Subject: Vagal Nerve Stimulation (VNS) for Epilepsy		**Original Effective Date:** 4/25/07
Policy Number: MCR-006	**Revision Date(s):** 6/19/08, 12/14/11, 6/12/14, 2/8/2021	
Review Date: 6/25/14, 12/16/15, 6/15/16, 9/19/17, 3/8/18, 9/18/19, 4/23/20, 2/8/2021		
MCPC Approval Date: 3/8/18, 9/18/19, 4/23/20, 2/8/21		

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DISCLAIMER

This Molina Clinical Review (MCR) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or

Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical review (MCR) document and provide the directive for all Medicare members. [1]

POSITION STATEMENT [1-3, 4-8, 9-73]

This MCP addresses the indications for use of an implantable vagus nerve stimulator (VNS) and a non-implantable transcutaneous VNS (tVNS) stimulator for the treatment of medically intractable seizures.

1. The Implantable Vagal Nerve Stimulation (VNS) may be considered ***medically necessary and may be authorized*** when **ALL** of the following criteria are met: [ALL]
   - ❑ Age of 4 years or older; and
   - ❑ Prescriber and physician administering the treatment is a Neurologist; and
   - ❑ Diagnosis of either: [ONE]
     - o Focal onset or generalized onset seizures; or
     - o Lennox-Gastaut syndrome; and all of the following [ALL]
   - ❑ Intractable epilepsy (also known as drug resistant epilepsy): [ALL]:
     - o Failure of at least one year of adherent therapy of at least two anti-seizure drugs[3b], and
     - o Continued seizures which have a major impact on activities of daily living; and
   - ❑ Not a suitable candidate for or has failed resective epilepsy surgery;
   - ❑ Request is for an FDA-approved device.

2. Transcutaneous VNS also known as active auricular transcutaneous electrical nerve stimulation is considered experimental, investigational and unproven due to insufficient evidence in the peer reviewed scientific literature that prove safety and efficacy for any indication.

CONTINUATION OF THERAPY

Surgical implantation of a vagal nerve stimulator or VNS routinely takes place in an outpatient surgery setting or with an overnight inpatient stay if the medical condition warrants an overnight stay. The surgery is typically performed under general anesthesia.

LIMITATIONS [1-8]

VNS Therapy is considered not medically necessary for any the following indications: [ALL]

- ❑ Requests that do not meet all of the above outlined criteria;
- ❑ Children under the age of 4 years;
- ❑ Requests for VNS for any other condition other than medically intractable partial onset epileptic seizure disorder that include but are not limited to all of the following: addiction, Alzheimer's disease, anxiety, autism, bipolar disorders, bulimia, cancer, cerebral palsy, chronic heart failure, chronic refractory hiccups, coma, craving, essential tremor, fibromyalgia, headache, ischemic stroke, memory and learning disability, migraine, multiple sclerosis, narcolepsy, obesity, obsessive-compulsive disorder, panic disorder, pain syndromes, posttraumatic stress disorder, sleep disorder, traumatic brain injury, primary Sjogren's syndrome, Tourette's syndrome);

- ❑ In patients with diagnosed progressive metabolic or degenerative disorders that will result in continued deterioration within a 6 to 12 month time frame (e.g., malignant brain neoplasm or Rasmussen's encephalitis);
- ❑ In patients where previous bilateral or left cervical vagotomy is contraindicated;
- ❑ In patients with a cardiac pacemaker or implantable cardioverter defibrillator (ICD)

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [3-4]

Vagal Nerve Stimulation

The implanted vagus nerve stimulator is a pacemaker-like device implanted under the skin in the left side of the chest through a small incision, with a second small incision made at the base of the neck. The surgery is performed under local, regional, or general anesthesia and lasts 45 minutes to two hours. Most often, it is performed as an outpatient surgery but some patients need to stay in the hospital overnight following surgery.

Transcutaneous vagal nerve stimulation (tVNS) has been proposed as a noninvasive alternative to implantable VNS for a variety of indications such as epilepsy, major depression, chronic tinnitus and headaches. Currently, there are two main ways to apply tVNS. One is to apply stimulation on the ear and the other is cervical noninvasive VNS, superficially applying stimulation in the vicinity of the vagus nerve using a specially designed device, (e.g. gammaCore).

Most commonly reported complications associated with VNS are hoarseness, neck and throat pain, nausea, vomiting, dyspnea, and coughing; typically these resolve with time or treatment. Less common complications include vocal cord paralysis, facial muscle paralysis, and infection. [7]

Epilepsy and Seizure: [3, 75]

Seizures have been defined as paroxysmal disorders of the central nervous system characterized by abnormal cerebral neuronal discharge, with or without loss of consciousness. Most seizures can be categorized as either focal or generalized according to whether the onset of electrical activity involves a focal region of the brain or both sides of the brain simultaneously. The clinical manifestations of seizures vary based on the location of the seizure in the brain and the amount of cortex that is involved. Focal seizures are further classified according to whether consciousness is altered or not during the event. The following are three subtypes seizures:

- *Focal Onset with Retained Awareness (formerly known as Simple partial seizures):* These seizures begin with an electrical discharge in one limited area of the brain. Some are related to head injury, brain infection, stroke, or tumor, but in most cases the cause is unknown. These do not involve an alteration of consciousness but may have observable motor components or may be a subjective sensory or emotional phenomenon.
- *Focal Onset with Impaired Awareness (formerly known as Complex partial seizures):* These seizures are the most common type of seizure in adults with epilepsy and are associated with altered awareness at the onset of the seizure or as it progresses, previously called complex partial seizures. During a typical focal seizure with impaired awareness, patients appear to be awake but are not in contact with others in their environment and do not respond normally to instructions or questions. Generally, these seizures may last up to 3 minutes followed by confusion, headache lasting a few hours.

- *Generalized Onset seizures:* Generalized tonic-clonic seizures begin with an abrupt loss of consciousness, sometimes in association with a scream or choking sound . These seizures affect both sides of the brain or groups of cells on both sides of the brain at the same time and are tonic-clonic seizures (also called grand mal seizures, major motor seizures, or convulsions). Postictal confusion or agitation is common.

Drug Resistant Epilepsy

The International League Against Epilepsy (ILAE) defines drug resistant epilepsy or refractory seizures as the failure of adequate trials of two tolerated and appropriately chosen and used anti-epileptic medications (whether as monotherapy or in combination) to achieve sustained seizure freedom. No seizure frequency requirement is necessary to meet the definition; thus, an individual with one seizure per year can be regarded as treatment resistant. The task force defines treatment success as the complete cessation of seizures for one year or three times the longest interseizure interval during the recent active phase of epilepsy. [3b]

FDA INDICATIONS [2A-F]

Epilepsy:

1. The FDA approved the NeuroCybernetic Prosthesis (NCP)® System (Cyberonics, Inc.) in July 1997 (P970003) for use as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with medically refractory, partial-onset seizures. In 2017, this approval was extended for use in patients 4 years of age and older. In 2017, the FDA considered new evidence for the expanded use of VNS for epilepsy in young children aged 4 and older. The prior approval was limited to children aged 12 and older. Based on an analysis of younger and older children and young adults in the pivotal trials used for the initial approval, a Japanese registry, and the Cyberonics Post-Market Surveillance database, the FDA [2f] concluded that:
   - VNS was an effective and safe treatment for the reduction of partial onset seizures in pediatric patients 4 to 11 years of age with refractory epilepsy.
   - The 12-month responder rate for pediatric patients 4 to 11 years of age with partial onset seizures in the Japan post-approval study was 39% (95% credible interval, 28% to 52%)
   - There were no unanticipated adverse device effects observed in pediatric patients 4 to 11 years of age. However, infection and extrusion of leads had a statistically greater incidence rate in patients 4 to 11 years of age compared to older children.
   - Younger patients may have a greater risk for wound infection when compared to adolescents and adults; therefore, the importance of monitoring for site infection as well as the avoidance of manipulation of the surgical site post implant in children should be emphasized.
   - Overall, treatment-emergent adverse events in patients 4 to 11 years of age were consistent with patients ≥ 12 years of age treated with VNS, and no new risks were identified.

2. The AspireSR Model 106 (Cyberonics Inc.) received FDA Premarket Approval (PMA) in February 2014 for epilepsy. Multiple recalls are listed on the FDA website database.
3. The gammaCore Non-invasive Vagus Nerve Stimulator FDA De Novo request (DEN150048) on April 14, 2017 (updated September 1, 2017) states the gammaCore is indicated for the acute treatment of pain

associated with episodic cluster headache in adult patients. On May 30, 2017, gammaCore-S (electroCore® Medical, LLC, Basking Ridge, NJ) received Class II clearance by the FDA through the 510(k) process (K171306). Approval was based on the predicate device gammaCore. The differences between the gammaCore-S and the gammaCore device is a change in the user interface. The indication for use states the gammaCore-S Non-invasive Vagus Nerve Stimulator is intended to provide noninvasive vagus nerve stimulation (nVNS) on the side of the neck. The gammaCore-S device is indicated for the acute treatment of pain associated with episodic cluster headache in adult patients. Each stimulation with gammaCore-S lasts two minutes. The patient controls the stimulation strength.[2e]

4. On November 27, 2018, the gammaCore Sapphire non-invasive Vagus Nerve Stimulator (K182369) expanded FDA 510(k) approval for adjunctive use for the preventive treatment of cluster headache in adult patients. The indications for use state that gammaCore Sapphire (non-invasive vagus nerve stimulator) is intended to provide non-invasive vagus nerve stimulation (nVNS) on the side of the neck. gammaCore is indicated for:
   - Adjunctive use for the preventive treatment of cluster headache in adult patients;
   - The acute treatment of pain associated with episodic cluster headache in adult patients;
   - The acute treatment of pain associated with migraine headache in adult patients.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) [1]

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Review (MCR) document and provide the directive for all Medicare members. The directives from this MCR document may be followed if there are no available NCD or LCD documents available and outlined below.

CMS has a National Coverage Determination (NCD) #160.18 for vagus nerve stimulation and covers VNS for patients with medically refractory partial onset seizures for whom surgery is not recommended or for whom surgery has failed".

SUMMARY OF MEDICAL EVIDENCE [9-73]

VNS in the Management of Epilepsy [9-30]

Summary:

The published peer reviewed literature is sufficient for implanted vagus nerve stimulation as a treatment for epilepsy in focal onset (formerly partial onset) seizures or generalized onset seizures and Lennox-Gastaut syndrome in adults and children who are over the age of 4 years and demonstrates net health benefit. The published peer reviewed literature is insufficient for transcutaneous vagus nerve stimulation as a treatment for any indication and demonstrates an incomplete assessment of net benefit versus harm. Additional research is needed to assess long term safety and efficacy.

The first case series of patients treated with vagus nerve stimulation (VNS) was reported in 1990.[25] This was followed by two large pivotal trials of VNS in patients with partial epilepsy, the E03 study and the E05 study. [11, 19, 21, 26, 29] Two long term studies conducted in 2007 continued to report a seizure frequency reduction and

severity up to 50 percent for a timeframe to four years post VNS implantation.[10, 16] The first study reported a 47 percent reduction in seizure severity and post-ictal period compared with a five month baseline pre-implantation over a six year period. The seizure reduction improved each year during the six year follow-up (e.g., 14%, 25%, 29%, 29%, 43% and 50%).[10] A second retrospective study reported a seizure reduction of 50% after mean follow up of 44 months. The mean number of seizures monthly pre-implantation were reported at 41 compared with 7 post implantation.[16] A Cochrane Review showed that VNS for partial seizures appears to be an effective and well tolerated treatment in 439 participants from five trials.[24] VNS has been shown in multiple studies to be safe and effective in decreasing the frequency and severity of seizures. [13, 17] Video electroencephalographic (EEG) monitoring should be performed on all patients prior to epilepsy procedures to ensure that the seizure can be precisely classified and that the seizures are epileptic and not non-epileptic seizures. Analysis of the sharp waves and interictal spikes on video EEG allows for the localization of seizures in relation to the patient's anatomy. [27]

There is an abundance of peer reviewed published literature that sufficiently demonstrates vagus nerve stimulation (VNS) therapy is appropriate when used as an adjunctive therapy for drug-resistant epilepsy (DRE) is. Efficacy has been verified by several randomized controlled trials (RCTs). [11, 14, 21, 22, 27, 29] and several prospective observational studies [9, 15, 18, 30] and numerous other studies indicate that approximately 25% to 30% of individuals with epilepsy do not achieve seizure control with anti-epileptic medications. [13, 20] VNS may be an option for those patients with drug resistant epilepsy who have either failed surgery or are not surgical candidates. Patients with bilateral or multiple foci or an unidentifiable focus are generally not candidates for resective epilepsy surgery. [28]

Children: [23 31-54]

Kawai et al. (2017) conducted a multicenter, open-label, long-term, and prospective observational study of the clinical efficacy and safety of VNS Therapy® for 362 adult and pediatric patients. The median age at VNS implantation was 23 years (range: 1 to 73 years); 215 patients were (59.4%) ≥19 years , 69 patients (19.1%) were between 12 and 19 years, and 78 patients (21.5%) were <12 years. All patients had a diagnosis of DRE with a median seizure frequency of 10.3 per week. The median duration of epilepsy prior to VNS implantation was 13 years. The patients had received a median of five AEDs (range: 1-17; mean: 5.7; standard deviation: 3.2) prior to implantation. In addition, 180 (49.7%) had prior cranial surgery for epilepsy and the average number of AEDs at registration was 3.4; underscoring the severity of their disease. The median decrease in all seizures after three, six, 12, 24, 36 months of VNS therapy, and at the last visit was 9.0%, 40.2%, 50.0%, 50.0%, 60.0%, and 60.0% in the patients younger than 12 years old at implantation. [44]

Orsoz et al (2014) conducted a large retrospective study to assess change in seizure frequency of the predominant seizure type (defined as the most disabling seizure) following VNS device implantation. Treating physicians collected data from patient records from baseline to 6, 12, and 24 months of follow-up. The analysis population included 347 children (aged 6 months to 17.9 years at the time of implant). At 6, 12, and 24 months after implantation, 32.5%, 37.6%, and 43.8%, respectively, of patients had≥50% reduction in baseline seizure frequency of the predominant seizure type. The responder rate was higher in a subgroup of patients who had no change in antiepileptic drugs (AEDs) during the study. Favorable results were also evident for all secondary

outcome measures including changes in seizure duration, ictal severity, postictal severity, quality of life, clinical global impression of improvement, and safety. Post hoc analyses demonstrated a statistically significant correlation between VNS total charge delivered per day and an increase in response rate. VNS Therapy is indicated as adjunctive therapy in children with focal, structural epilepsies, who for any reason are not good candidates for surgical treatment following the trial of two or more AEDs. Children with predominantly generalized seizures from genetic, structural epilepsies, like Dravet syndrome or Lennox-Gastaut syndrome, could also benefit from VNS Therapy. The results demonstrate that adjunctive VNS Therapy in children with drug-resistant epilepsy reduces seizure frequency and is well tolerated over a 2-year follow-up period. No new safety issues were identified. A post hoc analysis revealed a dose-response correlation for VNS in patients with epilepsy. [23]

A recent retrospective multicenter open-label study including adults and children reported 75% or greater seizure reduction in 24.3% of patients, 50% to 75% reduction in 19%, and a reduction of 25% to 50% in 10.8% of patients. The most significant improvements were reported in patients with complex partial seizures.[48] In a study reporting 10-year outcomes after VNS placement, 36.9% of patients reported greater than 90% seizure control; 90.8% had greater than 50% control; 15.4% experienced less than 50% improvement; and 15.4% were seizure free for more than two years. [35]

Klinkenberg et al. (2012) conducted a randomized controlled trial to evaluate the effects of vagus nerve stimulation (VNS) in children with intractable epilepsy on seizure frequency and severity and in terms of tolerability and safety. In this study 41 children (23 males; 18 females; mean age at implantation 11y 2mo, SD 4y 2mo, range 3y 10mo-17y 8mo) were included. Thirty-five participants had localization-related epilepsy (25 symptomatic; 10 cryptogenic), while six participants had generalized epilepsy (four symptomatic; two idiopathic). During a baseline period of 12 weeks, seizure frequency and severity were recorded using seizure diaries and the adapted Chalfont Seizure Severity Scale (NHS3), after which the participants entered a blinded active controlled phase of 20 weeks. During this phase, half of the participants received high-output VNS (maximally 1.75mA) and the other half received low-output stimulation (0.25mA). Finally, all participants received high-output stimulation for 19 weeks. For both phases, seizure frequency and severity were assessed as during the baseline period. At the end of the randomized controlled blinded phase, seizure frequency reduction of 50% or more occurred in 16% of the high-output stimulation group and in 21% of the low-output stimulation group ($p=1.00$). There was no significant difference in the decrease in seizure severity between participants in the stimulation groups. Overall, VNS reduced seizure frequency by 50% or more in 26% of participants at the end of the add-on phase The overall seizure severity also improved ($p<0.001$). The authors concluded that VNS is a safe and well-tolerated adjunctive treatment of epilepsy in children. Our results suggest that the effect of VNS on seizure frequency in children is limited. However, the possible reduction in seizure severity and improvement in well-being makes this treatment worth considering in individual children with intractable epilepsy. [45]

Helmers et al (2012) evaluated clinical outcomes, quality-adjusted life years (QALY), and costs associated with VNS in pediatric patients with drug-resistant epilepsy in a real-world setting. A retrospective analysis was conducted using Medicaid data (USA). Patients had ≥1 neurologist visits with epilepsy diagnosis, ≥1 procedure claims for VNS implantation, ≥1 AEDs, ≥6-months of Pre- and Post-VNS continuous enrollment. Pre-VNS period was 6-months and Post-VNS period extended from implantation until device removal, death, Medicaid

disenrollment, or study end (up to 3 years). Incidence rate ratios (IRR) and costs ($2010) were estimated. QALYs were estimated using number of seizure-related events. The results showed that for patients 1-11 years old (N = 238), hospitalizations and emergency room visits were reduced Post-VNS vs. Pre-VNS. Average total healthcare costs were lower Post-VNS vs. Pre-VNS ($18,437 vs. $18,839. For patients 12-17 years old (N = 207) hospitalizations and status epilepticus events were reduced Post-VNS vs. Pre-VNS. Average total healthcare costs were lower Post-VNS vs. Pre-VNS period ($14,546 vs. $19,695) and quarterly Lifetime QALY gain after VNS was 5.96 (patients 1-11 years) and 4.82 years (patients 12-17 years). The authors concluded that VNS in pediatric patients is associated with decreased resource use and epilepsy-related events, cost savings, and QALY gain. [41]

VNS and tVNS for Other Conditions [55-73]

VNS and tVNS has been used to treat patients with various other conditions such as those with addiction, Alzheimer's disease, anxiety, autism, bipolar disorders, bulimia, cancer, cerebral palsy, chronic heart failure, chronic refractory hiccups, coma, craving, essential tremor, fibromyalgia, headache, ischemic stroke, memory and learning disability, migraine, multiple sclerosis, narcolepsy, obesity, obsessive-compulsive disorder, panic disorder, pain syndromes, posttraumatic stress disorder, sleep disorder, traumatic brain injury, primary Sjogren's syndrome, Tourette's syndrome. VNS and tVNS are not FDA approved for these indications. Only preliminary studies have been performed; findings need to be validated through large randomized controlled studies with long term outcomes before safety and efficacy can be established. Therefore, the published peer reviewed literature is insufficient for vagus nerve stimulation as a treatment for any other indication and demonstrates an incomplete assessment of net benefit versus harm. Additional research is needed to assess long term safety and efficacy.

PROFESSIONAL ORGANIZATION GUIDELINES [5-8]

The American Academy of Neurology evidence-based guideline on vagal nerve stimulation for the treatment of epilepsy (2013) indicates that VNS may be considered for seizures in children, for Lennox-Gastaut syndrome (LGS) associated seizures, and for improving mood in adults with epilepsy (Level C). VNS may be considered to have improved efficacy over time (Level C). Children should be carefully monitored for site infection after VNS implantation. [6]

The National Institute for Health and Care Excellence (NICE):

In January 2012 (updated 2020), NICE published a clinical guideline addressing the diagnosis and management of epilepsy. The guideline states that vagus nerve stimulation is indicated for use as an adjunctive therapy in reducing the frequency of seizures in adults who are refractory to antiepileptic medication but who are not suitable for resective surgery. This includes adults whose epileptic disorder is dominated by focal seizures (with or without secondary generalization) or generalized seizures. Vagus nerve stimulation is indicated for use as an adjunctive therapy in reducing the frequency of seizures in children and young people who are refractory to antiepileptic medication but who are not suitable for resective surgery. This includes children and young people

whose epileptic disorder is dominated by focal seizures (with or without secondary generalization) or generalized seizures. [5]

The Washington State Health Authority (WSHA):

In April 2020 WHSA published a report entitled Vagal Nerve Stimulation for Epilepsy and Depression. The final evidence report states that: "VNS appears to be an appropriate treatment option for adults and children with treatment-resistant epilepsy, but there is a lack of robust evidence on the effectiveness of VNS for TRD in adults. The use of VNS is commonly associated with minor adverse events, such as coughing and voice alteration, which are often transient and tend to decrease over time. In some cases, adverse events can be minimized through adjustment of the stimulation parameters. However, if VNS equipment or its components fail, people can be exposed to rare, but serious harms." [8]

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
64553	Percutaneous implantation of neurostimulator electrodes; cranial nerve
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
64570	Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; ….with simple cranial nerve neurostimulator pulse generator / transmitter programming by physician or other qualified health care professional
95977	….with complex cranial nerve neurostimulator pulse generator / transmitter programming by physician or other qualified health care professional

HCPCS	Description
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each

L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

ICD-10	**Description: [For dates of service on or after 10/01/2015]**
G40.001-G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable
G40.101-G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures
G40.201-G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures
G40.311-G40.319	Generalized idiopathic epilepsy and epileptic syndromes

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    c) http://www.accessdata.fda.gov/cdrh_docs/pdf/p970003.pdf
    d) Class 2 Device Recall Cyberonics VNS Therapy AspireSR, Model 106 Generator: Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?id=177028
    e) gammaCore Non-invasive Vagus Nerve Stimulator Evaluation of Automatic Class III Designation De Novo Request. DEN150048. September 1, 2017. Accessed at: https://www.accessdata.fda.gov/cdrh_docs/pdf15/den150048.pdf
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76. IRO Peer Review: Advanced Medical Review (AMR):
a. Policy reviewed by a practicing physician board certified Board certified in Neurology. 6/3/14.
b. Policy reviewed by a practicing physician board certified in Pediatrics, Neurology with Special Qualification in Child, Neurodevelopmental Disabilities. 7/31/19
c. Policy reviewed by a practicing physician Board certified in Neurology, Sleep Medicine. 1/7/2021. Additional references reviewed by the peer reviewer include:
   - González HFJ, Yengo-Kahn A, Englot DJ. Vagus Nerve Stimulation for the Treatment of Epilepsy. Neurosurg Clin N Am. 2019 Apr;30(2):219-230. doi: 10.1016/j.nec.2018.12.005.
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REVISION/REVIEW HISTORY

4/25/07: New Policy
6/19/08, 12/14/11: Policy revised.
6/12/14: Policy reviewed and revised. Clinical criteria and coverage exclusions were updated.
12/16/15, 6/15/16 & 9/19/17: Policy reviewed, no changes.
3/8/18 & 9/18/19: Policy reviewed, no changes to criteria. Updated references, summary of medical evidence sections.
4/23/20: Policy reviewed, no changes.
2/8/2021: This policy is specific to epilepsy, the content for depression was removed and is now in a new policy MCP-393 VNS for Depression. VNS for epilepsy was completely revised with new criteria to include VNS as medically necessary for children who are age 4 and older instead of age 12 and includes the diagnosis of Lennox-Gastaut syndrome. Summary of medical evidence section condensed and includes literature search for children and other indications. Guidelines and FDA sections updated. Updated definitions of seizure classifications based on new guidelines. Transcutaneous VNS (tVNS) also known as active auricular transcutaneous electrical nerve stimulation was added and is considered experimental, investigational and unproven due to insufficient evidence in the peer reviewed scientific literature that prove safety and efficacy for any indication. Policy reviewed and vetted by a practicing physician Board certified in Neurology, Sleep Medicine.