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Ensuring Patient Access. Promoting Quality Care.

February 18, 2010

Leah Hole-Curry, JD - Program Director
Washington State Health Technology Assessment
676 Woodland Square Loop SE
Lacey, WA 98503

Dear Ms. Hole-Curry:

On behalf of the Neuromodulation Therapy Access Coalition (NTAC), I wish to submit the following comments regarding the proposed draft key questions on spinal cord stimulation (SCS) issued by the Health Technology Assessment (HTA) program.

Specifically, we recommend necessary changes to questions 1 and 3 to ensure a reasonable review of the clinical evidence on SCS. Specifically, the introduction of “return to work” in question 1(c) is not a relevant outcome measure, while question 3 inappropriately blends patient selection criteria with payer/insurance programs through which an individual obtains access to SCS. We recommend that the HTA amend both questions to more accurately guide the review of evidence on SCS.

Question 1: Of the sixteen therapies undertaken by the HTA for which key questions have been developed, there is no other instance in which “return to work” has been included as an assessment criterion. The concept of “return to work,” included in question 1(c) for SCS, is not a valid clinical measure for any therapy, because work status depends on circumstances beyond the control of both the patient and the intervention.

All therapies, including SCS, must be evaluated in relation to clinically appropriate measures. In the case of SCS, the primary outcome measure is the reduction in chronic pain that is refractory to other interventions. Secondary outcome measures might include increased physical function and decreased use of opioids; however, these measures must be considered secondary to the primary goal of reduction in chronic pain.

In addition, SCS is often a last-resort therapy for individuals with chronic pain. Therefore, including return to work as a outcome criteria is not only clinically inappropriate, it sets an unreasonable threshold for a therapy intended to provide relief of chronic pain when other options have failed.

In order to fairly address outcome measures for SCS, we therefore request that the HTA delete “return to work” as a criterion in question 1(c).

Question 3: SCS may have differential impacts based on the etiology of neuropathic pain and certain clinical sub-population categories.

However, the introduction of the workers' compensation program in this question blends clinical characteristics of patients with the payer program covering the therapy. As we have noted in our discussion of the University of Washington study commissioned by the Department of Labor and Industries (see NTAC's January 8, 2010 comment letter to the HTA), the notion of differences in safety and efficacy among payer types (i.e., presumed differences in outcomes within the state workers' compensation program) confounds, rather than clarifies, the specific clinical effects of a therapeutic intervention such as SCS.¹

As the UW authors state at the conclusion of their study, *“(t)he issues associated with involvement in the workers' compensation system may be a stronger influence than pain therapy on patient outcomes.”*

To be clear, we do acknowledge that one possible influence arising from workers' compensation is the risk of “secondary gain.” Rather than influencing clinical outcomes, secondary gain instead risks influencing *reported* outcomes; as such, it may be one of a number of factors that a physician screens for in evaluating the appropriateness of SCS as a therapy option. In this case, secondary gain (and the role of workers' compensation programs) is addressed in the process of patient selection for SCS, rather than as a factor that predicts the clinical success of the therapy.

Therefore, in order to appropriately address the importance of patient selection criteria for SCS, we recommend that question 3 be replaced with the following language (please note this version of question 3 also includes modifications to more accurately describe clinical characteristics of candidate patients):

3. *What is the evidence guiding patient selection criteria for spinal cord stimulation? Including:*
 - a. *Pain type (“nociceptive” vs. “neuropathic”)*
 - b. *Diagnosis (Postlaminectomy syndrome, complex regional pain syndrome, radicular neuropathic pain)*
 - c. *Differential impact by clinical sub-populations (e.g., age, gender)*
 - d. *Psychological co-morbidities, including secondary gain*
 - e. *Response to other pharmacological and interventional therapies*

Summary Recommendations:

- 1) Omit “return to work” in question 1, as this criterion appears in no other technology assessment and is not a valid clinical outcome measure for SCS or any therapy.

¹ Turner JA et al. Spinal cord stimulation for failed back surgery syndrome: Outcomes in a workers' compensation setting. PAIN (2009), doi: 10.1016/j.pain.2009.08.014

- 2) At a minimum, remove “workers’ compensation” from question 3, as its inclusion inappropriately introduces a payment program into a discussion of clinical measures.
- 3) Preferably, replace question 3 with the above language to more accurately guide the vendor’s review of evidence on patient selection criteria for SCS.

Thank you for your consideration of these comments. Please do not hesitate to contact me at eric@neuromodulationaccess.org or (651) 278-4238 with any questions.

Best regards,

A handwritten signature in black ink, appearing to read 'E. Hauth', with a long horizontal flourish extending to the right.

Eric Hauth, Executive Director

Cc Joshua Prager, MD (NTAC Chair)
David Kloth, MD (NTAC Vice Chair)