

Vagus Nerve Stimulation (VNS™) Therapy CY 2015 Comprehensive APCs: 0039 & 0318

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March 2014

Agenda

- VNS Therapy Overview
- CY 2015 Comprehensive APC 0039
- CY 2015 Comprehensive APC 0318
- Recommendations

VNS Therapy: FDA Indication for Epilepsy

“The VNS Therapy System is indicated for use as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with partial onset seizures, which are refractory to antiepileptic medications.”

NeuroCybernetic Prosthesis (NCP®) System; FDA Approval Letter, July 16, 1997

Vagus Nerve Stimulation (VNS) Therapy

Technology

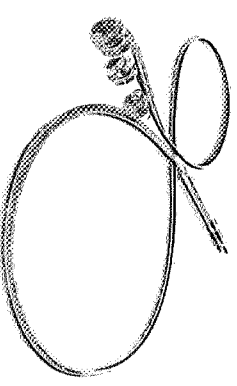
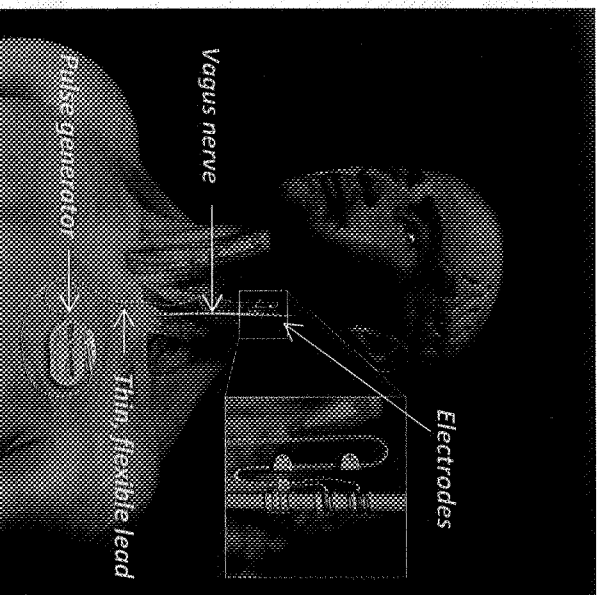
- Mild pulses applied to vagus nerve in neck send signals to brain
- Adjustable, automatic intermittent stimulation

Generators

- Placed subcutaneously in chest
- Pulse – 3rd generation
- DemiPulse™ – 4th generation
- AspireHC™ – 5th generation

Leads

- 302 base model
- Perennia™ lead
 - Increased durability
- Perennia Flex™ lead
 - More flexible Perennia lead



VNS Therapy

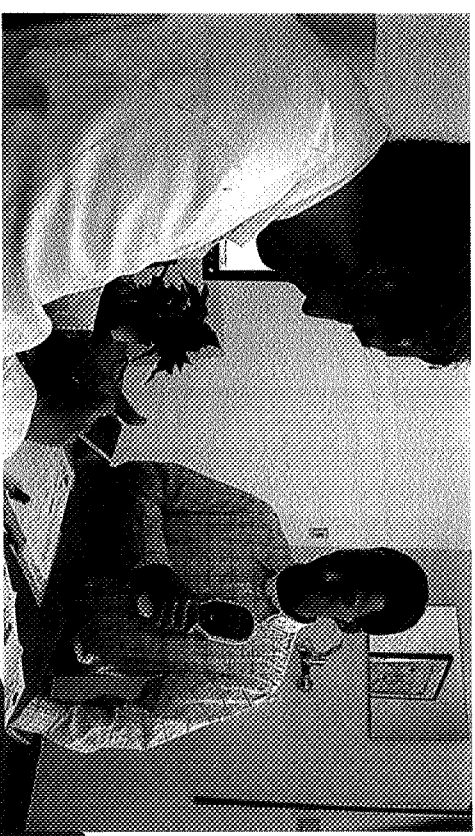
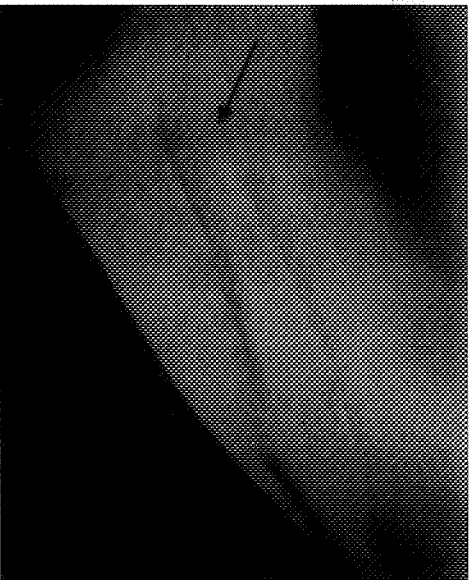
Procedure

- Typically 1-2 hour outpatient procedure
- Usually under general anesthesia
- Two small incisions
 - Upper chest area (pulse generator)
 - Neck area in skin crease (lead connection to vagus nerve)

Dosing System

- Handheld computer with specially designed software and wand
 - Communicates with the implanted pulse generator
- Easy to use, menu driven

Scar in neck crease at 3-months



Description of Issue - CY'15 Comprehensive APC 0039

1. In Final Rule, CMS proposed to eliminate APC 0315 (Level II Implantation of Neurostimulator Generator) and assign CPT 61886 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays) formerly to APC 0315, to Comprehensive APC 0318
2. We support elimination of APC 0315, but recommend that CPT 61886 be assigned to Comprehensive APC 0039 (Level I Implantation of a Neurostimulator)
3. With this change, all single, previously-identified device-dependent, neurostimulator-generator-only procedures would be assigned to one Comprehensive APC
4. This change would be consistent with CMS's Comprehensive APC policy to improve accuracy and transparency of payment for device-dependent services

Remap CPT 61886 to Comprehensive APC 0039

					Geometric Mean Cost for APC 0039	\$17,556	Geometric Mean Cost for APC 0039 if 61886 were included	\$18,160	
Primary HCPCS on Claim	Descriptor	Units of Primary HCPCS	Secondary HCPCS	Descriptor	Units of Secondary HCPCS	APC Assignment of Primary HCPCS	Final APC Assignment after Complex Comprehensive Policy	Number of Claims Usable in Rate-setting	Geometric Mean Cost of these Claims
64590	insrt/redo pn/gastr stimuli	1				0039	0039	8,385	\$ 17,080
61885	insrt/redo neurostim 1 array	1				0039	0039	3,150	\$ 18,207
63685	insrt/redo spine n generator	1				0039	0039	1,676	\$ 19,024
61886	Implant neurostim arrays	1				0315	0315	1,857	\$ 22,864

The Moran Company Analysis using data from the 2012 CMS claims file

Description of Issue – CY'15 Comprehensive APC 0318

1. For CY 2011, the AMA CPT Editorial Panel created new CPT code 64568 (Incision for implantation of cranial nerve stimulator pulse generator and electrode array) and CMS created a new APC 0318 (Implantation of Cranial Neurostimulator Pulse Generator and Electrode Array) to which CPT 64568 is the only procedure assigned
2. In Final Rule, CMS proposes to assign primary procedure codes for complex neurostimulation devices, including cranial, spine, and gastric neurostimulators, to Comprehensive APC 0318
3. Given the broad range of geometric mean values for the procedure codes assigned to APC 0318, we are concerned that the payment based on geometric mean cost for APC 0318 will be insufficient to cover hospital costs for these procedures and devices:
 - i. The geometric mean cost of \$25,491 is substantially lower than the cost for most of the procedure combinations assigned to APC 0318 and will result in some hospitals refusing to provide patient access to the VNS Therapy System
4. For this reason, we strongly suggest that CMS consider the possibility of establishing more than one complex APC per family of devices and test the possibility in the neurostimulation family in CY'15
 - i. Splitting APC 0318 into two complex APC's based on differences in resource consumption:
 - APC 0318“A”: VNS Therapy & Spinal Cord Stimulation = Geometric Mean Cost of \$28,116
 - APC 0318“B”: Peripheral/Gastric = Geometric Mean Cost of \$19,387

"Complex" Comprehensive APC 0318 without Split

					Geometric Mean Cost for alternate APC 0318	\$ 25,491			
Primary HCPCS on Claim	Descriptor	Units of Primary HCPCS	Secondary HCPCS	Descriptor	Units of Secondary HCPCS	APC Assignment of Primary HCPCS	Final APC Assignment after Comprehensive Policy	Number of Claims Usable in Rate-setting	Geometric Mean Cost of these Claims
64568	Inc for vagus n elect impl	1				0318	0318	689	\$ 27,180
63685	Insrt/redo spine n generator	1	63655	Implant neuroelectrodes	1	0039	0318	4,277	\$ 28,801
63685	Insrt/redo spine n generator	1	63650	Implant neuroelectrodes	2	0039	0318	2,527	\$ 28,137
63685	Insrt/redo spine n generator	1	63650	Implant neuroelectrodes	1	0039	0318	1,855	\$ 27,151
63685	Insrt/redo spine n generator	1	63663	Revise spine eltrd perq array	1	0039	0318	184	\$ 26,265
63685	Insrt/redo spine n generator	1	63664	Revise spine eltrd plate	1	0039	0318	139	\$ 27,649
63685	Insrt/redo spine n generator	1	63655	Implant neuroelectrodes	2	0039	0318	123	\$ 27,817
61885	Insrt/redo neurostim 1 array	2				0039	0318	186	\$ 21,230
64590	Insrt/redo pn/gastr stimuli	1	64555	Implant neuroelectrodes	1	0039	0318	115	\$ 25,768
64590	Insrt/redo pn/gastr stimuli	1	64575	Implant neuroelectrodes	1	0039	0318	148	\$ 25,843
64590	Insrt/redo pn/gastr stimuli	1	64581	Implant neuroelectrodes	1	0039	0318	3,064	\$ 18,819

The Moran Company Analysis using data from the 2012 CMS claims file

Split "Complex" Comprehensive APC 0318

					Geometric Mean Cost for APC 0318 A	\$ 28,116	Geometric Mean Cost for APC 0318 B	\$ 19,387	
Primary HCPCS on Claim	Descriptor	Units of Primary HCPCS	Secondary HCPCS	Descriptor	Units of Secondary HCPCS	APC Assignment of Primary HCPCS	Final APC Assignment after Complex Comprehensive Policy	Number of Claims Usable in Rate-setting	Geometric Mean Cost of these Claims
64568	Inc for vagus n elect impl	1				0318	0318A	689	\$ 27,180
63685	Insrt/reco spine n generator	1	63655	Implant neuroelectrodes	1	0039	0318A	4,286	\$ 28,789
63685	Insrt/reco spine n generator	1	63650	Implant neuroelectrodes	2	0039	0318A	2,333	\$ 28,026
63685	Insrt/reco spine n generator	1	63650	Implant neuroelectrodes	1	0039	0318A	2,074	\$ 27,386
63685	Insrt/reco spine n generator	1	63663	Revise spine eltrd perq array	1	0039	0318A	184	\$ 26,265
63685	Insrt/reco spine n generator	1	63664	Revise spine eltrd plate	1	0039	0318A	139	\$ 27,649
63685	Insrt/reco spine n generator	1	63655	Implant neuroelectrodes	2	0039	0318A	122	\$ 27,817
61885	Insrt/reco neurostim 1 array	2				0039	0318B	157	\$ 21,354
64590	Insrt/reco pn/gastr stim	1	64575	Implant neuroelectrodes	1	0039	0318B	148	\$ 25,843
64590	Insrt/reco pn/gastr stim	1	64555	Implant neuroelectrodes	1	0039	0318B	122	\$ 25,468
64590	Insrt/reco pn/gastr stim	1	64581	Implant neuroelectrodes	1	0039	0318B	3,064	\$ 18,319

The Moran Company Analysis using data from the 2012 CMS claims file

Recommendations

1. Remap CPT code 61886 to Comprehensive APC 0039

- i. Recommend remapping CPT 61886 to Comprehensive APC 0039 allowing all single, previously-identified device-dependent, neurostimulator-generator-only procedures to be assigned to one Comprehensive APC
- ii. This change would be consistent with CMS's Comprehensive APC policy to improve accuracy and transparency of payment for device-dependent services

2. Split “Complex” Comprehensive APC 0318

- i. Strongly recommend that CMS consider the possibility of establishing more than one complex APC per family of devices and test the possibility in the neurostimulation family in CY 2015
- iii. This can be accomplished by splitting APC 0318 into two complex APC's based on differences in resource consumption: 1) APC 0318“A” = VNS Therapy & SCS; 2) APC 0318“B” = Peripheral/Gastric
- iv. An analysis of the device-intensive costs within APC 0318 would be required in order to determine the extent to which averaging across all procedures will disadvantage VNS Therapy and SCS procedures. The analysis would look at the device costs within each combination and compare them to the historic proportion of device cost in the device-dependent APC's
- v. Splitting APC 0318 based on resource consumption will allow hospitals the ability to continue offering patient access to VNS Therapy (CPT 64568)

Thank you

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