May 31, 2017

Medical Advisory Committee
Oregon Workers’ Compensation Division
Attention: Juerg Kunz

Subject:
Clinical evidence for SCS to treat CRPS and FBSS

Dear Mr. Kunz,

This letter is in response to the Medical Advisory Committee’s request for peer reviewed studies directly relating to the efficacy of spinal cord stimulation (SCS). We thank the committee for the opportunity to participate in this process.

Medtronic is a global medical technology and services company with a comprehensive product portfolio. Medtronic’s Restorative Therapies Group manufactures spinal cord stimulators for the treatment of chronic, intractable pain of the trunk and limbs. FDA approved indications include failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS), radicular pain secondary to failed back surgery or herniated disk, refractory pain due to degenerative disk disease or herniated disk, peripheral causalgia, epidural fibrosis, and arachnoiditis. For this patient population with inadequate pain relief or intolerable side effects from medication, SCS is an important treatment option.

We have reviewed the studies that were evaluated by the MAC subcommittee (http://wcd.oregon.gov/medical/mac/Documents/scs.pdf). Our letter serves as a supplement to this literature search, and includes randomized controlled trials and meta-analyses that were not included in the initial literature search. Publications that disclose a relationship between Medtronic and at least one of the authors are bolded. Publications that are included in the MAC literature search are italicized.

Search Strategy
A literature search was performed via PubMed and Embase in March 2017. The search strategy included terms for spinal cord stimulation, complex regional pain syndrome, reflex sympathetic dystrophy, causalgia, guidelines, algorithm, failed back surgery syndrome, FBSS, failed back syndrome, postlaminectomy syndrome, FBS, and chronic back and leg pain and related terms.

Search Results
Our search identified a large body of literature that supports the use of SCS therapy for the treatment of pain related to FBSS and CRPS. There are multiple randomized controlled trials, as well as a number prospective and retrospective studies that describe the safety and efficacy of SCS when used to treat patients with these indications.
References: SCS and CRPS

Key:
- Publications that disclose a relationship between Medtronic and at least one of the authors are bolded.
- Publications that are included in the MAC literature search are italicized.

SCS in the Care Continuum


CRPS-only Patient Population Studies

Randomized Controlled Trials


Prospective Studies


Retrospective Studies


Mixed Pain Population Studies
Retrospective Studies


### Meta-Analyses and Therapy Reviews


**References: SCS and FBSS**

**Randomized Controlled Trials**


**Prospective Studies**


Retrospective Studies


**Therapy Reviews**


**Consensus Documents and Guidelines**

Recent consensus documents and guidelines have been published with the overall goal of providing SCS therapy to the appropriate patients, to improve outcomes, and to minimize complications and infections. A listing of some of these guidelines are below.


Thank you for the opportunity to provide additional clinical references. Please contact me if you have any questions.

Sincerely,

Mary E. Ryan
Senior Program Manager
State Government Affairs
Medtronic Restorative Therapies Group
763-526-8194
mary.e.ryan@medtronic.com