

Request for Level 6 Neurostimulator and Related Procedures APC

HOP PANEL PRESENTATION

NEUROMODULATION PAYMENT POLICY (NPP) COALITION

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Presentation Summary

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HCPCS Codes Involved:

The codes involve include 0266T, 0316T, 0424T, 64568 and 6188E. These represent system implants across various disease states.

APCs Affected:

CY 2021 proposed APC 5465, Level 5 Neurostimulator and Related Procedures

Description of the Issue:

The CY 2021 proposed Neurostimulator and Related Procedures APC structure allows for a smoother distribution of costs for certain procedures but does not solve the issue of five systems and procedures whose Geometric Mean Cost (GMC) far exceeds the proposed payment for APC 5465. This is due to the fact that spinal cord stimulation dominates the claims volume within the APC and has a much lower GMC compared to these technologies. This creates a financial burden for hospitals to provide these five therapies to Medicare beneficiaries, most of which have few or no other treatment options.

Clinical Description of the Services

These procedures represent unique, fully implantable stimulation systems which treat a wide range of disease states including heart failure, epilepsy, sleep apnea and treatment resistant depression.

Recommendation and Rationale for Change

For CY 2021, we recommend CMS create a Level 6 Neurostimulator and Related Procedures APC and reassign five HCPCS codes (0266T, 0316T, 0424T, 64568, 6188E) from APC 5465 to APC 546X. This will facilitate a smoother distribution of costs, and maintain clinical and resource homogeneity. This also supports CMS' policy of removing barriers for new technologies to ensure patient access to transformative technologies.

Potential Consequences of Not Making the Change

Hospitals will not be able to afford to offer these therapies to patients if the payment rate is consistently below the GMC of these five therapies. In addition, it creates substantial barriers to access for Medicare beneficiaries with limited or no other treatment options.

NPP Coalition

- NPP Coalition was formed in 2019, and includes companies with stimulation technologies to treat a range of diseases
 - CVRx – Barostimulation for heart failure (Carotid Sinus Baroreflex Activation Therapy)
 - LivaNova – Neurostimulation for epilepsy and treatment resistant depression (Vagal Nerve Stimulation)
 - Respicardia – Neurostimulation for central sleep apnea (Phrenic Nerve Stimulation)
 - JD LYMON Group (consultant and NPP Coalition convener)
- Purpose was to analyze the CMS hospital outpatient payment structure related to stimulation technologies and to recommend changes to better reflect hospital resource requirements and thereby helping ensure Medicare beneficiary have access to these technologies

Current State

- Today, the majority of stimulation system implants map to APC 5464
 - APC 5464 includes a collection of stimulation systems that treat a wide range of diseases (e.g. chronic pain, epilepsy, heart failure, sleep apnea, etc.)
- However, one technology, spinal cord stimulation (SCS), represents ~80% of claims in this classification and essentially sets the payment level for APC 5464
- As a result, stimulation system technologies that require substantially more resources represent a financial burden to hospitals
 - These technologies are all unique PMA devices which required greater research, development, and clinical evidence resources, contributing to their higher costs
 - Five CPT codes in this category (0266T, 0316T, 0424T, 64568, 6188E) have geometric mean costs (GMCs) which far exceed the payment assignment in this APC

Request for a New APC Level within the Neurostimulator and Related Procedures APCs

- A formal request was submitted to CMS in January 2020 to create a new Neurostimulator and Related Procedures APC that more appropriately reflects the resources required for these stimulation implant procedures
 - Specifically, it was requested that five (5) procedures be reassigned into a new APC
 - These five therapies represent procedures that treat much smaller patient populations than that of spinal cord stimulation, which dominates the current APC by volume and has a much lower GMC
 - The request supports CMS' policy of removing financial barriers to ensure Medicare patients have access to transformative technologies
 - The request also provides logical differentiation in APC assignment for full system implants vs. IPG replacements
- While this proposal was not included in the CY 2021 proposed OPPS rule, CMS did propose creation of a new Neurostimulator and Related Procedures APC to account for MRgFUS and a few other procedures, totalling ~800 annual claims

APC 5464/5465 Neurostimulator and Related Procedures

APC / CPT	Description	2020 Final (CMS-1717-FC)			2021 Proposed (CMS-1736-P)		
		Single Claims*	Geometric Mean Cost (GMC)*	% of APC Payment	Single Claims*	Geometric Mean Cost (GMC)*	% of APC Payment
5464/5	Neurostimulator and Related Procedures APCs	20,415	\$28,491	NA	18,388	\$28,876	N/A
0266T	Carotid barostim system	----	----	----	1	\$12,323*	41.1%
0427T	Central sleep apnea IPG	----	-----	----	1	\$16,731	55.8%
61886	Dual chamber IPG	3,150	\$23,820	83.6%	3,183	\$24,824	82.8%
0268T	Carotid barostim IPG	6	\$25,558	89.7%	10	\$38,028	126.9%
0424T	Central sleep apnea system	1	\$25,738**	NA	13	\$16,863**	NA
63685	Spinal cord stimulation system	16,314	\$29,022	101.9%	14,256	\$29,354	98.0%
64568	Vagus nerve stimulation system	891	\$37,642	132.1%	865	\$37,962	126.7%
6188E	Complexity adj. – IPG + lead	47	\$37,677	132.2%	56	\$38,550	128.6%
0316T	Morbid obesity IPG	3	\$39,442	138.4%	2	\$23,898	79.7%
0431T	Central sleep apnea IPG	3	\$43,521	152.8%	1	\$55,575	185.4%

* This technology received FDA approval on August 16, 2019, and has not yet commercialized. This single claim appears to be a hospital billing error.

** CPT 0424T does not include the cost of the device (C1823). Total calculated procedure GMCs including C1823 would be >\$42,000 in 2020 and >\$41,000 in 2021

Recommend that CMS Create a Level 6 Neurostimulator and Related Procedures APC effective for CY 2021

- We agree with CMS's comments that the CY 2021 proposed Neurostimulator and Related Procedures APC changes will "allow for a smoother distribution of the costs," specifically between existing APCs 5462 and 5463
- Further, we applaud CMS's willingness to create that new APC to solve significant GMC disparities, even if it is driven by a relatively modest number of claims (APC 5463 is supported by ~800 claims)
- However, the proposed rule does not address the even larger issue in the APC 5464 (and proposed APC 5465) that we highlighted in January, and would leave several resource intensive procedures in existing APC 5464 despite the fact that the GMCs greatly exceed that of spinal cord stimulation and the associated APC 5464 payment
- The GMC disparity for these 5 procedures (0266T, 0312T, 0424T, 64568 and 6188E) is significantly larger (~\$9K) and has a similar number of claims behind it (949) than the issue CMS is currently solving with its proposed creation of APC 5463, and we strongly urge CMS to address this during the CY 2021 rule making cycle
- We therefore urge CMS to create a Level 6 Neurostimulator and Related Procedures APC consistent with the rationale described in the CY 2021 proposed rule of smoothing costs
- Like the split of existing APC 5463, creating a Level 6 Neurostimulator and Related Procedures APC would allow for a smoother distribution of costs for all procedures in the Neurostimulator and Related Procedures APC family and would help ensure Medicare beneficiaries have continued access to critical stimulation therapies

A New Level 6 APC Distributes Costs More Evenly Across all Stimulation Technologies

APC	Neurostimulator and Related Procedures	Final 2020*		CMS Proposed 2021**		NPP Request for 2021	
		Single Claims	GMC	Single Claims	GMC	Single Claims	GMC
5461	Level 1	6,052	\$3,081	5,412	\$3,371	5,412	\$3,371
5462	Level 2	14,901	\$6,054	13,649	\$6,105	13,649	\$6,105
5463	Level 3	13,679	\$18,864	806	\$12,315	806	\$12,315
5464	Level 4	20,415	\$28,491	12,206	\$20,032	12,206	\$20,032
5465	Level 5	----	----	18,388	\$28,876	17,439	\$28,469
5466	Level 6	----	----	----	----	949	\$37,479

- Level 6 Neurostimulator and Related Procedures APC includes HCPCS codes 0266T, 0312T, 0424T, 64568 and 6188E

*Source: CMS-1717-FC, 2020 CN CPT Cost Stats 12202019.xls

**CMS-1736-P; 2021 NPRM APC Cost Stats.07242020.xls

Request Summary

- We request that CMS create a Level 6 Neurostimulator and Related Services APC effective January 1, 2021
- We request that CMS assign five HCPCS codes to this new Level 6 APC effective January 1, 2021, including the following:
 - CPT 0266T, 0312T, 0424T, 64568 and HCPCS 6188E
- We believe that creating this new APC more closely meets CMS' stated desire to provide a smoother distribution of costs for all procedures within this APC family, and ensures Medicare beneficiary access to these critical stimulation system technologies.