

# **Request to Reassign 0720T Under the OPPS**

**HOP Panel Meeting  
August 22, 2022**

# Presenters

Dr. Adrian Miranda, NeurAxis, Inc.  
John McInnes, MD, JD, Arnold & Porter



# Issue

New CPT Category III code effective July 1, 2022 to describe use of IB-Stim device

- 0720T Percutaneous electrical nerve field stimulation, cranial nerves, without implantation
- IB-Stim is a therapeutic device for adolescents with irritable bowel syndrome (IBS)

CMS assigned 0720T to APC 5722 Level 2 Diagnostic Tests

- APC assignment does not group 0720T with other clinically comparable procedures or with procedures of comparable resource use

We ask CMS to reassign 0720T to a more appropriate APC

- Option 1: APC 5431 Level 1 Nerve Procedures
- Option 2: APC 5312 Level 2 Lower GI Procedures
- Option 3: APC 1515 New Technology – Level 15 (\$1301-\$1400)

# IB-Stim Overview

The IB-Stim is a battery operated, **single-use** disposable percutaneous electrical nerve field stimulator (PENFS) system intended to be used in patients 11-18 years of age with functional abdominal pain associated with irritable bowel syndrome (IBS).

IB-Stim stimulator is placed behind the patient's ear and connected to stimulation needles on the auricle.

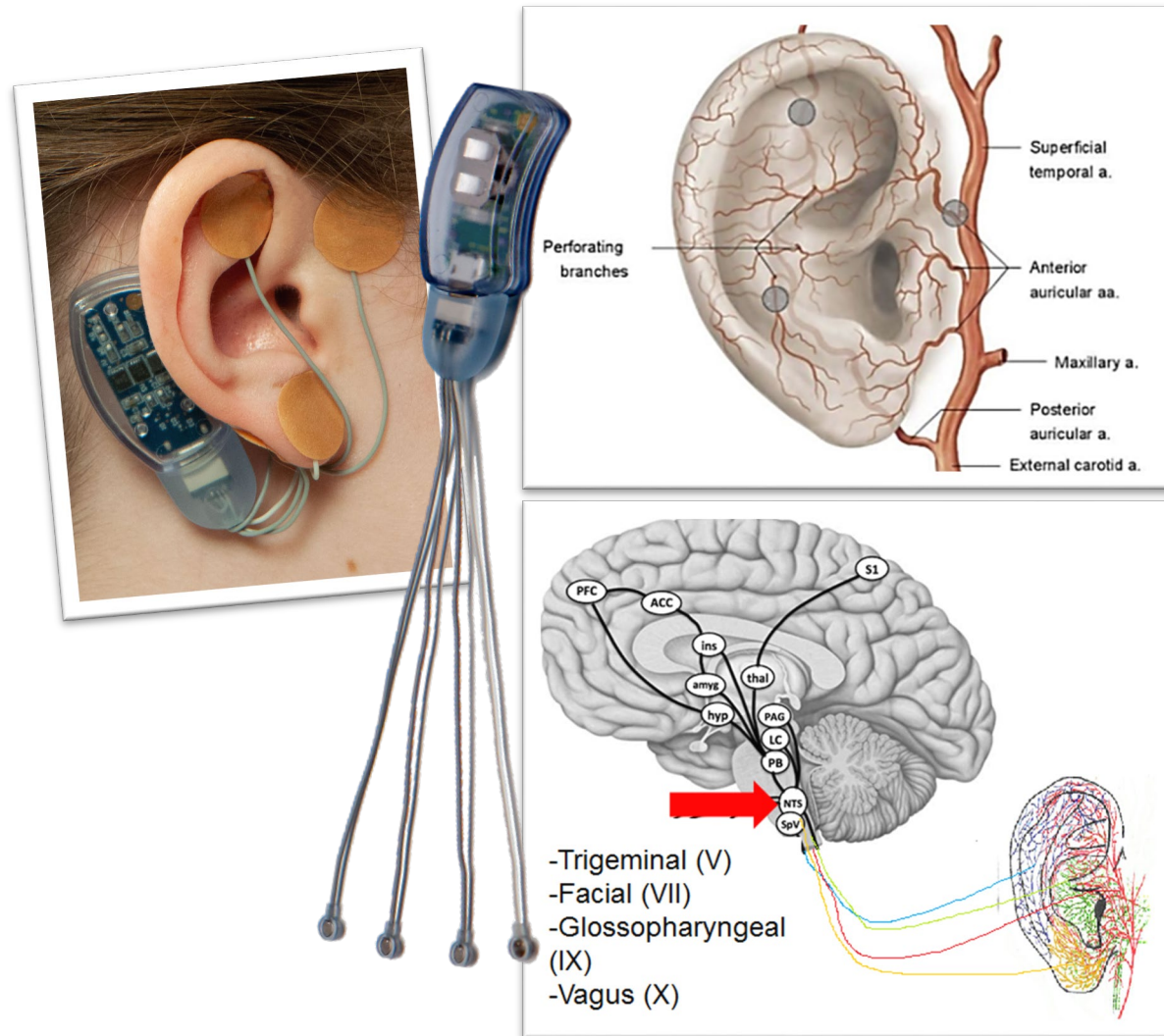
The IB-Stim is intended to be used for 120 hours per week up to 3 consecutive weeks, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination, as an aid in the reduction of pain when combined with other therapies for IBS.

FDA cleared the IB-Stim as a DeNovo, meaning the FDA determined the IB-Stim was a new product for which there was no legally marketed predicate device. The FDA created this new classification (PENFS) for the IB-STIM device.

**Each single use device has an invoice price of \$1195/device.**

# How IB-STIM works

IB-STIM is an established technology with demonstrated safety and efficacy



## How Does Neuromodulation Work?

1. Electrical impulses into cranial nerve bundles located in the ear allows direct access to the central nervous system
2. Reduces firing of amygdala neurons
3. Induces changes in brain pathways/connectivity
4. An alternative to pharmacotherapy

# IB-Stim Technology Differentiation

*IB-Stim is classified by the FDA as...*

**PENFS** (**P**ercutaneous Electrical Nerve Field Stimulation)

- Non-implanted nerve stimulator for functional abdominal pain relief. A device that stimulates nerves **remotely** from the source of pain with the intent to relieve functional abdominal pain. This generic type of device does not include devices designed to relieve pelvic pain.
- Placed on or near the auricle. Operates (MOA) to affect pain **centrally/remotely** from the site of application or the location of the pain/symptoms. It is not peripheral in placement or its MOA. Field refers to the “Field Effect” of broad stimulation of the neurovascular bundles that are anatomically located throughout the auricle, via a patented needle array design.

*IB-Stim is not...*

**PENS** (**P**eripheral Electrical Nerve Stimulation)

- Placed at the site of pain. Operates (MOA) via the peripheral nervous system.

**PNS** (**P**eripheral Nerve Stimulation)

- Placed at the site of pain. Operates (MOA) via the peripheral nervous system.

**PNFS** (**P**eripheral Nerve Field Stimulation)

- Placed at the site of pain. Operates (MOA) via the peripheral nervous system.

# Background on CPT Code 720T

## Typical Patient

- A 16-year-old female with a two-year history of chronic abdominal pain associated with irritable bowel syndrome who has failed to respond to changes in diet, lifestyle, over-the-counter therapies, and off-label medications is referred for placement of a percutaneous electrical nerve field stimulator.

## Procedure Description

- The physician examines the skin behind the ear. Transillumination of the ventral and dorsal aspects of the external ear is performed to visualize the cranial and occipital neurovascular bundles. The needle arrays are placed on the ventral/dorsal side of the ear lobe. The electrical nerve field stimulator is positioned behind the patient's ear, activated, and secured in place with adhesives.

## OPPS Statutory Principles

SSA § 1833(t)(2) SYSTEM REQUIREMENTS.—Under the payment system—

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are:

- comparable clinically and
- with respect to the use of resources . . . ;



## 0720T Differs Clinically from Other Procedures Assigned to APC 5722

- Almost all procedures assigned to APC 5722 (Level 2 Diagnostic Tests and Related Services) are diagnostic tests
  - 0720T is a therapeutic procedure to treat chronic abdominal pain associated with IBS in children and adolescents
  - Diagnosis of IBS has already been made and therapeutic procedure provides no additional diagnostic information
- Procedure codes assigned to APC 5722 describe testing associated with numerous different body systems (GI, respiratory, cardiovascular, nervous system, eye, etc) but more than 50% of single frequency claims volume are attributed to two pulmonary codes (94060 and 94726)
- Unclear why, but CMS has assigned a limited number of therapeutic procedures to APC 5722 including:
  - Transcranial Magnetic Stimulation (TMS) therapy (CPT codes 90867, 90868, 90869)
  - Therapeutic gastric intubation and aspiration (CPT code 43753)
  - CPR (CPT code 92950)
- We speculate that CMS may have assigned 0720T based on comparison with TMS the procedure, but these are substantially different services

# Procedure Comparison

|                     | TMS Therapy Procedure<br>(90867, 90868, 90869)            | IB-Stim Procedure<br>(0720T)  |
|---------------------|---|---|
| Indication          | Mental health conditions and movement disorders in adults | Abdominal pain associated with IBS in children and adolescents  |
| Stimulation Target  | Pre-frontal cortex of the brain                           | Cranial nerves to access CNS pain pathways  |
| Type of stimulation | Magnetic pulses   | Electrical impulses   |
| Stimulation device  | Capital equipment used for multiple patients in facility  | Single use, disposable device affixed in hospital that remains with patient after discharge                       |
| Course of therapy   | 40 minute session, 5 times per week for 4-6 weeks         | Worn continuously for 5 consecutive days followed by 2 days <u>rest</u> for three consecutive weeks of treatment. |

## 0720T Not Similar to Resource Use of TMS or Other Services Assigned to APC 5722

- 0720T is device dependent procedure for which cost of IB-Stim kit which includes stimulator and associated supplies is bulk of the cost of the service
  - As demonstrated in invoices submitted to CMS, IB-Stim kit costs \$1,195
  - We estimated additional costs of procedure using mean cost for percutaneous tibial nerve procedure (CPT code 64566) and estimate a total procedure cost for 0720T = \$1,323
- Procedures assigned to APC 5722 are substantially different
  - Almost no device costs (0.01% in 2022)
  - Geometric mean cost of APC 5722 (\$288) is a fraction of cost of IB-Stim device
  - Assignment of 0720T to APC 5722 would create a two times violation (if met threshold to be considered a significant procedure)

## 0720T Should be Assigned to a More Appropriate APC

- Recommended APC: APC 5431 Level 1 Nerve Procedures
  - Most clinically appropriate – describes therapeutic nerve procedures
  - Comparable procedure costs – most procedures assigned to APC 5431 have geometric mean costs between \$1,628 – \$1,886, similar to the estimated total procedure cost for 0720T of \$1,323
- Alternative (1): Clinical APC 5312 Level 2 Lower GI Procedures
  - Consistent with clinical indication to address abdominal pain
  - Comparable procedure costs – APC geometric mean cost = \$1,113
- Alternative (2): New Technology APC 1515 New Technology –Level 15 (\$1301 - \$1400)
  - 0720T is a unique procedure that is indicated for use in non-Medicare population; current APC structure is not well-suited to pay appropriately for this therapy
  - Assignment to a new technology APC would allow CMS to set an appropriate payment rate for the service

Thank You