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NEWS FLASH	If you treat a Medicare Advantage enrolled beneficiary and you have questions about their Medicare Advantage Plan, you may wish to contact that plan. A plan directory and MA claims processing contact directory are available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html on the CMS website. CMS updates this site on a monthly basis.

MLN Matters Number: MM5612 | Related Change Request (CR) #: 5612

Related CR Release Date: June 22, 2007 | Effective Date: May 4, 2007

Related CR Transmittal #: R1271CP and R70NCD | Implementation Date: July 23, 2007

Vagus Nerve Stimulation (VNS) for Resistant Depression

Note: This article was updated on June 20, 2013, to reflect current Web addresses. All other information remains unchanged.

Provider Types Affected

Physicians, hospitals, and other providers who bill Medicare carriers, fiscal intermediaries (FI), and Medicare Administrative Contractors (A/B MACs) for vagus nerve stimulation procedures.

Provider Action Needed

CR 5612, from which this article is taken, announces that CMS is issuing a national (non) coverage determination (NCD) stating that vagus nerve stimulation (VNS) is not reasonable and necessary for the treatment of resistant depression.

Therefore, effective May 4, 2007, CMS will deny VNS claims when resistant depression is the indication for the procedure.

Background

Vagus Nerve Stimulation (VNS) utilizes a battery-powered pulse generator (similar to a pacemaker), that is surgically implanted under the skin of the left chest and an electrical lead (wire) connected from the generator to the left vagus nerve; through which electrical signals are sent to the brain.

In 1999, the Centers for Medicare & Medicaid Services (CMS) issued a national coverage determination (NCD) that (effective for services performed on or after July 1, 1999) VNS is reasonable and necessary for patients with medically refractory partial onset seizures when surgery is not recommended or has failed.

On August 7, 2006, a formal request to reconsider resistant depression as an additional indication initiated a national coverage analysis, and CR 5612, from which this article is taken, communicates the findings of that analysis. Specifically in CR5612, CMS announces that it has reviewed the evidence and has concluded that vagus nerve stimulation (VNS) is not reasonable and necessary for the treatment of resistant depression under §1862(a)(1)(A) of the Social Security Act, and has issued a national noncoverage determination for this indication.

Therefore, effective May 4, 2007, CMS will deny or reject, as appropriate, VNS claims for resistant depression, as specified in the *Medicare National Coverage Determinations Manual*, Chapter 1, Part 2 (Sections 90 – 160.25 (Coverage Determinations)), Section 160.18 (Vagus Nerve Stimulation (VNS), Subsection C (Nationally Non-Covered Indications).

CR5612 contains some specifics about VNS coverage that you should be aware of:

- Carriers, FIs, and A/B MACs will continue to pay VNS claims for medically refractory partial onset seizures as specified in section 160.18.B of the *Medicare National Coverage Determination Manual*, identified when any of the following ICD-9-CM diagnosis codes appear on the claim:
    - 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), or
- Carriers, FIs, and A/B MACs will continue to deny/reject VNS claims for all other types of seizures as specified in section 160.18.C of the *Medicare National Coverage Determination Manual*.
- Physicians and hospitals will be liable for noncovered VNS procedures unless they issue an appropriate advance beneficiary notice (ABN), which should include the following language:

- Items or Service Section: "Vagus 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.")"

- When denying non-covered VNS services carriers, FIs, and A/B MACs will use the following messages:
  - Medicare Summary Notice (MSN) 16.10 "Medicare does not pay for this item or service;"
  - Claim Adjustment Reason Code (CARC) 50: "These are non-covered services because this is not deemed a "medical necessity" by the payer;" and
  - One of the following Remittance Advice Remark Code (RARC) messages, 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."
- Medicare carriers, FIs, and A/B MACs will also include group code CO (contractual obligation) or PR (patient responsibility) depending on liability.
- Carrier, FIs, and A/B MACs will not search their files to retract payment for claims already paid, but will adjust claims brought to their attention.

Finally, you should remember that this addition/revision of section 160.18 of the *Medicare National Coverage Determination Manual* 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.).

Additional Information

You can find the official instruction issued to your carrier, FI, or A/B MAC about the VNS NCD by looking at the two transmittals for CR5612. The first transmittal is at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R70NCD.pdf on the CMS website. That transmittal contains the amended Medicare National Coverage Determinations Manual, Chapter 1, Part 2 (Sections 90 – 160.25 -- Coverage Determinations), Section 160.18 (Vagus Nerve Stimulation (VNS), Subsection C (Nationally Non-Covered Indications). The second transmittal is at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1271CP.pdf and it contains the amended Medicare Claims Processing Manual, Chapter 32 (Billing Requirements for Special Services), Section 200 (Billing Requirements for Vagus Nerve Stimulation (VNS).

If you have any questions, please contact your carrier, FI, or A/B MAC at their toll-free number, which may be found at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html on the CMS website.