

MEDICAL POLICY – 7.01.20


Vagus Nerve Stimulation

BCBSA Ref. Policy: 7.01.20
 Effective Date: May 1, 2018
 Last Revised: April 3, 2018
 Replaces: N/A

RELATED MEDICAL POLICIES:	
2.01.526	Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders
7.01.63	Deep Brain Stimulation
7.01.143	Responsive Neurostimulation for the Treatment of Refractory Partial Epilepsy
7.01.150	Vagus Nerve Blocking Therapy for Treatment of Obesity
7.01.522	Gastric Electrical Stimulation
7.01.546	Spinal Cord Stimulation

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Introduction

The vagus nerve starts in the brain stem and runs down the neck, into the chest, and then down to the stomach area. Stimulating this nerve has been studied as a way to treat several different types of conditions. A small device that generates electricity is surgically placed in a person’s chest. A thin wire leads from the device to the vagus nerve. Vagus nerve stimulation may be used to treat seizures that don’t respond to medication. However, for other conditions it’s considered investigational (unproven). There is not yet enough information in published medical studies to show how well it works for other conditions. Similarly, non-implanted devices to stimulate the vagus nerve for treatment of any condition are also investigational due to lack of evidence that they improve one’s health.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Medical Necessity
Vagus nerve stimulation eg, NeuroCybernetic Prosthesis (NCP®) (Cyberonics)	<p>Vagus nerve stimulation may be considered medically necessary as a treatment of medically refractory seizures*.</p> <p>*Medically refractory seizures are defined as seizures that occur despite therapeutic levels of antiepileptic drugs or seizures that cannot be treated with therapeutic levels of antiepileptic drugs because of intolerable adverse events of these drugs. This indication is applicable for both pediatric and adult patients.</p>

Service	Investigational
Vagus nerve stimulation	<p>Vagus nerve stimulation is considered investigational as a treatment of other conditions, including but not limited to:</p> <ul style="list-style-type: none"> • depression • essential tremor • fibromyalgia • headaches • heart failure • obesity (see Related Policy 7.01.150) • tinnitus • traumatic brain injury • upper-limb impairment due to stroke
Non-implantable vagus nerve stimulation devices eg, gammaCore® (ElectroCore)	<p>Non-implantable (transcutaneous) vagus nerve stimulation devices are considered investigational for all indications.</p>

Documentation Requirements
<p>The medical records submitted for review should document that medical necessity criteria are met. The record should include documentation that member has medically refractory seizures as evidenced by:</p> <ul style="list-style-type: none"> • Persistent seizures in spite of therapeutic levels of antiepileptic medications



Documentation Requirements

OR

- Member has intolerable side effects of drug therapy

Vagus nerve stimulation has been evaluated for the treatment of obesity. This indication is addressed in a separate policy (see [Related Policies](#)).

Coding

Code	Description
CPT	
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
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
HCPCS	
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8684	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension



Code	Description
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

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

Medically refractory seizures are defined as:

- Seizures that occur in spite of therapeutic levels of antiepileptic drugs or
- Seizures that cannot be treated with therapeutic levels of antiepileptic drugs because of intolerable adverse effects of these drugs.

Evidence Review

Description

Stimulation of the vagus nerve can be performed by using a pulsed electrical stimulator implanted within the carotid artery sheath. This technique has been proposed as a treatment for refractory seizures, depression, and other disorders. There are also devices available that are implanted at different areas of the vagus nerve. This policy also addresses devices that stimulate the vagus nerve through the skin (transcutaneously).



Background

Vagus Nerve Stimulation (VNS)

VNS was initially investigated as a possible treatment alternative in patients with medically refractory partial-onset seizures for whom surgery is not recommended or for whom surgery has failed. Over time, the use of VNS has expanded to generalized seizures, and it has been investigated for a range of other conditions.

While the mechanisms for the therapeutic effects of VNS are not fully understood, the basic premise of VNS in the treatment of various conditions is that vagal visceral afferents have a diffuse central nervous system projection, and activation of these pathways has a widespread effect on neuronal excitability. An electrical stimulus is applied to axons of the vagus nerve, which have their cell bodies in the nodose and junctional ganglia and synapse on the nucleus of the solitary tract in the brainstem. From the solitary tract nucleus, vagal afferent pathways project to multiple areas of the brain. VNS may also stimulate vagal efferent pathways that innervate the heart, vocal cords, and other laryngeal and pharyngeal muscles, and provide parasympathetic innervation to the gastrointestinal tract.

A type of VNS device addressed in this policy consists of an implantable, programmable electronic pulse generator that delivers stimulation to the left vagus nerve at the carotid sheath. The pulse generator is connected to the vagus nerve via a bipolar electrical lead. Surgery for implantation of a vagal nerve stimulator involves implantation of the pulse generator in the infraclavicular region and wrapping two spiral electrodes around the left vagus nerve within the carotid sheath. The programmable stimulator may be programmed in advance to stimulate at regular intervals or on demand by patients or family by placing a magnet against the infraclavicular implant site.

Various types of devices that transcutaneously stimulate the vagus nerve have been developed as well. The U.S. Food and Drug Administration (FDA) has not approved any transcutaneous VNS devices.

Other types of implantable vagus nerve stimulators that are placed in contact with the trunks of the vagus nerve at the gastroesophageal junction are not addressed in this policy.

Indications

VNS was originally approved for the treatment of medically refractory epilepsy. Significant advances have been made since then in the surgical and medical treatment of epilepsy, and



newer, more recently approved medications are available. Despite these advances, however, 25% to 50% of patients with epilepsy experience breakthrough seizures or suffer from debilitating adverse effects of antiepileptic drugs. For these patients, VNS therapy has been used as an alternative or adjunct to epilepsy surgery or medications.

Based on observations that patients treated with VNS experience improvements in mood, VNS has been evaluated for the treatment of refractory depression. VNS has been investigated for multiple other conditions which may be affected by either the afferent or efferent stimulation of the vagus nerve, including headaches, tremor, heart failure, fibromyalgia, tinnitus, and traumatic brain injury.

Summary of Evidence

Vagus Nerve Stimulation

For individuals who have seizures refractory to medical treatment who receive VNS, the evidence includes RCTs and multiple observational studies. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCTs reported significant reductions in seizure frequency for patients with partial-onset seizures. The uncontrolled studies have consistently reported large reductions in a broader range of seizure types in both adults and children. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have treatment-resistant depression who receive VNS, the evidence includes an RCT, other nonrandomized comparative studies, and case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCT only reported short-term results and found no significant improvement for the primary outcome. Other available studies are limited by small sample sizes, potential selection bias, and lack of a control group in the case series. The evidence is insufficient to determine the effects of the technology on health outcomes.

Other Conditions

For individuals who have chronic heart failure who receive VNS, the evidence includes RCTs and case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCTs evaluating chronic heart failure did not show significant improvements in



the primary outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have upper-limb impairment due to stroke who receive VNS, the evidence includes a single pilot study. Relevant outcomes are symptoms, change in disease status, and functional outcomes. This pilot study has provided preliminary support for improvement in functional outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have other neurologic conditions (eg, essential tremor, headache, fibromyalgia, tinnitus, or autism) who receive VNS, the evidence includes case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Case series are insufficient to draw conclusions regarding efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

Transcutaneous Vagus Nerve Stimulation

For individuals with episodic cluster headaches who receive transcutaneous VNS, the evidence includes 3 RCTs. One RCT for a cluster headache showed a reduction in headache frequency but did not include a sham treatment group. Two randomized, double-blind, sham-controlled studies showed efficacy of achieving pain-free status within 15 minutes of treatment with noninvasive VNS in patients with episodic cluster headaches but not in patients with chronic cluster headaches. The RCTs for episodic cluster headaches are promising, however, additional studies with larger relevant populations are required to establish the treatment efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have other neurologic, psychiatric, or metabolic disorders (eg, epilepsy, depression, schizophrenia, headache, impaired glucose tolerance) who receive transcutaneous VNS, the evidence includes RCTs and case series for some of the conditions. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCTs are all small and have various methodologic problems. None showed definitive efficacy of transcutaneous VNS in improving patient outcomes. No controlled trials are published to date evaluating gammaCore for the acute treatment of migraine headache. The evidence is insufficient to determine the effects of the technology on health outcomes.



Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in [Table 1](#).

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02113033 ^a	Vagal Nerve Stimulation: safeGUARDing Heart Failure Patients	20	Mar 2016 (ongoing)
NCT02385526 ^a	ASCEND: Vagus Nerve Stimulation Titration Protocol to Improve Tolerance and Accelerate Adaptation	60	Apr 2017 (ongoing)
NCT02686034 ^a	A Prospective, Multi-centre, Randomized, Double-blind, Sham-controlled Study of gammaCore® Non-invasive Vagus Nerve Stimulator (nVNS), for the Acute Treatment of Migraine	300	Apr 2017 (ongoing)
NCT02378792 ^a	The Clinical Research on TsingHua Vagus Nerve Stimulator for Treatment of Refractory Epilepsy Enrollment	300	Dec 2017 (ongoing)
NCT02983448	Noninvasive Neuromodulation to Reserve Diastolic Dysfunction	26	Dec 2017 (ongoing)
NCT03062514 ^a	Vagus Nerve Stimulation for Pediatric Intractable Epilepsy (VNS-PIE)	84	Mar 2018
NCT02648191	Preoperative Treatment With Noninvasive Intra-auricular Vagus Nerve Stimulation Pending Bariatric Surgery. A Randomized, Controlled, Double-blind Trial	50	Apr 2018
NCT03380156	Effect of Transcutaneous Vagal Stimulation (TVS) on Endothelial Function and Arterial Stiffness in Patients With Heart Failure With Reduced Ejection Fraction	25	May 2018
NCT02359188	Influence of Transcutaneous Vagal Nerve Stimulation on Expression of microRNA, Cytokines, Chemokines and Neuropeptides as Well as Cerebral Resting State and Gastric Motility	60	Aug 2018
NCT01281293 ^a	A Post Market, Long Term, Observational, Multi-site Outcome Study to Follow the Clinical Course and Seizure Reduction of Patients With Refractory Seizures Who Are Being Treated With Adjunctive VNS Therapy	124	Dec 2018
NCT03163030 ^a	Autonomic Neural Regulation Therapy to Enhance	50	Dec 2018



NCT No.	Trial Name	Planned Enrollment	Completion Date
	Myocardial Function in Heart Failure With Preserved Ejection Fraction (ANTHEM-HFpEF) Study		
NCT03217929	Transcutaneous Auricular Vagus Nerve Stimulation (taVNS) for Food Craving in Obese Individuals: A Randomized, Sham-controlled, Double Blind Clinical Trial	54	Oct 2019
NCT03282110	Comprehensive Acupuncture for Depressive Disorder With Comorbid Psychogenic Pain: Randomized Controlled Study	60	Jun 2019
NCT03327649	Neuromodulation of Inflammation to Treat Heart Failure With Preserved Ejection Fraction	72	Dec 2019
NCT03320304^a	A Global Prospective, Multi-center, Observational Post-market Study to Assess short, Mid and Long-term Effectiveness and Efficiency of VNS Therapy® as Adjunctive Therapy in real-world patients With difficult to Treat Depression	500	Dec 2025
Unpublished			
NCT02562703	Transcutaneous Vagus Nerve Stimulation for Treating Major Depressive Disorder: a Phase II, Randomized, Double-blind Clinical Trial	40	Jul 2016 (unknown)
NCT02089243	Prospective Randomized Controlled Study of Vagus Nerve Stimulation Therapy in the Patients With Medically Refractory Medial Temporal Lobe Epilepsy; Controlled Randomized Vagus Nerve Stimulation Versus Resection (CoRaVNStiR)	40	Jul 2017 (unknown)
NCT01958125^a	A Randomized, Multicentre, Double-blind, Parallel, Sham-controlled Study of GammaCore®, a Non-invasive Neurostimulator Device for the Acute Relief of Episodic and Chronic Cluster Headache	120	Jan 2015 (completed)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

American Academy of Neurology

In 1999, the American Academy of Neurology released a consensus statement on the use of vagus nerve stimulation (VNS) in adults, which stated: "VNS is indicated for adults and



adolescents over 12 years of age with medically intractable partial seizures who are not candidates for potentially curative surgical resections, such as lesionectomies or mesial temporal lobectomies.”⁷⁹ The Academy updated these guidelines in 2013, stating: “VNS may be considered for seizures in children, for LGS [Lennox-Gastaut syndrome]-associated seizures, and for improving mood in adults with epilepsy (Level C). VNS may be considered to have improved efficacy over time (Level C).”⁸⁰ An update is reported to be in progress at the time of this policy update.

American Psychiatric Association

The American Psychiatric Association guidelines on the treatment of major depressive disorder in adults, updated in 2010, included the following statement on the use of VNS: “Vagus nerve stimulation (VNS) may be an additional option for individuals who have not responded to at least four adequate trials of antidepressant treatment, including ECT [electroconvulsive therapy],” with a level of evidence III (may be recommended on the basis of individual circumstances).⁸¹

European Headache Federation

In 2013, the European Headache Federation issued a consensus statement on neuromodulation treatments for chronic headaches, which made the following statement about the use of VNS: “Due to the lack of evidence, VNS should only be employed in chronic headache sufferers using a randomized, placebo controlled trial design.”⁸²

Medicare National Coverage

Medicare has a national coverage determination for VNS. Medicare coverage policy notes that “Clinical evidence has shown that vagus nerve stimulation is safe and effective treatment for patients with medically refractory partial onset seizures, for whom surgery is not recommended or for whom surgery has failed. Vagus nerve stimulation is not covered for patients with other types of seizure disorders that are medically refractory and for whom surgery is not recommended or for whom surgery has failed.”⁸³ Effective May 2007, VNS is not reasonable and necessary for resistant depression.



Regulatory Status

In 1997, the NeuroCybernetic Prosthesis (NCP®) System (Cyberonics), a VNS device, was approved by FDA through the premarket approval process for use in conjunction with drugs or surgery "...as an adjunctive treatment of adults and adolescents over 12 years of age with medically refractory partial onset seizures."¹ There have been subsequent expanded approvals. FDA product code: LYF

In May 2015, a related VNS therapy, AspireSR® (LivaNova), received supplemental premarketing approval from FDA, although the device was recalled in August 2017.² The AspireSR® device detects high heart rates associated with seizures and responds with stimulation. Adjunctive use of the AspireSR® for the treatment of epileptic seizures was indicated for patients over 4 years of age who suffer from partial-onset seizures that do not respond to antiepileptic medication.

In May 2017, the gammaCore-S® (electroCore), a noninvasive VNS device, was cleared for marketing by FDA through the 510(k) process (K171306) for the acute treatment of adults with episodic cluster headaches.³ When the device is applied to the side of the neck by the patient, mild electrical stimulation of the vagus nerve is carried to the central nervous system. Each stimulation using gammaCore-S® lasts 2 minutes. The patient controls the stimulation strength. FDA product code: PKR

Cerbomed (Erlangen, Germany) has developed a transcutaneous VNS (t-VNS®) system that uses a combined stimulation unit and ear electrode to stimulate the auricular branch of the vagus nerve, which supplies the skin over the concha of the ear. Patients self-administer electrical stimulation for several hours a day; no surgical procedure is required. The device received the CE mark in Europe in 2011, but has not been FDA approved for use in the United States.

On January 23, 2018 the FDA cleared the hand-held, noninvasive vagus nerve stimulator (nVS) gammaCore (electroCore LLC) for the acute treatment of migraine headache pain in adults. The new 510 (k) clearance expands the device's label from just treating episodic cluster headache pain. Clearance for the migraine indication was based on data from the unpublished PRESTO randomized sham-controlled trial with enrollees from 10 centers in Italy. U.S. commercial availability of the device for migraine headache is slated for the second quarter of 2018. FDA product code: PKR

Table 2 includes the updates pertinent to this policy.



Table 2. FDA-Approved or -Cleared Vagus Nerve Stimulators

Device Name	Manufacturer	Date Cleared	PMA / 510(k)	Indications
NeuroCybernetic Prosthesis (NCP®)	Cyberonics	1997	P970003	Indicated or adjunctive treatment of adults and adolescents >12 years of age with medically refractory partial onset seizures
		2005	P970003/S50	Expanded indication for adjunctive long-term treatment of chronic or recurrent depression for patients ≥18 years of age experiencing a major depressive episode and have not had an adequate response to ≥4 adequate antidepressant treatments
		2017	P970003/S207	Expanded indicated use as adjunctive therapy for seizures in patients ≥4 years of age with partial-onset seizures that are refractory to antiepileptic medications
gammaCore®	ElectroCore	2017	K171306	Indicated for acute treatment of pain associated with episodic cluster headache in adults using noninvasive VNS on the side of the neck
		2018	K173442	Indicated for acute treatment of pain associated with migraine headache in adults using noninvasive VNS on the side of the neck

FDA: Food and Drug Administration; PMA: premarket approval; VNS: vagus nerve stimulation.

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History

Date	Comments
06/25/98	Add to Surgery Section - New Policy
01/07/99	Coding Update - 1999 CPT coding release.
06/02/00	Replace Policy - Added cross-references to other stimulation policies.
01/08/02	Replace Policy - Title change; revised new indication for children, investigational as a treatment for depression. Held for notification, published 4/15/02.
09/12/03	Replace Policy - Information update; policy statement unchanged.
10/12/04	Replace Policy - Policy reviewed with literature search. FDA information and a reference added. Statement on investigational status of VNS treatment for essential tremor added.
09/13/05	Replace Policy - Policy updated with literature review and FDA approval of VNS for depression. Added headaches and essential tremor as investigational in the policy statement; remaining policy statements unchanged.
02/06/06	Codes updated - No other changes.
06/09/06	Disclaimer and Scope update - No other changes.
09/12/06	Replace Policy - Policy updated with June 2006 TEC Assessment (treatment-resistant depression) and literature review for other indications; policy statement unchanged; references added.
01/08/08	Replace Policy - Policy updated with literature search; no change in policy statement. References and codes added.
10/14/08	Replace Policy - Policy updated with literature search; no change in policy statement. References and codes added.
01/13/09	Replace Policy - Policy updated with literature search. Policy statement revised to indicate the VNS may be considered medically necessary in refractory seizures (both partial and generalized) and is investigational in treatment of obesity. References added.



Date	Comments
01/12/10	Replace Policy - Policy updated with literature search; no change to the policy statements. Rationale extensively reorganized and condensed. References added.
03/08/11	Replace Policy - Policy updated with literature search; references 30-32 have been added. No change to policy statements. ICD-10 codes added.
01/03/12	Deleted codes 64568, 64569, 64570 and 64573 removed.
06/26/12	Replace policy. Policy updated with literature search, references 26-28, 33, 34 added. Policy statement updated to include the addition of heart failure and fibromyalgia to the list of investigational conditions.
08/27/12	Update Related Policy – Add 2.01.50. Update coding section – ICD-10 codes are now effective 10/01/2014.
01/10/13	Coding update. New CPT codes 0312T – 0318T, effective 1/1/13, added to policy.
01/22/13	Update Related Policies. 2.01.50 replaced with 2.01.526.
02/15/13	Update Related Policies. Change title to policy 2.01.526.
05/28/13	Replace policy. Policy reviewed. Rationale section reformatted for readability, references renumbered to match the changes. A literature search through January 2013 did not prompt additions to the reference list. Vagus nerve blocking therapy codes (0312T-03127T) removed as inappropriate for this policy. Policy statement unchanged.
06/13/14	Annual Review. Policy updated with literature review through February 5, 2014. References 7, 13-17, 29-31, and 41-44 added. Policy statement updated to include the addition of tinnitus and traumatic brain injury to the list of investigational conditions. Rationale section reorganized.
01/26/15	Update Related Policy. Add 7.01.143.
03/13/15	Update Related Policies. Add 7.01.522.
05/27/15	Annual Review. Policy updated with literature review through January 27, 2015. Added vBloc Maestro system to Regulatory Status section. References 2, 14-17, 35, 40, 45-46, 51, 54-58, 62 added; others renumbered. Policy statements unchanged. Coding update: ICD-9 and ICD-10 diagnosis codes removed; ICD-9 procedure codes 02.93, 86.96, 86.97, and 86.98 removed; ICD-10 codes added for purposes of remediation.
09/01/15	Update Related Policies. Add 7.01.150.
05/01/16	Annual Review, approved April 12, 2016. Policy updated with literature review through January 20, 2016; references 44, 55, and 57 added. Regulatory Status section revised with device information. Policy statements unchanged.
03/01/17	Coding Update. Removed CPT code 95973 as it was deleted as of 01/01/2016.
08/25/17	Coding update, removed CPT codes 95971, 95972, 95974, and 95975. Policy moved to new format, no changes to policy statement.



Date	Comments
12/01/17	Annual Review, approved November 9, 2017. Policy updated with literature review through August 31, 2017. Multiple references added. Policy statements edited for clarity. The intent of policy statements unchanged. Removed CPT codes 61888 and 64570.
05/01/18	Annual Review, approved April 3, 2018. Policy updated with literature review through December 2017; references 2, 67-68, 77 and 84 added; reference 44 updated. Added information regarding transcutaneous device for treatment of migraine headache pain. Added note that VNS medical necessity criteria statement applies to both pediatric and adult patients. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.



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Premera:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Qualified sign language interpreters
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

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ይህ ማስታወቂያ አስፈላጊ መረጃ ይዟል። ይህ ማስታወቂያ ስለ ማመልከቻዎ ወይም የ Premera Blue Cross ሽፋን አስፈላጊ መረጃ ሊኖረው ይችላል። በዚህ ማስታወቂያ ውስጥ ቁልፍ ቀዳሾች ሊኖሩ ይችላሉ። የጤና ሽፋንዎን ለመጠበቅና በአስፋፈል እርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች እርምጃ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና የለምንም ክፍያ በቋንቋዎ እርዳታ እንዲያገኙ መሰታ አለዎት። በስልክ ቁጥር 800-722-1471 (TTY: 800-842-5357) ይደውሉ።

العربية (Arabic):

يحتوي هذا الإشعار على معلومات هامة. قد يحوي هذا الإشعار معلومات مهمة بخصوص طلبك أو التغطية التي تزيد الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تواريخ مهمة في هذا الإشعار. وقد تحتاج لاتخاذ إجراء في تواريخ معينة للحفاظ على تغطيتك الصحية أو المساعدة في دفع التكاليف. يحق لك الحصول على هذه المعلومات والمساعدة بلغتك دون تكبد أية تكلفة. اتصل بـ 800-722-1471 (TTY: 800-842-5357)

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本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

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Tsawb ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb. Tej zaum tsawb ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb txog koj daim ntawv thov kev pab los yog koj qhov kev pab cuam hnuv ntawm Premera Blue Cross. Tej zaum muaj cov hnuv tseem ceeb uas sau rau hauv daim ntawv no. Tej zaum koj kuj yuav tau ua qee yam uas peb kom koj ua tsis pub dhau cov caij nyoog uas teev tseg rau hauv daim ntawv no mas koj thiaj yuav tau txais kev pab cuam kho mob los yog kev pab them tej nqi kho mob ntawd. Koj muaj cai kom lawv muab cov ntshiab lus no uas tau muab sau ua koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

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본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

ລາວ (Lao):

ແຈ້ງການນີ້ມີຂໍ້ມູນສໍາຄັນ. ແຈ້ງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາຮ້ອງສະໝັກ ຫຼື ຄວາມຄົມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີ່ສໍາຄັນໃນແຈ້ງການນີ້. ທ່ານອາດຈະຈຳເປັນຕ້ອງດໍາເນີນການຕາມກຳນົດ ເວລາສະເພາະເພື່ອຮັກສາຄວາມຄົມຄອງປະກັນສະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເວັ້ນເວົ້ອງຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄດ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-722-1471 (TTY: 800-842-5357).

ភាសាខ្មែរ (Khmer):

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកកាមរយ: Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កិច្ចការផ្ទៃក្នុងដូចជា ធានា ដើម្បីនឹងរក្សាទុកការធានារ៉ាប់រងអនាគតរបស់អ្នក ឬប្រាក់ជំនួយចេញថ្លៃ។ អ្នកមានសិទ្ធិទទួលបានព័ត៌មាននេះ និងជំនួយនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

ਪੰਜਾਬੀ (Punjabi):

ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਨਵ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਰਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਦਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੋਂ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

فارسی (Farsi):

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کلیران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

Polskie (Polish):

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

Português (Portuguese):

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Română (Romanian):

Prezenta notificare conține informații importante. Această notificare poate conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența provizorie la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

Русский (Russian):

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Fa'asamoa (Samoan):

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganiitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

Український (Ukrainian):

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).