

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1271	Date: JUNE 22, 2007
	Change Request 5612

Subject: Vagus Nerve Stimulation (VNS) for Resistant Depression

I. SUMMARY OF CHANGES: CMS is issuing formalized instructions for processing claims involving VNS for treatment of refractory epilepsy and resistant depression.

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
N	32/Table of Contents
N	32/200.1/General
N	32/200.2/ICD-9 Diagnosis Codes for Vagus Nerve Stimulation (Covered since DOS on and after July 1, 1999)
N	32/200.3/Carrier/MAC Billing Requirements
N	32/200.4/Fiscal Intermediary Billing Requirements
N	32/200.5/Medicare Summery Notices (MSN), Remittance Advice Remark Codes (RARC) and Claims Adjustment Reason Code (CARC) Messages
N	32/200.6/Advance Beneficiary Notice and HINN Information

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 I	R H	Shared-System Maintainers				OTHER
								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 I	R H	Shared-System Maintainers				OTHER
								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 I E R	C A R R 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 Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

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200.3 Carrier/MAC Billing Requirements

200.4 Fiscal Intermediary Billing Requirements

200.5 Medicare Summary Notice (MSN), Remittance Advice Remark Code (RARC) and Claims Adjustment Reason Code (CARC) Messages

200.6 Advance Beneficiary Notice and HINN Information

200 - Billing Requirements for Vagus Nerve Stimulation (VNS)

200.1 - General

(Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

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 1999. Further coverage guidelines can be found in the National Coverage Determination Manual (Publication 100-03), Chapter 1, Section 160.18. Since the HCPCS codes for VNS can also be used for other indications, contractors must determine if the service being billed are for VNS and make a determination to pay or deny. CMS guidance on payment is listed below.

200.2 - ICD-9 Diagnosis Codes for Vagus Nerve Stimulation (Covered since DOS on and after July 1, 1999)

(Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

One of the following diagnosis codes must be reported, as appropriate, when billing for Vagus Nerve Stimulation:

- 345.41 Localization-related (focal) (partial) epilepsy and epileptic syndromes with complex partial seizures with intractable epilepsy*
- 345.51 Localization-related (focal) (partial) epilepsy and epileptic syndromes with simple partial seizures with intractable epilepsy*

200.3 - Carrier/MAC Billing Requirements

(Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

Effective for services performed on or after July 1, 1999, contractors are accepting claims submitted for vagus nerve stimulation for epilepsy and recurrent seizures.

Effective for services performed on or after July 1, 1999, CMS determined that vagus nerve stimulation is not reasonable and necessary for all other types of seizures which are refractory and for whom surgery is not recommended or for whom surgery has failed.

Effective for services performed on or after May 4, 2007, contractors will deny claims submitted for vagus nerve stimulation for resistant depression. Contractors need to update their local coverage determination policy to include this new NCD determination. There is no coverage for vagus nerve stimulation for patient with resistant depression.

200.4 - Fiscal Intermediary Billing Requirements

(Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

Effective for services performed on or after July 1, 1999, contractors are accepting claims submitted for vagus nerve stimulation for epilepsy and recurrent seizures.

Effective for services performed on or after July 1, 1999, CMS determined that vagus nerve stimulation is not reasonable and necessary for all other types of seizures which are refractory and for whom surgery is not recommended or for whom surgery has failed.

Effective for services performed on or after May 4, 2007, contractors will reject claims submitted for vagus nerve stimulation for resistant depression.

200.5 - Medicare Summary Notice (MSN), Remittance Advice Remark Code (RARC) and Claim Adjustment Reason Code (CARC) Messages (Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

The following messages are used by Medicare contractors when denying non-covered VNS services:

- *MSN: 16.10 "Medicare does not pay for this item or service."*
- *CARC: 50 "These are non-covered services because this is not deemed a "medical necessity" by the payer."*

The following R.ARC messages can be used depending on liability:

- *M27 Alert: The patient has been relieved of liability of payment of these items and services under the limitation of liability provision of the law. You, the provider, are ultimately liable for the patient's waived charges, including any charges for coinsurance, since the items or services were not reasonable and necessary or constituted custodial care, and you knew or could reasonably have been expected to know, that they were not covered.*

You may appeal this determination. You may ask for an appeal regarding both the coverage determination and the issue of whether you exercised due care. The appeal request must be filed within 120 days of the date you receive this notice. You must make the request through this office.

Or

- *M38 The patient is liable for the charges for this service as you informed the patient in writing before the service was furnished that we would not pay for it, and the patient agreed to pay.*

Contractors will also include group code CO (contractual obligation) or PR (patient responsibility) depending on liability.

***200.6 - Advance Beneficiary Notice and HINN Information
(Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)***

Physicians are liable for non-covered VNS procedures unless they issue an appropriate advance beneficiary notice (ABN). The following language should be included in the ABN:

*Items or Service Section:
“Vagas Nerve Stimulation”.*

*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.”)*

Note that the ABN is the appropriate notice for Part B services and is valid whether the language above is inserted or not.