WAPMU | WORLD ACADEMY *of* PAIN MEDICINE UNITED

Board of Directors

World Academy of Pain Medicine United

December 22, 2020

To the relevant Parties,

As a multidisciplinary group of interventional pain management physicians, we are writing on behalf of our chronic pain patients who can benefit from the use of peripheral nerve stimulation (PNS) systems. The draft medical policy "Peripheral Nerve Stimulation (PNS) and Peripheral Nerve Field Stimulation (PNFS)", MED205.036"[1] open for comment through 12-31-20 creates significant concern given the increasingly important place that PNS plays in our care decisions. Given the relative paucity of data supporting PNFS, compared to PNS, it is paramount to separate PNS from PNFS.

We are recommending HCSC decline to implement this draft policy and allow coverage of Peripheral Nerve Stimulation (PNS), when medically necessary, in the treatment of patients suffering from moderate to severe chronic pain who have failed conservative treatment. This includes those who are at risk of exceeding opioid use limits as established by Centers for Disease Control (CDC)[2] Guideline for Prescribing Opioids for Chronic Pain, which states that "Patients should receive appropriate pain treatment based on a careful consideration of the benefits and risks of treatment options."

**Peripheral Nerve Stimulation (PNS) is considered medically necessary in the treatment of chronic pain when the patient continues to experience moderate to severe pain after failing two prior conservative treatments and when:**

Pain requires opioid use beyond 30 days, or;

Pain has not resolved within the normal time course of healing, as discerned by the physician or;

Pain continues or is expected to continue for longer than 3 months from its initial onset.

**PNS is an Important and Clinically-substantiated Treatment Option, worthy of consideration during the Opioid Crisis**

As interventional pain management physicians it is critically important that we offer **ALL** patients safe and effective treatment options to address their chronic pain. Unfortunately, this drafted policy, will achieve the opposite effect. Patients insured by HCSC will endure other more expensive and invasive or continued long-term opioid use.

This draft policy is a direct contradiction to the BCBS Association's (BCBSA) and HCSC's commitment and plans for how to reduce opioid use in an effort to combat the Nation's Opioid Epidemic in which you "aim to identify members who may be at risk of opioid addiction and abuse; work with doctors, other

health care professionals, and community partners to prevent or reduce the risk of addiction and abuse"[3] and "ensure BCBS members are routinely provided alternatives to opioids through a mutual decision made inside the doctor's office and take a comprehensive approach to addressing the opioid epidemic through prevention, intervention, and treatment".[4]

Clinically significant reductions in opioid use across multiple indications have been demonstrated following PNS. Chmiela et al (2020) reported on a 30-year review of PNS in the management of Complex Regional Pain Syndrome. At baseline, 62% of patients were on chronic opioid therapy, compared with only 41% at 12 months. Pain scores were also decreased significantly at 12 months post-treatment ($p<0.001$). Significant reductions in opioid use have also been demonstrated following implantation of PNS leads for up to 60 days in both the amputee and the low back pain patient populations. An RCT conducted among those with post-amputation pain (Gilmore et al, 2020) demonstrated a 70% reduction in opioid use among those taking moderate to high doses and ≥50% reduction in opioid use at three months post treatment (average reduction 82%). In another study, substantial reductions in opioid use were also demonstrated in 73% of low back pain subjects taking opioids at baseline, even among patients with daily baseline opioid consumption ≥ 50 milligram morphine equivalents, rated by the CDC as high-risk for opioid overdose (Gilmore et al, 2019a).

**Clinical Rationale Supporting Coverage**

HCSC also states they will "assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms."

This drafted non-coverage policy of PNS appears to have missed the evidence validating PNS improves net health outcomes in chronic pain patients. Important outcomes in the successful treatment of chronic pain include but are not limited to pain relief, decreased pain interference, and improved function. The use of a PNS lead temporarily implanted for up to 60 days has been studied most extensively. The aggregate responder rate across 12 studies (3 RCTs, 6 prospective case series, and 3 case reports) in which patients reported ≥50% pain relief and/or ≥50% improvement in pain interference at end of treatment was 77% with a mean reduction in pain intensity of 81% and mean reduction in pain interference of 90% among responders (Gulati et al., 2020). Similar percentages of subjects had sustained relief of pain and/or improvements in pain interference at one year (76%). Responders at one year reported 82% average reductions in pain and 87% reductions in pain interference. As it relates to safety, no device-related serious adverse events were reported across any of the above trials.

HCSC further indicates that medical policies are "based on current peer-reviewed scientific literature…supported by FDA-approved labeling and nationally recognized authoritative references...and CMS coverage policy."[5] PNS meets all of the above items and therefore, in accordance with HCSC's own guidance, PNS should be a covered procedure when medically necessary.

It must be noted that the policy references society guidelines from 2010 is outdated given that no FDA-cleared PNS systems were commercially available in 2010. The American Society of Regional Anesthesia and Pain Management, Neuromodulation Special Interest Group has published guidance stating that "PNS is warranted when following circumstances exist: 1) SCS is unsuitable for any reason, such as the central neuro-axis is difficult to access or alterations and coagulation are unmitigable, or 2) a situation better suits peripheral nerve stimulation than SCS".[6]

HCSC recognizes chronic, non-cancer pain is responsible for a high burden of illness and also recognizes the efficacy of neurostimulation treatment modalities in the treatment of chronic pain as evidenced by the positive coverage policy for the implantation of a Spinal Cord Stimulator (SURG 7.12.009)[7]. This policy has deemed that neurostimulation, SCS in this case, is medically necessary when specific criterion are met, including when (1) other treatment modalities have been tried and failed, (2) pain is neuropathic in nature, (3) no significant untreated drug habituation or addiction, and (4) documentation of at least 50% pain relief is achieved during temporary stimulation.

HCSC also recognizes the efficacy of stimulation treatments in other disease spaces as evidenced by the following positive coverage policies when patients meet specific criterion requirements, many of which are akin to Spinal Cord Stimulation coverage policy and are in-line with our request for PNS coverage.

Percutaneous Tibial Nerve Stimulation (PTNS) MED205.035

Sacral Nerve Neuromodulation/Stimulation SUR710.018

Gastric Electrical Stimulation (GES) SUR709.031

Treatment with PNS is regularly made available to patients insured by other commercial plans, Medicare, and Medicare Advantage[8]; but HCSC insured patients are up against an inequality and disparity in accessing this non-opioid, minimally-invasive and well-researched treatment option for their chronic pain. Moreover, PNS is offered, and supported by the health ministries, to patients residing in other countries, such as Canada and the United Kingdom.

**Temporary and Permanently Implanted PNS Systems**

Peripheral nerve stimulation is a treatment that has been in use since the 1960's; however, the devices we have had access to previously were not designed for use in the periphery and often necessitated invasive neurosurgery. Fortunately, over the past several years, new devices have been approved by the FDA and the body of evidence supporting PNS is expanding significantly, including the publication of multiple randomized controlled trials, with several others in process.

The demonstrated safety and efficacy of devices intended for use in the periphery has been compelling to the National Institutes of Health and the US Department of Defense who have supported research and development in the form of highly competitive grants and contracts. PNS efficacy has been demonstrated by the publication of multiple peer-reviewed studies and its utility and place in the care pathway can be understood by the recognition PNS has received at multiple physician societies and congresses. It is estimated that approximately 5,000 – 10,000 patients have been treated since the FDA

approved dedicated PNS systems. The overwhelming majority of these systems have been prescribed and implanted by physicians trained in interventional pain medicine, most of whom are board-certified in physical medicine and rehabilitation or in anesthesiology and who have also completed an ACGME approved interventional pain management fellowship.

The consideration of a permanently implanted PNS system is typically preceded by use of a temporarily implanted lead placed under image-guidance, such as ultrasound. Such a temporary implanted "trial stage" lead is often in place for less than 7 days. Temporary leads may now be safely left in place for up to 60 days such that their extended use allows temporary PNS may result in a definitive treatment and consideration of a permanently implanted system may be obviated or significantly delayed, affording HCSC a cost-effective alternative to a permanent implant in some patients. Gilmore et al (2020) in a double-blinded randomized controlled trial (RCT) versus placebo using PNS in the very challenging population of patients with neuropathic pain following amputation, demonstrated a significant treatment effect compared to placebo and the ability to provide sustained and significant pain relief at 12 months in patients with a history of residual and/or phantom limb pain up to fifteen years following amputation. When the patient reports a 50% or greater decrease in pain following placement of temporary lead, implantation of a permanently implanted lead (or leads) and pulse generator is appropriate. Percutaneous lead implantation procedures are coded as CPT 64555, and pulse generator or receiver implantation procedures are coded using CPT 64590.

**Overview of PNS Clinical Outcomes**

In addition to what has been summarized above, Deer et al (2016), in another placebo-controlled RCT, demonstrated clinically significant pain relief in 38% of patients with pain of peripheral origin who were randomly assigned to receive PNS, compared to only 10% of those who were randomized to the placebo group. No serious adverse events were reported.

Wilson, et al (2014) demonstrated clinically and statistically significant reductions in shoulder pain dropping from pain categorized as severe (7.5/10) to mild (3.0/10) at 16 weeks versus an active control group receiving physical therapy who demonstrated no significant change in pain scores (7.6 to 6.1). Participants who received PNS in this trial had a 65.3% reduction in pain by the end of treatment that was maintained at a 60.0% reduction in pain at the end of the follow-up period 12 weeks after treatment.

Chae, et al (2005) reported similar results in another blinded multi-site, RCT in which there was a 66% reduction in shoulder pain by the end of treatment that continued to be clinically significant in 93% of subjects at 12 months.

Most recently, another PNS device has received FDA approval. The clinical data included in the submission have been reported by Gilligan et al (2020) regarding the results of an RCT comparing medial branch PNS versus placebo in patients with low back pain in which 78% of patients reported a substantial improvement in pain, as measured by visual analog scale, and improvement in physical and social function, as measured by the Oswestry Disability Index over baseline, or both of these measures.

Similarly, positive results in the treatment of low back pain using PNS have been demonstrated by Gilmore (2019b) and Deer (2020) using a temporarily implanted lead for up to 60 days.

A list of PNS-related peer-reviewed publications and presentations related to in-press or in-process manuscripts is located in Appendix A.

**Specific Request to continue patient access to PNS in the Management of Chronic Pain**

As has been demonstrated above, PNS is an invaluable treatment option for patients suffering from chronic pain. **PNS provides a safe and efficacious pain management solution that furthers our efforts in reducing opioid use and preventing both opioid abuse and opioid addiction.** In the absence of access to PNS, we will increasingly need to pursue more invasive and costly devices or surgery, or become more reliant on opioid medications for pain control.

A definition of chronic pain has recently been proposed by Dr. Peter Staats, President of the World Institute for Pain, and by other leaders across multiple physician specialties and professional societies focused on pain management to include anesthesiologists, neurosurgeons, and physical medicine and rehabilitation physicians. This definition, incorporated into the proposed language below, is quite germane to PNS in light of its utility in the midst of the opioid crisis in those patients who have failed two less invasive therapies.

**We suggest the following changes to this draft policy:**

**<u>Peripheral Nerve Stimulation (PNS) is considered medically necessary in the treatment of chronic pain when the patient continues to experience moderate to severe pain after failing two prior conservative treatments and when:</u>**

**Pain requires opioid use beyond 30 days, or;**

**Pain has not resolved within the normal time course of healing, as discerned by the physician or;**

**Pain continues or is expected to continue for longer than 3 months from its initial onset.**

Sincerely,

On behalf of the Board of Directors,

Amitabh Gulati, MD FIPP CIPS, ASRA-PMUC

President of the World Academy of Pain Medicine United

Board of Directors:

Einar Ottestad, MD FIPP CIPS  Mark Friedrich Hurdle, MD FIPP CIPS  David Spinner, MD FIPP CIPS

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[1] HCSC Draft Policy MED205.036 Peripheral Nerve Stimulation (PNS) and Peripheral Nerve Field Stimulation (PNFS)

[2] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain United States, 2016

[3] HCSC/BCBS TX Company Info Addressing What Matters

[4] Blue Cross Blue Shield Association Affirms Opioids Should Not be Prescribed as First or Second Line of Pain Therapy with Dr. Trent Haywood, Chief Medical Officer, March 2018

[5] HCSC Administrative Policy ADM1001.032 Experimental, Investigational and/or Unproven Procedures/Services

[6] American Society of Regional Anesthesia and Pain Management Neuromodulation Special Interest Group /PNS

[7] HCSC Policy SURG 7.12.009 Spinal Cord Stimulation (SCS)

[8] CMS National Coverage Determination (NCD) for Electrical Nerve Stimulators (160.7)

**Appendix A**

**PNS-related publications, presentations, and in-process manuscripts**

Chae, J., David, T.Y., Walker, M.E., Kirsteins, A., Elovic, E.P., Flanagan, S.R., & Fang, Z.P. Intramuscular electrical stimulation for hemiplegic shoulder pain: a 12 month follow-up of a multicenter randomized controlled trial. American Journal of Physical Medicine and Rehabilitation, 2005; 84(11):832-842.

Chmiela MA, Hendrickson M, Hale J, Ling C, Telefus P, Sagir A, Stanton-Hicks M. Direct Peripheral Nerve Stimulation for the Treatment of Complex Regional Pain Syndrome: A 30-Year Review. Neuromodulation, 2020, epub ahead of print.

Cohen S, Gilmore C, Kapural L, Hopkins T, Desai M, DePalma M, Li S, Burgher A, Deer T, Plunkett T, McGee M, Boggs J. Reductions in Opioid Consumption with Percutaneous Medial Branch Peripheral Nerve Stimulation for Chronic Low Back Painas presented at the Military Health Research Symposium August 21, 2019, Kissimmee, FL.

Cohen SP, Gilmore CA, Kapural L, Hanling S, Plunkett A, McGee MJ, Boggs JW. Percutaneous Peripheral Nerve Stimulation for Pain Reduction and Improvements in Functional Outcomes in Chronic Low Back Pain. Mil Med. 2019;184(Supplement_1):537-541.

Cohen SP, Gilmore CA, Rauck RL, Lester DD, Trainer RJ, Phan T, Kapural L, North JM, Crosby ND, Boggs JW. Percutaneous Peripheral Nerve Stimulation for the Treatment of Chronic Pain Following Amputation.Military Medicine, 2019; 10.1093/milmed/usz114.

Deer TR, Gilmore C, Desai, M, Li S. DePalma M, Hopkins T, Burgher A, McGee M, Boggs J. Percutaneous PNS of the Medial Branch Nerves for the Treatment of Chronic Axial Back Pain in Patients following Radiofrequency Ablation. Pain Medicine, 2020, in press. View Manuscript Poster Here.

Deer, TR, Pope J, Benyamin R, Vallejo R, Friedman A, Caraway D, Staats P, Grigsby E, McRoberts P, McJunkin T, Shubin R, Vahedifar P, Tavanaiepour D, Levy R, Kapural L, Mejhail N. Prospective, Multicenter, Randomized, Double-Blinded, Partial Crossover Study to Assess the Safety and Efficacy of the Novel Neuromodulation System in the Treatment of Patients with Chronic Pain of Peripheral Nerve Origin. Neuromodulation, 2016; 19(1):91-100.

Gilligan et al, Summary of Safety and Effectiveness of Medial Branch Stimulation for the Treatment of Low Back Pain https://www.accessdata.fda.gov/cdrh_docs/pdf19/P19...Accessed December 17, 2020.

Gilmore CA, Ilfeld BM, Rosenow JM, Li S, Desai MJ, Hunter CW, Rauck RL, Nader A, Mak J, Cohen SP, Crosby ND, Boggs JW. Percutaneous 60-day Peripheral Nerve Stimulation Implant Provides Sustained Relief of Chronic Pain Following Amputation: 12-month Follow-Up of a Randomized, Double-Blind, Placebo-Controlled Trial. Regional Anesthesia and Pain Medicine, 2020; 45:44-51. View Manuscript Poster Here.

Gilmore CA, Kapural L, McGee M, Boggs JW. Percutaneous Peripheral Nerve Stimulation for Chronic Low Back Pain: Prospective Case Series with One Year of Sustained Relief following Short-term Implant. Pain Pract. 2019b; 20(3):310-320.

Gilmore CA, Kapural L, McGee MJ, Boggs JW. Percutaneous Peripheral Nerve Stimulation (PNS) for the Treatment of Chronic Low Back Pain Provides Sustained Relief.Neuromodulation, 2018; 22(5):615-620.

Gilmore, C, Kapural, L, Hopkins T, Desai M, Li S, DePalma M, Deer TR, Burgher A, McGee M, Boggs J. Reductions in Opioid Consumption Reported among Chronic Low Back Pain Patients Following Percutaneous Peripheral Nerve Stimulation (PNS) of the Medial Branch Nerves for up to 60 Days. 2020, in press, and as presented at American Society of Regional Anesthesia and Pain Medicine November 2019a.

Gilmore, C.A., Kapural, L, McGee, M.J., Boggs, J.W. (2018).Minimally invasive percutaneous peripheral nerve stimulation (PNS) reduces pain and disability in chronic low back pain. As presented at 2018 World Congress on Regional Anesthesia and Pain Medicine (ASRA).

Gulati A, Desai MJ, Rosenow JM, Cohen SP, Crosby ND, Boggs JW. (2020). A Review of Clinical Evidence for Percutaneous Peripheral Nerve Stimulation Demonstrating Sustained Relief of Chronic Pain in a Majority of Subjects. As presented at 2020 American Society for Pain and Neuroscience (ASPN). View Manuscript Poster Here.

Ilfeld B.M., Ball S.T., Gabriel R.A., Sztain J.F., Monahan A.M., Abramson W.B., Khatibi B., Said E.T., Parekh J., Grant S.A., Wongsarnpigoon A., Boggs J.W. A Feasibility Study of Percutaneous Peripheral Nerve Stimulation for the Treatment of Postoperative Pain Following Total Knee Arthroplasty. Neuromodulation, 2018; 22(5):653-660

Ilfeld BM, Ball ST, Cohen SP, Hanling SR, Fowler IM, Wongsarnpigoon A, Boggs JW. Percutaneous Peripheral Nerve Stimulation to Control Postoperative Pain, Decrease Opioid Use, and Accelerate Functional Recovery Following Orthopedic Trauma. Mil Med, 2019; 184(Suppl 1):557-564.

Ilfeld, B. M., et al., Infection Rates of Electrical Leads Used for Percutaneous Neurostimulation of the Peripheral Nervous System.Pain Pract, 2017; 17(6):753-762.

Ilfeld, B.M. and S.A. Grant, Ultrasound-Guided Percutaneous Peripheral Nerve Stimulation for Postoperative Analgesia: Could Neurostimulation Replace Continuous Peripheral Nerve Blocks?Reg Anesth Pain Med, 2016; 41(6):720.

Ilfeld, B.M., Gilmore, C.A., Grant, S.A., Bolognesi, M. P., Del Gaizo, D.J., Wongsarnpigoon, A., & Boggs, J.W. Ultrasound-guided percutaneous peripheral nerve stimulation for analgesia following total knee arthroplasty: a prospective feasibility study.Journal of Orthopaedic Surgery and Research, 2017; 12(1):4.

Ilfeld, B.M., Grant, S.A., Gilmore, C.A., Chae, J., Wilson, R.D., Wongsarnpigoon, A., & Boggs, J.W. Neurostimulation for Postsurgical Analgesia: A Novel System Enabling Ultrasound-guided Percutaneous Peripheral Nerve Stimulation.Pain Practice, 2016; 17(7):892-901.

Ilfeld, B.M., J.J.t. Finneran, R.A. Gabriel, E.T. Said, P.L. Nguyen, W.B. Abramson, B. Khatibi, J.F. Sztain, M.W. Swisher, P. Jaeger, D.C. Covey, M.J. Meunier, E.R. Hentzen, and C.M. Robertson, Ultrasound-guided percutaneous peripheral nerve stimulation: neuromodulation of the suprascapular nerve and brachial plexus for postoperative analgesia following ambulatory rotator cuff repair. A proof-of-concept study.Reg Anesth Pain Med, 2019; 44(3):310-318.

Ilfeld, Brian M., et al., Ultrasound-Guided Percutaneous Peripheral Nerve Stimulation: Neuromodulation of the Sciatic Nerve for Postoperative Analgesia Following Ambulatory Foot Surgery, a Proof-of-Concept Study. Regional Anesthesia and Pain Medicine, 2018; 43(6):580–589.

Kapural L, Gilmore CA, Chae J, et al. Percutaneous Peripheral Nerve Stimulation for the Treatment of Chronic Low Back Pain: Two Clinical Case Reports of Sustained Pain Relief.Pain Pract, 2017; 18(1):94-103.

Ilfeld, B. M., et al., Ultrasound-guided percutaneous peripheral nerve stimulation for analgesia following total knee arthroplastyJournal of Orthopaedic Surgery and Research (2017)

Shellock, FG, Zare A, Ilfeld BM, Chae J, Strother, RB.Vitro Magnetic Resonance Imaging Evaluation of Fragmented, Open-Coil, Percutaneous Peripheral Nerve Stimulation Leads.Neuromodulation, 2018; 21(3):276-283.

Staats, P. Neuromodulation as an Alternative to Opioid in the Evolving Health Care Crisis– A Supplement to Pain Medicine News (2017)

Wilson, R.D., Gunzler, D.D., Bennett, M.E., & Chae, J. Peripheral nerve stimulation compared with usual care for pain relief of hemiplegic shoulder pain: a randomized controlled trial.American Journal of Physical Medicine & Rehabilitation/Association of Academic Physiatrists, 2014; 93(1):17.

Wilson, R.D., Harris, M. A., Gunzler, D.D., Bennett, M.E., & Chae, J. (2014). Percutaneous peripheral nerve stimulation for chronic pain in subacromial impingement syndrome: a case series.Neuromodulation, 2014; 17(8):771-776.