

New Code CPT 645X1 Assigned an Inappropriate Device Offset % per CMS Rules

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Hypoglossal Nerve Stimulation for OSA: Predecessor Code CPT 64568 → New Code CPT 645X1 Device Offset Calculation Oversight for CPT 645X1

- FDA approved an implantable Hypoglossal Nerve Stimulation (HGNS) system in 2014
 - Manufactured by Inspire Medical Systems
- HGNS stimulates the 12th Cranial Nerve for treatment of moderate to severe Obstructive Sleep Apnea (OSA) in patients who failed CPAP
- In 2016, the AMA CPT Panel published a 'CPT Assistant' document for HGNS, with an update in 2018
 - Clearly states that CPT 64568 plus Add-On code CPT 0466T should be used to code the HGNS procedure
 - CPT 64568 (without an Add-on Code) is also used to code Vagal Nerve (10th Cranial Nerve) Stimulation for treatment of Seizures/Epilepsy because the two implants are very similar & 64568 is described as "...Implantation of a Cranial nerve neurostimulator system..."
- In 2020, the AMA CPT Panel decided to create new Cat I code for HGNS: CPT 645X1, to be effective in 2022, and to continue use of CPT 64568 for coding VNS for treatment of Epilepsy
 - The two procedures (HGNS & VNS) continue to share the same code for a device replacement/ battery changeout: CPT 61886
- CMS did not use the Predecessor Code's (CPT 64568) claims data to calculate the Device Offset (85.71% for 2019) for this Device Intensive Procedure, rather defaulted to 31%
- The resulting ASC payment proposal for CPT 645X1 is \$7,423 below the ASC proposed payment for the Predecessor Code CPT 64568, and far below the cost of the Device + Procedure
 - ASC proposal for 64568: **\$24,962**
 - ASC proposal for 645X1: **\$17,539**

Device Offset Calculation Rules – Predecessor Code, as Defined by CPT, Determines New Code’s Device Offset

The CMS publication of the **CY 2021 Final OPPS Rule**, Federal Register/Vol. 85, No. 249/Tuesday, December 29, 2020/Rules and Regulations 86015, states:

“... since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code.”

“Under this policy, claims data from clinically related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we apply the device offset percentage derived from the existing clinically related or similar HCPCS code’s claims data to the new HCPCS code for determining the device offset percentage.”

New Code CPT 645X1 Has a Predecessor Code Assigned in 2016: CPT 64568 – Implantation of a Cranial Nerve Stimulator System

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Hypoglossal Nerve Stimulator

New Category III codes have been established in the Current Procedural Terminology (CPT®) 2017 code set to report implantation of a hypoglossal nerve stimulation system that includes the placement of a chest wall sensor. Previously, this entire service was reported with code 64999, *Unlisted procedure, nervous system* (see CPT Assistant September 2011). This article provides an overview of these changes.

New Category III Codes

The new codes describe the implantation, revision, replacement, or removal of the chest wall sensor(s) attached to a cranial nerve neurostimulator electrode array and pulse generator for the treatment of selected patients with obstructive sleep apnea. Note that these new codes will be effective for use on January 1, 2017 and they are available on the CPT Category III website at www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/about-cpt/category-iii-codes.page. Publication of the Category III codes to the CPT website takes place on a semiannual basis when the codes have been approved by the CPT Editorial Panel. The full set of temporary Category III codes for emerging technology, services, procedures, and service paradigms are published annually in the code set for each CPT publication cycle. As part of the electronic distribution, there is a six-month implementation period from the initial release date (ie, codes released on January 1 are eligible for use on July 1, and codes released on July 1 are eligible for use on January 1).

- **0467T** Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator
 - ▶ (Do not report 0467T in conjunction with 0466T, 0468T) ◀
 - ▶ (For revision or replacement of cranial nerve [eg, vagus nerve] neurostimulator electrode array, including connection to existing pulse generator, use 64569) ◀
- **0468T** Removal of chest wall respiratory sensor electrode or electrode array
 - ▶ (Do not report 0468T in conjunction with 0466T, 0467T) ◀
 - ▶ (For removal of cranial nerve [eg, vagus nerve] neurostimulator electrode array and pulse generator, use 64570) ◀

Category III code 0466T is an add-on code to report in conjunction with code 64568 for the primary placement of a hypoglossal nerve stimulator and generator that includes a chest wall sensor electrode or electrode array. If the surgeon were to insert a hypoglossal nerve stimulator that does not require or include a chest wall sensor electrode or electrode array, then only code 64568 may be reported.

Codes 0467T and 0468T, which are not add-on codes, may be reported for either the revision and replacement or removal of the chest wall sensor electrode or electrode array, respectively. If the hypoglossal nerve stimulator array and generator were also revised, replaced, or removed, existing codes 64569 or 64570 may be reported.◆

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The 2019 Device Offset Calculation for the CPT 645X1 Predecessor Code, CPT 64568, is 85.71%

AMA		CMS Addendum P			CMS			Allowing Comprehensive APC's (Hospital)	Hospital	
HCCPS	Description	SI	APC	Device Offset %	Total Frequency	Single Frequency	Geometric Mean Cost	Geo Mean Cost of all Singles w/o device lines packaged	Device Cost	Device Proportion
64568	Incision for implantation of cranial nerve neurostimulator electrode array and pulse generator	J1	5465 Level 5 Neuro	85.71%	1,010	995	\$37,924.41	\$5,419.40	\$32,505.01	85.71%

The Device Offset assignment for CPT 645X1 should be the same as for its Predecessor Code, CPT 64568, which is 85.71%

Recommendation to CMS

- Use the Device Offset Percentage from Predecessor Code CPT 64568 to calculate the Device Offset Percentage for new code CPT 645X1
 - 85.71%
- Multiple Procedure Discounting determination for CPT 645X1 should be consistent with its Predecessor Code CPT 64568, and with other implantable neurostimulation systems (Deep Brain Stimulation (CPT 61885), Sacral Nerve Stimulation (CPT 64590), and Spinal Cord Stimulation (CPT 63650))
 - Multiple Procedure Discounting: “NO”