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Re: Carelon Proposed Clinical Appropriateness Guidelines and Criteria for Spinal Cord Stimulation (SCS) in Non-Surgical Low Back Pain

Dear. Dr. Mandel,

ASPN is currently comprised of more than 4,000 physicians from the specialties of Anesthesiology, Neurology, Neurosurgery, Orthopedics, Physical Medicine and Rehabilitation and Preventive Medicine & Public Health. Our membership comprises a significant proportion of physicians who perform neuromodulation procedures like Spinal Cord Stimulation. We are concerned about Carelon's recent policy decision to deny coverage for spinal cord stimulation in patients with non-surgical low back pain. We are deeply concerned about some of the scientific inaccuracies expressed in the policy which will ultimately affect patient's quality of life.

The current policy restrictions implemented by Carelon Medical Benefits Management regarding spinal cord stimulation (SCS) for non-surgical refractory back pain represent a significant departure from evidence-based medicine and established clinical practice guidelines. Recent high-quality research, including network meta-analyses and comprehensive literature reviews, demonstrates that these restrictions will deny patients access to a proven, cost-effective treatment while potentially exposing them to greater risks from alternative therapies. The policy's requirements for mandatory surgical consultation and positioning SCS as a "last resort" treatment contradict modern pain management principles and emerging evidence supporting earlier intervention with neuromodulation therapies.

I. Clinical Evidence Contradicts Carelon's Restrictive Approach

a. Superior Efficacy of Spinal Cord Stimulation

Recent network meta-analysis research provides compelling evidence for the effectiveness of SCS in treating non-surgical refractory back pain (NSRBP). The Eldabe et al. study, a comprehensive analysis of neurostimulation interventions, demonstrated that closed-loop SCS resulted in statistically and clinically significant reductions in pain intensity, with a mean

difference of 32.72 points (95% credible interval 15.69-49.78) compared to conventional medical management[1]. These findings represent substantial pain relief that far exceeds the clinically meaningful threshold typically used in pain research.[1]

The study further revealed significant improvements in secondary outcomes, including Oswestry Disability Index scores and health-related quality of life measures, when SCS was compared to fixed-output stimulation systems. These improvements in functional outcomes directly address the core goals of chronic pain management: not merely reducing pain scores but restoring patients' ability to participate in meaningful activities and improving their overall quality of life.

Contemporary clinical evidence also supports the use of high-frequency stimulation systems, which have demonstrated superior outcomes compared to traditional low-frequency approaches. [2]The DISTINCT study, the largest randomized controlled clinical trial in SCS for nonsurgical back pain patients, showed that advanced stimulation techniques achieved significant back pain reduction in a substantial percentage of patients compared to only 7.1% with conventional medical management.[3]

Cost-Effectiveness and Healthcare Utilization

The economic evaluation component of the Eldabe meta-analysis provides crucial insights into the cost-effectiveness of SCS therapy. The analysis, performed from the perspective of the UK National Health Service, reported results as incremental cost per quality-adjusted life-year (QALY), demonstrating favorable economic outcomes for SCS interventions. This economic

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[1] Eldabe, S., Nevitt, S., Bentley, A., Mekhail, N. A., Gilligan, C., Billet, B., ... & Duarte, R. V. (2024). Network Meta-analysis and Economic Evaluation of Neurostimulation Interventions for Chronic Nonsurgical Refractory Back Pain. *The Clinical Journal of Pain*, *40*(9), 507-517.

[2] Kapural, L., Jameson, J., Johnson, C., Kloster, D., Calodney, A., Kosek, P., ... & Patel, N. P. (2022). Treatment of nonsurgical refractory back pain with high-frequency spinal cord stimulation at 10 kHz: 12-month results of a pragmatic, multicenter, randomized controlled trial. *Journal of Neurosurgery: Spine*, *37*(2), 188-199.

[3] Deer, T., Gilligan, C., Falowski, S., Desai, M., Pilitsis, J., Jameson, J., ... & Yue, J. (2023). Treatment of refractory low back pain using passive recharge burst in patients without options for corrective surgery: findings and results from the DISTINCT study, a prospective randomized multicenter controlled trial. *Neuromodulation: Technology at the Neural Interface*, *26*(7), 1387-1399.

evidence is particularly relevant given healthcare systems' increasing focus on value-based care and the need to optimize resource allocation while improving patient outcomes.[4]

Studies have consistently shown that SCS implementation leads to reductions in healthcare utilization, including decreased hospitalizations, clinic visits, and opioid usage. These findings suggest that earlier implementation of SCS, rather than restricting it to "last resort" status, may actually reduce overall healthcare costs while improving patient outcomes.

II. Problematic Policy Requirements and Their Clinical Implications

a. Inappropriate Mandatory Surgical Consultation Requirement

Carelon's requirement that "Surgery is being considered and documented by appropriate surgical consult" before approving SCS is clinically inappropriate and potentially harmful. This requirement fundamentally misunderstands the patient population most suitable for SCS therapy. The comprehensive literature review demonstrates that SCS is specifically indicated for patients with non-surgical refractory back pain - individuals who by definition do not have surgical pathology requiring intervention.

Mandating surgical evaluation for non-surgical candidates creates several significant problems. First, it introduces unnecessary delays in care, particularly given the limited availability of spine surgeons for non-urgent appointments for patients without obvious surgical indications. Second, it may expose patients to risks associated with unnecessary surgical evaluations and potential inappropriate recommendations for surgical interventions that are not indicated.

Board-certified pain specialists possess the necessary expertise to evaluate and treat chronic pain using multimodal approaches, including SCS. These physicians undergo specialized training in pain pathophysiology, neuromodulation techniques, and comprehensive pain management strategies. Requiring additional surgical consultation for patients who have already been appropriately evaluated by pain specialists represents an unnecessary duplication of services and may delay access to effective treatment.

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[4] Eldabe, S., Nevitt, S., Bentley, A., Mekhail, N. A., Gilligan, C., Billet, B., ... & Duarte, R. V. (2024). Network Meta-analysis and Economic Evaluation of Neurostimulation Interventions for Chronic Nonsurgical Refractory Back Pain. *The Clinical Journal of Pain*, *40*(9), 507-517.

b. **Inappropriate Designation as "Last Resort" Therapy**

The policy's designation of SCS as a "late or last resort after documented failure of at least 6" treatments contradicts modern evidence-based pain management principles. This restriction reflects outdated thinking about chronic pain management and fails to incorporate substantial advances in our understanding of pain pathophysiology and treatment approaches.

The last fifteen years have clearly demonstrated the limitations and risks of prolonged pharmacological therapy, particularly opioid-based treatments, for chronic pain. The opioid crisis has highlighted the dangers of continuing to pursue ineffective pharmacological approaches when safer, more effective alternatives are available. Research consistently shows that earlier implementation of interventional therapies, including SCS, can prevent the development of central sensitization and chronic pain syndromes while reducing patients' exposure to potentially harmful medications.

Contemporary pain management guidelines from multiple professional organizations support a multimodal approach that incorporates interventional therapies earlier in the treatment algorithm, rather than reserving them as final options. The literature review confirms that SCS technology has evolved significantly, with modern systems offering improved safety profiles, enhanced programming capabilities, and superior outcomes compared to earlier generations of devices.[5]

III. **International and National Best Practices and Evidence-Based Guidelines**

a. **Comprehensive Assessment Protocols**

International guidelines for SCS implementation provide a framework for appropriate patient selection that differs significantly from Carelon's restrictive approach. The New Zealand ACC guidelines demonstrate a comprehensive, evidence-based approach to SCS patient selection that emphasizes functional improvement rather than arbitrary treatment sequence requirements.

These guidelines require interdisciplinary assessment including pain management specialists, psychologists, and rehabilitation professionals, but do not mandate unnecessary surgical consultation for non-surgical patients. The focus remains on holistic patient evaluation,

[5] Deer, T. R., Grider, J. S., Lamer, T. J., Pope, J. E., Falowski, S., Hunter, C. W., ... & Mekhail, N. (2020). A systematic literature review of spine neurostimulation therapies for the treatment of pain. *Pain medicine*, *21*(7), 1421-1432.

optimization of conservative treatments, and appropriate patient selection based on evidence-based criteria rather than administrative barriers[4].

The ACC guidelines also recognize that psychological factors may impact SCS outcomes but emphasize that these factors should be identified and managed rather than used as exclusion criteria[4]. This approach aligns with contemporary understanding of chronic pain as a biopsychosocial condition requiring comprehensive, individualized treatment approaches.

In addition to the evidence and arguments already outlined, the American Society of Pain and Neuroscience (ASPN) has published comprehensive, evidence-based clinical guidelines that directly support the use of spinal cord stimulation (SCS) for non-surgical low back pain. According to the ASPN guidelines, SCS is recommended for patients with chronic low back pain who have failed conservative therapies and are not candidates for surgery, based on robust data from multiple randomized controlled trials and systematic reviews. The guidelines emphasize that SCS provides significant and sustained pain relief, functional improvement, and reduction in opioid consumption for this patient population. ASPN also highlights that advancements in SCS technology—including high-frequency and closed-loop systems—have further improved outcomes and broadened the applicability of SCS to patients with non-surgical refractory back pain. By aligning policy with ASPN's recommendations, Carelon would be following a consensus of leading pain specialists and supporting access to a therapy that is both clinically effective and supported by high-level evidence for non-surgical low back pain.[6]

IV. **Technology Advances and Treatment Options**

The literature review identifies multiple categories of current SCS treatment options, including low-frequency traditional SCS, high-frequency SCS, burst SCS, and differential target multiplexed SCS. These technological advances have significantly improved treatment outcomes and reduced adverse effects, supporting earlier consideration of SCS in appropriate patients.

Closed-loop SCS systems represent a particular advancement, providing real-time adjustment of stimulation parameters based on physiological feedback. The meta-analysis evidence shows

[6] Sayed, D., Grider, J., Strand, N., Hagedorn, J. M., Falowski, S., Lam, C. M., ... & Deer, T. (2022). The American Society of Pain and Neuroscience (ASPN) evidence-based clinical guideline of interventional treatments for low back pain. *Journal of pain research*, 3729-3832.

superior outcomes for these advanced systems compared to conventional approaches, suggesting that patients who are denied access to modern SCS technologies may be disadvantaged compared to those receiving appropriate care.

V. Safety Profile and Risk Mitigation

The comprehensive literature review demonstrates that modern SCS has an acceptable safety profile with well-characterized complication rates. Key complications are typically minor and manageable, including temporary lead migration, infection rates consistent with other implantable devices, and hardware-related issues that can be addressed through appropriate clinical management.

The safety profile of SCS compares favorably to many alternative treatments, particularly prolonged opioid therapy or repeated spinal injections. The reversible nature of SCS therapy provides additional safety advantages, as the system can be removed if complications occur or if the therapy proves ineffective.[7]

Recommendations for Policy Revision

1. Evidence-Based Patient Selection Criteria

Carelon should revise its policy to align with evidence-based guidelines that focus on appropriate patient selection rather than arbitrary procedural barriers. Patient selection should be based on comprehensive evaluation by qualified pain management specialists who can assess the appropriateness of SCS therapy in the context of the patient's overall clinical condition and treatment history.

The requirement for surgical consultation should be eliminated for patients with non-surgical refractory back pain, as this requirement is clinically inappropriate and potentially harmful. Instead, the policy should recognize the expertise of board-certified pain specialists in evaluating and managing chronic pain conditions.

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[7] Eldabe, S., Buchser, E., & Duarte, R. V. (2016). Complications of spinal cord stimulation and peripheral nerve stimulation techniques: a review of the literature. *Pain Medicine*, *17*(2), 325-336.

2. **Timing of SCS Implementation**

The policy should be revised to permit consideration of SCS earlier in the treatment algorithm, consistent with evidence supporting multimodal pain management approaches. Rather than requiring SCS to be a "last resort," the policy should allow for appropriate sequencing of treatments based on individual patient factors, disease progression, and response to previous interventions.

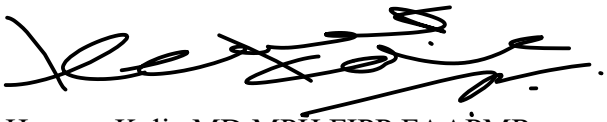
This revision would align with emerging evidence suggesting that earlier implementation of effective interventional therapies may prevent progression to more severe chronic pain states and reduce patients' exposure to less effective or potentially harmful treatments.

Conclusion

Carelon's current policy restrictions for SCS in non-surgical refractory back pain lack scientific justification and contradict established evidence-based medicine principles. The substantial body of high-quality research, including recent network meta-analyses and comprehensive literature reviews, demonstrates the safety, efficacy, and cost-effectiveness of SCS for appropriately selected patients.

The policy's requirements for mandatory surgical consultation and designation of SCS as "last resort" therapy will deny patients access to proven treatments while potentially exposing them to greater risks from prolonged use of less effective alternatives. These restrictions appear to prioritize administrative convenience over evidence-based patient care and optimal clinical outcomes.

We strongly urge Carelon to revise this policy to align with current scientific evidence and established clinical practice guidelines. Such revision would better serve patients with chronic pain while supporting healthcare providers in delivering evidence-based, compassionate care. The implementation of appropriate, evidence-based guidelines for SCS would demonstrate Carelon's commitment to supporting optimal patient outcomes while maintaining appropriate oversight of healthcare resources.



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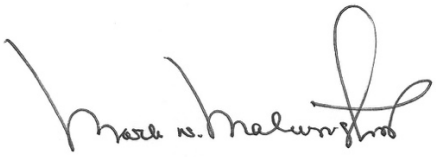

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