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Medtronic

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

1. **Poree L**, **Krames E**, **Pope J**, **Deer TR**, **Levy R**, **Schultz L**. **Spinal cord stimulation as treatment for complex regional pain syndrome should be considered earlier than last resort therapy**. *Neuromodulation.* **2013**;**16**(**2**):**125-141**.

2. **Krames E**, **Poree L**, **Deer T**, **Levy R**. **Implementing the SAFE Principles for the Development** of Pain Medicine Therapeutic Algorithms That Include Neuromodulation Techniques. *Neuromodulation.* **2009**;12(2):104-113.

3. **Stanton-Hicks MD**, **Burton AW**, **Bruehl SP**, et al. **An updated interdisciplinary clinical pathway for CRPS: report of an expert panel**. *Pain Pract.* **2002**;**2**(**1**):**1-16**.

4. **Dworkin RH**, **O'Connor AB**, **Kent J**, et al. **Interventional management of neuropathic pain: NeuPSIG recommendations**. *Pain.* **2013**;**154**(**11**):**2249-2261**.

5. van Eijs F, Stanton-Hicks M, Van Zundert J, et al. Evidence-based interventional pain medicine according to clinical diagnoses. 16. Complex regional pain syndrome. *Pain Pract.* 2011;11(1):70-87.

6. Cruccu G, Aziz TZ, Garcia-Larrea L, et al. EFNS Guidelines on Neurostimulation Therapy for **neuropathic pain**. *Eur J Neurol.* **2007**;**14**(**9**):**952-970**.

7. **Taylor, R. S., Desai, M. J., Rigoard, P. and Taylor, R. J. (2014), Predictors of Pain Relief Following Spinal Cord Stimulation in Chronic Back and Leg Pain and Failed Back Surgery Syndrome: A Systematic Review and Meta-Regression Analysis.** Pain Pract**, 14: 489–505. doi:10.1111/papr.12095**

8. **Kumar, K., Rizvi, S., Nguyen, R., Abbas, M., Bishop, S. and Murthy, V. (2014), Impact of Wait times on Spinal Cord Stimulation Therapy Outcomes.** Pain Pract**, 14: 709–720. doi:10.1111/papr.12126**

CRPS-only Patient Population Studies

Randomized Controlled Trials

9. Kemler MA, Barendse GA, van Kleef M, et al. Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. *N Engl J Med.* 2000;343(9):618-624.

10. van Eijs F, Smits H, Geurts JW, et al. Brush-evoked allodynia predicts outcome of spinal cord stimulation in complex regional pain syndrome type 1. *Eur J Pain.* 2010;14(2):164-169.

11. Kemler MA, De Vet HC, Barendse GA, Van Den Wildenberg FA, Van Kleef M. The effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two years' follow-up of the randomized controlled trial. *Ann Neurol.* 2004;55(1):13-18.

12. Kemler MA, de Vet HC, Barendse GA, van den Wildenberg FA, van Kleef M. Effect of spinal cord stimulation for chronic complex regional pain syndrome Type I: five-year final follow-up of patients in a randomized controlled trial. *J Neurosurg.* 2008;108(2):292-298.

13. Kemler MA, Furnee CA. Economic evaluation of spinal cord stimulation for chronic reflex sympathetic dystrophy. *Neurology.* 2002;59(8):1203-1209.

Prospective Studies

14. *Geurts JW, Smits H, Kemler MA, Brunner F, Kessels AG, van Kleef M. Spinal cord stimulation for complex regional pain syndrome type I: a prospective cohort study with long-term follow-up. Neuromodulation. 2013;16(6):523-529; discussion 529.*

15. van Eijs F, Geurts JW, Van Zundert J, et al. Spinal cord stimulation in complex regional pain syndrome type I of less than 12-month duration. *Neuromodulation.* 2012;15(2):144-150; discussion 150.

16. Harke H, Gretenkort P, Ladleif HU, Rahman S. Spinal cord stimulation in sympathetically maintained complex regional pain syndrome type I with severe disability. A prospective clinical study. *Eur J Pain.* 2005;9(4):363-373.

17. Forouzanfar T, Kemler MA, Weber WE, Kessels AG, van Kleef M. Spinal cord stimulation in complex regional pain syndrome: cervical and lumbar devices are comparably effective. *Br J Anaesth.* 2004;92(3):348-353.

18. Calvillo O, Racz G, Didie J, Smith K. Neuroaugmentation in the treatment of complex regional pain syndrome of the upper extremity. *Acta Orthop Belg.* 1998;64(1):57-63.

Retrospective Studies

19. Bennett DS, Alo KM, Oakley J, Feler CA. Spinal Cord Stimulation for Complex Regional Pain Syndrome I [RSD]: a Retrospective Multicenter Experience from 1995 to 1998 of 101 Patients. *Neuromodulation.* 1999;2(3):202-210.

20. *Kumar K, Rizvi S, Bnurs SB. Spinal cord stimulation is effective in management of complex regional pain syndrome I: fact or fiction. Neurosurgery. 2011;69(3):566-578; discussion 5578-5580.*

Mixed Pain Population Studies

Retrospective Studies

21. Mekhail NA, Mathews M, Nageeb F, Guirguis M, Mekhail MN, Cheng J. Retrospective review of 707 cases of spinal cord stimulation: indications and complications. *Pain Pract.* 2011;11(2):148-153.

22. Hayek SM, Veizi E, Hanes M. Treatment-Limiting Complications of Percutaneous Spinal Cord Stimulator Implants: A Review of Eight Years of Experience From an Academic Center Database. *Neuromodulation.* 2015;18(7):603-608; discussion 608-609.

23. Reig E, Abejon D. Spinal cord stimulation: a 20-year retrospective analysis in 260 patients. *Neuromodulation.* 2009;12(3):232-239.

24. Williams KA, Gonzalez-Fernandez M, Hamzehzadeh S, et al. A multi-center analysis evaluating factors associated with spinal cord stimulation outcome in chronic pain patients. *Pain Med.* 2011;12(8):1142-1153.

25. Sanders RA, Moeschler SM, Gazelka HM, et al. Patient Outcomes and Spinal Cord Stimulation: A Retrospective Case Series Evaluating Patient Satisfaction, Pain Scores, and Opioid Requirements. *Pain Pract.* 2016;16(7):899-904.

26. Quigley DG, Arnold J, Eldridge PR, et al. Long-term outcome of spinal cord stimulation and hardware complications. *Stereotact Funct Neurosurg.* 2003;81(1-4):50-56.

27. Chivukula S, Tempel ZJ, Weiner GM, et al. Cervical and cervicomedullary spinal cord stimulation for chronic pain: efficacy and outcomes. *Clin Neurol Neurosurg.* 2014;127:33-41.

28. *Sears NC, Machado AG, Nagel SJ, et al. Long-term outcomes of spinal cord stimulation with paddle leads in the treatment of complex regional pain syndrome and failed back surgery syndrome. Neuromodulation. 2011;14(4):312-318; discussion 318.*

Meta-Analyses and Therapy Reviews

5. van Eijs F, Stanton-Hicks M, Van Zundert J, et al. Evidence-based interventional pain medicine according to clinical diagnoses. 16. Complex regional pain syndrome. *Pain Pract.* 2011;11(1):70-87.

29. Grabow TS, Tella PK, Raja SN. Spinal cord stimulation for complex regional pain syndrome: an evidence-based medicine review of the literature. *The Clinical Journal of Pain.* 2003;19(6):371-383.

30. Cameron T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. *J Neurosurg.* 2004;100(3 Suppl Spine):254-267.

31. Prager JP. What does the mechanism of spinal cord stimulation tell us about complex regional pain syndrome? *Pain Med.* 2010;11(8):1278-1283.

32. Bennett DS, Brookoff D. Complex Regional Pain Syndromes (Reflex Sympathetic Dystrophy and Causalgia) and Spinal Cord Stimulation. *Pain Medicine.* 2006;7(suppl 1):S64-S96.

33. Rodriguez MJ, Fernandez-Baena M, Barroso A, Yanez JA. Invasive Management for Pediatric Complex Regional Pain Syndrome: Literature Review of Evidence. *Pain Physician.* 2015;18(6):621-630.

34. Oaklander AL, Horowitz SH. The complex regional pain syndrome. *Handbook of clinical neurology / edited by P.J. Vinken and G.W. Bruyn.* 2015;131:481-503.

References: SCS and FBSS

Randomized Controlled Trials

1. **Kumar K**, **Taylor RS**, **Jacques L**, et al. **Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome**. *Pain.* **2007;132(1-2):179-188**.

2. **Kumar K**, **Taylor RS**, **Jacques L**, et al. **The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation**. *Neurosurgery.* **2008;63(4):762-770; discussion 770**.

3. **Manca A**, **Eldabe S**, **Buchser E**, **Kumar K**, **Taylor RS**. **Relationship between health-related quality of life, pain, and functional disability in neuropathic pain patients with failed back surgery syndrome**. *Value Health.* **2010;13(1):95-102**.

4. **Eldabe S**, **Kumar K**, **Buchser E**, **Taylor RS**. **An analysis of the components of pain, function, and health-related quality of life in patients with failed back surgery syndrome treated with spinal cord stimulation or conventional medical management**. *Neuromodulation.* **2010;13(3):201-209**.

5. **North RB**, **Kidd DH**, **Farrokhi F**, **Piantadosi SA**. **Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial**. *Neurosurgery.* **2005;56(1):98-106; discussion 106-107**.

6. **Schultz DM**, **Webster LR**, **Kosek P**, **Dar U**, **Tan Y**, **Sun M**. **Sensor-driven position-adaptive spinal cord stimulation for chronic pain**. *Pain Physician.* **2012;15(1):1-12**.

Prospective Studies

7. ***Rigoard P, Jacques L, Delmotte A**, et al. **An algorithmic programming approach for back pain symptoms in failed back surgery syndrome using spinal cord stimulation with a multicolumn surgically implanted epidural lead: a multicenter international prospective study**. Pain Pract. **2015;15(3):195-207**.*

8. **Delmotte A**, **Jacques L**, **Kumar K**, et al. **The Franco-Canadian multicolumn spinal cord stimulation prospective study: A subgroup analysis focusing on the decisive role of lead positioning**. *Neurochirurgie.* **2015;61(S1):S83-S89**.

9. Deer T, Skaribas I, Nelson C, et al. Interim Results From the Partnership for Advancement in Neuromodulation Pain Registry. *Neuromodulation.* 2014;17(7):656-664.

10. *Slavin KV, Vaisman J, Pollack KL, et al. Treatment of chronic, intractable pain with a conventional implantable pulse generator: a meta-analysis of 4 clinical studies. The Clinical Journal of Pain. 2013;29(1):78-85.*

11. *Turner JA, Hollingworth W, Comstock BA, Deyo RA. Spinal cord stimulation for failed back surgery syndrome: outcomes in a workers' compensation setting. Pain. 2010;148(1):14-25.*

12. Hollingworth W, Turner JA, Welton NJ, Comstock BA, Deyo RA. Costs and cost-effectiveness of spinal cord stimulation (SCS) for failed back surgery syndrome: an observational study in a workers' compensation population. *Spine (Phila Pa 1976).* 2011;36(24):2076-2083.

13. **Ohnmeiss DD**, **Rashbaum RF**. **Patient satisfaction with spinal cord stimulation for predominant complaints of chronic, intractable low back pain**. *Spine J.* **2001**;**1**(**5**):**358-363**.

14. Barolat G, Oakley JC, Law JD, North RB, Ketcik B, Sharan A. Epidural spinal cord stimulation with a multiple electrode paddle lead is effective in treating intractable low back pain. *Neuromodulation.* 2001;4(2):59-66.

15. Sharan A, Cameron T, Barolat G. Evolving patterns of spinal cord stimulation in patients implanted for intractable low back and leg pain. *Neuromodulation.* 2002;5(3):167-179.

16. **Burchiel KJ**, **Anderson VC**, **Brown FD**, et al. **Prospective, multicenter study of spinal cord stimulation for relief of chronic back and extremity pain**. *Spine (Phila Pa 1976).* **1996**;**21**(**23**):**2786-2794**.

17. **Burchiel KJ**, **Anderson VC**, **Wilson BJ**, **Denison DB**, **Olson KA**, **Shatin D**. **Prognostic factors of spinal cord stimulation for chronic back and leg pain**. *Neurosurgery.* **1995**;**36**(**6**):1101-1110; discussion 1110-1101.

Retrospective Studies

18. Hayek SM, Veizi E, Hanes M. Treatment-Limiting Complications of Percutaneous Spinal Cord Stimulator Implants: A Review of Eight Years of Experience From an Academic Center Database. *Neuromodulation.* 2015;18(7):603-608; discussion 608-609.

19. Sanders RA, Moeschler SM, Gazelka HM, et al. Patient Outcomes and Spinal Cord Stimulation: A Retrospective Case Series Evaluating Patient Satisfaction, Pain Scores, and Opioid Requirements. *Pain Pract.* 2016;16(7):899-904.

20. Mekhail NA, Mathews M, Nageeb F, Guirguis M, Mekhail MN, Cheng J. Retrospective review of 707 cases of spinal cord stimulation: indications and complications. *Pain Pract.* 2011;11(2):148-153.

21. Williams KA, Gonzalez-Fernandez M, Hamzehzadeh S, et al. A multi-center analysis evaluating factors associated with spinal cord stimulation outcome in chronic pain patients. *Pain Med.* 2011;12(8):1142-1153.

22. Reig E, Abejon D. Spinal cord stimulation: a 20-year retrospective analysis in 260 patients. *Neuromodulation.* 2009;12(3):232-239.

23. Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. *Neurosurgery.* 2006;58(3):481-496; discussion 481-496.

Therapy Reviews

24. **Frey ME**, **Manchikanti L**, **Benyamin RM**, **Schultz DM**, **Smith HS**, **Cohen SP**. **Spinal cord stimulation for patients with failed back surgery syndrome: a systematic review**. *Pain Physician.* **2009;12(2):379-397**.

25. Simpson EL, Duenas A, Holmes MW, Papaioannou D, Chilcott J. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation. *Health Technol Assess.* 2009;13(17):iii, ix-x, 1-154.

26. Sparkes E, Raphael JH, Duarte RV, LeMarchand K, Jackson C, Ashford RL. A systematic literature review of psychological characteristics as determinants of outcome for spinal cord stimulation therapy. *Pain.* 2010;150(2):284-289.

27. Brook AL, Georgy BA, Olan WJ. Spinal cord stimulation: a basic approach. *Tech Vasc Interv Radiol.* 2009;12(1):64-70.

28. Hussain A, Erdek M. Interventional pain management for failed back surgery syndrome. Pain *Pract.* 2014;14(1):64-78.

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.

29. **Deer T. R. et. al. The Appropriate Use of Neurostimulation: Avoidance and Treatment of Complications of Neurostimulation Therapies for the Treatment of Chronic Pain.** Neuromodulation. **2014; 17: 571-598.**

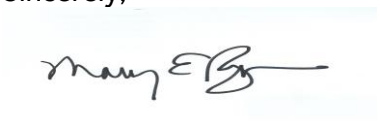
30. **Deer T. R. et. al. The Neurostimulation Appropriateness Consensus Committee (NACC) Safety Guidelines for the Reduction of Severe Neurological Injury.** Neuromodulation. **2017 Jan;20(1):15-30**

31. **Deer T. R. el. al. The Neurostimulation Appropriateness Consensus Committee (NACC) Recommendations for Infection Prevention and Management.** Neuromodulation. **2017 Jan;20(1):31-50.**

32. **Deer T. R. et al. The Neurostimulation Appropriateness Consensus Committee (NACC): Recommendations on Bleeding and Coagulation Management in Neurostimulation Devices.** Neuromodulation. **2017 Jan;20(1):51-62.**

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

Sincerely,



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