



# ENSURING MEDICARE BENEFICIARY ACCESS TO Peripheral Nerve Stimulation Therapy in the Hospital Outpatient site of care

## **Presented by:**

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CMS Hospital Outpatient Payment (HOP) Panel Meeting

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**Neuralace Medical**  
Axon Therapy®



# HOP Panel Request for CY2026

## 1. Recommend to CMS:

- Assign CPTs 0766T and 0767T from APC 5722 to **APC 5431** Level 1 Nerve Procedure [*CY 2025 HOP panel meeting recommendation*]
- APC 5431 is a more clinically and resource appropriate APC assignment

## 2. Recommend to CMS:

- Payment status indicator change from “N” to “S” for CPT 0767T [*CY2025 HOP panel meeting recommendation*]
- CPT 0767T was not intended to be ‘packaged’ or bundled into payment for CPT 0766T
- 0766T applies to the 1<sup>st</sup> nerve; (MUE of 1)
- 0767T is applicable for separate reporting, for each additional nerve, when performed

## 3. Alternative recommendation: Assign CPT 0766T and 0767T to APC 5724 Level 4 Diagnostic Tests & Related Services from APC 5722 Level 2 Diagnostic Tests & Related Services

Background: [August 26, 2024 Meeting Presentations, Recommendations – Updated 09/04/2024 \(ZIP\)](#)



# Summary of Issue

- CY2025: CMS did **NOT** follow the HOP Panel CY2025 recommendations for AMA CPT 0766T\* and 0767T\*\*
  1. CPT code 0766T assigned to **APC 5722** Level 2 Diagnostic Tests & Related Service for CY2025, which did NOT mitigate the Medicare access and financial **barriers** from the initial CY2024 APC 5721 assignment
  2. CY 2025 payment status Indicator remained **“N”** for CPT 0767T, continuing the patient and facility access and financial **barriers** when treatment to additional nerve is deemed medically necessary
- CY 2025 APC **5722 Level 2 Diagnostic Tests & Related Services** assignment, does **NOT** categorize 0766T or 0767T with other procedures that are comparable clinically or from a resource use perspective
- **CY 2025 APC 5722 assignment for CPT 0766T and NO payment status for 0767T has continued to create an extreme barrier for Medicare beneficiary access** to this non-invasive and non-opioid therapy in the Hospital outpatient site of care **due to the negative financial impact** of the inappropriate APC assignment and CPT 0767T status indicator

\* \*\* AMA CPT 0766T and 0767T describe Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and mapping of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization) procedures. FDA clearance - <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K233364>

# Axon Therapy

- FDA-cleared to stimulate peripheral nerves for relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or relief of chronic painful diabetic peripheral neuropathy in the lower extremities (for patients 18 and older)
- First and only 100% non-invasive electroceutical platform cleared by FDA for the treatment of painful diabetic neuropathy
- Using magnetic pulses, engages sensory, pain, and motor fibers mechanistically to recondition the Central Nervous System<sup>1</sup> by eliminating noxious pain signals to the brain, reducing chronic neuropathic pain for respondent patients by up to 87%
- After only one treatment, respondent patients report a 54% decrease in pain on average<sup>2</sup>, and a 72% average decrease after three treatments.<sup>3</sup> Non-responders identified after 1-2 treatments<sup>4</sup>
- Represents breakthrough for chronic neuropathic pain management that can minimize dependence on opioids and other medications with potentially adverse side effects by an average of 51%<sup>4</sup>
- General treatment protocol is 5-6 treatments in first month and then once per month thereafter

1. Deer T et al. 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.

2. VA Augusta Clinical Equipment Evaluation (CEC).

3. In Respondent Patients, VA Augusta Clinical Equipment Evaluation (CEC).

4. Bedder M, Parker L. Magnetic Peripheral Nerve Stimulation (mPNS) for Chronic Pain. JPain Res. 2023;16:2365-2373.



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Technology

# Rationale for APC Assignment 5431

1. **APC 5431 Level 1 Nerve Procedure**, is the most clinically appropriate APC assignment for CPTs 0766T and 0767T, as categorically, the APC applies to and includes therapeutic NERVE procedures intended to stimulate the nerve and address pain
2. Peripheral **NERVE** stimulation (PNS) describes a therapeutic procedure to the nerve and requires identification and mapping of the injured nerve and treatment location, as well as non-invasive nerve conduction localization when performed. Treatment is manually administered by the QHCP and is intended to relieve chronic neuropathic pain
3. **Axon is a therapeutic nerve procedure and not a diagnostic**, with an estimated facility cost of \$1500 per Axon treatment
4. **APC 5431** is comparable from resource use perspective, with a geometric mean cost of \$2,031 and a CY2026 proposed reimbursement rate of \$1,999

# Alternative Recommendation: APC 5724

*Axon Therapy is best represented by APC 5431. Alternative recommendation within the Diagnostic Tests & Related Services APC family is APC 5724. Axon Therapy is comparable to CPT 0720T (64X11) assigned to APC 5724. Axon Therapy is a more powerful and technologically complex resource driven therapy*

APC FAMILY: Diagnostic Tests and Related Services		
NAME	IB STIM Percutaneous Electrical Field Stimulation	AXON Therapy Peripheral Nerve Stimulation
AMA CPT CODE	64XXX EFF 01/01/2026 (FORMER 0720T)	0766T AND 0767T
CY 2025 APC	5724 Level 4 Diagnostic Tests and Related Services	5722 Level 2 Diagnostic Tests and Related Services
FDA IFU	Relief of chronic and debilitating abdominal pain associated with irritable bowel syndrome (IBS) pain in Children and Adolescents [ <a href="https://www.accessdata.fda.gov/cdrh_docs/pdf24/K241533.pdf">https://www.accessdata.fda.gov/cdrh_docs/pdf24/K241533.pdf</a> ]	Relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities for adults 18 and older. [ <a href="https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233364.pdf">https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233364.pdf</a> ]
Stimulation Target	Peripheral nerves	Peripheral nerves
Stimulation - Modality	Electrical	Electromagnetic
Stimulator components	IB-Stim stimulator with inserted, but not activated batteries. Sterile Wire Harness for use with IB-Stim stimulator only. Transilluminator. Exact field strength of PENFS isn't available in any provided context	Hardware consisting of 1.6 Tesla magnetic stimulator, proprietary software, a stimulation coil, a liquid cool unit, and a cart
Procedure - Description	Placement of 4 small needle arrays (finger pressure placement) in predetermined positions. Attached to small battery powered stimulator which is covered in Tegaderm.	Application of mPNS is dependent on the anatomical location of the nerve innervating the painful region. The location to place the coil is usually proximal to the painful site. The coil is placed on or just over the skin and stimulation is activated and gradually increased as the coil is moved while mapping the point of maximal stimulation. Determining the correct position is a combination of induced stimulation paresthesia and motor responses correlating to the specific nerve innervation.

# Summary: APC Reassignment is critical for facilitating beneficiary access to this non-invasive, opioid-sparing pain therapy

## Issue:

- Current and proposed CY2026 APC 5722 assignment for CPTs 0766T and 0767T presents critical barrier for HOP facility utilization and Medicare Beneficiary access to AXON Therapy
- CMS did not follow HOPS CY2025 recommendations for reassignment to APC5431 and SI payment indicator change to “S” for 0767T
- **Continued placement in APC 5722** with geometric mean of \$225 and CY2026 proposed rate of \$221 and 0767T SI of ‘N’, is financially unacceptable for all stakeholders to include the HOP provider/facility, the technology manufacturer, and more importantly, **Medicare beneficiaries’ access will continue to be greatly impeded**

## Request:

- **Recommend to CMS: CPT 0766T and 0767T should be assigned to APC 5431, Level 1 Nerve Procedures**
  - Most appropriate clinically and procedurally, as APC 5431 describes *therapeutic nerve treatments*
  - Comparable from resource use perspective, with a geometric mean cost of \$2,031 and a proposed CY2026 reimbursement rate of \$1,999
- **Alternative recommendation:** APC 5724 assignment, Level 4 Diagnostic Tests & Related Services
  - If CPTs 0766T and 0767T are to remain in the Diagnostic & Related Services APC family, reassign to APC 5724.
  - Most comparable procedure costs within the APC family, with total geometric mean cost of \$893 and proposed reimbursement rate of \$879.
  - Revise payment status indicator for 0767T to “S” to ensure separate payment for treatment of an additional nerve beyond the first nerve in the patient encounter





# THANK YOU!

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