

Change to National Coverage Determination may affect your Medicare coverage

The Centers for Medicare & Medicaid Services (CMS) sometimes change the coverage rules that apply to an item or service under Medicare. When this happens, CMS issues a National Coverage Determination, or NCD.

NCDs tell us:

- What benefits and services are covered
- What benefits and services are changing
- What Medicare will pay for an item or service

CMS recently issued an update to the NCD that applies to the following service:

Vagus Nerve Stimulation (VNS) for treatment resistant depression (TRD)

Here is a description of the change to the NCD. This affects services given **on or after February 15, 2019**

Services affected	Additional information
<p>The Centers for Medicare and Medicaid Services (CMS) issued an NCD to update Vagus Nerve Stimulation (VNS) for treatment resistant depression (TRD)</p>	<p>Vagus Nerve Stimulation (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.</p> <p>Effective for services performed on or after February 15, 2019, the Centers for Medicare & Medicaid Services (CMS) covers FDA-approved VNS devices for TRD through Coverage with Evidence Development (CED) when offered in a CMS-approved clinical study. For more information on the approval of CED for VNS, go to CMS Coverage-with-Evidence-Development/VNS</p>

Services affected (continued)	Additional information
<p>The Centers for Medicare and Medicaid Services (CMS) issued an NCD to update Vagus Nerve Stimulation (VNS) for treatment resistant depression (TRD)</p>	<p>The following criteria must be used to identify patients with TRD:</p> <ul style="list-style-type: none"> • The patient must be in a major depressive disorder (MDD) episode for \geq two years or have had at least four episodes of MDD, including the current episode. In order to confirm the patient has MDD, accepted diagnostic criteria from the most current edition of the Diagnostic and Statistical Manual for Mental Disorder (DSM) and a structured clinical assessment are to be used. • The patient’s depressive illness meets a minimum criterion of four prior failed treatments of adequate dose and duration as measured by a tool designed for this purpose. • The patient is experiencing a major depressive episode (MDE) as measured by a guideline recommended depression scale assessment tool on two visits, within a 45-day span prior to implantation of the VNS device. <p>Patients must maintain a stable medication regimen for at least four weeks before device implantation.</p> <p>If patients with bipolar disorder are included, the condition must be carefully characterized. Patients must not have:</p> <ul style="list-style-type: none"> • Current or lifetime history of psychotic features in any major depressive episode • Current or lifetime history of schizophrenia or schizoaffective disorder • Current or lifetime history of any other psychotic disorder • Current or lifetime history of rapid cycling bipolar disorder • Current secondary diagnosis of delirium, dementia, amnesia, or other cognitive disorder

Services affected (continued)	Additional information
<p>The Centers for Medicare and Medicaid Services (CMS) issued an NCD to update Vagus Nerve Stimulation (VNS) for treatment resistant depression (TRD)</p>	<ul style="list-style-type: none"> • Current suicidal intent • Treatment with another investigational device or investigational drugs <p>VNS is non-covered for the treatment of TRD when furnished outside of a CMS-approved CED study and all other indications of VNS for the treatment of depression are non-covered.</p> <p>Patients 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.</p> <p>This summarizes CMS Transmittal R10145NCD.</p>

We're here to help you

Mercy Care Advantage is an HMO SNP with a Medicare contract and a contract with the Arizona Medicaid Program. Enrollment in Mercy Care Advantage depends on contract renewal. This information is not a complete description of benefits. Contact the plan for more information. Limitations, copayments, and restrictions may apply. Benefits and/or copayments/coinsurance may change on January 1 of each year. The formulary, pharmacy network, and/or provider network may change at any time. You will receive notice when necessary. See Evidence of Coverage for a complete description of benefits, exclusions, limitations and conditions of coverage. If you have questions, Mercy Care Advantage Member Services representatives are available to help you 8:00 a.m. - 8:00 p.m., 7 days a week. Please call 602-586-1730 or 1-877-436-5288 (TTY 711).