate that successful GNRFA is associated with reduced analgesic use [48-51] and improvements in EQ-5D [52,53] and WOMAC scores [54,55], whereas untreated moderate-to-severe KOA is linked to increased opioid use, particularly among older adults with impaired mobility [56]. Removing coverage for this procedure would directly contradict Medicare's efforts to combat the opioid epidemic. CMS has consistently promoted non-opioid pain management, and delisting a safe, effective, and durable alternative would represent a significant policy misalignment.

Furthermore, removing coverage for GNRFA would effectively eliminate one of the few viable interventional options for managing residual, chronic pain following TKA, a condition affecting 10–20% of patients, many of whom are elderly, frail, or ineligible for revision surgery.

GNRFA is both efficacious and safe [34,35,48,52,53,55,57-62]. Adverse events are uncommon and generally minor, typically limited to transient discomfort, with no significant safety concerns reported across more than 30 studies encompassing thousands of procedures [42].

If access to GNRFA were removed, downstream consequences would likely include increased opioid prescriptions with their associated morbidity and healthcare costs, unnecessary total knee replacements in patients who could otherwise delay or avoid surgery with adequate pain relief, accelerated functional decline, reduced mobility, increased caregiver burden among elderly or frail patients, higher rates of emergency visits for uncontrolled pain, and missed opportunities to treat chronic post-TKA pain for which few alternatives exist. These outcomes would likely increase healthcare utilization and costs rather than reduce them, directly opposing the goals of value-based care initiatives. From a cost standpoint, based on the 2024 Medicare Part B National Summary Data file, genicular nerve blocks and ablations accounted for $17,686,110 [25]. Knee arthroplasty accounted for $708,809,643, and knee revision accounted for $33,929,327. Based on these data, it would require only a ~2.5% increase in TKA spending to erase all "savings" from cutting GNRFA. Given the clinical reality that many GNRFA-eligible patients will progress to surgery or require revision in the absence of this minimally invasive option, even small upticks in TKA volume (alone or alongside revisions) would be expected to increase, not decrease, Medicare spending.

CONCLUSION AND REQUESTED ACTION

Eliminating coverage not only contradicts CMS's opioid-reduction and value-based care goals but will inevitably lead to increased overall program costs through higher utilization of less effective or more expensive alternatives.

We respectfully yet strongly urge CMS and the MACs to rescind this proposed LCD. If immediate rescission is not possible, we request that its issuance be postponed to allow collaboration with the undersigned societies in developing evidence-based LCDs that incorporate the latest research and key clinical considerations, ensuring appropriate coverage criteria for these procedures.

There is a precedent from 2013-2014 for the direct involvement of the majority of the societies listed below in working with the CMS and the MACs to develop LCDs for interventional spine procedures. Initially established in 2013 and facilitated by the International Pain and Spine Intervention Society (IPSIS), the Multisociety Pain Workgroup (MPW) was convened to develop coverage recommendations to guide the CMS Contractor Medical Directors (CMDs) in revising all interventional spine LCDs [63]. The MPW achieved consensus in developing collaborative recommendations, most of which were implemented by the CMDs to streamline interventional pain LCDs. Following the success of this initial effort in 2013-2014, the MPW has been convened regularly over the years to address additional initiatives aimed at preserving appropriate patient care access.

On behalf of the societies listed below and the broader Pain Medicine, Spine, Musculoskeletal Medicine, and Radiology communities, we appreciate the opportunity to provide these comments and stand ready to collaborate on scientifically rigorous and patient-centered LCDs. For additional information, please contact Sarah Cartagena, IPSIS Director of Health Policy, at scartagena@ipsismed.org.

Sincerely,

Multisociety Pain Workgroup

American Association of Neurological Surgeons
American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
American College of Radiology
American Society of Anesthesiologists
American Society of Neuroradiology
American Society of Regional Anesthesia and Pain Medicine
American Society of Spine Radiology
Congress of Neurological Surgeons
International Pain and Spine Intervention Society
North American Neuromodulation Society
North American Spine Society
Society of Interventional Radiology

Supporting Organizations

American Academy of Neurology
American Association of Orthopaedic Surgeons
American Interventional Headache Society
American Medical Society for Sports Medicine
American Osteopathic College of Physical Medicine and Rehabilitation
Association of Pain Program Directors
American Society for Surgery of the Hand Professional Organization
American Society of Pain and Neuroscience
American Society of Peripheral Nerve
California Medical Association
Pacific Spine and Pain Society
Women Innovators in Pain Management

References

1. Zis P, Daskalaki A, Bountouni I, Sykioti P, Varrassi G, Paladini A. Depression and chronic pain in the elderly: links and management challenges. Clin Interv Aging. 2017 Apr 21;12:709-720. doi: 10.2147/CIA.S113576. PMID: 28461745; PMCID: PMC5407450
2. Khalid S, Sambamoorthi U, Umer A, Lilly CL, Gross DK, Innes KE. Increased odds of incident Alzheimer's disease and related dementias in presence of common non-cancer chronic pain conditions in Appalachian older adults. J Aging Health. 2022 Mar;34(2):158-172. doi: 10.1177/08982643211036219. Epub 2021 Aug 5. PMID: 34351824.
3. Interagency Pain Research Coordinating Committee. National Pain Strategy: a comprehensive population health-level strategy for pain. Washington, DC: US Department of Health and Human Services, National Institutes of Health; 2016. https://www.iprcc.nih.gov/node/5/national-pain-strategy-report
4. Ditre JW, Zale EL, LaRowe LR. A reciprocal model of pain and substance use: transdiagnostic considerations, clinical implications, and future directions. Annu Rev Clin Psychol. 2019 May 7;15:503-528. doi: 10.1146/annurev-clinpsy-050718-095440. Epub 2018 Dec 19. PMID: 30566371.
5. Rikard SM, Strahan AE, Schmit KM, Guy GP Jr. Chronic pain among adults - United States, 2019-2021. MMWR Morb Mortal Wkly Rep. 2023 Apr 14;72(15):379-385. doi: 10.15585/mmwr.mm7215a1. PMID: 37053114; PMCID: PMC10121254
6. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical practice guideline for prescribing opioids for pain - United States, 2022. MMWR Recomm Rep. 2022 Nov 4;71(3):1-95. doi: 10.15585/mmwr.rr7103a1. PMID: 36327391; PMCID: PMC9639433.
7. U.S. Department of Health and Human Services. Pain management best practices inter-agency task force report: updates, gaps, inconsistencies, and recommendations. Washington, DC: HHS; 2019 May 9. Available from: https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf
8. Busse JW, Wang L, Kamaleldin M, et al. Opioids for chronic noncancer pain: a systematic review and meta-analysis. JAMA. 2018 Dec 18;320(23):2448-2460. doi: 10.1001/jama.2018.18472. PMID: 30561481; PMCID: PMC6583638.
9. Finnerup NB, Attal N, Haroutounian S,et al. Pharmacotherapy for neuropathic pain in adults: a systematic review and meta-analysis. Lancet Neurol. 2015 Feb;14(2):162-73. doi: 10.1016/S1474-4422(14)70251-0. Epub 2015 Jan 7.
10. Lin CC, Callaghan BC, Burke JF, et al. Prescription opioid initiation for neuropathy, headache, and low back pain: a US population-based medicare study. J Pain. 2023 Dec;24(12):2268-2282. doi: 1016/j.jpain.2023.07.011. Epub 2023 Jul 17.
11. Centers for Medicare & Medicaid Services. CMS Roadmap: Strategy to Fight the Opioid Crisis. Baltimore, MD: CMS; 2019. Available from: https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf
12. Malekian N, Bastani PB, Oveisgharan S, Nabaei G, Abdi S. Preventive effect of greater occipital nerve block on patients with episodic migraine: A randomized double-blind placebo-controlled clinical trial. Cephalalgia. 2022;42(6):481-489.

doi:10.1177/03331024211058182
13. May A, Evers S, Goadsby PJ, et al; European Academy of Neurology Task Force. European Academy of Neurology guidelines on the treatment of cluster headache. Eur J Neurol. 2023 Oct;30(10):2955-2979. doi: 10.1111/ene.15956. Epub 2023 Jul 28. PMID: 37515405.
14. Mustafa MS, Bin Amin S, Kumar A, et al. Assessing the effectiveness of greater occipital nerve block in chronic migraine: a systematic review and meta-analysis. BMC Neurol. 2024 Sep 7;24(1):330. doi: 10.1186/s12883-024-03834-6
15. Tanyel Saraçoğlu T, Bılır A, Güleç MS. Effectiveness of combining greater occipital nerve block and pulsed radiofrequency treatment in patients with chronic migraine: a double-blind, randomized controlled trial. Head Face Med. 2024 Sep 11;20(1):48. doi: 10.1186/s13005-024-00449-7
16. Ertilav E, Aydın ON. Comparison of the efficacy of repeated greater occipital nerve block and pulsed radiofrequency therapy in chronic migraine patients: a randomized controlled study. J Oral Facial Pain Headache. 2024 Sep;38(3):100-107. doi: 10.22514/jofph.2024.031. Epub 2024 Sep 12
17. Friedman BW, Irizarry E, Williams A, et al. A randomized, double-dummy, emergency department-based study of greater occipital nerve block with bupivacaine vs intravenous metoclopramide for treatment of migraine. headache. 2020 Nov;60(10):2380-2388. doi: 10.1111/head.13961. Epub 2020 Sep 27.
18. Koonalintip P, Yamutai S, Setthawatcharawanich S, Thongseiratch T, Chichareon P, Wakerley BR. Network meta-analysis comparing efficacy of different strategies on medication-overuse headache. J Headache Pain. 2025 Feb 26;26(1):43. doi: 10.1186/s10194-025-01982-9. Erratum in: J Headache Pain. 2025 Apr 16;26(1):81. doi: 10.1186/s10194-025-02031-1.
19. Chowdhury D, Tomar A, Deorari V, Duggal A, Krishnan A, Koul A. Greater occipital nerve blockade for the preventive treatment of chronic migraine: A randomized double-blind placebo-controlled study. Cephalalgia. 2023 Feb;43(2):3331024221143541. doi: 10.1177/03331024221143541.
20. Hokenek NM, Ozer D, Yılmaz E, et al. Comparison of greater occipital nerve and supra orbital nerve blocks methods in the treat ment of acute migraine attack: a randomized double-blind controlled trial. Clin Neurol Neurosurg. 2021;207:106821. [PMID: 34304069] doi:10.1016/j.clineuro.2021.106821
21. Bruehl S. Complex regional pain syndrome. BMJ. 2015 Jul 29;351:h2730. doi: 10.1136/bmj.h2730. PMID: 26224572.
22. Rocha R de O, Teixeira MJ, Yeng LT, et al. Thoracic sympathetic block for the treatment of complex regional pain syndrome type I: a double-blind randomized controlled study. Pain. 2014;155(11):2274-2281. doi:10.1016/j.pain.2014.08.015
23. Harden RN, McCabe CS, Goebel A, et al. Complex regional pain syndrome: practical diagnostic and treatment guidelines, 5th Edition. Pain Med. 2022;23(Suppl 1):S1-S53. doi:10.1093/pm/pnac046
24. Benzon HT, Elmofty D, Shankar H, et al. Use of corticosteroids for adult chronic pain interventions: sympathetic and peripheral nerve blocks, trigger point injections - guidelines from the American Society of Regional Anesthesia and Pain Medicine, the American Academy of Pain Medicine, the American Society of Interventional Pain Physicians, and the International Pain and Spine Intervention Society. Reg Anesth

Pain Med. 2025 Mar 12:rapm-2024-105593. doi: 10.1136/rapm-2024-105593. Epub ahead of print. PMID: 39019502.a
25. Part B National Summary Data File (Previously known as BESS) | CMS. Accessed November 5, 2025. https://www.cms.gov/data-research/statistics-trends-and-reports/part-b-national-summary-data-file
26. SohrabiAsl M, Shirani M, Jahanbakhshi A, Iranmehr A. Efficacy and challenges: minimally invasive procedures for trigeminal neuralgia treatment in multiple sclerosis - a systematic review and meta-analysis. Stereotact Funct Neurosurg. 2024;102(3):156-168. doi: 10.1159/000538516. Epub 2024 Apr 22. PMID: 38648730.
27. Chen L, Xu M, Zou Y. Treatment of trigeminal neuralgia with percutaneous glycerol injection into Meckel's cavity: experience in 4012 patients. Cell Biochem Biophys. 2010 Nov;58(2):85-9. doi: 10.1007/s12013-010-9094-z. PMID: 20717747.
28. Texakalidis P, Xenos D, Tora MS, Wetzel JS, Boulis NM. Comparative safety and efficacy of percutaneous approaches for the treatment of trigeminal neuralgia: A systematic review and meta-analysis. Clin Neurol Neurosurg. 2019 Jul;182:112-122. doi: 10.1016/j.clineuro.2019.05.011. Epub 2019 May 14. PMID: 31121470.
29. Taha JM, Tew JM Jr. Honored guest presentation: therapeutic decisions in facial pain. Clin Neurosurg. 2000;46:410-31. PMID: 10944692.
30. Bick SKB, Eskandar EN. Surgical treatment of trigeminal neuralgia. Neurosurg Clin N Am. 2017 Jul;28(3):429-438. doi: 10.1016/j.nec.2017.02.009. Epub 2017 Mar 24. PMID: 28600016.
31. Noorani I, Lodge A, Vajramani G, Sparrow O. Comparing percutaneous treatments of trigeminal neuralgia: 19 years of experience in a single centre. Stereotact Funct Neurosurg. 2016;94(2):75-85. doi: 10.1159/000445077. Epub 2016 Apr 13. PMID: 27071078.
32. Nascimento RFV, Pipek LZ, de Aguiar PHP. Is percutaneous balloon compression better than microvascular decompression to treat trigeminal neuralgia? A systematic review and meta-analysis. J Clin Neurosci. 2023 Mar;109:11-20. doi: 10.1016/j.jocn.2023.01.002. Epub 2023 Jan 10. PMID: 36634472.
33. Kanjanapanang N, Madrid R, Lin P, et al. Effectiveness of genicular nerve radiofrequency ablation in osteoarthritis and post-surgical knee pain: systematic review. Pain Medicine. 2025; pnaf115, https://doi.org/10.1093/pm/pnaf115
34. Makkar JK, Warrier G, Ghai B, et al. Effect of radiofrequency ablation of genicular nerves on the isokinetic muscle strength of knee joint in patients with osteoarthritis knee: A randomized double-blind sham controlled clinical trial. Pain Med. 2024 Aug 5:pnae077. doi: 10.1093/pm/pnae077. Epub ahead of print. PMID: 39102829.
35. Das G, Das S, Sharma VS, Amatya SP, Hota SR, Milton AH. Efficacy and safety of conventional and cooled radiofrequency ablation in patients with advanced knee osteoarthritis: A prospective, randomized, double-blind study. Indian J Pain. 2025;39(1):18-23. doi:10.4103/ijpn.ijpn_81_24
36. Almeida M, Saragiotto BT, Hunter DJ, et al. Efficacy and safety of minimally invasive interventions targeting the genicular nerves for knee osteoarthritis: A meta-analysis. Osteoarthritis Cartilage. 2025 May;33(5):535-547. doi: 10.1016/j.joca.2025.02.780. Epub 2025 Mar 5. PMID: 40054598.

37. Barreto RB, Barreto AJ, do Nascimento ALM, Carvalho DMB, Queiroz B. Efficacy and safety of genicular nerve ablation techniques for knee osteoarthritis: a systematic review and meta-analysis of sham-controlled randomized trials. Pain Medicine (Malden, Mass.). 2025;:pnaf140. doi:10.1093/pm/pnaf140.
38. Wu L, Li Y, Si H, et al. Radiofrequency ablation in cooled monopolar or conventional bipolar modality yields more beneficial short-term clinical outcomes versus other treatments for knee osteoarthritis: a systematic review and network meta-analysis of randomized controlled trials. Arthroscopy: The Journal of Arthroscopic & Related Surgery: Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association. 2022;38(7):2287-2302. doi:10.1016/j.arthro.2022.01.048.
39. Fogarty AE, Burnham T, Kuo K, et al. The effectiveness of fluoroscopically guided genicular nerve radiofrequency ablation for the treatment of chronic knee pain due to osteoarthritis: a systematic review. American Journal of Physical Medicine & Rehabilitation. 2022;101(5):482-492. doi:10.1097/PHM.0000000000001813.
40. Chen AF, Mullen K, Casambre F, Visvabharathy V, Brown GA. Thermal nerve radiofrequency ablation for the nonsurgical treatment of knee osteoarthritis: a systematic literature review. The Journal of the American Academy of Orthopaedic Surgeons. 2021;29(9):387-396. doi:10.5435/JAAOS-D-20-00522.
41. Soetjahjo B, Adriansyah D, Yudistira MB, et al. The analgesic effectiveness of genicular nerve-targeted cooled and pulsed radiofrequency ablation for osteoarthritis knee pain: a systematic review and meta-analysis. Pain Physician. 2024 Sep;27(7):357-373. PMID: 39353105.
42. Ajrawat P, Radomski L, Bhatia A, et al. Radiofrequency procedures for the treatment of symptomatic knee osteoarthritis: a systematic review. Pain Medicine (Malden, Mass.). 2020;21(2):333-348. doi:10.1093/pm/pnz241.
43. Zhang H, Wang B, He J, Du Z. Efficacy and safety of radiofrequency ablation for treatment of knee osteoarthritis: a meta-analysis of randomized controlled trials. The Journal of International Medical Research. 2021;49(4):3000605211006647. doi:10.1177/03000605211006647.
44. Antunes Júnior CR, de Oliveira Pinto RC, Barreto ESR, et al. Efficacy and safety of nerve ablation techniques versus sham procedures in knee osteoarthritis: a systematic review and meta-analysis of randomized clinical trials. Pain Practice: The Official Journal of World Institute of Pain. 2025;25(7):e70073. doi:10.1111/papr.70073.
45. Hunter CW, Deer TR, Jones MR, et al. Consensus guidelines on interventional therapies for knee pain (STEP guidelines) from the American Society of Pain and Neuroscience. J Pain Res. 2022 Sep 8;15:2683-2745. doi: 10.2147/JPR.S370469. PMID: 36132996; PMCID: PMC9484571.
46. Das G, Surange P, Agarwal A, et al. Radiofrequency ablation in chronic pain syndromes: An evidence- and consensus-based Indian Society for the Study of Pain Guidelines, 2022. Indian Journal of Pain 36(Suppl 1):p S2-S23, December 2022. | DOI: 10.4103/ijpn.ijpn_123_22
47. Multi-Society Guidelines on Knee Joint Radiofrequency Ablation. Internal Working Document. *Publication anticipated early 2026.*
48. Santana-Pineda MM, Vanlinthout LE, Santana-Ramírez S, Vanneste T, Van Zundert J, Novalbos-Ruiz JP. A randomized controlled trial to compare analgesia and

functional improvement after continuous neuroablative and pulsed neuromodulative radiofrequency treatment of the genicular nerves in patients with knee osteoarthritis up to one year after the intervention. Pain Med. 2021 Mar 18;22(3):637-652. doi: 10.1093/pm/pnaa309. PMID: 33179073.
49. Wong PK, Kokabi N, Guo Y, Reiter D, Reimer NB, Oskouei S, Gonzalez FM. Safety and efficacy comparison of three- vs four-needle technique in the management of moderate to severe osteoarthritis of the knee using cooled radiofrequency ablation. Skeletal Radiol. 2021 Apr;50(4):739-750. doi: 10.1007/s00256-020-03619-1. PMID: 32968824.
50. Tate Q, Meiling JB, Burnham TR, Conger A, McCormick ZL. A pilot study of an expanded genicular nerve radiofrequency ablation protocol for the treatment of chronic knee pain. Pain Med. 2022 Mar 2;23(3):599-602. doi: 10.1093/pm/pnab329. PMID: 34791455.
51. Guven Kose S, Kirac Unal Z, Kose HC, Celikel F, Akkaya OT. Ultrasound-guided genicular nerve radiofrequency treatment: prospective randomized comparative trial of a 3-nerve protocol versus a 5-nerve protocol. Pain Med. 2023 Jul 5;24(7):758-767. doi: 10.1093/pm/pnad025. PMID: 36869680.
52. Chen AF, 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. doi: 10.1186/s12891-020-03380-5. PMID: 32517739; PMCID: PMC7285532.
53. Chen AF, Khalouf F, Zora K, et al. Cooled radiofrequency ablation compared with a single injection of hyaluronic acid for chronic knee pain: a multicenter, randomized clinical trial demonstrating greater efficacy and equivalent safety for cooled radiofrequency ablation. J Bone Joint Surg Am. 2020 Sep 2;102(17):1501-1510. doi: 10.2106/JBJS.19.00935. PMID: 32898379.
54. El-Hakeim EH, Elawamy A, Kamel EZ, Goma SH, Gamal RM, Ghandour AM, Osman AM, Morsy KM. Fluoroscopic guided radiofrequency of genicular nerves for pain alleviation in chronic knee osteoarthritis: a single-blind randomized controlled trial. Pain Physician. 2018 Mar;21(2):169-177. PMID: 29565947.
55. Sarı S, Aydın ON, Turan Y, Özlülerden P, Efe U, Kurt Ömürlü İ. 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. 2018 Oct;21(10):1772-1778. doi: 10.1111/1756-185X.12925. PMID: 27515095.
56. Jackson J, Iyer R, Mellor J, Wei W. The burden of pain associated with osteoarthritis in the hip or knee from the patient's perspective: a multinational cross-sectional study. Adv Ther. 2020 Sep;37(9):3985-3999. doi: 10.1007/s12325-020-01445-4. Epub 2020 Jul 29. PMID: 32729010; PMCID: PMC7444392.
57. Choi WJ, Hwang SJ, Song JG, Leem JG, Kang YU, Park PH, Shin JW. Radiofrequency treatment relieves chronic knee osteoarthritis pain: a double-blind randomized controlled trial. Pain. 2011 Mar;152(3):481-487. doi: 10.1016/j.pain.2010.09.029. PMID: 21055873.

58. McCormick ZL, Reddy R, Korn M, et al. A prospective randomized trial of prognostic genicular nerve blocks to determine the predictive value for the outcome of cooled radiofrequency ablation for chronic knee pain due to osteoarthritis. Pain Med. 2018 Aug 1;19(8):1628-1638. doi: 10.1093/pm/pnx286. PMID: 29300971.
59. 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 Jan;43(1):84-91. doi: 10.1097/AAP.0000000000000690. PMID: 29095245; PMCID: PMC5768219.
60. Davis T, Loudermilk E, DePalma M, 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:rapm-2018-100051. doi: 10.1136/rapm-2018-100051. PMID: 30772821.
61. Hunter C, Davis T, Loudermilk E, Kapural L, DePalma M. Cooled radiofrequency ablation treatment of the genicular nerves in the treatment of osteoarthritic knee pain: 18- and 24-month results. Pain Pract. 2020 Mar;20(3):238-246. doi: 10.1111/papr.12844. PMID: 31605667; PMCID: PMC7078815.
62. Lyman J, Khalouf F, Zora K, et al. Cooled radiofrequency ablation of genicular nerves provides 24-Month durability in the management of osteoarthritic knee pain: Outcomes from a prospective, multicenter, randomized trial. Pain Pract. 2022 Jul;22(6):571-581. doi: 10.1111/papr.13139. PMID: 35716058; PMCID: PMC9541208.
63. International Pain and Spine Intervention Society. Multisociety Pain Workgroup (MPW). https://www.ipsismed.org/page/MPW (Accessed 11/5/2025)