

May 13, 2024

Sue Birch, MBA, BSN, RN
Director
Washington State Health Care Authority
Cherry Street Plaza
626 8th Avenue SE
Olympia, Washington 98501
shtap@hca.wa.gov

Dear Ms. Birch:

The undersigned medical specialty societies, comprising physicians who utilize or perform interventional pain procedures to accurately diagnose and treat patients suffering from spine pathologies, would like to take this opportunity to express our strong support for coverage of spinal cord stimulation (SCS) and concerns about the ongoing deliberations regarding SCS coverage by the Health Technology Clinical Committee (HTCC). Collaborating with the Washington State Spinal Cord Stimulator Workgroup, our mutual goal is to ensure the most compelling evidence for SCS is presented, ensuring its accessibility to suitable patients with refractory pain conditions. We are dedicated to prioritizing the well-being of all residents of Washington State in a fair and financially prudent manner.

Our societies have a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved.

While we acknowledge the committee's dedication and effort in addressing this issue, we have reservations regarding the process. During the November 17th meeting, the HTCC heard multiple presentations supporting SCS. Those presentations were intended to educate the HTCC about the technology and its evidence base to assist them in evaluating SCS's utility for patients with various indications. The presentation from the Washington State SCS Workgroup was followed by detailed questions to the clinical expert and discussions amongst the committee informed by the workgroup. These detailed and engaged deliberations concluded with positive straw votes for four conditions:

Complex Regional Pain Syndrome (CRPS)
Painful Diabetic Peripheral Neuropathy (PDN)
persistent pain after spinal surgery or "Failed back surgery syndrome" (FBSS) and
Nonsurgical Refractory Low Back Pain

At the meeting's close, the decision was made to establish a subgroup tasked with defining coverage guidelines, followed by a continuation meeting. This was later rescinded behind closed doors, averting an open meeting process, and draft coverage criteria were subsequently developed without any input from clinical experts or practitioners with SCS experience. The draft coverage proposed by the Agency Medical Director contained many concerning proposals:

- reversal of the straw votes of 11/17/2023 ([pages 108-109](#))

- exclusion of FDA-approved, evidence-based waveforms (BurstDR), which likely represent a significant misunderstanding of the Hara study ([p112](#))
- coverage criteria with no evidence basis ([p113](#))

We anticipated that the formal vote would align with the preliminary consensus, as indicated during the 11/17/2023 meeting; however, the formal vote was postponed until coverage conditions were thoroughly discussed and established at a later session.

The conduct of the subsequent February 16th meeting was troublesome. While it was an “open” meeting, public participation was prohibited. Experts were not invited to participate or available to address questions or provide clarification about the technology or its evidence. This was quite unfortunate since the panel was confused and misinformed about SCS, which was clear from the many misstatements made regarding SCS, including the process of an SCS trial, mechanisms of action, and details of the implantation and maintenance of SCS systems. The reassessment process of coverage conditions and a formal vote has now been extended to a 3rd meeting on May 17th. We are concerned that this delay will further diminish the Committee’s recollection and appreciation for the data presented during the November meeting, including suggested conditions of coverage.

In the interest of informing the discussions with both evidence and clinical expertise, we are requesting the following for the upcoming meeting in May:

Clinical experts should be invited to present evidence-based coverage suggestions based on prior submitted information and presentations.

The committee should re-review the previous evidence-based presentations or allow them to be delivered again, considering the time that has elapsed since the HTCC heard them in November.

Clinical experts should be invited to attend to address questions and provide clarification to assist with HTCC decision-making.

The undersigned societies would welcome the opportunity to work with the WA HTCC to establish a reasonable coverage policy to eliminate inappropriate utilization and ensure appropriate patient access to SCS. We offer our ongoing input and expertise in this matter. If you have any questions or wish to discuss our suggestions, please contact Sarah Cartagena, Director of Health Policy at the International Pain and Spine Intervention Society, at scartagena@ipsismed.org.

Sincerely,

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