

Policy: MP051

Section: Medical Benefit Policy

Subject: Vagus and Trigeminal Nerve Stimulation

Applicable line of business:

Commercial	x	Medicaid	x
Medicare	x	ACA	x
CHIP	x		

I. Policy: Vagus and Trigeminal Nerve Stimulation

II. Purpose/Objective:

To provide a policy of coverage regarding Vagus and Trigeminal Nerve Stimulation

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care — that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

The vagus nerve (10th cranial nerve) is a mixed nerve carrying both somatic and visceral afferent and efferent signals. The basic premise of vagus nerve stimulation in the treatment of epilepsy is that the vagal visceral afferents have a diffuse central nervous system projection, and activation of these pathways has a widespread effect upon neuronal excitability and synchronization. Besides activation of well-defined reflexes, vagal stimulation produces evoked potentials recorded from the cerebral cortex, hippocampus, thalamus, and the cerebellum. Stimulation of the vagus nerve has been shown to decrease seizure frequency and severity.

Vagus nerve stimulation has also been recently purported to provide some degree of long-term adjunctive benefit in the treatment of chronic or recurrent depression refractory to multiple therapeutic antidepressant treatment modalities.

The vagus nerve stimulation system is comprised of an implantable pulse generator and lead, and an external programming system used to change stimulation settings.

The trigeminal nerve (5th cranial nerve) is responsible for sensation in the face and motor functions such as biting and chewing. It is the largest, and most complex of the cranial nerves. Electrical stimulation of the nerve branch has been used to treat trigeminal neuropathic pain, trigeminal neuralgia, supraorbital neuralgia, postherpetic neuralgia, and other facial pain syndromes. Investigators have also studied the potential of trigeminal nerve stimulation to reduce symptoms of treatment-resistant epilepsy, depression, post-traumatic stress disorder and attention-deficit hyperactivity disorder.

INDICATIONS: Requires Prior Authorization by a Plan Medical Director or Designee

For EPILEPSY:

Conventional implantable (open-loop) vagus nerve stimulator, may be considered medically necessary in members with a diagnosis of medically refractory partial-onset seizures*, for which surgery is not recommended or surgery has failed to control the events, and in which pharmacologic therapy has been maximized

*Partial onset seizures are divided into 3 subtypes:

- a. Simple partial seizures: No alteration of consciousness, but may exhibit observable motor components, or may be solely a subjective sensory or emotional phenomenon.
- b. Complex partial seizures: Involves an alteration of consciousness and may include automatisms, movements and staring, followed by a period of confusion, occasional amnesia and fatigue.
- c. Complex partial seizures, secondarily generalized: Partial onset seizures that progress to involve both sides of the brain and result in complete loss of consciousness. These patients may continue on to experience a generalized tonic/clonic seizure. The presence of an aura prior to the generalized seizure, the observation of a focal symptom at the seizure onset, or a postictal focal deficit indicates the focal nature of the seizure.

Electronic analysis of an implanted neurostimulator pulse generator system for vagus nerve stimulation is considered medically necessary when the implantation has met the criteria for coverage.

For DEPRESSION:

FOR COMMERCIAL AND MEDICAID BUSINESS SEGMENT:

Consideration for coverage will default to the Behavioral Health department policies and/or applicable behavioral health vendor's policies.

FOR MEDICARE BUSINESS SEGMENT:

On February 15, 2019 CMS issued an NCD that covers FDA approved vagus nerve stimulation (VNS) devices for treatment resistant depression (TRD) through Coverage with Evidence Development (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.

NOTE: Services related to component reimplantation or replacement in members previously approved for the implantation, or members having had the implantation prior to enrollment in the Plan, and who otherwise meet criteria for coverage, do not require prior authorization.

EXCLUSIONS:

At this time, published, peer-reviewed, medical literature to support the long-term efficacy of this treatment for Depression is limited. With the exception of Medicare CED program coverage, the Plan currently considers the use of vagus nerve stimulation in the treatment of recurrent or chronic major depression refractory to multiple maximized antidepressant therapeutic antidepressant treatment modalities to be **unproven** and **NOT COVERED**.

The Plan considers the use of Vagus Nerve Stimulation for the treatment of all other conditions, including but not limited to treatment of obesity, heart failure, seizure types other than partial onset, etc. to be **unproven** and **NOT COVERED**.

The Plan considers the use of responsive or "closed-loop" vagus nerve electrical stimulators that utilize the detection and stimulation of heart rate including but not limited to the AspireSR and SenTiva Model 1000 for the treatment of epilepsy to be **unproven** and **NOT COVERED**.

The Plan considers the use of vagus nerve electrical stimulators and transcutaneous vagus nerve stimulation (e.g., gammaCore-S®) for the prevention of chronic migraine and/or cluster headache to be **unproven** and **NOT COVERED**.

The Plan considers the use of external or transcutaneous (non-implantable) trigeminal nerve stimulation devices (e.g., Monarch® eTNS System, Cefaly®) for the treatment of epilepsy and headache to be and **NOT COVERED**.

The Plan considers the use of distal transcutaneous electrical peripheral nerve stimulation (e.g., Nerivo), for the treatment of episodic and chronic migraine headache to be **unproven** and **NOT COVERED**.

The Plan considers the use of vagus nerve electrical stimulators and transcutaneous vagus nerve stimulation for the treatment of tinnitus to be **unproven** and **NOT COVERED**.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment**.

CODING ASSOCIATED WITH: Vagus Nerve Stimulation

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or

the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- 61885 Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
 - 61886 with connection to two or more electrode arrays
 - 64553 percutaneous implantation of neurostimulator electrode array; cranial nerve
 - 64568 Open implantation of cranial nerve (e.g. vagus nerve) neurostimulator electrode array and pulse generator
 - 64569 Revision or replacement of cranial nerve (eg. vagus nerve) neurostimulator electrode array, including connection o 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 and 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, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
 - 95974 complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour
 - 95975 complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)
 - 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 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 complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
 - A4543 Supplies for transcutaneous electrical nerve stimulator, for nerves in the auricular region, per month
 - C1767 generator neurostimulator (implantable) non-rechargeable
 - C1778 lead, neurostimulator (implantable)
 - C1787 patient programmer, neurostimulator
 - C1816 receiver and/or transmitter, neurostimulator (implantable)
 - C1820 generator, neurostimulator (implantable), non high-frequency with rechargeable battery and charging system
 - C1822 generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
 - C1897 lead, neurostimulator test kit (implantable)
 - 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, nonrechargeable, includes extension
 - L8687 implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
 - L8688 implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
 - L8689 external recharging system for battery (internal) for use with implantable neurostimulator, replacement only
 - K1020 Non-invasive vagus nerve stimulator
 - K1016 – Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
 - K1017 – Monthly supplies for use of device coded at K1016
 - K1023 Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm (Nerivio)
- Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Technology Evaluation Center, TEC Assessment Program, "Chronic Vagus Nerve Stimulation for Treatment of Seizures", Vol 13(9), May 1998.

Salinsky MC, Uthman BM, Ristanovic RK, Wernicke JF, Tarver WB, " Vagus Nerve Stimulation for the Treatment of Medically Intractable Seizures: Results of a 1-Year Open Extension Trial", *Archives of Neurology*, 53(11):1176-1180, Nov 1996.

Murphy JV, Hornig G, Schallert G, "Left Vagal Nerve Stimulation in Children With Refractory Epilepsy: Preliminary Observations", *Archives of Neurology*, 52(9):886-889, Sept 1995.

Tatum WO, Benbadis SR, Vale FL, "The Neurosurgical Treatment of Epilepsy", *Archives of Family Medicine*, 9(10):1142-1147, Nov/Dec 2000.

Herman ST, Pedley TA, "New Options for the Treatment of Epilepsy", *JAMA* 280(8):693-694, Aug 26, 1998.

Fisher RS, Handforth A, "Reassessment: Vagus Nerve Stimulation for Epilepsy", A Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology, *Neurology* 53:666-669; 1999.

Vagus Nerve Stimulation, Cornell University Medical College, Department of Neurology & Neuroscience, <http://www.med.cornell.edu>

Vagus Nerve Stimulation, Baylor College of Medicine, <http://www.bcm.tme.edu/neurol/index.html>

Implantable Neurostimulation Devices, Health Technology Advisory Committee, Sept 1998.

Murphy, JV, " Left Vagal Nerve Stimulation in Children With Medically Refractory Epilepsy", *Journal of Pediatrics*, 134(5):563-566, May 1999.

Labar D, " Vagus Nerve Stimulation for Intractable Epilepsy in Children", *Developmental Medicine and Child Neurology* 2000, 42:496-499.

Ravish VP, Stong B, Bebin M, Mathisen J, Grabb PA, " Efficacy of Vagal Nerve Stimulation in Children with Medically Refractory Epilepsy", *Neurosurgery*, 47(6):1353-1357, Dec. 2000.

Crumrine P, "Vagal Nerve Stimulation in Children", *Seminars in Pediatric Neurology*, 7(8)216-223, Sept. 2000.

Geisinger Technology Assessment Committee, Vagal Nerve Stimulation in Children, Jan 9, 2002.

Nahas Z, Marangell LB, Husain MM, et. al. Two-year outcome of vagus nerve stimulation (VNS) for treatment of major depressive episodes. *Journal of Clinical Psychiatry*. 2005;66:1097-1104

Rush AJ, Sackeim HA, Marangell LB, et.al. Effects of 12 months of vagus nerve stimulation in treatment-resistant depression: A Naturalistic study. *Biological Psychiatry* 2005;58:355-363.

George MS, Rush AJ, Marangell LB, et. al. A one-year comparison of vagus nerve stimulation with treatments usual for treatment-resistant depression. *Biological Psychiatry* 2005;58:364-373.

Rush AJ, Marangell LB, Sackeim HA, et. al. Vagus nerve stimulation for treatment-resistant depression: A randomized, controlled acute phase trial. *Biological Psychiatry* 2005;58:347-354.

ECRI Institute. Target database (online) Implantable vagus nerve stimulator for treatment-resistant depression. ECRI current as of May 2007.

Camilleri M, Toouli J, Herrera MF, et al. Intra-abdominal vagal blocking (VBLOC therapy): Clinical results with a new implantable medical device. *Surgery*. 2008;143(6):723-731.

Toouli J, Kow L, Collins J, Wray NH, Tweden KS, Vollmer MC, Wilson RR, Freston JW, Billington CJ. Intra-abdominal vagal blocking reduces calorie intake, enhances satiation and reduces hunger during significant and sustained weight loss in obese subjects [abstract M1255]. *Gastroenterology* 2008;134(4):A-370.

ECRI Institute Forecast (online) Vagus nerve blocking for obesity. ECRI current as of 09/01/09.

Zannad F, De Ferrari GM, Tuinenburg AE, et al. Chronic vagal stimulation for the treatment of low ejection fraction heart failure: results of the NEural Cardiac TherApy foR Heart Failure (NECTAR-HF) randomized controlled trial. *Eur Heart J*. 2015 Feb 14;36(7):425-33.

Premchand, RK, Sharma, K, Mittal, S, et al. Autonomic regulation therapy via left or right cervical vagus nerve stimulation in patients with chronic heart failure: results of the ANTHEM-HF trial. *Journal of cardiac failure*. 2014 Nov;20(11):808-16.

Ryvlin P, Gilliam FG, Nguyen DK, et al. The long-term effect of vagus nerve stimulation on quality of life in patients with pharmaco-resistant focal epilepsy: The PuLsE (Open Prospective Randomized Long-term Effectiveness) trial. *Epilepsia*. 2014 Jun;55(6):893-900.

Panebianco M, Rigby A, Weston J, et al. Vagus nerve stimulation for partial seizures. *Cochrane Database Syst Rev*. 2015 Apr 3;4:CD002896.

Morris GL 3rd, Gloss D, Buchhalter J, et al. Evidence-based guideline update: vagus nerve stimulation for the treatment of epilepsy: report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2013 Oct 15;81(16):1453-9.

Ikramuddin S, Blackstone RP, Brancatisano A, et al. Effect of reversible intermittent intra-abdominal vagal nerve blockade on morbid obesity: the ReCharge randomized clinical trial. *JAMA*. 2014 Sep 3;312(9):915-22.

Silberstein SD, Calhoun AH, Lipton RB, et al; EVENT Study Group. Chronic migraine headache prevention with noninvasive vagus nerve stimulation: The EVENT study. *Neurology*. 2016b;87(5):529-538.

Silberstein SD, Mechtler LL, Kudrow DB, et al; ACT1 Study Group. Non-invasive vagus nerve stimulation for the acute treatment of cluster headache: Findings from the randomized, double-blind, sham-controlled ACT1 Study. *Headache*. 2016a;56(8):1317-1332.

Holle-Lee D, Gaul C. Noninvasive vagus nerve stimulation in the management of cluster headache: Clinical evidence and practical experience. *Ther Adv Neurol Disord*. 2016;9(3):230-234

Goadsby PJ, de Coo IF, Silver N, et al; ACT2 Study Group. Non-invasive vagus nerve stimulation for the acute treatment of episodic and chronic cluster headache: A randomized, double-blind, sham-controlled ACT2 study. *Cephalalgia*. Jan 2017

Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Vagus Nerve Stimulation (VNS) (160.18)

ECRI. gammaCore Sapphire Noninvasive Vagus Nerve Stimulator (electroCore, LLC) for Treating and Preventing Migraines. ECRI; 2021 Feb 5

Tassorelli C, Grazzi L, de Tommaso M, et al. PRESTO Study Group. Noninvasive vagus nerve stimulation as acute therapy for migraine: The randomized PRESTO study. *Neurology*. 2018 Jun 15.

Grazzi L, Tassorelli C, de Tommaso M5, et al; PRESTO Study Group. Practical and clinical utility of non-invasive vagus nerve stimulation (nVNS) for the acute treatment of migraine: A post hoc analysis of the randomized, sham-controlled, double-blind PRESTO trial. *J Headache Pain*. 2018;19(1):98.

Martelletti P, Barbanti P, Grazzi L, et al; PRESTO Study Group. Consistent effects of non-invasive vagus nerve stimulation (nVNS) for the acute treatment of migraine: Additional findings from the randomized, sham-controlled, double-blind PRESTO trial. *J Headache Pain*. 2018;19(1):101.

Vecchio E, Bassez I, Ricci K, et al. Effect of non-invasive vagus nerve stimulation on resting-state electroencephalography and laser-evoked potentials in migraine patients: Mechanistic insights. *Front Hum Neurosci*. 2018;12:366

Straube A, Ellrich J, Eren O, et al. Treatment of chronic migraine with transcutaneous stimulation of the auricular branch of the vagal nerve (auricular t-VNS): a randomized, monocentric clinical trial. *J Headache Pain*. 2015;16:543.

Bajwa ZH, Smith JH. Acute treatment of migraine in adults. UpToDate 2018

Bajwa ZH, Smith JH. Preventive treatment of migraine in adults. UpToDate 2018

Centers for Medicare & Medicaid Services (CMS). Proposed Decision Memo for Vagus Nerve Stimulation for Treatment of Resistant Depression (TRD) (CAG-00313R2)

Chou DE, Shnayderman Y, Yurakh M, Winegarner D, et al. Acute migraine therapy with external trigeminal neurostimulation (ACME): A randomized controlled trial. *Cephalalgia*. 2019 Jan;39(1):3-14.

Diener HC, et al. Non-invasive vagus nerve stimulation (nVNS) for the preventive treatment of episodic migraine: the multicentre, double-blind, randomised, sham-controlled PREMIUM trial. *Cephalalgia* 2019 Oct;39(12):1475-1487.

Stavrakis S, et al. TREAT AF (transcutaneous electrical vagus nerve stimulation to suppress atrial fibrillation): a randomized clinical trial. *JACC Clin Electrophysiol* 2020 Mar;6(3):282-291.

Hamilton P, Soryal I, Dhahri P, et al. Clinical outcomes of VNS therapy with AspireSR (including cardiac-based seizure detection) at a large complex epilepsy and surgery centre. *Seizure*. 2018 May;58:120-126

Stanak M, Wolf S, Jagoš H, Zebenholzer K. The impact of external trigeminal nerve stimulator (e-TNS) on prevention and acute treatment of episodic and chronic migraine: A systematic review. *J Neurol Sci*. 2020 May 15;412

Hayes, Inc. Health Technology Assessment. Noninvasive Vagus Nerve Stimulation with gammaCore for Prevention or Treatment of Cluster Headache. Lansdale, PA: Hayes, Inc., May 2020, June 2021

Stegeman I, Velde HM, Robe PAJT, et al. Tinnitus treatment by vagus nerve stimulation: A systematic review. *PLoS One*. 2021;16(3):e0247221

ECRI. Vivistim Paired VNS System (MicroTransponder, Inc.) for improving upper limb function after stroke. ECRI; 2021 Sep.

Lampros M, Vlachos N, Zigouris A, et al. Transcutaneous vagus nerve stimulation (t-VNS) and epilepsy: A systematic review of the literature. *Seizure*. 2021 Oct;91:40-48

Mao H, Chen Y, Ge Q, Ye L, Cheng H. Short- and long-term response of vagus nerve stimulation therapy in drug-resistant epilepsy: A Systematic Review and Meta-Analysis. *Neuromodulation*. 2021 Aug 14

Simpson HD, Schulze-Bonhage A, Cascino GD, et al. Practical considerations in epilepsy neurostimulation. *Epilepsia*. 2022; 63(10):2445-2460.

Stavrakis S, Elkholey K, Morris L, et al. Neuromodulation of inflammation to treat heart failure with preserved ejection fraction: a pilot randomized clinical trial. *J Am Heart Assoc*. 2022; 11(3):e023582.

Panebianco M, Rigby A, Marson AG. Vagus nerve stimulation for focal seizures. *Cochrane Database Syst Rev*. Jul 14 2022; 7(7): CD002896

This policy will be revised as necessary and reviewed no less than annually.

Devised: 7/99

Revised: 12/01, 02/02 (expanded coverage to members < 12 yrs old); 02/04; 10/05 (added information related to depression); 5/06 (add definition); 11/09; 11/10 (coding); 11/16; 10/17 (added headache exclusion); 10/18; 10/19 (add Medicare CED coverage for depression); 10/21 (Title, add exclusions), 10/22 (add tinnitus exclusion); 10/24 (add electronic analysis, revise unproven language)

Reviewed: 02/03; 2/05, 10/07, 10/08, 11/11, 11/12, 11/13, 11/14, 11/15, 10/20, 10/23

CMS UM Oversight Committee Approval: 12/23

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Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health

Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

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