Bruce Broussard, Chief Executive Officer
George Renaudin, President Medicare & Medicaid
Kate Goodrich, MD, MHS Senior Vice President, Chief Medical Officer
Manisah Dhuria, MD, MBA, Associate Vice President, Physician Leadership
Humana
500 W. Main St.
Louisville, KY 40202

Dear Mr. Broussard, Mr. Renaudin, and Drs. Goodrich and Dhuria:

We are writing for the more than 98,000 members our undersigned societies to express our grave concerns regarding Humana's new Medicare Advantage policy, HUM-1140-000 [PDF], effective January 1, 2024, which excludes from coverage peripheral nerve stimulators (PNS) for treating chronic pain. This policy contradicts Medicare's longstanding practice of covering and paying for the reasonable and necessary use of PNS for chronic pain management. We ask Humana to revise this ill-advised policy.

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

Humana's policy on PNS appears inconsistent with the Noridian Local Coverage Decision and the CMS National Coverage Decision (NCD 160.7). We believe it is crucial to address this issue promptly to ensure equitable access to essential medical treatments for individuals suffering from chronic, intractable pain.

As you may know, Medicare Fee-For-Service (FFS) covers PNS services, as outlined in the CMS National Coverage Determination Manual section 160.7. This section explicitly states that payment may be made under the prosthetic device benefit for implanted peripheral nerve stimulators to treat chronic, intractable pain. Furthermore, Section 1852 of the Social Security Act mandates that Medicare Advantage plans, including Humana, cover all benefits available under Medicare Parts A and B. This requirement is reinforced by the Medicare Managed Care Manual, which emphasizes the need for Medicare Advantage enrollees to have access to all medically necessary Part A and Part B services.

According to the 2024 Medicare Advantage and Part D Final Rule (CMS-4201-F), Medicare Advantage plans must comply with National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), which are the clinical criteria guidelines ensuring that enrollees receive access to the same medically necessary care as those in Traditional Medicare.^{1,2}

When specific Medicare coverage criteria are not fully established, MA organizations are permitted to develop their own internal coverage criteria, provided they are based on current evidence and made publicly available to CMS, enrollees, and providers. There is an established CMS National Coverage Decision (NCD 160.7) which covers this therapy.

Humana's policy explicitly prohibits payment for electrical stimulators and stimulation for pain treatment using peripheral nerve stimulators covered by Medicare, including percutaneously implanted PNS and peripherally implanted nerve stimulation. Medicare conducts a comprehensive, evidence-based review process before issuing a national coverage decision. Between 2018 and 2022, Medicare covered and paid for over 46,000 PNS services, underscoring the widespread recognition of its efficacy in managing chronic pain. It is concerning that Humana's coverage policy would deny access to these vital services for its beneficiaries.

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. Hundreds of clinical studies supporting the efficacy of PNS have been published in peer-reviewed literature, with demonstrated efficacy of this therapy in treating neuropathic cranial pain, postamputation/stump pain, chronic pelvic pain, lower extremity pain, peripheral neuropathic pain, and 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.

We have included a list of studies and systematic reviews that support the safety and efficacy of PNS for treating chronic pain conditions. They are attached to this letter for your review.

¹ https://www.cms.gov/newsroom/press-releases/cms-finalizes-rule-expand-access-health-information-and-improve-prior-authorization-process

² https://www.cms.gov/newsroom/fact-sheets/2024-medicare-advantage-and-part-d-final-rule-cms-4201-f

Given the demonstrated effectiveness of PNS in pain management, it is imperative that Humana revise its policy to align with Medicare's coverage and ensure equitable access to this essential treatment for its beneficiaries.

We stand ready to provide any additional information or support to facilitate this process. Ensuring access to effective pain management treatments is essential for improving the quality of life for individuals suffering from chronic pain, and we believe that equal coverage of PNS by Humana is a crucial step in achieving this goal. We are requesting Humana to reconsider Medicare Advantage policy, HUM-1140-000.

Thank you for your attention to this matter. We look forward to your prompt response and collaboration on this important issue.

Sincerely,

North American Spine Society

Society for Interventional Radiology

American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American Society of Anesthesiologists
American Society of Neuroradiology
American Society of Regional Anesthesia and Pain Medicine
American Society of Spine Radiology
Congress of Neurological Surgeons
International Pain and Spine Intervention Society
North American Neuromodulation Society

cc: Jeremy Willard, Deputy Director, CMS
Heather Barkes Director, Division of Policy, Analysis, and Planning Department of
Health and Human Services, CMS
Christopher McClintick, Health Insurance Specialist, Division of Policy, Analysis and
Planning, CMS
TJ Sutphin, New Technology Liaison, CMS

Notable PNS Studies and Papers

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- 4. 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
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- 10. 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.
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- <u>Blind, Placebo-Controlled Trial.</u> Regional Anesthesia and Pain Medicine, 2020; 45:44-51
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