Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
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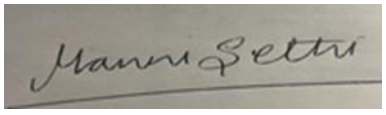
Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 7/1/2026
Policy Number: CCP.1515	Effective Date: 7/1/2022 Revision Date: 6/1/2026
Policy Name: Vagus nerve stimulation for post-stroke upper limb rehabilitation	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Vagus nerve stimulation for post-stroke upper limb rehabilitation

Clinical Policy ID: CCP.1515

Recent review date: 6/2026

Next review date: 7/2027

Policy contains: Rehabilitation; stroke; upper limb; vagus nerve stimulation; Vivistim.

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First- CHIP, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First- CHIP's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

Vagus nerve stimulation as an adjunct to rehabilitation in members with upper limb impairment after stroke is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Guideline-directed stroke rehabilitation services.

Background

Stroke is a leading cause of serious long-term disability. In the United States, stroke occurs in an estimated 800,000 people annually, and approximately two-thirds survive and require rehabilitation. Upper limb impairment is a common consequence, resulting in paresis, abnormal muscle tone, sensory disturbances, and reduced coordination (Tsao, 2022). Up to 22% of patients experience shoulder pain associated with shoulder subluxation and motor weakness in the first year following stroke (Winstein, 2016).

Customized rehabilitation applies focused, repetitive practice to maximize residual function, level of independence, and quality of life. Recovery targets the surviving brain tissue with the goal of promoting neural

repair (National Institute of Neurological Disorders and Stroke, 2023). Treatments in stroke recovery are considered nonvascular, both pharmacological and nonpharmacological, and are initiated in the subacute to chronic phases (days to years) after stroke (Lin, 2018).

Conventional interventions used in stroke recovery include physical, occupational, and speech therapy. Electrical neurostimulation has been proposed as adjunctive treatment to enhance recovery. Novel invasive approaches, such as transcranial magnetic stimulation and deep brain stimulation, target post-stroke deficits such as motor, language, memory, and neglect (Lin, 2018). Transcutaneous electrical nerve stimulation and neuromuscular electrical stimulation have been studied for treating hemiplegic shoulder pain, albeit with limited success (Winstein, 2016).

Vagus nerve stimulation is a neuromodulatory adjunct intended to pair electrical activation of vagal afferent pathways with repetitive, task-specific rehabilitation. In implanted systems, a pulse generator is placed in the pectoral region and connected to a lead placed around the left cervical vagus nerve. Transcutaneous approaches stimulate superficial vagal afferents through external electrodes, most commonly at the auricular branch, and avoid implantation but vary substantially by stimulation target, intensity, frequency, and treatment schedule (Everard, 2026; Wan, 2026).

The mechanism is incompletely understood. Proposed effects include activation of neuromodulatory pathways, cortical excitability changes, and motor cortex plasticity during task practice. The intervention is not intended to replace physical or occupational therapy; rather, clinical trials have evaluated whether stimulation paired with structured upper extremity rehabilitation augments motor learning and functional recovery (Everard, 2026; Yu, 2026).

The U.S. Food and Drug Administration has granted premarket approval for the MicroTransponder® Vivistim® Paired VNS System for stimulation of the vagus nerve during rehabilitation therapy to reduce upper extremity motor deficits and improve motor function in patients with chronic ischemic stroke and moderate to severe arm impairment (U.S. Food and Drug Administration, 2021).

This implanted device evidence should be distinguished from the transcutaneous VNS evidence base, which remains heterogeneous and does not establish equivalence to implanted paired VNS for post-stroke upper extremity rehabilitation. No transcutaneous vagus nerve stimulators have been approved for this indication (Wan, 2026; U.S. Food and Drug Administration, 2026).

Findings

Clinical guidelines

Clinical guidelines offer limited but evolving support for vagus nerve stimulation as an adjunctive therapy in stroke rehabilitation, particularly for improving upper extremity function. The guideline from the American Heart Association and American Stroke Association notes that evidence for most stroke rehabilitation interventions, including those targeting upper extremity improvements, remains mixed or incomplete, without directly addressing vagus nerve stimulation (Winstein, 2016).

A 2024 guideline from the Department of Veterans Affairs and Department of Defense provides the clearest stance on vagus nerve stimulation. It concludes that pairing vagus nerve stimulation with task-specific rehabilitation may enhance motor recovery by modulating neural networks and increasing neuroplasticity. However, the clinical evidence is limited in quality and scope, with studies often having small sample sizes, potential publication bias, and a focus on short-term rather than long-term outcomes. Interventions involving surgically implanted vagus nerve stimulators carry risks, including postoperative complications, the need for recurrent surgeries to replace batteries, and contraindications common in stroke patients, such as cardiac

arrhythmias and sleep apnea. High initial costs and varying patient willingness to undergo invasive procedures further restrict clinical use.

The newer evidence syntheses do not materially change this guideline-level uncertainty. The 2026 Cochrane review found very low-certainty evidence for short-term upper extremity motor function, upper extremity activity, and quality of life, and low-certainty evidence for serious adverse events. These findings support continued caution in routine coverage determinations despite a directionally favorable short-term motor signal (Everard, 2026).

Systematic reviews and meta-analyses

Recent systematic reviews and meta-analyses expand the evidence base but do not resolve the main policy uncertainty. The highest-value synthesis for coverage determination is the 2026 Cochrane review, which included 10 randomized trials with 547 participants evaluating invasive or transcutaneous VNS paired with rehabilitation. Compared with rehabilitation alone, VNS paired with rehabilitation showed a statistically favorable short-term effect on upper extremity motor function, but the certainty of evidence was very low because of risk of bias, heterogeneity, and imprecision. Evidence for upper extremity activity and quality of life was also very low certainty, and evidence for serious adverse events was low certainty (Everard, 2026).

The non-Cochrane meta-analyses were directionally favorable but less decisive for coverage. Yu (2026) included 16 randomized trials with 819 participants and reported improvements in Fugl-Meyer Assessment Upper Extremity scores, Wolf Motor Function Test scores, activities of daily living, and depressive symptoms, while emphasizing unresolved questions about patient selection, device configuration, stimulation parameters, treatment scheduling, and durability. Zhou (2025) included 18 randomized trials with 954 participants and reported favorable pooled effects across upper extremity motor function, hand function, swallowing, strength, functional independence, and Modified Barthel Index scores; however, individual trials remained small, outcomes were heterogeneous, and certainty varied by outcome. Wan (2026) focused on transcutaneous auricular VNS and reported favorable pooled effects across motor function, mental health, activities of daily living, and neurophysiologic measures, but this evidence does not establish equivalence to implanted paired VNS and remains outside an FDA-approved post-stroke upper extremity rehabilitation indication (Yu, 2026; Zhou, 2025; Wan, 2026).

Taken together, the newer reviews support biologic plausibility and a consistent short-term impairment-based motor signal. They do not establish durable, patient-centered improvement sufficient to change the investigational conclusion, because the most rigorous synthesis judged the certainty of benefit very low and because evidence remains heterogeneous across stimulation modality, stroke phase, treatment dose, rehabilitation protocol, and outcome measurement (Everard, 2026).

Primary Clinical Evidence

The primary evidence supporting the clinical efficacy of implanted vagus nerve stimulation comes from a pivotal randomized controlled trial with 108 participants (n = 108) (Dawson, 2021), supported by two earlier pilot studies (Dawson, 2016, 2020; Kimberley, 2018). These studies consistently show statistically significant but modest improvements in motor function when vagus nerve stimulation is combined with conventional rehabilitation compared to rehabilitation alone. Dawson (2021) reported a clinically meaningful response rate of 47% in the stimulation group compared to 25% in controls, with significant improvements in Fugl-Meyer Assessment-Upper Extremity and Wolf Motor Function Test scores at 90 days. However, Kwakkel (2021) cautions that improvements of 2.5 to 3 points on the Fugl-Meyer scale, while statistically significant, may not represent substantial clinical benefits.

Subgroup analyses confirm consistent outcomes across diverse patient demographics, including gender, age, stroke chronicity, baseline severity, paretic side, and country of treatment (Dawson, 2023). The device

implantation and stimulation settings (0.8 mA, 30 Hz, 100 ms pulse width) were standardized, with therapy regimens involving six weeks of intensive in-clinic rehabilitation followed by prescribed home therapy. Extended follow-ups indicate sustained motor function improvements and quality-of-life enhancements (Dawson, 2020, 2021).

Longer-term evidence from the VNS-REHAB program suggests durability of response in selected participants treated with implanted paired VNS, including 1-year outcomes reported by Kimberley (2025). These findings are clinically relevant but should be interpreted as follow-up evidence rather than a substitute for blinded randomized long-term comparative effectiveness. The available long-term reports do not resolve generalizability to transcutaneous devices, acute or subacute stroke populations, less structured rehabilitation protocols, or broader patient-centered outcomes.

Safety evidence

The 2026 Cochrane review found low-certainty evidence that VNS paired with rehabilitation may result in little to no increased risk of serious adverse events compared with rehabilitation alone. Zhou (2025) similarly found no clear treatment-attributable adverse event excess in pooled randomized evidence. These findings are reassuring but imprecise. For implanted systems, surgical risks, infection, lead- or generator-related complications, hoarseness, cough, dyspnea, and device maintenance remain relevant to clinical decision-making. For transcutaneous systems, adverse event concerns are lower, but stimulation target, dose, monitoring, and device characteristics vary across studies (Everard, 2026; Zhou, 2025).

Safety evaluations across clinical trials consistently report that vagus nerve stimulation is generally well-tolerated, with most adverse events being mild to moderate. Dawson (2021) documented 334 adverse events among participants (n = 108), primarily mild, with the most common being pain related to device implantation. Serious events were rare, with only one transient vocal cord paresis reported, and device removal was mainly due to study discontinuation rather than complications. Surgical adverse event rates for stroke rehabilitation patients were lower compared to those receiving vagus nerve stimulation for epilepsy or depression (Liu, 2022a).

In 2025, we restructured the findings section into distinct sections (clinical guidelines, systematic reviews and meta-analyses, primary clinical evidence, and safety evidence), notably adding the updated 2024 Department of Veterans Affairs/Department of Defense Clinical Practice Guideline and a new systematic review on vagus nerve stimulation (Kalagara, 2025).

In 2026, we updated the background to distinguish implanted paired vagus nerve stimulation from transcutaneous approaches; added evidence from a 2026 Cochrane review and 2025-2026 systematic reviews and meta-analyses (Everard, 2026; Yu, 2026; Zhou, 2025; Wan, 2026; Kimberley, 2025). No policy changes were warranted.

References

On May 19, 2026, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “stroke rehabilitation (MeSH),” “vagus nerve stimulation (MeSH),” “vagus nerve stimulation,” and “stroke.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

6/2022: initial review date and clinical policy effective date: 7/2022

6/2023: Policy references updated.

6/2024: Policy references updated.
6/2025: Policy references updated.
6/2026: Policy references updated.

Related codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1515 This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code description
64568-64570	Open implantation, revision or replacement, or removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator.
95970, 95976-95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter; without programming or with simple or complex cranial nerve neurostimulator programming.
C1767	Generator, neurostimulator, implantable, nonrechargeable.
C1778	Lead, neurostimulator, implantable.
C1827	Generator, neurostimulator, implantable, nonrechargeable, with implantable stimulation lead and external paired stimulation controller.
E0721	Transcutaneous electrical nerve stimulator for nerves in the auricular region.
E0735	Non-invasive vagus nerve stimulator.
A4543	Supplies for transcutaneous electrical nerve stimulator for nerves in the auricular region, per month.