

April 28, 2026

Margaret-Mary Wilson, MD, MBA, MRCP, FNCMP
Chief Medical Officer and Executive Vice President, UnitedHealth Group

Anne Docimo, MD, MBA
Chief Medical Officer

Dear Drs. Wilson and Docimo,

On behalf of the North American Neuromodulation Society (NANS), we appreciate the opportunity to provide clinical and scientific input regarding United Healthcare's medical policy on Implantable Vagus Nerve Stimulation (iVNS) Paired Rehabilitation for Chronic Upper-Limb Impairment After Ischemic Stroke which currently classifies this therapy as not medically necessary. We believe this determination is inappropriate and denies access to this valuable therapy for many individuals who could benefit.

NANS is a multidisciplinary professional society representing clinicians and scientists specializing in neuromodulation therapies for the treatment of neurological disease and disorders. Our membership includes leaders in clinical research, guideline development, and real-world implementation of neuromodulation technologies. Based on the totality of available evidence, it is the position of NANS that iVNS Paired Rehabilitation meets accepted standards for medical necessity and should not be considered investigational. Including iVNS Paired Rehabilitation as an accepted therapy will give patients and providers the only FDA-approved option to consider when restoring neurological function after an ischemic stroke. In the absence of access to this surgical therapy, patients will have no alternative options available to restore function.

The classification of this therapy as "unproven and not medically necessary" is inconsistent with over twenty years of neuromodulation research, including multiple randomized controlled trials in post-stroke recovery and the most current, high-quality peer-reviewed evidence which represents the highest level of evidence for any intervention. The policy appears to conflate findings from iVNS studies with those from unrelated transcutaneous stimulation research, while also relying on outdated sources that fail to incorporate Class I evidence, long-term outcomes, or rigorous peer-reviewed analyses. Specifically, United Healthcare Medical Policy: Vagus and External Trigeminal Nerve Stimulation (Policy Number: 2026T0101NN), effective January 1, 2026 states that under this policy, implantable vagus nerve stimulation is classified as unproven and not medically necessary for upper limb impairment related to stroke, citing insufficient evidence of efficacy. Upper limb impairment post-stroke is explicitly listed among the non-covered indications.

Level 1 evidence from the multicenter, randomized, triple-blinded, sham-controlled VNS-REHAB trial demonstrates that iVNS paired with intensive rehabilitation produces clinically meaningful improvements in upper extremity motor impairment compared with rehabilitation alone in patients with chronic ischemic stroke, with responder rates approximately twice those observed in control participants. Patients receiving active iVNS demonstrated significantly greater improvement in motor function, as measured by the Fugl–Meyer Assessment–Upper Extremity (FMA-UE), compared with the control group. Clinically meaningful FMA-UE improvement occurred in 47% VNS vs 24% control group ($p=0.0098$). Improvements were also reflected in functional measures, including the Wolf Motor Function Test (WMFT) which improved by 57% VNS vs 22% control ($p<0.0001$) supporting translation of impairment-level gains into meaningful task performance. This improves quality of life in this otherwise debilitated patient population by allowing them to resume activities of daily living with reduced or no assistance, which increases independence, reduces cost and caregiver burden. Treatment effects are consistent across age, sex, time since stroke, and lesion characteristics. This level 1 evidence led to FDA approval in 2021. Prospective follow-up extending to two and three years after implantation has shown sustained gains in FMA-UE and functional outcome measures, with responder rates increasing over time and no evidence of regression toward baseline. Similar to VNS in epilepsy, this has cost-effectiveness benefit as it can prevent long-term reduction in hospitalizations, rehabilitation needs, and improvements in quality of life.

Surgical implantation of vagus nerve stimulators in stroke survivors has been shown to be safe and well-tolerated, with low rates of serious adverse events and perioperative complication profiles comparable to those reported in epilepsy and depression populations, even among patients receiving antiplatelet or anticoagulant therapy. Therefore, any and all safety concerns should be removed from the policy.

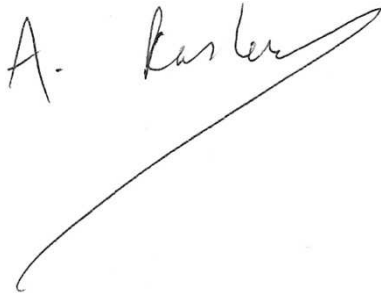
In summary, we strongly urge UHC to reconsider its position and to revise this policy to be in alignment with current evidence and expert clinical consensus. Patients should not be denied access to an FDA-approved, well-studied, cost-effective, and life-changing therapy based on restrictive criteria and outdated references. We welcome the opportunity to collaborate on creating a more patient-centered and evidence-driven policy that reflects the current state of stroke rehabilitation.

We urge UHC to:

- Cover the service as medically necessary in a discreet patient population in accordance with FDA approval, which states “The Vivistim® Paired VNS System is intended to be used to stimulate the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment.” Details to be included below:

- Chronic upper limb impairment due to ischemic stroke with persistent impairment of ADLs and IADLs
- 6 months since ischemic stroke
- History of rehabilitation therapy following stroke (inpatient and/or outpatient)
- Fugl-Meyer Upper Extremity (FMA-UE) between 20 and 50
- Absence of severe spasticity
- Absence of complete sensory loss in affected limb
- No history of prior vagotomy
- Ability to complete intensive rehabilitation program of 3 sessions per week for 6 weeks (90-120 minutes each)
- Remove concerns related to safety.
- Expand the evidence review to include peer reviewed studies published from 2023 to 2025 that clarify methodology, patient selection, and long-term outcomes.
- Revise Policy #2025T0101LL to distinguish implantable paired VNS from transcutaneous VNS.

Respectfully submitted,



Ahmed Raslan, MD, FAANS
President, North American Neuromodulation Society

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