Medical Policy

Vagus Nerve Stimulation

Policy Number: OCA 3.51
Version Number: 14
Version Effective Date: 08/01/16

Product Applicability

All Plan* Products

Well Sense Health Plan
- New Hampshire Medicaid
- NH Health Protection Program

Boston Medical Center HealthNet Plan
- MassHealth
- Qualified Health Plans/ConnectorCare/Employer Choice Direct
- Senior Care Options ◊

Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

Vagus nerve stimulation (VNS) is considered medically necessary for eligible members who are 13 years of age or older with medically refractory partial onset seizures (with or without secondary generalized seizures), for whom resection epileptic surgery is not recommended or for whom resection epileptic surgery has failed. Other applications of vagus nerve stimulation, including the treatment for generalized seizures without partial onset seizure activity, are considered experimental and investigational. Prior authorization is required.
It will be determined during the Plan’s prior authorization process if the service is considered medically necessary for the requested indication. See Plan policy, *Medically Necessary* (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment. See the Plan’s policy, *Experimental and Investigational Treatment* (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment.

**Description of Item or Service**

**Vagus Nerve Stimulation (VNS):** Vagus nerve stimulation is a treatment for epilepsy where electrical pulses are delivered to the cervical portion of the vagus nerve via a battery-powered generator that is implanted. Vagus nerve stimulation is indicated for use as an adjunctive therapy for decreasing the frequency, shortening the duration, and/or reducing the severity of seizures in patients who are medically refractory to antiepileptic medication and who are not candidates for resection epilepsy surgery or if surgery has failed. The only device currently approved by the Food and Drug Administration (FDA) for vagus nerve stimulation (VNS), the VNS Therapy System (Cyberonics Inc.), consists of a programmable generator that is implanted subcutaneously into the patient’s chest and delivers pulses of current via electrodes attached to the vagus nerve in the left side of the neck.

**Medical Policy Statement**

Vagus nerve stimulation is considered medically necessary for a member when ALL of the following criteria are met and documented in the medical record, as specified below in items 1 through 6:

1. The member has medically refractory partial onset seizures (with or without secondary generalized seizures); AND

2. Member continues to have greater than one (1) seizure per month despite treatment; AND

3. Member has failed treatment with maximally tolerated/therapeutic dose of at least two (2) first-line antiepilepsy drugs (AED) (with medications administered as monotherapies or in combination); AND

4. The member is 13 years of age or older on the date of service; AND

5. Resection epileptic surgery is not recommended for the member or epileptic surgery has failed; AND

6. The vagus nerve stimulator is FDA approved for the treatment of medically refractory partial onset seizures (with or without secondary generalized seizures) and will be used according to FDA-approved specifications.
Limitations

1. According to the U.S. Food and Drug Administration (FDA), vagus nerve stimulation (with a device such as of the VNS Therapy™ System) cannot be used on patients with a history of bilateral or left cervical vagotomy.

2. Other applications of vagus nerve stimulation that do not meet medical criteria specified in the Medical Policy Statement section of this policy are considered experimental and investigational, including but not limited to the treatment of at least ONE (1) of the following conditions, as specified below in items a through n:

   a. Alzheimer's disease; OR
   b. Anxiety and mood disorders; OR
   c. Autism; OR
   d. Bipolar disorders; OR
   e. Cerebral palsy; OR
   f. Depression; OR
   g. Essential tremors; OR
   h. Fibromyalgia; OR
   i. Headaches; OR
   j. Heart failure; OR
   k. Modifying eating behavior and weight in adults with depression; OR
   l. Obesity; OR
   m. Sleep disorders; OR
   n. Treatment for generalized seizures without partial onset seizure activity diagnosed by at least ONE (1) of the following tests, as specified below in items (1) through (3):

      (1) Neuroimaging evaluation (e.g., MRI, CT scanning); OR
(2) Electroencephalography (EEG); OR

(3) Video electroencephalographic (EEG) monitoring.

3. Vagus nerve stimulation for any indication for a member younger than age 13 on the date of service is considered experimental and investigational.

4. Contraindications to treatment include at least ONE (1) of the following, as specified below in items a through c:

   a. Concurrent use of seizure-provoking medication; OR

   b. Intoxication due to drugs of abuse within 48 hours of seizure; OR

   c. Sudden cessation of heavy alcohol use within 48 hours of a seizure.

5. The use of an automatic stimulation mode in a vagus nerve stimulator activated in response to the detected increase in heart rate (which may be a sign of an impending seizure) is considered experimental and investigational due to insufficient evidence of this additional functionality to inform evidence-based clinical decisions.

   (Note: The AspireSR Model of the VNS Therapy™ System by Cyberonics Inc. can deliver stimulation in the normal and magnet modes. However, when programmed for the AutoStim mode, the AspireSR requires no patient interaction to trigger the delivery of electrical stimulation and is automatically activated in response to the detected increase in heart rate which is presumed to be a sign of an impending seizure. According to the manufacturer, the AutoStim mode should never be used in patients with significant arrhythmias being treated with pacemakers and/or an implantable defibrillator, beta-blockers, or any other treatment that may impact the intrinsic heart rate. The Plan considers the automatic stimulation mode to be experimental and investigational for all patient populations until the clinical utility and clinical validity of this mode is consistently documented.)

Definitions

Medically Refractory Seizures: Seizures that continue to occur after treatment with therapeutic levels of antiepileptic medications or seizures that cannot be treated with antiepileptic medications because the side effects are not tolerable. Medically refractory seizures occur when a patient continues to have seizures despite treatment with a maximally tolerated dose of a first-line antiepilepsy drug (AED) as monotherapy or in combination with at least one adjuvant medication.

Vagus Nerve: Also known as the pneumogastric or 10th cranial nerve, the vagus nerve is a mixed nerve with motor and sensory functions. The vagus nerve starts at the brainstem and ends in the colon. The

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vagus nerve controls the sensory and motor functions of the pharynx, larynx, trachea, lungs, heart, esophagus, stomach, and bowel.

**Applicable Coding**

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United State by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
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<tbody>
<tr>
<td>61885</td>
<td>Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array</td>
</tr>
<tr>
<td>61886</td>
<td>Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays</td>
</tr>
<tr>
<td>61888</td>
<td>Revision or removal of cranial neurostimulator pulse generator or receiver</td>
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<tr>
<td>64553</td>
<td>Percutaneous implantation of neurostimulator electrode array; cranial nerve</td>
</tr>
<tr>
<td>64568</td>
<td>Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator</td>
</tr>
<tr>
<td>64569</td>
<td>Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator</td>
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</table>
Clinical Background Information

Epilepsy is a recurrent paroxysmal disorder of cerebral function that is associated with a sudden and brief attack of altered consciousness, motor activity, or sensory phenomena. Convulsive seizures are the most common form of epilepsy and result from simultaneous electrical discharge of groups of nerve cells within the brain. Epilepsy can be the result of injury, infection, structural abnormalities in the brain, abnormal fetal brain development, or exposure to toxins, but in many cases the cause is unknown.

The two (2) major risks that are associated with epilepsy include status epilepticus and sudden death. Status epilepticus is a severe, life-threatening condition where prolonged seizures occur, lasting 10 minutes or longer, or when the person does not regain consciousness between the seizures. Seizures have been defined as a paroxysmal disorder of the central nervous system that is associated with abnormal cerebral neuronal discharge, with or without loss of consciousness. Seizures have been further subclassified into those with a generalized onset (beginning throughout the brain), partial onset (having a discrete focal onset), or partial onset with secondary generalization. These types of seizures can be easily confused but are treated differently.

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There are two (2) principal subtypes of partial-onset seizures:

1. Simple partial seizures: Simple partial seizures are partial onset seizures that do not involve alteration of consciousness; this type of seizure may have observable motor components or may be a subjective sensory or emotion phenomenon. The individual remains conscious but may experience unusual feelings or sensations.

2. Complex partial seizure: Complex partial seizures are partial onset seizures that involve loss of consciousness. The individual has a change in or loss of consciousness.

Generalized seizures are the result of abnormal neuronal activity that is widespread throughout the brain. The types of generalized seizures include the following, as specified below in items 1 through 6:

1. Absence seizures: The individual may appear to be staring into space and/or have jerking, twitching muscle movements.

2. Atonic seizures: The individual has a sudden loss of muscle tone leading to falls or involuntary nodding of the head.

3. Clonic seizures: The individual has repeated jerking movements of muscles on both sides of the body.

4. Myoclonic seizures: The individual has jerks or twitches of muscles in the upper body, arms, or legs.

5. Tonic-clonic seizures: The individual has a mixture of symptoms including stiffening of the body and repeated jerking of the arms and/or legs as well as a loss of consciousness.

6. Tonic seizures: The individual has stiffening of the back, leg, and arm muscles.

Partial seizures with secondary generalization represent a third category of seizures. These begin as simple or complex partial seizures but then spread (generalize) to the rest of the brain and look like generalized tonic-clonic seizures.

Significant advances have occurred regarding medical and surgical treatment for epilepsy, but despite treatment some patients with epilepsy continue to experience seizures or suffer from serious side effects from epilepsy medications. Vagus nerve stimulation (VNS) is an adjunctive therapy for reducing the frequency, shortening the duration, and/or reducing the severity of seizures in patients with partial onset seizures (with or without secondary generalized seizures) who are medically refractory to antiepileptic medication and who are not candidates for resection epilepsy surgery or if surgery has failed. The basis of VNS in the treatment of various conditions is that its connections link diffusely into the central nervous system, and activation of these pathways has a widespread effect on decreasing neuronal excitability, thereby theoretically controlling seizures.

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The vagus nerve stimulator is a simple device consisting of two (2) electrodes, an externally programmable pulse generator, and a battery pack. The vagus nerve implantation surgery involves wrapping two (2) spiral electrodes around the left vagus nerve within the carotid sheath. The electrodes are connected to a impulse generator pack that is implanted along with the battery pack under the skin in the upper left chest area. The left vagus nerve is the preferred site of stimulation due to the higher risks of cardiac arrhythmias with right vagus nerve stimulation as it innervates the sinoatrial node and thus influences heart rate and rhythm. The procedure lasts about 50-90 minutes with the patient under general or local anesthesia. Typically, patients may stay in the hospital one (1) day or be discharged the same day. The stimulator may be programmed in advance by the neurologist to stimulate at regular intervals or upon demand when the individual senses the onset of a seizure by using a magnet that can be worn on the wrist like a bracelet or clipped to a belt or pants. Side effects of VNS include hoarseness and a tingling sensation that is associated with stimulation. Complications of VNS include coughing and throat pain during stimulation and post-operative infections relating to the procedure. In 1997 the U.S. Food and Drug Administration (FDA) approved a vagus nerve stimulation device for the treatment of seizures; the system was formerly named the NeuroCybernetic Prosthesis® (NCP) System and is now called VNS Therapy™ System (Cyberonics, Inc.); the device was approved for use as an adjunctive treatment of adults and adolescents over 12 years of age with medically refractory partial onset seizures.

The early versions of the VNS device provided electrical stimulation in normal mode (chronic intermittent pulses) or magnet mode usually worn on the patient’s arm (pulses triggered by a magnetic interface with the implant for on-demand stimulation). Different parameters of electrical stimulation can be programmed such as current strength, pulse width, pulse train frequency, current on and off times as well as magnet current strength. Generator models currently available: 102 Pulse, 102 Pulse Duo, 103 Demipulse, 104 Demipulse Duo, 105 Aspire HC, and 106 Aspire SR.

Recently, the AspireSR Model 106 (Cyberonics Inc.) received FDA Premarket Approval (PMA). The newest modification to the VNS implant detects tachycardia heart rates, which may be associated with an impending seizure, and automatically delivers stimulation to the vagus nerve. Like its predecessors, the AspireSR can also deliver stimulation in the normal and magnet modes. However, when programmed for the AutoStim mode, the AspireSR requires no patient interaction to trigger the delivery of electrical stimulation and is automatically activated in response to the detected increase in heart rate which is presumed to be a sign of an impending seizure. According to the manufacturer, the AutoStim mode should not be used in patients with significant arrhythmias being treated with pacemakers and/or an implantable defibrillator, beta-blockers, or any other treatment that may impact the intrinsic heart rate. The U.S. Food and Drug Administration (FDA) has documented class 2 device recalls for the Cyberonics VNS Therapy AspireSR Generator Model 106.

A major depressive episode or major depression is a serious medical illness that disrupts the individual’s mood, behavior, thought processes, and physical health. There are currently three (3) major treatment modalities that have clinical evidence of effectiveness in the treatment of major depression: antidepressant drug therapy, psychotherapy, and electroconvulsive therapy (ECT). VNS

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Therapy™ System (Cyberonics, Inc.) was approved for marketing by the FDA for the adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to antidepressant treatments. There has been research on VNS as a treatment option for refractory depression, and some recipients have reported an improvement in mood; however, long-term data is limited on the safety and effectiveness of this procedure for treating depression.

At the time of the Plan’s most recent policy review, the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) 160.18 for vagus nerve stimulation (VNS) includes medically necessary indications for the treatment of medically refractory partial onset seizures, as well as limitations in coverage. The NCD states that VNS is not reasonable and necessary for the treatment of other types of seizure disorders and/or for depression. Verify CMS criteria in the applicable NCD or local coverage determination (LCD) in effect on the date of the prior authorization request for a Senior Care Options member.

References


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Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Vagus Nerve Stimulation for Treatment of Seizures. NCD Manual Section Number 160.18. Publication Number 100-3. July 1, 1999. Version Number 2. Effective May 4, 2007. Accessed at: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=230&ncdver=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NC%7CAL%7CNCD%7CMEDCAC%7CTA%7CMCD&ArticleType=Ed%7CKey%7CSAD%7CFAQ&PolicyType=Final&s=---%7C5%7C66%7C67%7C9%7C38%7C63%7C41%7C64%7C44&KeyWord=Vagus+nerve+stimulation&KeyWordLookUp=Doc&KeyWordSearchType=And&kq=true&bc=IAAAACAAAgAA&


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George MS et al. A One Year Comparison of Vagus Nerve Stimulation with treatment as usual for Treatment Resistant Depression. Biol Psychiatry 2005 Sep 1;58(5):364-73.


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<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Approved by</th>
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<tr>
<td>Regulatory Approval: N/A</td>
<td>06/09/06 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)</td>
<td>Quality and Clinical Management Committee (Q&amp;CMC)</td>
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<td>Internal Approval: 05/09/06</td>
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*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for the Well Sense Health Plan New Hampshire Medicaid Product(s): 01/01/13
*Effective Date for the Senior Care Options Product(s): 01/01/16

Policy Revisions History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
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<tr>
<td>04/24/07</td>
<td>Added codes and references.</td>
<td>Version 2</td>
<td>04/24/07: Utilization Management Committee (UMC) 05/03/07: QIC</td>
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<tr>
<td>05/13/08</td>
<td>Updated clinical criteria to include that VNS is investigational when used to modify eating behavior and weight in adults with depression.</td>
<td>Version 3</td>
<td>05/13/08: MPCTAC 05/20/08: UMC 05/28/08: QIC</td>
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<tr>
<td>05/26/09</td>
<td>No changes to clinical criteria. Updated references and coding.</td>
<td>Version 4</td>
<td>05/26/09: MPCTAC 05/26/09: UMC 06/24/09: QIC</td>
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<tr>
<td>05/01/10</td>
<td>Updated clinical background information and coding.</td>
<td>Version 5</td>
<td>05/25/10: MPCTAC 06/23/10: QIC</td>
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<tr>
<td>05/01/11</td>
<td>Updated references. No changes to clinical criteria.</td>
<td>Version 6</td>
<td>05/18/11: MPCTAC 06/22/11: QIC</td>
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<tr>
<td>05/01/12</td>
<td>No changes made to clinical criteria. References and CPT code definitions updated, applicable HCPCS code added, and notations for 2011 codes in code definitions deleted.</td>
<td>Version 7</td>
<td>05/16/12: MPCTAC 06/27/12: QIC</td>
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<tr>
<td>08/01/12</td>
<td>Off cycle review for Well Sense Health Plan. Revised Summary Statement, reformatted Medical Policy Statement,</td>
<td>Version 8</td>
<td>08/13/12: MPCTAC 09/06/12: QIC</td>
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<table>
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<th>Date</th>
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<th>Review Dates</th>
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<tr>
<td>03/01/13</td>
<td>Revised the introductory paragraph in Applicable Coding section. Revised Summary and Description of Item or Service sections. Added medical criteria to Medical Policy Statement section (formerly titled Clinical Guideline Statement section). Added criteria to Limitations section, updated language in introductory paragraph of Applicable Coding section, added text to Clinical Background Information section, updated and added references, and changed name of policy category from “Clinical Coverage Guidelines” to “Medical Policy.” Referenced the following Plan policies: Medically Necessary (OCA: 3.14) and Experimental and Investigational Treatment (OCA: 3.12).</td>
<td>07/01/13</td>
<td>03/20/13: MPCTAC 04/18/13: QIC</td>
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<td>08/14/13 and 08/15/13</td>
<td>Off cycle review for Well Sense Health Plan and merged policy format. Incorporate policy revisions dated 03/01/13 (as specified above) for the Well Sense Health Plan product; these policy revisions were approved by MPCTAC on 03/20/13 and QIC on 04/18/13 for applicable Plan products.</td>
<td>Version 10</td>
<td>08/14/13: MPCTAC (via electronic vote) 08/15/13: QIC</td>
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<tr>
<td>04/01/14</td>
<td>Review for effective date 08/01/14. Updated Summary, Description of Item or Service, Clinical Background Information, and References sections. Revised medical criteria to specify medical necessity of service for partial onset seizures (with or without secondary generalized seizures) in the Medical Policy Statement and Limitations sections. Added limitations.</td>
<td>08/01/14</td>
<td>04/16/14: MPCTAC 05/14/14: QIC</td>
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<td>04/01/15</td>
<td>Review for effective date 08/01/15. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available. Changed age criteria.</td>
<td>08/01/15</td>
<td>04/15/15: MPCTAC 05/13/15: QIC</td>
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### Policy Revisions History

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<tr>
<th>Date</th>
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<tbody>
<tr>
<td>11/25/15</td>
<td>Review for effective date 01/01/16. Updated template with list of applicable products and notes. Revised language in the Applicable Coding section.</td>
<td>01/01/16</td>
<td>01/01/16: MPCTAC</td>
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<td>Version 13</td>
<td>11/25/15: MPCTAC</td>
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<td>(electronic vote)</td>
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<td>12/09/15: QIC</td>
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<tr>
<td>04/01/16</td>
<td>Review for effective date 08/01/16. Updated Clinical Background Information, References, and Reference to Applicable Laws and Regulations. Revised criteria in the Medical Policy Statement and Limitations sections.</td>
<td>08/01/16</td>
<td>04/20/16: MPCTAC</td>
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<td>05/23/16: QIC</td>
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### Last Review Date

04/01/16

### Next Review Date

04/01/17

### Authorizing Entity

QIC

### Other Applicable Policies

- Medical Policy - *Experimental and Investigational Treatment*, policy number OCA 3.12
- Medical Policy - *Medically Necessary*, policy number OCA 3.14
Reference to Applicable Laws and Regulations


Disclaimer Information: +

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.