

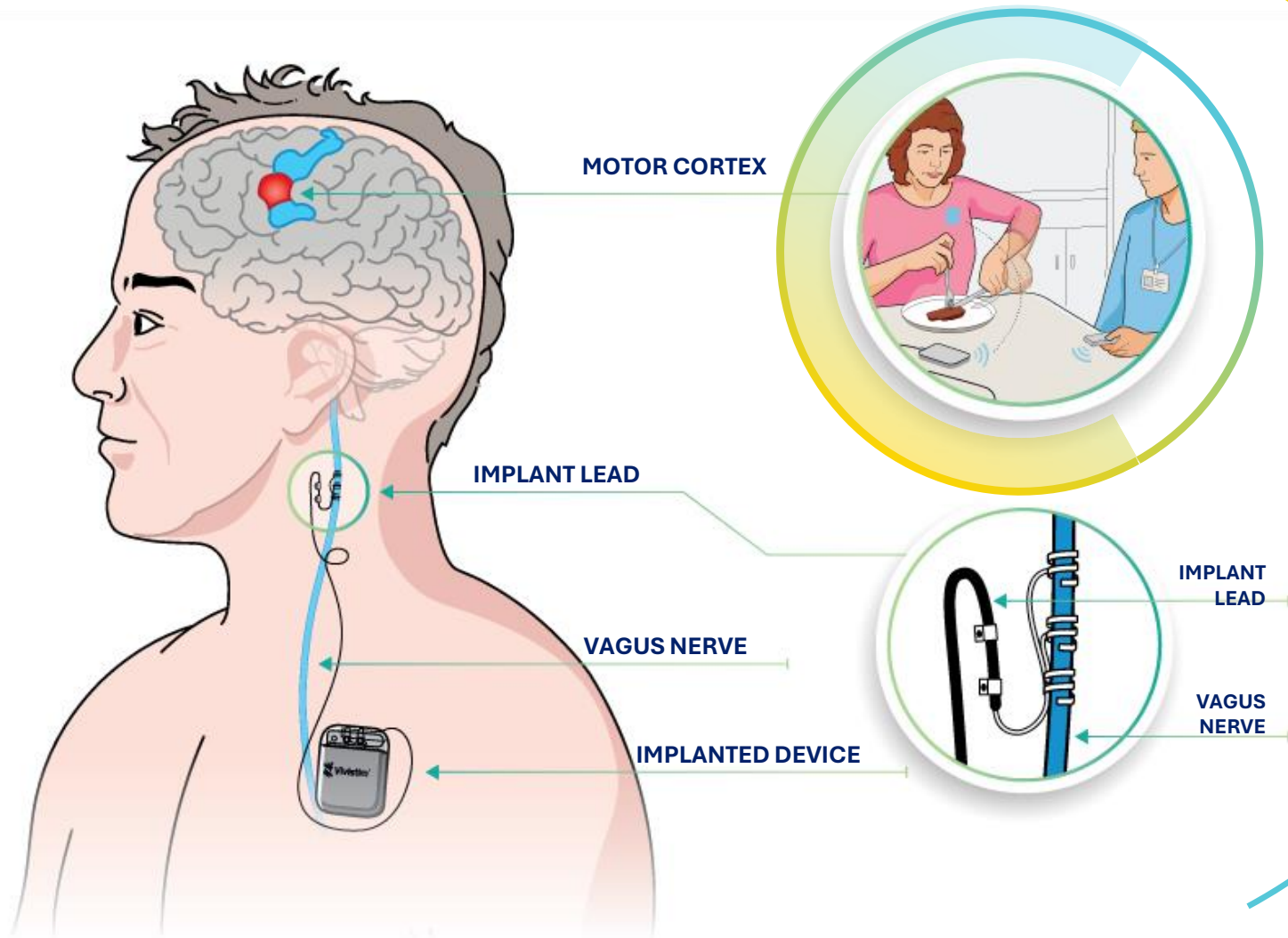
# **Vivistim<sup>®</sup> Paired Vagus Nerve Stimulation**

## **Neurorestoration for Chronic Stroke Survivors**

**Request to Assign CPT Code 64568 to New Tech APC 1580**

# Vivistim Therapy Can Help Break Through Chronic Stroke Limitations

Through the Principals of Neuroplasticity

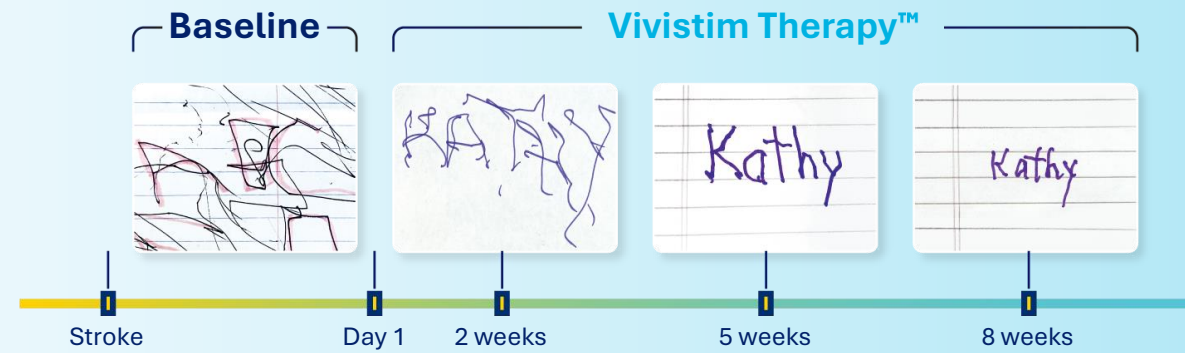


Vivistim is the only FDA-approved neurostimulation device used in chronic ischemic stroke patients with moderate to severe arm impairment.

It combines vagus nerve stimulation (VNS) with upper extremity rehabilitation and daily home activities to help reestablish the brain connections necessary for relearning motor function.

**Pairing Vivistim with intensive rehab can result in significant and sustained improvements in arm and hand function.**

# Patients Are Seeing Remarkable Improvements with Vivistim®



## Vivistim Patient

69 years old, 3 years post stroke, actual handwriting examples

**“It has been life-changing...**

**I am doing things that I never thought I’d be able to do again.”**

”

# Vivistim Paired VNS System Milestones

| Milestone  | 2021   | 2022   | 2023   | 2024  | 2025 | 2026  |  |
|--|--|--|--|---|------|---|--|
| <b>PMA Approval</b><br>Break Through Device Designation  | <br>August 27, 2021 |  |  |   |      |   |  |
| <b>New Technology Add-On Payment Duration</b>            |  | <br>October 1, 2022 |                     |   |      | <br>September 30, 2025 |  |
| <b>Transitional Pass-Through Duration</b>                |  |  | <br>January 1, 2023 |  |      |   | <br>December 31, 2025 |
| <b>Potential Access Issue for Medicare Beneficiaries</b> |  |  |  |   |      | <br>January 1, 2026    |  |

# Payment Misalignment Creates Access Risk

## Vivistim Cost vs. Medicare Payment

- **Initial implant of the Vivistim System is coded with 64568 + C1827**
  - 64568: Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
  - C1827: Generator, neurostimulator (implantable), nonrechargeable, with implantable stimulation lead and external paired stimulation controller
- **Implant procedure cost of the Vivistim System is \$50,569 across 74 single claims\* (64568 + C1827)**
  - Current APC assignment of this procedure is APC 5465, Level 5 Neurostimulator and Related Services (\$30,474)
  - When TPT expires, the total hospital payment will no longer reflect cost
  - If no action is taken, hospitals will incur an extensive financial loss per procedures effective January 1, 2026, causing a significant negative impact on Medicare beneficiary access to this technology
- **Proposed solution to address this issue:**
  - **Assign 64568 to New Tech APC 1580**
    - With no Level 6 Neurostimulator APC proposed, assigning CPT 64568 to New Tech APC 1580 follows CMS's established precedent for comparable stimulation technologies after TPT ends

# The Problem with APC 5465

## High-Cost, Low-Volume Procedures Are Drowned Out

- **APC 5465 is currently dominated by three high-volume, lower-cost procedures:**
  - 63685 (Spinal Cord Stimulator for pain control): 8,587 claims
  - 64582 (Hypoglossal Nerve Stim for obstructive sleep apnea): 4,687 claims
  - 61886 (Deep brain stimulation generator placement): 2,628 claims
  - These codes cluster near the geometric mean of \$32,023 and drive payment for the entire APC
- **For CY 2026, 61885 is proposed to be added to APC 5465, contributing an additional 2,839 claims**
  - This will increase the volume concentration in the APC even further
- **Paired VNS Procedures are reported only when CPT 64568 and C1827 are billed together**
  - \*74 single-frequency claims, reported cost: **\$50,569**
  - Proposed CY 2026 Payment of APC 5465: **\$31,752**
  - This will create a significant financial loss of **\$18,817** per procedure for hospitals offering Vivistim therapy
- **CMS acknowledges some procedures may be overpaid or underpaid, but this variation in payment is not sustainable for low volume, high-cost procedures like Vivistim**

# Comparable Procedures Were Assigned to New Tech APCs When TPT Expired Based on Reported Cost vs. APC 5465 Payment

- **CPT 0266T/64XX5 (Carotid sinus baroreflex system) and CPT 33276 (Phrenic nerve stimulation system)**
  - Both initially assigned to APC 5465 and received Transitional Pass-Through (TPT) status for 3 years
  - Based on reported costs significantly higher than the payment rate for APC 5465, both procedures were assigned to a New Technology APC after TPT expired
  - Both procedures are proposed to remain in New Technology APC 1580 for CY 2026 based on the cost of the respective procedures
  - Both represent distinct technologies with high costs and limited volume
- **Vivistim is uniquely identified by CPT 64568 + C1827**
  - Reported cost of 64568 + C1827 is \$50,569 consistent with 0266T/64XX5 and 33276
  - Significant financial issue created when TPT expires without a change in APC assignment of 64568
- **CMS used placement into New Tech APCs to preserve access to other low-volume, high-cost stimulation technologies when TPT expired**
  - We are requesting consistent treatment for Paired VNS through reassignment to New Tech APC 1580, consistent with CMS precedent for similar technologies after TPT expiration



# Our Request for Paired VNS Procedures

We respectfully request the HOP Panel recommend that CMS:

- **Assign CPT 64568 to New Tech APC 1580 Effective January 1, 2026**

- While CMS stated in the CY 2025 Final Rule that 64568 should remain in Level 5 due to available claims data, this does not reflect the cost of Vivistim therapy as well as traditional VNS
- Reassignment to New Tech APC 1580 follows CMS precedent for other stimulation procedures (i.e., 0266T/64XX5, 33276) with similar cost and volume characteristics
- This will help preserve Medicare patient access when Transitional Pass-Through ends on 12/31/25

- We continue to support the Neuromodulation Payment Policy Coalition's request to create a Level 6 Neurostimulator APC

- However, since CMS is not proposing to create a Level 6 Neurostimulator APC in 2026, reassignment of CPT 64568 to **New Tech APC 1580 is required to maintain Medicare access to Vivistim therapy**



**Thank you!**