

May 29, 2017

Juerg Kunz Medical Advisory Committee State of Oregon Workers' Compensation Division Juerg.Kunz@oregon.gov

Dear Juerg,

Abbott wishes to provide comment to the Oregon Workers Compensation Medical Advisory Committee regarding the review of evidence supporting the use of spinal cord stimulators for the management of chronic pain.

At Abbott, we're committed to helping people live their best possible life through the power of health. For more than 125 years, we've brought new products and innovative technologies to the world that create more possibilities for more people at all stages of life. In particular, Abbott's Neuromodulation division develops innovative Spinal Cord Stimulation (SCS) systems used in the treatment of patients with chronic intractable pain of the trunk and limbs. Today, 74,000 Abbott employees are working to help people live not just longer, but better, in the more than 150 countries we serve.

Spinal cord stimulation is a form of neuromodulation used to relieve chronic intractable pain of neuropathic or ischemic origin and has historically been reserved to treat pain that has failed to respond to conventional measures.

We would advocate for a comprehensive review of the full body of published clinical and economic evidence supporting the use of spinal cord stimulation (SCS) in appropriate patients. In addition to a review of the clinical and economic evidence, we would also advocate a thorough review of the health technology assessments of SCS done by various governmental organizations around the globe, including those from Australia, Belgium, Canada, France, and the United Kingdom. Similarly, based upon their careful review of the published literature which evaluates the use of SCS, most US commercial payers also include the use of SCS as a covered benefit for their beneficiaries when specific criteria are met.

When evaluating the evidence supporting the use of spinal cord stimulation for the treatment and/or management of chronic pain, it is important to remember that this modality is typically considered as a treatment option only at the later stages of the overall treatment continuum when all other alternatives have been unsuccessful.

There are also several other specific factors to consider when evaluating the evidence regarding the use of SCS. Most of the published literature regarding SCS has had some level of industry support as there is very little, if any, non-industry support available for clinical research of this type. There are also very few SCS studies with a specific focus on the US workers compensation population, although most SCS studies have a larger preponderance of working age subjects rather than older (65+) patients typical of Medicare beneficiaries. Due to the very nature of spinal cord stimulation, such as the characteristic paresthesia inherent in most forms of SCS and/or the need for individualized device programming necessary for optimal efficacy, it is not always possible to utilize clinical trial protocols with a double-blind research design and/or sham treatment arms. Furthermore, due to the long-term nature of chronic intractable pain, the use of SCS in the later stages of the treatment continuum, and the length of treatment time associated with SCS systems, any cost-effectiveness analysis of this treatment modality must utilize an appropriate long-term time horizon.

I have attached a document with a set of additional references for your committee's review. The publications on this list are intended to supplement those listed on a previous document from a similar review in 2016.

As you evaluate the full body of research regarding SCS, critically assess the integrity of the research design, study execution, and results for these publications, and account for the additional considerations identified above, we believe that you will find an appropriate level of evidence which supports the use of SCS to treat the chronic intractable pain in specific types of patients in a manner that enables you to advance a leading workers' compensation system that represents integrity and fairness for Oregonians.

Sincerely,

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# Additional Spinal Cord Stimulation References for Consideration

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## **Clinical Studies**

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