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Michelle Gabbert, DO
Senior Medical Director-Chief Health Office/Medical Affairs Department
Institute of Clinical Oversight and Guidance
Medical Coverage Policy, Prevention and Health Equity
CIGNA
900 Cottage Grove Rd
Bloomfield, CT 06002-2920
Michelle.gabbert@cigna.com

Dear Dr. Gabbert:

We are writing for the more than 88,000 members of our undersigned societies to support coverage of peripheral nerve stimulation (PNS) for treating chronic pain.

The current depiction of PNS as lacking medical necessity, as outlined in your Medical Coverage Policy from March 15, 2024, is incongruent with the extensive body of evidence supporting its efficacy in pain management. It is imperative to recognize that this characterization of PNS does not reflect the demonstrated effectiveness of this therapy for patients suffering from chronic pain.

Our members include pain medicine physicians, anesthesiologists, neurologists, neurosurgeons, orthopedic surgeons, physiatrists, psychologists, radiologists, urologists, engineers, scientists, and other health care professionals. We are all dedicated to improving the care patients receive when dealing with chronic neurologic disorders, including severe debilitating chronic pain.

Peripheral nerve stimulation has proven to be an effective treatment for many chronic pain conditions, including intractable knee, shoulder, and back pain where treatment options are limited. There is level I evidence across numerous clinical studies supporting the efficacy of PNS published in peer-reviewed literature, with demonstrated efficacy of this therapy in treating neuropathic cranial pain, post-amputation phantom limb and residual limb pain, chronic pelvic pain, lower extremity pain, peripheral neuropathic pain, and chronic post-surgical pain. Peripheral nerve stimulation consistently results in improvement in pain, reduced disability, lower opioid use, and improvement in quality of life for people affected by chronic pain.

By dismissing PNS as "not medically necessary," CIGNA denies patients access to a treatment modality that has been recommended in treatment guidelines created by physician societies. These guidelines are founded upon rigorous scientific evidence, affirming the efficacy of PNS and its capacity to alleviate suffering in individuals grappling with chronic pain. Considering the compelling evidence supporting the efficacy of PNS and

its alignment with reputable society-based treatment guidelines, there is an urgent need for CIGNA to reconsider its characterization of PNS and revise Policy Number 0539.

The current CIGNA guidance is in direct opposition to the society-based treatment guidelines which state that the following indications for peripheral nerve stimulation are supported as Extremely Recommendable (good evidence that the measure is effective and that benefits outweigh the harms) or Recommendable (at least moderate evidence that the measure is effective and that benefits exceed harms):

- Occipital neuralgia and migraine headache
- Chronic hemiplegic shoulder pain.
- Lower extremity neuropathic pain.
- Upper extremity neuropathic pain.
- Lower extremity post-amputation pain, including phantom limb and residual limb pain
- Axial low back pain via stimulation of medial branch nerves

We have included a list of studies and systematic reviews at the end of this letter that support the safety and efficacy of PNS in treating chronic pain conditions.

We stand ready to provide any additional information or support to facilitate reconsideration of CIGNA's denial of access to critically important therapies for patients with intractable chronic pain. Ensuring access to effective pain management treatments is essential for improving the quality of life for individuals suffering from chronic pain. Thank you for your attention to this matter. We look forward to your prompt response and collaboration on this important issue.

Respectfully submitted,
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American Society of Anesthesiologists
American Society of Neuroradiology
Congress of Neurological Surgeons
North American Neuromodulation Society
North American Spine Society
Society for Interventional Radiology

Notable PNS Studies and Papers

1. Li AH, Bhatia A, Gulati A, et al. Role of peripheral nerve stimulation in treating chronic neuropathic pain: an international focused survey of pain medicine experts. *Regional Anesthesia & Pain Medicine* 2023;48:312-318. <https://rapm.bmj.com/content/48/6/312>
2. Helm S, Shirsat N, Calodney A, Abd-Elsayed A, Kloth D, Soin A, Shah S, Trescot A. Peripheral Nerve Stimulation for Chronic Pain: A Systematic Review of Effectiveness and Safety. *Pain Ther.* 2021 Dec;10(2):985-1002. doi: 10.1007/s40122-021-00306-4. Epub 2021 Sep 3. PMID: 34478120; PMCID: PMC8586061
3. Trent AR, Chopra P, Jain A. Peripheral Nerve Stimulator. [Updated 2023 Mar 13]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. <https://www.ncbi.nlm.nih.gov/books/NBK539703/>
4. Deer TR, Esposito MF, McRoberts WP, Grider JS, Sayed D, Verrills P, Lamer TJ, Hunter CW, Slavin KV, Shah JM, Hagedorn JM, Simopoulos T, Gonzalez DA, Amirdelfan K, Jain S, Yang A, Aiyer R, Antony A, Azeem N, Levy RM, Mekhail N. A Systematic Literature Review of Peripheral Nerve Stimulation Therapies for the Treatment of Pain. *Pain Med.* 2020 Aug 1;21(8):1590-1603. doi: 10.1093/pm/pnaa030. PMID: 32803220.
5. Strand N, D'Souza RS, Hagedorn JM, Pritzlaff S, Sayed D, Azeem N, Abd-Elsayed A, Escobar A, Huntoon MA, Lam CM, Deer TR. Evidence-Based Clinical Guidelines from the American Society of Pain and Neuroscience for the Use of Implantable Peripheral Nerve Stimulation in the Treatment of Chronic Pain. *J Pain Res.* 2022 Aug 23;15:2483-2504. doi: 10.2147/JPR.S362204. PMID: 36039168; PMCID: PMC9419727. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9419727/>
6. Jonathan M. Hagedorn, Thomas P. Pittelkow, Markus A. Bendel, Susan M. Moeschler, Vwaire Orhurhu, Joaquin Sanchez-Sotelo, The painful shoulder arthroplasty: appropriate work-up and review of interventional pain treatments, *JSES Reviews, Reports, and Techniques*, Volume 2, Issue 3, 2022, Pages 269-276, ISSN 2666-6391, <https://doi.org/10.1016/j.xrtr.2022.04.008>
7. Kurt E, van Eijk T, Henssen D, Arnts I, Steegers M. Neuromodulation of the suprascapular nerve. *Pain Physician* 2016; 19:E235-E239. https://www.researchgate.net/profile/Erkan-Kurt/publication/290156978_Neuromodulation_of_the_Suprascapular_Nerve/links/5b4f93a045851507a7ad5e0a/Neuromodulation-of-the-Suprascapular-Nerve.pdf

8. Pope JE, Carlson JD, Rosenberg WS, Slavin KV, Deer TR. Peripheral nerve stimulation for pain in extremities: an update. *Prog Neurol Surg* 2015;29:139-57. <https://doi.org/10.1159/000434667>
9. Mazzola, A., & Spinner, D. (2020). Ultrasound-guided peripheral nerve stimulation for shoulder pain: anatomic review and assessment of the current clinical evidence. *Pain Physician*, 23(5), E461. <https://www.painphysicianjournal.com/current/pdf?article=NzEzNg%3D%3D&journal=130>
10. Mansfield JT, Desai MJ. Axillary peripheral nerve stimulation for chronic shoulder pain: a retrospective case series. *Neuromodulation* 2020;23:812-8. <https://doi.org/10.1111/ner.13096>
11. Elahi F, Reddy CG. Neuromodulation of the suprascapular nerve. *Pain Physician* 2014; 17:E769-E773. <https://www.painphysicianjournal.com/current/pdf?article=MjE5OA%3D%3D&journal=85>
12. Dey S. Comparing neuromodulation modalities involving the suprascapular nerve in chronic refractory shoulder pain: retrospective case series and literature review. *Clin Shoulder Elb.* 2021 Mar;24(1):36-41. doi: 10.5397/cise.2021.00038. Epub 2021 Mar 2. PMID: 33652511; PMCID: PMC7943385.
13. Chitneni A, Berger AA, Orhurhu V, Kaye AD, Hasoon J. Peripheral Nerve Stimulation of the Saphenous and Superior Lateral Genicular Nerves for Chronic Pain After Knee Surgery. *Orthop Rev (Pavia).* 2021 May 31;13(2):24435. doi: 10.52965/001c.24435. PMID: 34745463; PMCID: PMC8567809. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8567809/>
14. Hasoon J, Chitneni A, Urits I, Viswanath O, Kaye AD. Peripheral Stimulation of the Saphenous and Superior Lateral Genicular Nerves for Chronic Knee Pain. *Cureus.* 2021 Apr 29;13(4):e14753. doi: 10.7759/cureus.14753. PMID: 34084679; PMCID: PMC8163353. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8163353/>
15. Chih-Peng Lin, MD, PhD, Ke-Vin Chang, MD, PhD, Wei-Ting Wu, MD, Levent Özçakar, MD, Ultrasound-Guided Peripheral Nerve Stimulation for Knee Pain: A Mini-Review of the Neuroanatomy and the Evidence from Clinical Studies, *Pain Medicine*, Volume 21, Issue Supplement_1, August 2020, Pages S56–S63, <https://doi.org/10.1093/pm/pnz318>
16. Zhu, Cheng-Cheng, Akshat Gargya, and Naeem Haider. "A Case Report of Three Patients Who Underwent Temporary Peripheral Nerve Stimulation for Treatment of Knee Pain Secondary to Osteoarthritis." *Cureus* 15.6 (2023).

17. Vangeison CT, Bintrim DJ, Helms J, Saha AK, Samant AN, and Chung M. (2023) The role of peripheral nerve stimulation in refractory non-operative chronic knee osteoarthritis. *Pain Management* 2023 13:4, 213-218.
18. Busch, Clayton, et al. "Peripheral Nerve Stimulation for Lower Extremity Pain." *Biomedicines* 10.7 (2022): 1666. <https://www.mdpi.com/1720372>
19. Fritz AV, Ferreira-Dos-Santos G, Hurdle MF, Clendenen S. Ultrasound-guided Percutaneous Peripheral Nerve Stimulation for the Treatment of Complex Regional Pain Syndrome Type 1 Following a Crush Injury to the Fifth Digit: A Rare Case Report. *Cureus*. 2019 Dec 29;11(12):e6506. doi: 10.7759/cureus.6506. PMID: 32025427; PMCID: PMC6988727. <https://pubmed.ncbi.nlm.nih.gov/32025427/>
20. Yaccarino V, Jin MY, Abd-Elsayed A, Kraemer JM, Sehgal N. Peripheral Nerve Stimulation in Painful Conditions of the Upper Extremity-An Overview. *Biomedicines*. 2022 Nov 1;10(11):2776. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9687108/>
21. Dabby R, Sadeh M, Goldberg I, Finkelshtein V. Electrical stimulation of the posterior tibial nerve reduces neuropathic pain in patients with polyneuropathy. *J Pain Res*. 2017 Nov 29;10:2717-2723. doi: 10.2147/JPR.S137420. PMID: 29238215; PMCID: PMC5716322. <https://pubmed.ncbi.nlm.nih.gov/29238215/>
22. Deer T, Pope J, Benyamin R, et al. 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; 19:91-100. *Pain Physician*: September/October 2020 23:E461-E474 E474 www.painphysicianjournal.com
23. Hanyu-Deutmeyer, Aaron, and Scott G. Pritzlaff. "Peripheral nerve stimulation for the 21st century: sural, superficial peroneal, and tibial nerves." *Pain Medicine* 21.Supplement_1 (2020): S64-S67. https://academic.oup.com/painmedicine/article/21/Supplement_1/S64/5893272
24. Colini Baldeschi, Gianni, et al. "Peripheral nerve stimulation in the treatment of chronic pain syndromes from nerve injury: a multicenter observational study." *Neuromodulation: Technology at the Neural Interface* 20.4 (2017): 369-374. https://www.neurimpulse.com/pubblicazioni/pubbl_8.pdf
25. Mobbs, R. J., S. Nair, and P. Blum. "Peripheral nerve stimulation for the treatment of chronic pain." *Journal of clinical neuroscience* 14.3 (2007): 216-221.

26. Oswald J, Shahi V, Chakravarthy KV. Prospective case series on the use of peripheral nerve stimulation for focal mononeuropathy treatment. *Pain Management* 2019; 9:551-558. <https://pubmed.ncbi.nlm.nih.gov/31686589/>
27. Steven Mach, Saba Javed, Grant H. Chen, Billy K. Huh, Peripheral Nerve Stimulation for Back Pain in Patients With Multiple Myeloma as Bridge Therapy to Radiation Treatment: A Case Series, *Neuromodulation: Technology at the Neural Interface*, Volume 26, Issue 3, 2023, Pages 694-699, ISSN 1094-7159, <https://www.sciencedirect.com/science/article/abs/pii/S1094715923000272>
28. Mainkar, Ojas, et al. "Pilot study in temporary peripheral nerve stimulation in oncologic pain." *Neuromodulation: Technology at the Neural Interface* 23.6 (2020): 819-826.
29. PNS of the Occipital Nerve for the Treatment of Occipital Neuralgia: Slavin, Konstantin V., Hrachya Nersesyan, and Christian Wess. "Peripheral neurostimulation for treatment of intractable occipital neuralgia." *Neurosurgery* 58.1 (2006): 112-119.
30. Urits I, Schwartz RH, Patel P, Zeien J, Connor D, Hasoon J, Berger AA, Kassem H, Manchikanti L, Kaye AD, Viswanath O. A Review of the Recent Findings in Minimally Invasive Treatment Options for the Management of Occipital Neuralgia. *Neurol Ther.* 2020 Dec;9(2):229-241. doi: 10.1007/s40120-020-00197-1. Epub 2020 Jun 2. PMID: 32488840; PMCID: PMC7606364.
31. Al-Jehani H, Jacques L. Peripheral nerve stimulation for chronic neurogenic pain. *Prog Neurol Surg.* 2011;24:27-40. doi: 10.1159/000323017. Epub 2011 Mar 21. PMID: 21422774.
32. Weiner R, Reed KL. Peripheral neurostimulation for control of intractable occipital neuralgia. *Neuromodulation* 1999; 2:217221. <https://www.sciencedirect.com/science/article/abs/pii/S1094715921003822>
33. Gilligan C, Volschenk W, Russo M, Green M, Gilmore C, Mehta V, Deckers K, De Smedt K, Latif U, Georgius P, Gentile J, Mitchell B, Langhorst M, Huygen F, Baranidharan G, Patel V, Mironer E, Ross E, Carayannopoulos A, Hayek S, Gulve A, Van Buyten JP, Tohmeh A, Fischgrund J, Lad S, Ahadian F, Deer T, Klemme W, Rauck R, Rathmell J, Maislin G, Heemels JP, Eldabe S; ReActiv8-B Investigators. Long-Term Outcomes of Restorative Neurostimulation in Patients With Refractory Chronic Low Back Pain Secondary to Multifidus Dysfunction: Two-Year Results of the ReActiv8-B Pivotal Trial. *Neuromodulation.* 2023 Jan;26(1):87-97. doi: 10.1016/j.neurom.2021.10.011. Epub 2021 Dec 18. PMID: 35088722. [https://www.neuromodulationjournal.org/article/S1094-7159\(21\)06386-8/fulltext](https://www.neuromodulationjournal.org/article/S1094-7159(21)06386-8/fulltext)

34. Kaye, A.D., Ridgell, S., Alpaugh, E.S. et al. Peripheral Nerve Stimulation: A Review of Techniques and Clinical Efficacy. *Pain Ther* 10, 961–972 (2021).
<https://doi.org/10.1007/s40122-021-00298-1>
<https://link.springer.com/article/10.1007/s40122-021-00298-1>
35. Deer TR, Eldabe S, Falowski SM, Huntoon MA, Staats PS, Cassar IR, Crosby ND, Boggs JW. Peripherally Induced Reconditioning of the Central Nervous System: A Proposed Mechanistic Theory for Sustained Relief of Chronic Pain with Percutaneous Peripheral Nerve Stimulation. *J Pain Res.* 2021 Mar 12;14:721-736.
36. Pritzlaff SG, Latif U, Rosenow JM, Chae J, Wilson RD, Huffman WJ, Crosby ND, Boggs JW, A Review of Prospective Studies Regarding Percutaneous PNS Treatment in the Management of Chronic Pain, *Pain Management*, May 2024
37. Hatheway, John, et al. "Clinical study of a micro-implantable pulse generator for the treatment of peripheral neuropathic pain: 3-month and 6-month results from the COMFORT-randomised controlled trial." *Regional Anesthesia & Pain Medicine* (2024).
38. Goree JH, Grant SA, Dickerson DM, Ilfeld BM, Eshraghi Y, Vaid S, Valimahomed AK, Shah JR, Smith GL, Finneran JJ, Shah NN, Guirguis MN, Eckmann MS, Antony AB, Ohlendorf BJ, Gupta M, Gilbert JE, Wongsarnpigoon A, Boggs JW, Randomized Placebo-Controlled Trial of 60-Day Percutaneous Peripheral Nerve Stimulation Treatment Indicates Relief of Persistent Postoperative Pain, and Improved Function After Knee Replacement, *Neuromodulation: Technology at the Neural Interface*, May 2024.
39. Gutierrez GJ, Zurn CA, Crosby ND, Sustained Relief of Complex Regional Pain Syndrome (CRPS) Pain Following a 60-Day Peripheral Nerve Stimulation: A Report of Three Cases, *Cureus*, February 2024.
40. Huntoon MA, Slavin KV, Hagedorn JM, Crosby ND, Boggs JW, A Retrospective Review of Real-world Outcomes Following 60-day Peripheral Nerve Stimulation for the Treatment of Chronic Pain, *Pain Physician*, May 2023.
41. Gilmore CA, Deer TR, Desai MJ, Hopkins TJ, Li S, DePalma MJ, Cohen SP, McGee MJ, Boggs JW, Durable patient-reported outcomes following 60-day percutaneous peripheral nerve stimulation (PNS) of the medial branch nerves, *Interventional Pain Medicine*, March 2023.
42. Pingree MJ, Hurdle MGB, Spinner DA, Valimahomed A, Crosby ND, Boggs JW. Real-world evidence of sustained improvement following 60-day peripheral nerve stimulation treatment for pain: a cross-sectional follow-up survey, *Pain Management*, May 2022.

43. Naidu R, Li S, Desai MJ, Sheth S, Crosby ND, Boggs JW, 60-Day PNS Treatment May Improve Identification of Delayed Responders and Delayed Non-Responders to Neurostimulation for Pain Relief, *Journal of Pain Research*, March 2022.
44. 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.