

# Health Technology Assessment

## Vagal Nerve Stimulators: Epilepsy

### Public Comments and Responses

August 3<sup>rd</sup>, 2009

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## Hayes Inc. RESPONSE TO PUBLIC COMMENTS

*Hayes Inc. is an independent vendor contracted to produce evidence assessment reports for the WA HTA program on behalf of The MED Project at Oregon State Health Science University. For transparency, all comments received during the comments process are included. However, comments related to program decisions, process, or other matters not pertaining to the report are acknowledged through inclusion, but are not within the scope of response for report accuracy and completeness.*

### Response to industry comments

#### Cyberonics

1. *Section of the letter entitled “Healthcare Utilization Reduced with VNS Therapy” (cited references included Bernstein et al., 2007 and Holmes et al., 2004)*

The Bernstein et al. (2007) article is described in the Economic Evaluations section of the report. We added additional information from this study to this section to address the manufacturer’s feedback.

Data from the Holmes et al. (2004) article are presented in Table 1. This article does not present data directly pertaining to healthcare utilization and thus does not meet criteria for inclusion in the Economic Evaluations section.

2. *Section of the letter entitled “Nonadherence to AEDs Increases Healthcare Costs” (cited references were Faught et al. 2008 and Faught et al. 2009)*

The references supplied by the manufacturer address how nonadherence to antiepileptic drugs increases healthcare costs. However, these references do not contain economic evaluation data directly pertaining to the use of VNS therapy for epilepsy and are thus not included in the Economic Evaluations section.

3. *Section of the letter entitled “Depression” (cited reference of Sperling et al. 2009)*

The data reported by Sperling et al. (2009) is discussed in the Economic Evaluations section of the VNS for Depression report.

## PUBLIC COMMENTS

Cyberonics = 3 pages

July 24, 2009



Ms. Leah Hole-Curry, JD  
Director – Health Technology Assessment  
Health Care Authority  
676 Woodland Square Loop SE  
P.O. Box 42712  
Olympia, WA 98504-2712

**RE: HTA Draft Report – Vagus Nerve Stimulation (VNS Therapy™)**

Dear Ms. Hole-Curry:

Cyberonics, Inc. appreciates this opportunity to comment on the Draft Report from the Washington HTA. We know that VNS Therapy offers cost-effective and unique therapeutic benefits to patients whose epilepsy or depression is not sufficiently controlled with drugs.

## **Epilepsy**

### **Healthcare Utilization Reduced With VNS Therapy**

We know that healthcare utilization of patients whose seizures were not controlled decreased when those patients received VNS Therapy.

As we previously submitted, Bernstein, et al (2006) demonstrated that patients implanted with VNS Therapy experienced significant decreases in healthcare utilization.<sup>1</sup>

- A healthcare utilization study of 138 consecutive VNS patients from Kaiser Permanente compared the fourth quarter of year 4 after implantation with average utilization during the year before implantation and found
  - 91% decrease in outpatient visits
  - 99% decrease in emergency department (ED) visits
  - 67% decrease in the length of hospital stays
  - 70% decrease in hospital admissions

These decreases in healthcare utilization applied to the entire group, irrespective of changes in seizure frequency.

Many patients with uncontrolled seizures experience drop seizures that lead to injuries and result in healthcare utilization of ED visits and hospitalizations. VNS Therapy has been shown to decrease the number of drop seizures experienced by patients with epilepsy.<sup>2</sup>

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<sup>1</sup> Bernstein AL et al. Vagus nerve stimulation therapy for pharmaco-resistant epilepsy: effect on health care utilization. *Epil Behav* 2007;10:134-137.

<sup>2</sup> Holmes MD et al. Effect of vagus nerve stimulation on adults with pharmaco-resistant generalized epilepsy syndromes. *Seizure* 2004;13:340-345.

- Holmes et al (2004) studied 16 patients with pharmaco-resistant generalized epilepsy syndromes who received VNS Therapy. The study concluded, “The benefits of reduced seizure frequency and reduced risk of injury merit consideration of VNS Therapy for patients with pharmaco-resistant generalized seizure syndromes.”
  - Patients experienced a statistically significant overall median seizure frequency reduction of 43.3%
  - Types of seizures that may involve a fall or collapse decreased with reductions in the frequency of
    - Myoclonic seizures: 60% reduction
    - Tonic seizures: 75% reduction
    - Atonic seizures: 99% reduction
    - Clonic seizures: 87%

### **Nonadherence to AEDs Increases Healthcare Costs**

Medication nonadherence in patients with refractory epilepsy can result in major increase in morbidity and mortality. Serious health consequences can result from nonadherence with seizure medication, presenting additional challenges to clinicians treating patients with epilepsy.<sup>3</sup>

Faught et al (2008) evaluated claims data from over 33,000 patients comprising 388,564 quarters from 3 state Medicaid programs. They reported that patients did not adhere to their AED regimens during 26% of those quarters. The study also showed that Nonadherence to AED's:

- Contributes significantly to mortality and other serious clinical events
- Increases the risk of death by more than a 3-fold
- Is associated with a higher incidence of fractures and injuries due to motor vehicle accidents
- Increases significantly healthcare utilization
  - 16% increase in ED visits
  - 39% increase in hospitalizations
  - 76% increase in inpatient days

“In the interest of both patient well being and costs, state Medicaid programs should have a vested interest in strategies aiming to reduce AED nonadherence.”<sup>4</sup> Clinicians, payers, and drug innovators should promote treatment strategies for epilepsy that offer an increased likelihood of adherence.<sup>3</sup>

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<sup>3</sup> Faught E, et al. Nonadherence to antiepileptic drugs and increased mortality: Findings from the RANSOM study. *Neurology* 2008; 71 (20): 1572-1578.

<sup>4</sup> Faught E, Weiner J, Guerin A. Impact of nonadherence to antiepileptic drugs on health care utilization and costs: Findings from the RANSOM study. *Epilepsia*. 2009;50(3):501-509.

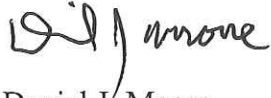
As a proven adjunctive treatment for patients with refractory epilepsy, VNS Therapy's automatic delivery ensures adherence for patients whose seizures are not controlled by anti-epileptic medications only.

## **Depression**

- Sperling W et al (2009) studied 9 patients with treatment-resistant depression who received VNS Therapy
  - Average length of hospitalization of 65 days per year, averaged over the 5 years before implantation, was significantly reduced in the first post-implantation year to an average of 44 days, a savings of 7350€.
  - Average number of outpatient consultations was reduced from 33 to 14 per year, a savings of 570€.
  - Average number of medications was reduced from 4.1 to 2.7 per year, a savings of 600€
  - Average savings for the year after VNS implantation was 1905€, roughly \$2,700

I hope you find these materials helpful with the technology evaluation of VNS Therapy. If you have any questions or require any additional information on the treatment of VNS Therapy of either refractory epilepsy or treatment-resistant depression, please feel free to e-mail Stan Jackson, National Director of Reimbursement at [Stanley.Jackson@cyberonics.com](mailto:Stanley.Jackson@cyberonics.com).

With best regards,



Daniel J. Moore  
President & Chief Executive Officer