



California
Department of
Health Services

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TO: ALL COUNTY CALIFORNIA CHILDREN SERVICES (CCS) PROGRAM
ADMINISTRATORS, MEDICAL CONSULTANTS, AND STATE
CHILDREN'S MEDICAL SERVICES (CMS) BRANCH STAFF

SUBJECT: VAGAL NERVE STIMULATOR (VNS) IMPLANTATION

I. PURPOSE

The purpose of this numbered letter is to transfer responsibility for review of VNS implantation requests from the CMS Branch Office to CCS County and CMS Branch Regional Offices, and to provide guidance on the authorization of VNS implantations.

II. BACKGROUND

N.L.: 09-0899 provided policy guidance on new medical treatment modalities which required authorization by the CMS Branch Office. VNS implantations were included in N.L.: 09-0899 as one of these new medical treatment modalities/interventions. This numbered letter provides policy and policy implementation for the authorization of VNS implantations by CCS County and CMS Branch Regional Offices.

Children with epilepsy refractory to medical therapy or who experience intolerable side effects from anticonvulsant medication may benefit from placement and activation of a VNS (Cyberonics, Houston, Texas). The VNS was approved by the Food and Drug Administration (FDA) in July 1997, for use as adjunctive therapy for people 12 years of age and older with partial-onset seizures refractory to medical therapy.

Since 1997, VNS therapy has been shown in published studies to be effective in children under 12 years of age and is a benefit of Medi-Cal and CCS for children and adults. Dr. Jerome Murphy and colleagues have studied VNS therapy in children (Murphy J., et al. (1999) Left VNS: experience in 60 children with pharmacoresistant epilepsy. *Journal of Pediatrics* 134:563-6). They report that after three months of VNS

therapy in 60 children (3.5 to 18 years), the seizure rate was reduced by a median of 22 percent, after 6 months by 31 percent, after 12 months by 34 percent, and after 18 months by 42 percent.

Another study by Dr. Sandra Helmers and colleagues evaluated children treated at six centers with VNS therapy and reported average seizure reduction of 36.1 percent at 3 months and 44.7 percent at 6 months (Helmers S., et al. (2001) Vagus nerve stimulation therapy in pediatric patients with refractory epilepsy: retrospective study. *Journal of Child Neurology* 16:843-8).

The VNS system consists of a battery-operated generator and a bipolar lead. It is implanted subcutaneously (usually in the infraclavicular fossa) and attached to the left vagus nerve in the neck. Use of the right vagus nerve has been associated with bradycardia; therefore, the left vagus nerve is preferred. The battery has an average life of 5 to 12 years, depending on the model and stimulation settings. The VNS, in addition to providing programmable stimulation, can be turned on intermittently by use of an external magnet swiped over the generator in an effort to abort a seizure that has started. The exact mechanism of action of the VNS as an antiepileptic device is uncertain, but involves complex neurologic and chemical brain mediators.

III. POLICY

Effective the date of this letter, CCS County and Regional Offices shall authorize VNS implantation when all of the following are met:

- A. Child meets program eligibility for CCS for treatment services; and
- B. there is a request for VNS implantation and a medical report recommending VNS implantation from a CCS approved neurosurgeon, or other CCS approved surgeon (e.g., thoracic surgeon, vascular surgeon, pediatric surgeon, otolaryngologist) with pediatric expertise and with experience in VNS implantation (having performed at least three VNS implantations in children);
- C. there is either a CCS approved neurologist's report recommending VNS implantation or there is indication that a CCS approved neurologist referred the child to the surgeon for consideration of VNS implantation;
- D. there is documentation of intractable seizures even with anticonvulsant medications. "Intractable" is defined as at least one seizure per month which results in unacceptable interference with the child's ability to function in spite of

the use of appropriate anticonvulsants at appropriate dosages for the child's seizure type;

- E. there is not a seizure focus in the brain that could be surgically treated or the family refuses surgery to treat a seizure focus; and
- F. if the child is less than two years of age, the CCS approved surgeon is affiliated with a CCS approved tertiary hospital.

IV. POLICY IMPLEMENTATION

Authorization:

- A. The procedure codes used to bill for the VNS implantation are not included in any CCS Service Code Grouping (SCG) and need to be individually authorized to the surgeon.
- B. The surgeon should request the appropriate codes which will include the code used for VNS placement and the codes for surgical implantation of the electrodes. The surgeon should also be authorized SCG 01 on the same Service Authorization Request. SCG 01 will cover, for example, the visit, room charges, supplies, medications anesthesia, and/or sedation.
- C. VNS implantation is generally done as an outpatient procedure because the VNS device is not separately reimbursed when the recipient is an inpatient. If the surgeon/hospital is requesting inpatient placement, then the surgeon/hospital should be informed that they will not be able to be reimbursed for the device.
- D. If there is not an authorization in place for a CCS approved neurologist, then an authorization shall be issued to a CCS approved neurologist who will follow-up and make adjustments to the VNS. All the necessary codes for analyzing and making adjustments are included in SCG 01.

If you have any questions regarding this numbered letter, please contact your state regional office medical consultant.

Original Signed by Marian Dalsey, M.D., M.P.H.

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Children's Medical Services Branch