

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 70	Date: JUNE 22, 2007
	Change Request 5612

Subject: Vagus Nerve Stimulation (VNS) for Resistant Depression

I. SUMMARY OF CHANGES: CMS has determined that VNS is not reasonable and necessary for the treatment of resistant depression.

This addition/revision of section 160.18 of Pub.100-03 is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare Appeals Council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

New / Revised Material

Effective Date: May 4, 2007

Implementation Date: July 23, 2007

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	Chapter / Section / Subsection / Title
R	1/Table of Contents
R	1/160.18/Vagus Nerve Stimulation (VNS)

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2007 operating budgets.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B	D M E	F I	C A R R E R	D M R C	R E H I	Shared-System Maintainers				OTHER
								F I S S	M C S	V M S	C W F	
	continue to deny VNS claims for resistant depression as specified in section 160.18.C of Pub 100-03, Medicare National Coverage Determination Manual.											
5612.2.1	Effective for claims with dates of service on or after May 4, 2007, contractors shall continue to reject VNS claims for resistant depression as specified in section 160.18.C of Pub 100-03, Medicare National Coverage Determination Manual.	X		X								
5612.3	Contractors shall continue to pay VNS claims for medically refractory partial onset seizures as specified in section 160.18.B of Pub 100-03, Medicare National Coverage Determination Manual.	X		X	X							
5612.3.1	Contractors shall continue to identify medically refractory partial onset seizures when either of the following ICD-9-CM diagnosis codes appears on the claim: 345.41 345.51	X		X	X							
5612.4	Contractors shall continue to deny VNS claims for all other types of seizures as specified in section 160.18.C of Pub 100-03, Medicare National Coverage Determination Manual.	X			X							
5612.4.1	Contractors shall continue to reject VNS claims for all other types of seizures as specified in section 160.18.C of Pub 100-03, Medicare National Coverage Determination Manual.	X		X								
5612.5	Contractors shall advise (via the MLN article) that physicians and hospitals will be liable for noncovered VNS procedures unless they issue an appropriate advance beneficiary notice (ABN).	X		X	X							
5612.5.1	Contractors shall advise physicians and hospitals to include the following language in the ABN: Items or Service Section: "Vagas Nerve Stimulation".	X		X	X							

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B	D M E	F I	C A R R I C E R	D M R R I	R H	Shared-System Maintainers				OTHER
		M A C	M A C					F I S S	M C S	V M S	C W F	
	Because Section: "As specified in section 160.18 of Pub.100-03, Medicare National Coverage Determination Manual, Medicare will not pay for this procedure as it is not a reasonable and necessary treatment for (select either "your type of seizure disorder" or "resistant depression.")											
5612.6	Contractors shall use Medicare Summary Notice (MSN) 16.10 "Medicare does not pay for this item or service." Spanish translation: "Medicare no paga por este artículo o servicio." Contractors shall use Claim Adjustment Reason Code 50: "These are non-covered services because this is not deemed a "medical necessity" by the payer."	X		X	X							
5612.6.1	Contractors shall use Remittance Advice Remark Codes M27 or M38 dependant on liability.	X		X	X							
5612.6.2	Contractors shall use Group Code CO or PR dependant on liability.	X		X	X							
5612.7	Contractors need not search their files to retract payment for claims already paid. However, contractors shall adjust claims brought to their attention.	X		X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B	D M E	F I	C A R R I C E R	D M R R I	R H	Shared-System Maintainers				OTHER
		M A C	M A C					F I S S	M C S	V M S	C W F	
5612.8	A provider education article related to this	X		X	X							

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B M A C	D M E M A C	F I M A C	C A R R I E R	D M R R I C	R E H I C	Shared-System Maintainers				OTHER
							F I S	M C S	V M S	C W F		
	instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.											

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use the space below:

V. CONTACTS

Pre-Implementation Contact(s):

National Coverage: Beverly Lofton, beverly.lofton@cms.hhs.gov or 410-786-7136
 Provider Claims Processing: Bill Ruiz, william.ruiz@cms.hhs.gov or 410-786-9283
 Physician Claims Processing: April Billingsley, april.billingsley@cms.hhs.gov or 410-786-0140

Post-Implementation Contact(s): Regional Office

VI. FUNDING

A. TITLE XVIII Contractors:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

B. Medicare Administrative Contractors:

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare National Coverage Determinations Manual

Chapter 1, Part 2 (Sections 90 – 160.25)

Coverage Determinations

Table of Contents

(Rev. 70, 06-22-07)

160.18 - Vagus Nerve Stimulation (VNS) (Effective May 4, 2007)

160.18 - Vagus Nerve Stimulation (VNS) (Effective May 4, 2007)
(Rev. 70, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

A. General

VNS is a pulse generator, similar to a pacemaker, that is surgically implanted under the skin of the left chest and an electrical lead (wire) is connected from the generator to the left vagus nerve. Electrical signals are sent from the battery-powered generator to the vagus nerve via the lead. These signals are in turn sent to the brain. FDA approved VNS for treatment of refractory epilepsy in 1997 and for resistant depression in 2005.

B. Nationally Covered Indications

Effective for services performed on or after July 1, 1999, VNS is reasonable and necessary for patients with medically refractory partial onset seizures for whom surgery is not recommended or for whom surgery has failed.

C. Nationally Non-Covered Indications

Effective for services performed on or after July 1, 1999, VNS is not reasonable and necessary for all other types of seizure disorders which are medically refractory and for whom surgery is not recommended or for whom surgery has failed.

*Effective for services performed on or after May 4, 2007, VNS is not reasonable and necessary for resistant depression. (Information on the national coverage analysis leading to this determination can be found at:
http://www.cms.hhs.gov/mcd/viewnca.asp?where=index&nca_id=195.)*

D. Other

Also see §160, “Electrical Nerve Stimulators.”

(This NCD last reviewed May 2007.)