



VAGUS NERVE STIMULATION

115

## **Centers for Medicare & Medicaid Services**

### **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates CMS-1506-P**

- I. Cyberonics' Comments regarding the changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates**
- II. Cyberonics' Presentation to CMS on October 5, 2006**
- III. Supporting Documents (see Table of Contents)**

#### *United States Indication for Use:*

##### **Depression:**

*The VNS Therapy System is indicated for the adjunctive long-term treatment of chronic or recurrent depression for patients of 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments.*

##### **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 anti-epileptic medications.*



VAGUS NERVE STIMULATION

October 5, 2006

Honorable Mark McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1506-P  
P.O. Box 8011  
Baltimore, Maryland 21244

**Re: Proposed Hospital Outpatient Prospective Payment System  
and CY 2007 Payment Rates**

Dear Dr. McClellan:

Cyberonics, Inc. appreciates the considerable effort CMS has put into the development of the Outpatient Prospective Payment System (OPPS). As the sole manufacturer of the VNS Therapy System, we would like to take this opportunity to comment on the Proposed Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates (CMS-1506-P, *Federal Register*, Vol. 71, No. 163, Tuesday, August 23, 2006, p. 49505).

Cyberonics does not receive reimbursement directly from CMS, but the proposed changes to the OPPS have an impact on the nature of our business. The proposed decrease to ambulatory payment classification (APC) 0039 is of great concern. More than 70% of all VNS Therapy patients elect neurostimulator replacement upon battery depletion, which is also known as end-of-service (EOS). It is concerning that the proposed rate for APC 0039, the only APC that is billed in a VNS Therapy System EOS replacement procedure, would not allow a hospital to recoup their costs for the procedure and the device.

**See Addendum A** for detailed analyses of the OPPS data and more complete comments on the problems and issues with the proposed rate and rate setting methodology.

**See Addendum B** for a complete description of Cyberonics, Inc. and our mission, the approved indications for VNS Therapy, and a history of Medicare's NCD for epilepsy- and depression-related facts.

**See Supporting Documents** (Item 4b) for detailed analyses of the economic burden of epilepsy and depression for Medicare beneficiaries using the 2004 5% Standard Analytical File.

### Proposed 2007 Payment for APC 0039

As shown in Table 1, the 2007 proposed rates for ambulatory payment classification (APC) 0039, Level I Implantation of Neurostimulator, would reimburse hospitals approximately 6.7% less than in 2006.

**Table 1**  
**2007 Proposed Payment for APC 0039 vs. 2006 Actual Payment Rate**

Procedure	CPT Code	APC	APC Payment 2006	APC Payment 2007 Proposed	2006 v. 2007 Change	2006 v. 2007 % Change Adjusted
Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling	61885	0039	\$11,603	\$10,829	- \$774	- 6.7%

### Impact of Significant Methodology Changes to Identifying Single Procedure Claims

In 2004, HCPCS code 61885 was put in its own APC (0039). As shown in Table 2, the unadjusted median cost calculated by CMS for this code since 2004 show significantly change the manner in which it identifies single procedure claims over the years, which has negatively affected the median cost for this code. Additionally, we see significant impact of this methodology on the payment weight history which has reduced 42% since 2002 and 25% since 2004. The APC 0039 payment rate has been reduced by 31% since 2002 and 15.6% since 2004.

**Table 2: Payment Weight History, List Price, and APC 0039 Payment Rate**

Particular	Description	2004	2005	2006	2007 Proposed
Payment Weight	HCPCS- 61885 Insertion or replacement of cranial neurostimulator	235.1866	219.9203	194.9690	175.9328
VNS Therapy List Price	Model 102 & 102R	\$11,999	\$11,999	\$11,999	
APC 0039 payment rate	Insertion or replacement of cranial neurostimulator	\$12,832	\$12,532	\$ 11,603	\$10,829

## **Implant Procedure and Device Acquisition Costs**

On average it costs hospitals \$3,000 to perform the VNS Therapy System neurostimulator replacement procedure (excluding device costs). Hospital acquisition cost for the Model 102 NCP in 2006 was \$11,999.

The data clearly demonstrate device acquisition and procedure costs, \$15,000 in total have been undervalued in APC 0039 for EOS replacement procedures as proposed. The payment amount proposed, \$10,829 is lower than hospital device acquisition cost and without consideration for implantation procedure costs. It is important to note that hospital acquisition cost for the Model 102 NCP System in 2004, 2005 and 2006 remained the same \$11,999.

In review of the 2007 Proposed OPPS Payment Rate for 61885 Adjusted by Wage Index for APC 0039, 298 hospitals submitted VNS Therapy claims. Of these hospitals, zero hospital's wage adjusted payments exceeded \$15,000 (a level that covers device and procedure costs), 14 hospital's wage adjusted payments covered the device but not the procedure, and 284 hospital's wage adjusted payment were less than the \$12,000 acquisition cost of a VNS Therapy neurostimulator (see Supporting Document, Item 2).

## **Data Issues**

The data included in the claims database for APC 0039 present many of the same concerns as in years past. VNS Therapy System claims were not captured or they were eliminated from the rate setting analysis as in the past due to the single v. multiple claims criteria applied by CMS in their analysis. The majority of VNS Therapy System implants are a simultaneous implant of the neurostimulator and lead, thus creating a claim that is lost to the "multi" claim file instead of being captured as a "single" claim. In addition, for EOS replacement procedures, if the hospital codes a secondary procedure for any particular reason that claim would also be lost to the "multi" claim file.

A thorough analysis of the claims which grouped to APC 0039 and were included in the proposed rate further explains why the proposed rate would not cover a hospital's cost for VNS Therapy implant (device and procedure). Factors contributing to an insufficient rate include:

- a decision by CMS not to use correctly coded claims (i.e. eliminating multi-procedure claims),
- refusal by CMS to acknowledge that charge compression exists,
- the decision to deny use of external data and
- the ongoing failure of hospitals to correctly code and bill for services provided

In addition to the above mentioned structural problems with rate setting methodology, perhaps the biggest factor contributing to the undervaluing of APC 0039 is an analysis of the procedures within APC 0039 grouped by diagnosis. This analysis clearly shows that the claims used for rate setting purposes where a diagnosis of epilepsy and depression were present (the only claims associated with VNS Therapy System implants) were significantly under represented. Epilepsy

and depression related claims accounted for only 111 of the 726 claims or 15% of the procedures. Median cost for the VNS Therapy related claims are among the highest in the group.

### **Recommendations**

Appropriate payment to hospitals will ensure that Medicare beneficiaries continue to have access to medical technologies like the VNS Therapy System in the outpatient hospital department. Our recommendations are outlined below:

- **Stabilizing Rates** – In terms of VNS Therapy System reimbursement, CMS made good progress with the 2006 rates and we would urge CMS to consider options that would maintain payment rates at no less than 100% of the 2006 rates plus the annual update factors applied to all APCs.

The APC 0039 payment rate has been reduced by 31% since 2002 and 15.6% since 2004. The proposed payment rate for APC 0039 would be the fourth decrease in a five year period. Changes that result in a decrease in year over year payment rates create financial issues for hospitals, especially in an environment where costs are rising.

- **Utilization of external data to validate rates and/or justify changes to be incorporated into the APCs medians** - Cyberonics recommends that CMS make adjustments, as it has in previous years for APC 0039 that more accurately represent acquisition cost of the device and procedure-related services, including the incorporation of external data provided by manufacturers and other stakeholders into the median cost calculations.
- **We request that CMS make a special consideration for device based APCs where supply cost is over 75% of the proposed APC rate** because these APCs are severely impacted by charge compression due to hospitals not charging adequately, as well as the impact of proposed OPPS payment rates for 61885 adjusted by the wage index.

Sincerely,



Max Gill, MBA  
*Senior Director, Reimbursement*  
Cyberonics, Inc.  
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## **Addendum A**

We will provide detailed comments on topics raised by the proposed rule below:

### **Section IV “*Proposed Payment Changes for Devices, Device-Dependent APCs.*”**

- Proposed 2007 Payment Rate for VNS Therapy
- “C” Codes for Implantable Devices
- Data and Methodology
- Cost to Charge Ratio
- Wage Index
- Recommendations

### **Implant Procedure and Device Acquisition Costs**

More than 70% of all VNS Therapy patients elect neurostimulator replacement upon battery depletion also known as end-of-service (EOS). It is concerning that the proposed rate for APC 0039 by itself, the only APC that is billed in an EOS replacement procedure, would not allow a hospital to recoup their costs for the procedure and the device. On average it costs hospitals approximately \$3,000 (includes OR staff, OR time, OR supplies, recovery, etc) to perform the VNS Therapy System neurostimulator replacement procedure (excluding device costs). Hospital acquisition cost for the Model 102 NCP System in 2005 was \$11,999, total costs for the device and the procedure would be ~\$15,000.

### **Proposed 2007 Payment Rate for VNS Therapy**

As shown in Table 1, the 2007 proposed rates for ambulatory payment classification (APC) 0039, Level I Implantation of Neurostimulator and APC 0225, Level I Implantation of Neurostimulator Electrodes would reimburse hospitals approximately the same in total as 2006. Thus, continuing to provide access to those Medicare beneficiaries in need of VNS Therapy as an initial implant.

However, the proposed decrease to APC 0039 is our greatest concern. As you can see, device acquisition and procedure costs have been undervalued in APC 0039 for EOS replacement procedures as proposed. The relative weight for APC 0039 would not get a hospital back to cost. The amount reflected is lower than hospital acquisition cost and without consideration for implantation procedure costs.

**Table 1**  
**2007 Proposed Payment for APC's 0039 and 0225 Vs. 2006 Actual Payment Rates**

<b>Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling</b>	61885	0039	\$11,603	\$10,829	- \$774	- 6.7%
<b>Incision and implantation of neurostimulator electrodes; cranial nerve</b>	64573	0225	\$ 14,928	\$14,413	-\$515	-3.4%

The year-to-year fluctuation in the individual APC rates cause concern. Stabilization of rates is what hospitals need to be able to provide consistent access to "device dependent APCs." One way to avoid that possibility would be to at least maintain the current 2006 medians.

Consistent with previous year's comments and this year's rate setting data and methodology, we have great concern going forward. The inclusion of external data and other such considerations in the past has created reimbursement rates for APCs like APC 0039 and APC 0225, which allow Medicare beneficiaries access to technologies like VNS Therapy. However, as we will discuss later in the data section, hospitals have not established correct coding and billing for devices, and there are no disincentives in the system for incorrect coding and billing (see Summary Document (Item 1) for Medicare UB-92 Claim Forms from 12 states).

We urge CMS to consider the previous OPPS changes made in 2006 in order to remain consistent with the original intent of the statute. As device codes were not required in 2003, were optional in 2004, and phased-in 2005, little improvement has been observed based on the sample claims collected from 12 states and 13 hospitals (see Summary Document (Item 1) for Medicare UB-92 Claim Forms from 12 states)..

**"C" Codes for Implantable Devices:**

Proposing to base CY 2007 OPPS device-dependent APC medians on CY 2006 claims data is concerning given the fluctuation in the claims data, and changes in CMS's methodologies. Below you can see a year-by-year "C" code requirement for APC 0039:

CY 2000 - pass thru on specific device C codes (C1048)  
 CY 2001 - pass thru on Category C codes (C1048 becomes C1767)  
 CY 2002 - pass thru on C1767  
 CY 2003 - C codes not required

CY 2004 – C codes optional

CY 2005 – C codes requirement was phased-in but only enforced on specific APCs

CY 2006 – C codes required but only enforced on device dependent APCs

Hospitals had no incentive before CY 2006, or during the phase-in period of 2005, to correctly code claims with C codes. By requiring that all “C” codes be billed, and returning claims without them, or providing some other incentive to improve coding, we believe that hospitals will be more vigilant in reporting the total costs of providing device-related services.

#### **Data and Methodology:**

- Data
  - VNS Therapy claims not represented
    - Number of hospitals coding for VNS Therapy captured declines
    - Number of VNS Therapy patients captured declines
  - Inadequate/missing charges
- Methodology
  - Charge Compression/Cost-to-charge-ratio
  - Wage Index.

The Moran Company (TMC) provided Cyberonics a thorough analysis of the 2005 Medicare Public Use File (1/1/05 – 12/31/05). After reviewing the claims data and CMS’s methodology, it became clear why the payment rate calculated for APC 0039 as proposed in the August 23, 2006 rule is inadequate for hospitals performing VNS Therapy neurostimulator EOS replacement procedures. Below we address our specific concerns with elements of the Proposed OPPS rule as related to APC 0039.

#### **Data**

TMC created a data set that was highly comparable to the data published by CMS in the proposed rule. See table 2 below, which shows minimal variation between the two for claims that fit the “Single” evaluation criteria.

Table 2: Comparison of CMS and TMC calculation of single claims and median costs for APC0039

<b>Claims</b>	610	720	17%
<b>Median</b>	10,866	11,332	4%



## Summary of Data Issues

The data included in the claims database for APC 0039 present several concerns. Again, as noted in the 2005 file, VNS Therapy claims were not captured or they were eliminated from the rate setting analysis as in the past due to the single v. multiple claims exclusion rule created by CMS. 81.5% of VNS Therapy System implants are a simultaneous implant of the neurostimulator and lead, thus creating a claim that is lost to the “multi” claim file instead of being captured as a “single” claim. In addition, for EOS replacement procedures, if the hospital codes a secondary procedure for any particular reason that claim would also be lost to the “multi” claim file.

381 hospitals submitted claims, which grouped to the APC 0039 single file. Further analysis of those claims explains why the proposed rate for APC 0039 would not cover a hospital’s cost for VNS Therapy implant (device and procedure). On average, charges and costs for procedures and devices are lower than expected. The average procedure charge was \$4,450 while the average device charge was \$29,357. When you apply the Cost-to-Charge Ratio (CCR) the average procedure cost becomes \$1,321 and the average device cost becomes \$10,899; well below the hospital’s actual costs for a VNS Therapy neurostimulator implant.

We further broke down the procedures within APC 0039 by diagnosis to better understand what types of procedures were represented. Specifically, CPT code 61885 (insertion or replacement of cranial neurostimulator pulse generator or receiver, single electrode array) should be accompanied by an epilepsy and depression diagnosis if it were for a VNS Therapy implant. TMC pulled 726 single claims for APC 0039.

As you can see in Table 3 below, VNS Therapy related claims accounted for only 15% of the procedures in that group. *Similar to the numbers we have reported in previous years, we know based on implant cards collected that Medicare beneficiaries accounted for approximately 1,050 or 18.5% of our total implants in CY 2005. Of those 1,050 Medicare cases, roughly 200 or 20% were EOS replacement procedure cases, which supports the fact that VNS Therapy implants are severely underrepresented in the rate setting data.*

Table 3: Conditions of on claims with 61885 or 64573

Disease category	# Claims	%	Single Claims, 61885		Single Claims, 64573	
				%		%
Seizure Disorder Only	725	40%	73	10%	55	79%
Both Seizure Disorder and Depression	51	3%	6	1%	3	4%
Depression Only	77	4%	32	4%	3	4%
Other	968	53%	615	85%	9	13%
<b>Total</b>	<b>1821</b>	<b>100%</b>	<b>726</b>	<b>100%</b>	<b>70</b>	<b>100%</b>

The median procedure charge was \$3,857 while the median device charge was \$25,990. When applying the Cost-to-Charge Ratio (CCR) the median procedure cost becomes \$1,138 and the median device cost becomes \$8,449. This will be below the hospital’s actual costs for a VNS Therapy neurostimulator implant.

The above concerns combined with the methodology used to calculate weights and payments leave the VNS Therapy neurostimulator underrepresented/undervalued in APC 0039. Without data that is representative of the VNS Therapy System it is not possible to properly reflect costs of VNS Therapy.

### **Cost-to-charge Ratio**

Charges for higher cost technologies have been reduced too much under CMS's current methodology of applying department-specific or hospital-specific cost-to-charge ratios to amounts on claims demonstrating "charge compression." The 2005 charge data for higher-cost technologies like the VNS Therapy System shows that hospitals are still not marking up these technologies at a rate adequate to recapture their costs once the cost-to-charge ratio is applied. As a result, CMS's current application of cost-to-charge ratios creates an underestimation of the hospital's costs, undermining the base APC rate.

Current device acquisition costs to the Hospital for neurostimulator implant procedures are approximately \$12,000 before any overhead costs for implantation, but the median costs for these items after the cost-to-charge ratio adjustment of claims are calculated to be 29% below the acquisition cost (see CMS Presentation, Section 2, page 16).

### **Wage Index**

CMS's application of wage index on the device portion of the APC will continue to further undervalue technologies. For the 298 hospitals making single VNS Therapy claims, 298 hospitals submitted claims. Of these hospitals, zero hospital's wage adjusted payments exceeded \$15,000 (a level that covers device and procedure costs), 14 hospital's wage adjusted payments covered the device but not the procedure, and 284 hospital's wage adjusted payment were less than the \$12,000 acquisition cost of a VNS Therapy neurostimulator.

### **Summary**

Cyberonics believes that CMS must continue to consider additional data and alternative methodological approaches. We urge CMS to conduct in-depth analyses of the claims, review additional information, consider alternative methodologies, and recalculate APC's like 0039 to assure that more complete and accurate hospital costs are captured and reimbursed.

### **Recommendations**

We hope that CMS will incorporate the recommendations below for CY 2007 rate setting and into the future. Appropriate payment to the hospitals will ensure that Medicare beneficiaries continue to have access to medical technologies like the VNS Therapy System in the outpatient hospital department. Our recommendations are outlined below:

- **Stabilizing Rates** – In terms of VNS Therapy System reimbursement, CMS made good progress with the 2006 rates and we would urge CMS to consider options that would

maintain payment rates at no less than 100% of the 2006 rates plus the annual update factors applied to all APCs.

Since CY 2002 there has been a 31% decrease to APC 0039. The proposed payment rate for APC 0039 would be the fourth decrease in a five year period. Changes that result in a decrease in year over year payment rates create financial issues for hospitals, especially in an environment where costs are rising.

- **Utilization of external data to validate rates and/or justify changes to be incorporated into the APCs medians** - Cyberonics recommends that CMS make adjustments, as it has in previous years for APC 0039 that more accurately represent acquisition cost of the device and procedure-related services, including the incorporation of external data provided by manufacturers and other stakeholders into the median cost calculations.
- **Eliminate Wage Index on Claims where more than 75% is Device Related** -Exempt the device portion of the APC rate for specific devices from the wage index or net payment will continue to result in access problems for Medicare beneficiaries. When the cost of devices exceeds a specific threshold or a percentage of the APC rate, CMS should specify the portion of the APC attributable to the devices, and should exempt this portion from the wage index, since device costs are not generally subject to local wage variations.

The steps taken in developing the 2005 rates, including the use of manufacturers' and other outside data sources for specific device-related APCs, especially APC 0039, were important improvements that should be incorporated into the ongoing methodology for developing APC rates. We appreciate the opportunity to provide comments on the Proposed Rule on Changes to the Medicare Outpatient Prospective Payment System and Payment Rates for Calendar Year 2007. We also look forward to working with CMS to resolve our concerns.

## **Addendum B**

### **Cyberonics Mission:**

“To improve the lives of people touched by epilepsy, depression and other chronic disorders that may prove to be treatable with our patented therapy, VNS.”

### **Background on FDA Approval for VNS Therapy:**

On July 16, 1997, the FDA approved the NCP System (the predecessor to the VNS Therapy System) for use “as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over twelve (12) years of age with partial onset seizures that are refractory to antiepileptic medications.”<sup>1</sup>

On July 15, 2005, the FDA approved the VNS Therapy System “for the adjunctive long-term treatment of chronic or recurrent depression for patients eighteen (18) years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments.”<sup>2</sup>

- Chronic or recurrent depression is defined as a current major depressive episode that is of at least 2 years in duration or a current major depressive episode in a patient with a history of multiple prior episodes of depression.
- The definition of a failed adequate treatment is the lack of response to established medications and/or ECT administered at adequate doses for an adequate duration.
- Chronic or recurrent depression is also known as treatment-resistant depression (TRD)

### **Commercial Use of VNS Therapy**

Since its original FDA approval, VNS Therapy has been implanted in over 40,000 patients with epilepsy worldwide who have accumulated over 100,000 patient years of experience with VNS Therapy, including approximately 8,000 Medicare beneficiaries that have accumulated approximately 20,000 patient years of experience. Through July 15, 2006, more than 1,500 patients with TRD also have begun treatment with VNS Therapy.

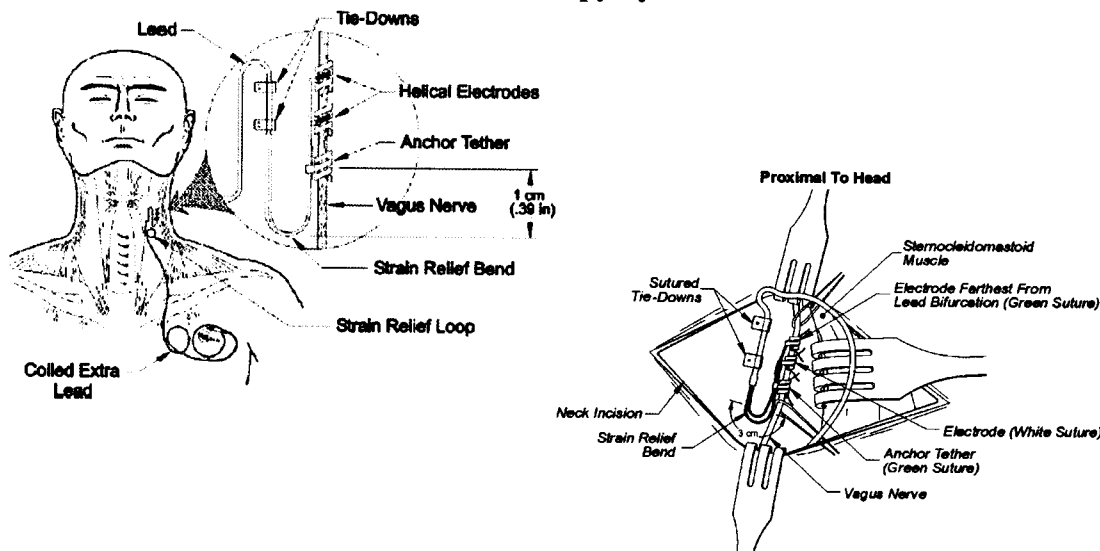
The epilepsy and TRD studies as well as commercial use in both epilepsy and depression demonstrate that VNS Therapy is associated with accumulating and durable effectiveness, tolerable side effects that are reported less frequently over time, no pharmacological interactions with other treatments, and high patient continuation rates.

## VNS Therapy Overview: Product Description and Surgical Procedure

### A. Product Description: Components of the VNS Therapy System

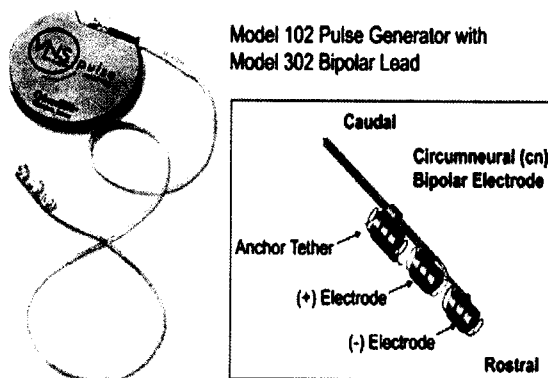
**Model 102 Generator.** This multi-programmable pacemaker-like device is powered by a lithium carbon monofluoride battery encased within a titanium can, weighs 25 grams, and measures 6.9 mm x 52.2 mm x 51.6 mm. Battery life average is 6 years, dependent upon stimulation parameters. New VNS Therapy implants use the single pin receptacle Model 102 generator.

**Illustration 1.1: VNS Therapy System Placement**



**Model 102R Generator.** With the exception of the dual pin receptacle, the Model 102 and Model 102R generators are the same. Earlier generator versions were manufactured with a dual pin receptacle and were compatible with the Model 300 electrode. During battery replacement when a patient may have an older electrode with a dual pin connector, the surgeon will use the Model 102R generator and may not be required to replace the electrode at that time.

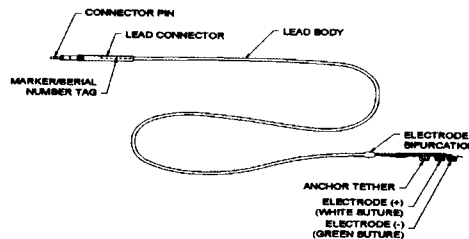
**Illustration 1.2: Model 102 Pulse Generator with Model 302 Bipolar Lead**



**Model 302 Electrode.** Two versions of the Model 302 electrode exist. Selection of the Model 302-20 or Model 302-30 electrode will depend upon the anatomical requirements of the patient.

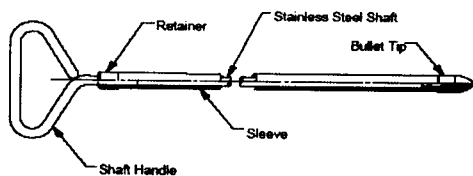
Model 302 electrodes are encased within a 43 cm polyurethane sheath, include a stainless steel connector 1.27 mm in diameter, and three platinum/iridium alloy helical coils.

Illustration 1.3: Model 302 Electrode



*Model 402 Tunneling Tool.* This single-use surgical tool is used to aid in subcutaneous routing of the lead from the neck incision to the chest incision

Illustration 14: Model 402 Tunneling Tool



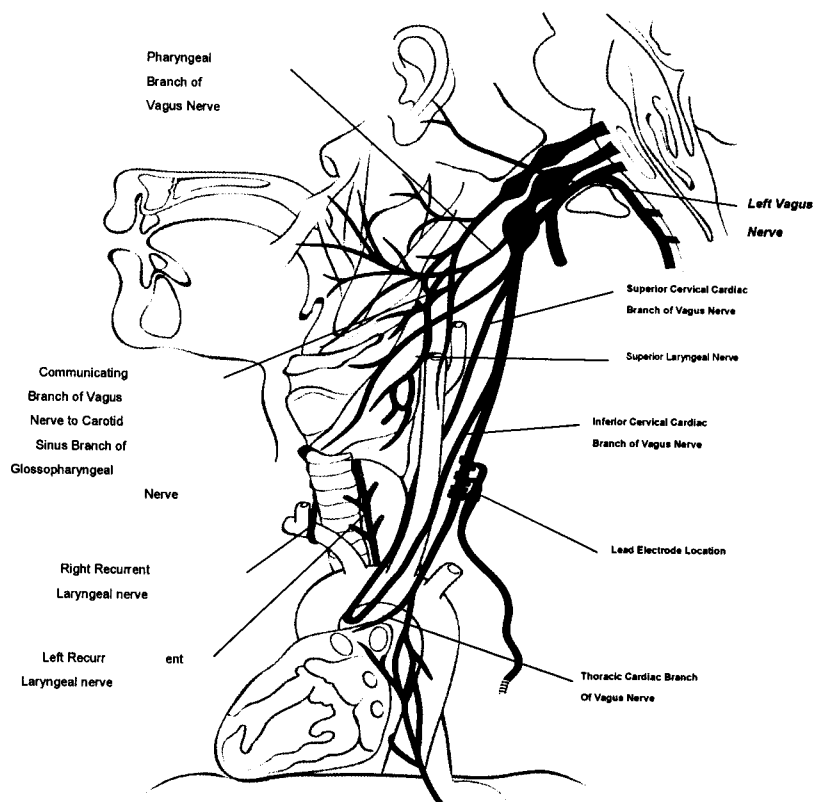
*Dosing Computer & Programming Wand.* Physicians and hospitals are equipped with hand held computers connected with a dosing wand. Software allows for communication between the computer and implanted neurostimulator, stimulation parameters of which may be adjusted to meet the clinical needs unique to the patient. Retrievable data may be evaluated by the clinician and stored for later reference.

For a complete description of the VNS Therapy System components, please see the detailed product labeling available at <http://www.vnstherapy.com/depression/hcp/Manuals/default.aspx>.

## **B. Surgical Implant Procedure**

Typically performed on an outpatient basis, the device implantation requires a similar surgical approach to carotid endarterectomy (see Illustration 1.1). Surgery is performed under general anesthesia and lasts approximately 1 to 2 hours. Historically, neurosurgeons, otolaryngologists, and general and vascular surgeons have been trained and competently performed the implant procedure. No special operating room equipment is required.

Illustration 1.5: Anatomy of the Left Vagus Nerve (X Cranial Nerve)



The patient is placed in the supine position with the head turned slightly to the right. The surgeons will mark on the left neck the transverse incision site within the skin crease midway between clavicle and mastoid process for electrode placement. Cyberonics recommends a transverse incision be performed to “hide” the scar in neck, but a vertical incision may be used for a thick neck. An incision site is also marked at the front fold of the left axilla or on the left frontal chest wall and aligned to the center of the clavicle for generator placement.

The surgeon will expose  $\geq 3$ cm of nerve inside the carotid sheath. Cyberonics recommends the surgeon avoid excessive handling of the nerve to prevent injury and preserve branches off the vagus, and avoid allowing the nerve to dry out. The surgeon will create a subcutaneous pouch superior to the pectoralis major for generator placement. Having exposed the left vagus nerve, the surgeon is directed to form a 3 cm strain relief bend. The surgeon is then directed to anchor the electrode to the adjacent fascia with tie downs away from carotid.

The tunneling tool is used to subcutaneously pass the electrode from the nerve to the generator (always tunneling from the neck to the chest). Three helical coils are wrapped around the exposed vagus nerve, while the pin attached to the electrode is then attached to the generator. Implantation of the VNS Therapy System may be performed by a trained and qualified surgeon.

Intraoperatively, the surgeon completes intraoperative testing using the hand held computer and dosing wand to ensure system integrity. Studies show that the most frequently reported surgical complication is infection, which occurs in approximately 2% of cases, with less than half of those requiring device explant.

For a complete description of the VNS Therapy System device implant procedure, please see the detailed product labeling available at <http://www.vnstherapy.com/depression/hcp/Manuals/default.aspx>.

### **History and Medicare's National Coverage Decision on VNS Therapy**

**On July 16, 1997 the United States Food and Drug Administration (FDA) approved Vagus Nerve Stimulation (VNS) Therapy as an adjunctive treatment for patients with medically refractory partial onset seizures.**

VNS Therapy represented the first new approach to the treatment of epilepsy in nearly 100 years and payers moved quickly to assess the evidence supporting VNS Therapy and issue favorable coverage and payment policies to ensure access to those who needed this therapy.

- CMS (formerly HCFA) National Coverage Policy issued April 1999.
- National Blue Cross and Blue Shield Technology Evaluation Center reviewed at February 10, 1998 meeting: The NCP System meets all coverage criteria.
- CHAMPUS/TRICARE.
- Kaiser, United, Aetna and virtually all payers cover and reimburse VNS Therapy.

In the eight years since FDA approval, patients living with medically refractory epilepsy have gained almost universal access to VNS Therapy. The value of VNS Therapy to improve the lives of people with poorly controlled epilepsy is now overwhelmingly supported with a very large peer reviewed literature with over 100,000 patient years of experience worldwide. The rationale for CMS's National Coverage Decision and the favorable coverage decisions made by the vast majority of private payers and State Medicaid organizations was and remains as follows:

- Epilepsy is a Chronic and Expensive Disorder,
- VNS Provides Long Term Seizure Control and Quality of Life and
- Long Term Seizure Control and Quality of Life Results in Reduced Healthcare Utilization and Savings for Payers.

**On July 15, 2005, the FDA approved VNS Therapy for treatment resistant depression (TRD). Americans with TRD for the first time have an informatively-labeled, long-term treatment option.**

- Major Depressive Disorder (MDD) is one of the most prevalent and serious illnesses in the US, affecting nearly 19 million Americans over the age of 18 in any given year.



- MDD is associated with increased mortality due to suicide and co-morbid general medical conditions including heart disease and stroke.
- Depressed patients use twice the healthcare services as non-depressed patients. Total annual costs of depression in the U.S. exceed \$80 billion including \$30 billion in annual direct treatment costs.
- Studies show that annual healthcare costs for patients with TRD exceed \$40,000 per patient per year, approximately six times the cost of those without TRD.
- Peer reviewed publications of VNS Therapy studies in TRD have demonstrated that adding VNS Therapy to a patient's treatment regimen increases response and remission rates 2 to 4 times over the long term.

We are actively working with public and private payers to provide the peer review evidence supporting the use of VNS Therapy for TRD in developing favorable coverage much like in epilepsy.

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<sup>1</sup> Epilepsy Physician's Manual. VNS Therapy (TM) Pulse Model 102 Generator and VNS Therapy (TM) Pulse Duo Model 102R Generator. August 2002. [http://www.vnstherapy.com/manuals/doc\\_download.asp?docid={CAA703FE-8965-4E47-848E-AAEFB5E142A5}](http://www.vnstherapy.com/manuals/doc_download.asp?docid={CAA703FE-8965-4E47-848E-AAEFB5E142A5})

<sup>2</sup> Depression Physician's Manual. VNS Therapy (TM) Pulse Model 102 Generator and VNS Therapy (TM) Pulse Duo Model 102R Generator. December 2005. [http://www.vnstherapy.com/manuals/doc\\_download.asp?docid={6360242F-390A-4676-BDE0-7034395B834B}](http://www.vnstherapy.com/manuals/doc_download.asp?docid={6360242F-390A-4676-BDE0-7034395B834B})



VAGUS NERVE STIMULATION

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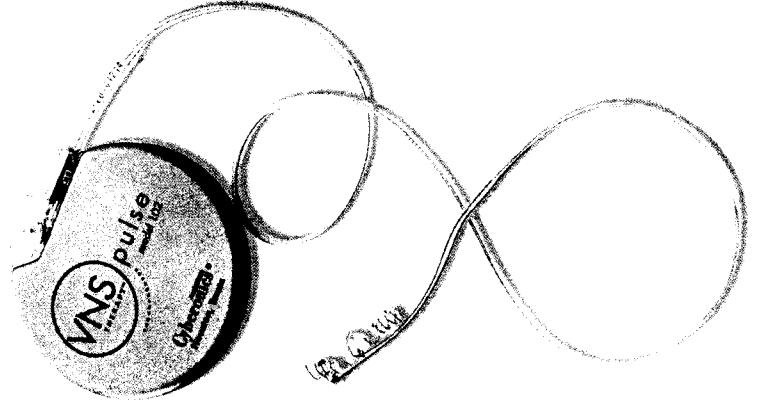
# Meeting with CMS on APC 0039 Implantation Neurostimulator

Cyberonics, Inc  
Shawn Lunney  
Max Gill

Hart Health Strategies  
Vicki Hart

The Moran Company  
Mary Jo Braid-Forbes

October 5, 2006

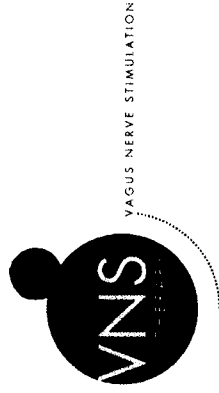




# Background Information for Cyberonics, Inc.

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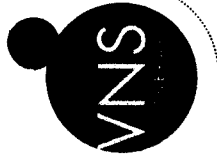
- ◆ **Cyberonics was founded in 1987**
- ◆ **Located in Houston, Texas**
- ◆ **Product: VNS Therapy System**
- ◆ **Indications: Refractory epilepsy and treatment-resistant depression (TRD)**
- ◆ **Publicly traded since February 1993 (CYBX)**
- ◆ **More than 600 US and 20 international employees**
- ◆ **FY05 worldwide sales = \$100 million**
- ◆ **Medicare patients CY2005 = 18.5% of VNS Therapy implants**



# Annual Costs of Epilepsy and Depression

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- ◆ **Epilepsy annual healthcare costs exceed \$12.5 billion and indirect costs surpass \$10 billion**
- ◆ **Depression annual healthcare costs exceed \$80 billion, \$30 billion in direct costs**

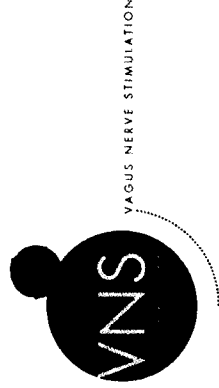


# Medicare < 65 Year Age Group Annual Costs of Epilepsy and Depression

- Major ICD-9 classification breakdowns ranked Mental Disorder spending 4<sup>th</sup> highest at approximately 9% of the total spending
- At disease level, mood disorder ranked 6<sup>th</sup> highest among disease classifications at approximately \$1.2 billion
- Compare with Epilepsy (ranked 86<sup>th</sup>) with \$100 million in spending

Ranking	Type of primary diagnosis on claim	Number of claims	Total dollars	Percent of total
1	Diseases of the Circulatory System	15,069,500	\$ 5,741,882,351	14.2%
2	Diseases of the Genitourinary System	11,783,100	\$ 4,739,144,552	11.7%
3	Diseases of the Respiratory System	12,828,280	\$ 3,513,712,856	8.7%
4	Mental Disorders	15,026,380	\$ 3,500,831,677	8.7%
5	Injury and Poisoning	7,401,560	\$ 3,450,743,308	8.5%
Ranking	Description	ICD-9, first 3 digits	Total of claim amount	Count of claims
1	Chronic Kidney Disease	585	\$ 3,624,267,803	5,498,160
2	Schizophrenic Disorders	295	\$ 1,458,206,985	4,494,040
3	Complication Graft, Device, & implants	996	\$ 1,408,354,337	1,079,780
4	Diabetes Mellitus	250	\$ 1,347,194,931	8,313,640
5	Chronic Ischemic Heart Disease	414	\$ 1,206,584,467	1,767,600
6	Mood Disorder	296	\$ 1,176,266,503	5,289,860
7	Other Diseases of Lung	518	\$ 914,040,189	1,269,900
8	Heart Failure	428	\$ 875,816,885	1,579,260
9	Symptoms- Respiratory & Chest Pain	786	\$ 843,010,466	6,151,400
10	General Symptoms	780	\$ 836,795,900	5,389,040

The Moran Company Analysis using data from the 2004 5% Standard Analytic Files (SAF) this analysis included all seven sources (Inpatient, Outpatient, Part B, Durable Medical Equipment, Home Health, Hospice, and Skilled Nursing facility)



# Annual Medicare Costs for TRD

- ◆ **1.1M (2.8%) of 2004 Medicare beneficiaries had a primary diagnosis of TRD**
- ◆ **103,000 (0.26%) of 2004 Medicare beneficiaries had TRDEH**
- ◆ **In 2004, BEFORE PART D medication expenses, TRDEH cost Medicare \$31,000 to \$40,000/patient/year or a total of \$3.3 billion, including \$1.7 billion per year of hospitalization costs**
- ◆ **At an average VNS Therapy-prescribed age of 53, TRDEH represents \$40 billion of pre-Part D premature benefits exposure (12 years X \$3.3B/year)**

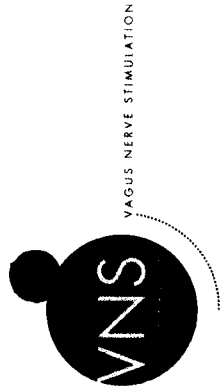
**Annual Cost Based on 2004 5% SAF Medicare Files**

	Total # of Medicare Beneficiaries	Total \$s	
		<65 yrs	>65 yrs
<b>MDD (Primary)</b>	<b>1,120,000</b>	<b>520,000</b>	<b>600,000</b>
<b>4 TRD DX + IP</b>	<b>80,000</b>	<b>46,000</b>	<b>34,000</b>
<b>TRD + ECT</b>	<b>13,000</b>	<b>5,000</b>	<b>8,000</b>
<b>TRD + ECT + IP</b>	<b>10,000</b>	<b>4,000</b>	<b>6,000</b>
		<b>\$17,000</b>	<b>\$20,000</b>
		<b>\$31,000</b>	<b>\$35,000</b>
		<b>\$33,000</b>	<b>\$34,000</b>
		<b>\$40,000</b>	<b>\$39,000</b>

DX=Diagnosis, IP=Inpatient, ECT= Electroconvulsive Therapy, SAF= Standard Analytic Files

Moran analysis of the 5% standard analytic file for Medicare claims in 2004.

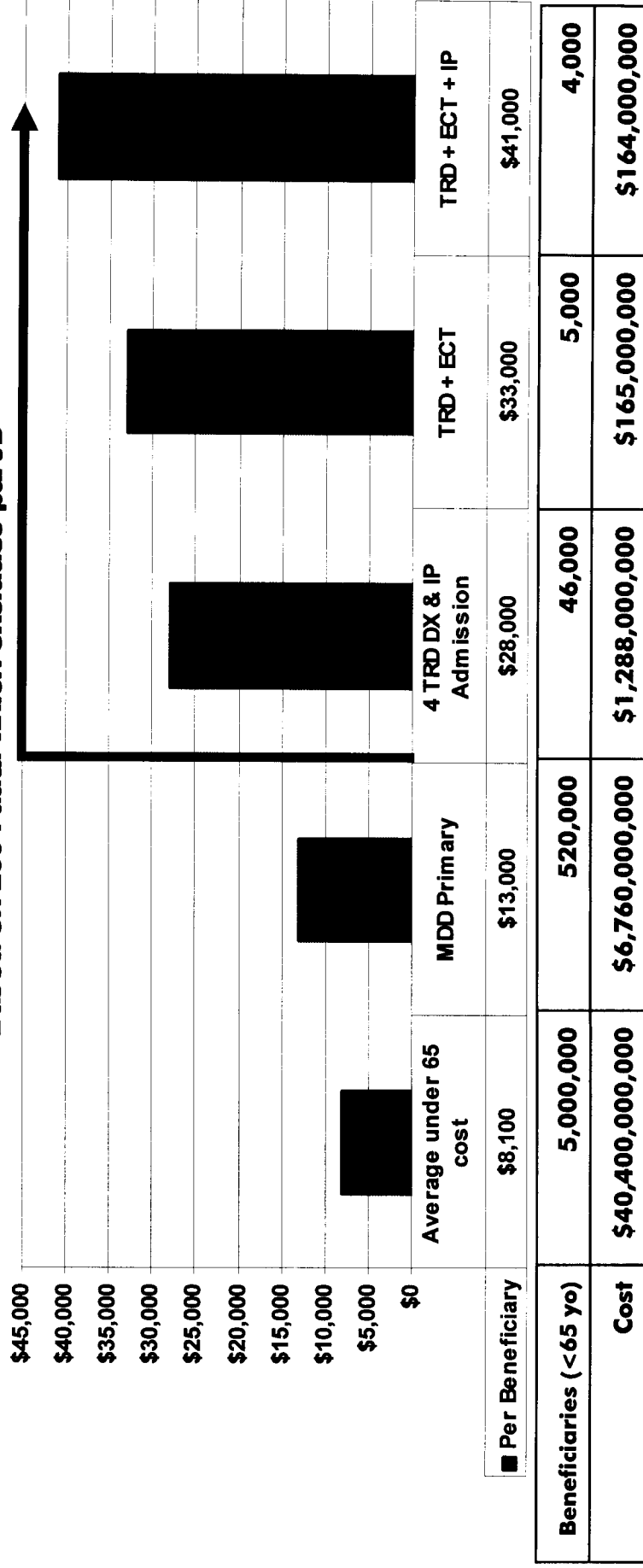
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# TRDEH Results in Premature Medicare Beneficiaries

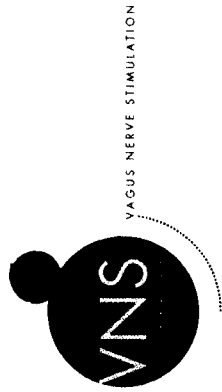
**Under age 65 Medicare beneficiaries with TRDEH consume 4 to 5 times the average annual costs of under age 65 beneficiaries**

**Under 65 Years of Age: Direct Medicare Beneficiary Cost Comparison**  
Based on 2004 data which excludes part D



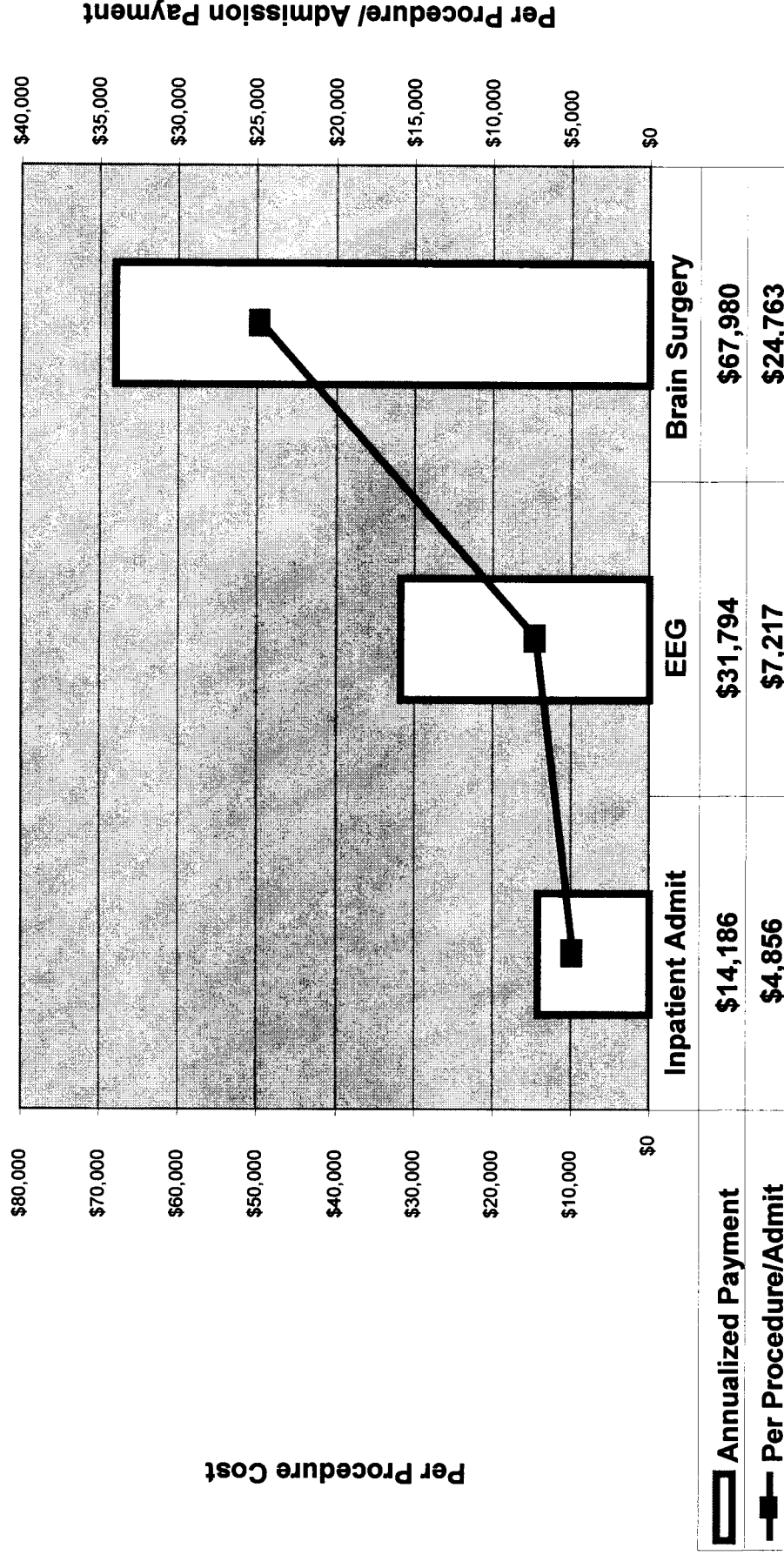
Moran analysis of the 5% standard analytic file for Medicare claims in 2004.

**Confidential – Do Not Distribute**



# The same story as in epilepsy: Where VNS Therapy is working

Medicare Epilepsy Beneficiary Payment for Under 65 year based on 2004



The Moran Company Analysis using data from the 2004 5% Standard Analytic Files (SAF) this analysis included all seven sources (Inpatient, Outpatient, Part B, Durable Medical Equipment, Home Health, Hospice, and Skilled Nursing facility)

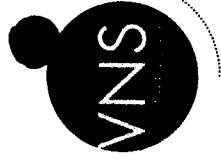




# Description VNS Therapy

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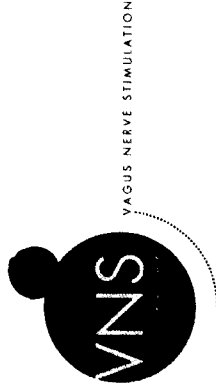
- ◆ **Initial implant consists of neurostimulator/neuroelectrode**
- ◆ **~70% of all patients elect replacement upon battery depletion**
- ◆ **Replacement = neurostimulator only**
- ◆ **~\$15,000 cost device & procedure**



# Description of Issue

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- ◆ 2007 proposed cuts for APC 0039 reduce payment by 6.7%
- ◆ The decreases would be the Fourth reduction in 5 years
- ◆ 31% reduction in rates from 2002 to 2006
- ◆ VNS Therapy claims account for only 15% of the single claims
- ◆ Coding is poor
- ◆ Charges are low
- ◆ Cost-to-charge ratio (CCR) and wage index magnify the problem



# Historical and Proposed Payment Rates for APC 0039

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◆ CY 2002 =	\$15,489	
◆ CY 2003 =	\$11,876	-23.3%
◆ CY 2004 =	\$12,832	+ 8.4%
◆ CY 2005 =	\$12,532	- 2.3%
◆ CY 2006 =	\$11,603	- 7.4%
◆ CY 2007 (Proposed) =	\$10,829	- 6.7%

***Total decrease in proposed payment  
rates of 31% since CY 2002 and  
15.6% since CY 2004***

# Lack of Consistency on “C” Codes for Devices

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**CMS decision to use only correctly coded claims that include the appropriate C-code for all device-related APCs is a step in the right direction.**

- ◆ **CY 2000 - pass thru on specific device C codes (C1048)**
- ◆ **CY 2001 – pass thru on Category C codes (C1048 becomes C1767)**
- ◆ **CY 2002 – pass thru on C1767**
- ◆ **CY 2003 – C codes deleted**
- ◆ **CY 2004 – C codes optional**
- ◆ **CY 2005 – C codes requirement was phased-in but only enforced on specific APCs**
- ◆ **CY 2006 – C codes required but only enforced on device dependent APCs**



# Data: Highly Comparable Data Set

## APC 0039

<b>CMS</b> <b>Claims – 610</b> <b>Median - \$10,866</b>	<b>Moran Company</b> <b>Claims – 720</b> <b>Median - \$11,332</b>
<b>% Variance</b> <b>Claims 17%</b> <b>Median 4%</b>	



# Historical and Proposed Payment Weight for APC 0039

Significant impact of methodology on the payment weight history which has reduced 42% since 2002 and 25% since 2004.

Particular	Description	2004	2005	2006	2007 Proposed
Payment Weight	HCPCS- 61885	235.1866	219.9203	194.9690	175.9328
VNS Therapy List Price	Model 102 & 102R	\$11,999	\$11,999	\$11,999	
APC 0039	Payment Rate	\$12,832	\$12,532	\$ 11,603	\$10,829

# The Impact of Weight Index on Devices based APC's

The weight index on device based APCs is significant especially for APCs where supply cost is over 75% or higher.

<b>APC Cost Breakdown</b>	<b>0039</b>	<b>0225</b>
<b>Proposed APC Payment</b>	<b>\$10,829</b>	<b>\$14,413</b>
<b>Supply Cost</b>	<b>81.0%</b>	<b>78.0%</b>
<b>Rooms (OR, treatment, obs, recovery, ASC)</b>	<b>16.0%</b>	<b>18.5%</b>
<b>Anesthesia</b>	<b>2.0%</b>	<b>2.0%</b>
<b>Pharmacy</b>	<b>1.0%</b>	<b>1.5%</b>



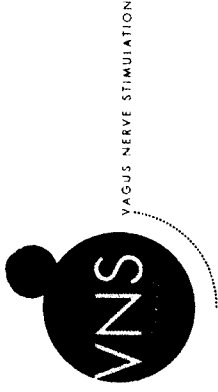
## Wage Index APC 0039

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- ◆ **For the 298 hospitals submitting depression and epilepsy claims under APC 0039, how many hospital's wage adjusted payment will exceed \$15,000?**
- ◆ **Zero hospitals cover device & procedure**
- ◆ **14 hospitals less than device & procedure**
- ◆ **284 hospitals less than device**

See Supporting Documents (Item 2) for a list of hospitals with wage index breakdown





# Charge Compression Impact on Device Based APC's 0039

Median Cost of the device on the single claim used for the rate setting is 29% below the device cost. The systematic under estimate of the cost of high cost devices occur because charges for high cost items are marked up at lower percentage than low cost items. This has been called "Charge Compression" and been documented for pharmaceuticals\* (see Supporting Documents – Item 3).

Particular	APC 0039
Average Charges	\$29,357
Average Cost	\$10,899
Median Charges	\$25,990
Median Cost	\$8,449

29% below the device cost

\* MJ Braid, K Forbes and DW Moran, "Pharmaceutical Charge Compression under the Medicare Outpatient Prospective Payment System" Journal of Health Care Finance Spring 2004, p21-33.



# Summary

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- ◆ **Proposed payment APC 0039 is not adequate to promote patient access**
- ◆ **Single claims focusing on minority within APC**
- ◆ **VNS Therapy claims not represented, frequency/volume extremely low**
- ◆ **Medicare volume is estimated at ~ 18.5% of ~5700 VNS Therapy implants = over 1,050 implants**
- ◆ **Median Cost of the device on the single claim used for the rate setting is 29% below the device cost**
- ◆ **Device/supply lines did not have sufficient average costs**
- ◆ **Zero hospitals cover device & procedure cost for APC 0039**



VAGUS NERVE STIMULATION

## Recommendations

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- ◆ **Stabilize Rates: maintain payment rate at 100% of 2006 rates + annual update factor applied to all APCs**
- ◆ **Utilize external data to validate rates and justify changes to medians**
- ◆ **Special consideration for device based APCs where supply cost is over 75% of the proposed APC rate**