June 3, 2024

Sue Birch, MBA, BSN, RN
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Via e-mail: shtap@hca.wa.gov

Dear Ms. Birch:

We applaud the recent proposed coverage policy changes regarding spinal cord stimulation (SCS) for the indications of failed back surgery syndrome, peripheral diabetic neuropathy (PDN) and nonsurgical refractory back pain (NSRBP). This extends a widely successful therapeutic modality to patients suffering from these conditions in Washington State who were previously denied access to a pain treatment that has been proven across dozens of clinical trials to be safe, effective, and cost-effective in the long term. However, we were very concerned to learn that the draft findings proposed by the HTA Committee contain several elements that are poorly aligned with standard of care for SCS therapy for the proposed covered conditions, and wish to provide guidance for consideration by the Committee.

We have several concerns with the language surrounding coverage for all three covered indications:

Failed back surgery syndrome (FBSS): The requirement of a minimum of 12 months of failed conservative medical management (CMM) is twice that of most policies that require a minimum of 6 months. Mandating that patients suffer from severe, intractable pain for such an extended period of time will lead to detrimental impacts on mood, function and quality of life for patients. The use of language limiting to neuropathic pain only for patients with FBSS is unnecessary and inappropriate, given that many patients experience mixed nociceptive and neuropathic elements of chronic pain in this condition. The language should be revised to specify that patients should be experiencing neuropathic pain, but not *exclusively* neuropathic pain. The 2019 Health and Human Services Pain Management Task Force urges payors to extend "consistent and timely insurance coverage" for evidence-based interventions including neuromodulation.[1] Given the updated CDC guidelines regarding opioid prescribing, every reasonable attempt should be made to prevent unnecessary escalation of opioid medication for patients with chronic non-cancer pain, which is far more likely with such a lengthy period of time required for patients experiencing severe FBSS.[2] The requirement of a 7-to-14-day trial is inconsistent with the most recently published guidelines suggesting a maximum 10-day trial in order to not unnecessarily expose patients to a higher infection risk, and points out that most studies report a trial duration of 5-7 days. [1] By requiring a minimum of 7 days for an SCS trial, patients on chronic anticoagulation who must hold their anticoagulation therapy starting 24 hours prior to trial lead insertion may be exposed to greater risk of a thrombotic event when 5 days may be adequate to assess a trial response. Other policies (specifically Aetna and Premara) require a minimum trial of 3 days. Most manufacturer leads are not approved for more than 10 days use during an SCS trial. We recommend that the Committee consider imposing a minimum trial duration of a shorter period of time (3-5 days), and not necessarily impose a maximum trial duration. Finally, the highly specific requirements regarding baseline function is not consistent with other policies, which do not typically use a specific scale or require a specific degree of improvement, if they are required at all. Most policies require a 50% improvement in pain and either a nonspecific degree of functional improvement OR require functional improvement only if the 50% threshold for pain is not met. Also, in accordance with recently published guidelines regarding SCS trials,[3] assessment of functional improvement should be individualized based

on a patient's unique characteristics and lifestyle, and may include ability to participate in activities specific to an individual patient. The requirement of baseline ≥21% ODI is not evidence-based, nor aligned with clinical guidelines or the industry standard.

Language appearing in the corrected version of the draft findings and recommendations inappropriately denies coverage patients with FBSS or NSRBP if they have an open or pending worker's compensation claim. As we noted in our initial letter to HCA on October 2, 2023, we are concerned about the weight given to the thirteen-year-old Hollingworth, et al. study of Washington Workers' Compensation patients, with its low 5% response rate for SCS, which is truly an outlier versus other published SCS studies.

Nonsurgical Refractory Back Pain (NSRBP): We support the committee's decision to cover this condition. However, our positions as stated above regarding the requirements for minimum of 12 months (as opposed to 6 months) of failed CMM, baseline ODI score ≥ 21%, and consideration of removing the requirement that pain be exclusively neuropathic also apply to the condition of NSRBP. We also object to denial of coverage to those with a worker's compensation claim as noted above.

Painful Diabetic Neuropathy (PDN): While support the committee's decision to cover this condition, we disagree for the reasons outlined above that patients should be required to fail 12 months of CMM. This places an undue burden of pain and suffering upon patients. Additionally, the requirement of documented sensory loss is inconsistent with the inclusion and exclusion criteria of published clinical trials demonstrating the efficacy of SCS for PDN.[4] We also object to the requirement of greater than 50% pain reduction in addition to reduction of chronic opioid medications or objective and clinically meaningful degree of functional improvement. Traditional opioid medications are not recommended for the treatment of PDN and should not be considered in the criteria for coverage for SCS for this condition.[5,6] As described above, what is considered objectively and clinically meaningful in terms of functional improvement can vary considerably from patient to patient, and this requirement is typically only considered if patients experience *less than* 50% pain improvement during their trial.

In short, we agree with the Committee's consideration to extend coverage of SCS for the treatment of FBSS, NSRBP, and PDN, but wish to point out inconsistencies between the considered determination policies and the standard of care according to published clinical trials, guidelines, and the practices of other insurance companies including United Healthcare, Aetna, Premera Blue Cross, and BCBS Anthem.

- Patients may be expected to fail 6 months of CMM, but 12 months is unnecessarily long and imposes undue suffering on patients.
- Limiting SCS therapy to patients experiencing *exclusively* neuropathic pain is inappropriate given that most patients may experience more than one source of pain, including nociceptive pain.
- Trial length is typically 5-7 days and imposing a 7–14-day trial requirement is inconsistent with nationally published guidelines and other standard practice.
- The requirement of a baseline ODI score ≥21% is not evidence-based, nor an accepted or recommended way to assess a patient's candidacy for SCS trial or therapy. Functional improvement *during* an SCS trial may be considered in patients who have equivocal pain improvement (less than 50%), but should not be considered in a patient's candidacy for therapy.
- For PDN, objective and documented sensory loss should not be a requirement to proceed with SCS trial, as this is inconsistent with published studies regarding SCS for PDN.

We do hope that, in the future, the Washington State Health Care Authority may reconsider its position on denial of SCS for complex regional pain syndrome (CRPS). Spinal cord stimulation has been

demonstrated to be an excellent treatment for patients with CRPS who have failed CMM with improved pain, function and quality of life with reduced opioid utilization.[7] Spinal cord stimulation has also been found to be cost effective in the treatment of CRPS compared to CMM alone.[8] All major commercial payors and guidelines recommend the use of SCS for CRPS, and such access should not be denied to patients in Washington State.

Thank you for considering our concerns regarding the recently announced draft policies. We believe we are ideologically aligned in pursuing the best evidence-based care for patients suffering with chronic pain, to improve function, quality of life, and reduce unnecessary use of medications. We offer our suggestions in support of the efforts being made the HTA Committee to improve access to therapies that can substantially improve the lives of patients living with chronic pain.

Respectfully submitted on behalf of the 40,000+ members our undersigned societies represent,

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

References

1. U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html
2. 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;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1
3. Shanthanna H, Eldabe S, Provenzano DA, et al. Evidence-based consensus guidelines on patient selection and trial stimulation for spinal cord stimulation therapy for chronic non-cancer pain. Reg Anesth Pain Med. Jun 2023;48(6):273-287. doi:10.1136/rapm-2022-104097
4. Petersen EA, Stauss TG, Scowcroft JA, et al. Effect of High-frequency (10-kHz) Spinal Cord Stimulation in Patients With Painful Diabetic Neuropathy: A Randomized Clinical Trial. JAMA Neurol. Jun 1 2021;78(6):687-698. doi:10.1001/jamaneurol.2021.0538
5. Waldfogel JM, Nesbit SA, Dy SM, et al. Pharmacotherapy for diabetic peripheral neuropathy pain and quality of life: A systematic review. Neurology. May 16 2017;88(20):1958-1967. doi:10.1212/wnl.0000000000003882
6. Pop-Busui R, Boulton AJ, Feldman EL, et al. Diabetic Neuropathy: A Position Statement by the American Diabetes Association. Diabetes Care. Jan 2017;40(1):136-154. doi:10.2337/dc16-2042
7. Oliveira MJ, Matis GK. Spinal cord stimulation as a treatment option for complex regional pain syndrome: a narrative review. Br J Neurosurg. Dec 22 2022:1-5. doi:10.1080/02688697.2022.2159930
8. Zhou X, Zhou Y, Zhang X, Jiang F. Economic evaluation of management strategies for complex regional pain syndrome (CRPS). Front Pharmacol. 2024;15:1297927. doi:10.3389/fphar.2024.1297927