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National Coverage Determination (NCD) 160.18 Vagus Nerve Stimulation (VNS)

MLN Matters Number: MM11461 Revised
Related Change Request (CR) Number: 11461
Related CR Release Date: June 23, 2020
Effective Date: February 15, 2019
Related CR Transmittal Number: 10199NCD
Implementation Date: July 22, 2020

Note: We revised this article to reflect the revised CR11461, issued on June 23, 2020. The CR revision clarified instructions for the MACs and changed the implementation date to July 22, 2020. In the article, we changed the implementation date, the CR release date, transmittal number, and the web address of the CR. All other information remains the same.

PROVIDER TYPE AFFECTED

This MLN Matters Article is for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 11461 notifies MACs that effective for claims with dates of service on or after February 15, 2019, the Centers for Medicare & Medicaid Services (CMS) will cover Food and Drug Administration (FDA) approved vagus nerve stimulation (VNS) devices for treatment resistant depression (TRD) through Coverage with Evidence Development (CED) for patients that meet specific conditions of coverage and criteria. Please make sure your billing staffs are aware of this change.

BACKGROUND

VNS is an example of neurostimulation therapy, which targets specific regions of the brain. VNS provides indirect modulation of brain activity through the stimulation of the vagus nerve. The implanted VNS system includes a pulse generator, which is surgically inserted underneath the skin of the chest. For treatment of TRD, it is subcutaneously connected to an electrode attached to the left vagus nerve in the neck.

KEY POINTS

Section 160.18 of the "Medicare National Coverage determination Manual" establishes conditions of coverage for VNS.

The scope of this reconsideration is limited to VNS for TRD. Effective for claims with dates of service on or after February 15, 2019, CMS will cover FDA-approved VNS devices for TRD

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through CED when offered in a CMS-approved, double-blind, randomized, placebo-controlled trial with a follow-up duration of at least one year with the possibility of extending the study to a prospective longitudinal study when the CMS-approved, double-blind, randomized placebo-controlled trial has completed enrollment, and there are positive interim findings. There are specific study and patient criteria that must be met.

Individuals who receive placebo VNS will be offered active VNS at the end of the trial.

VNS is non-covered for the treatment of TRD when furnished outside of a CMS-approved CED study.

All other indications of VNS for the treatment of depression are nationally non-covered.

Patients previously implanted with a VNS device for TRD may receive a VNS device replacement if it is required due to the end-of-battery life, or any other device-related malfunction. These patients do not require either ICD-10 diagnosis codes or CED-related coding. These claims will require the –KX modifier attesting to the reasonable and necessary need for the replacement device based off NCD160.18 criteria.

NOTE: VNS for medically refractory seizures and hypoglossal nerves continue to be processed as they are currently.

NOTE: A subsequent CR will be issued shortly that will provide updates to the "Claims Processing Manual" and instructions for processing claims through the CMS shared systems in regard to VNS for TRD.

ADDITIONAL INFORMATION

The official instruction, CR11461, issued to your MAC regarding this change is available at https://www.cms.gov/files/document/r10199ncd.pdf.

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

DOCUMENT HISTORY

Date of Change	Description
June 24, 2020	We revised this article to reflect the revised CR11461, issued on June 23, 2020. The CR revision clarified instructions for the MACs and changed the implementation date to July 22, 2020. In the article, we changed the implementation date, the CR release date, transmittal number and the web address of the CR. All other information remains the same.
June 1, 2020	Initial article released.