Medical Policy

Occipital Nerve Stimulation

Policy Number: OCA 3.501
Version Number: 14
Version Effective Date: 04/01/16

Product Applicability

<table>
<thead>
<tr>
<th>Well Sense Health Plan</th>
<th>Boston Medical Center HealthNet Plan</th>
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<tr>
<td>☑ New Hampshire Medicaid</td>
<td>☑ MassHealth</td>
</tr>
<tr>
<td>☑ NH Health Protection Program</td>
<td>☑ Qualified Health Plans/ConnectorCare/Employer Choice Direct</td>
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<tr>
<td>☑ Senior Care Options ◊</td>
<td>☑ Senior Care Options ◊</td>
</tr>
</tbody>
</table>

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

The Plan considers the use of occipital nerve stimulation for the treatment of intractable occipital neuralgia, cluster headaches, migraines, or for any other indication to be experimental and investigational. Plan prior authorization is required.

It will be determined during the Plan’s prior authorization process if the service is considered experimental and investigational for the requested use. See the Plan’s policy, Experimental and Investigational Treatment (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment.

Occipital Nerve Stimulation

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Description of Item or Service

**Occipital Nerve Stimulation (ONS):** Electrical stimulation to the occipital nerve is used to prevent or reduce the severity and frequency of head and/or neck pain associated with headache disorders, including occipital neuralgia, migraine headaches, and/or cluster-type headaches in patients who have not responded to medication and other conservative therapy. The device consists of a subcutaneously implanted pulse generator (in the chest wall or abdomen) attached to extension leads that are tunneled to join electrodes placed across one or both occipital nerves within the subcutaneous tissues at the base of the skull. The procedure requires a subcutaneous incision at the base of the skull (with the tips of the electrodes placed over the occipital nerves) and another subcutaneous incision in the chest wall or abdomen for the pulse generator. This type of peripheral nerve stimulation technique provides continuous or intermittent electrical stimulation to modulate the activity of the occipital nerve(s) and its branches and thereby reducing the severity and frequency of headaches.

Medical Policy Statement

The Plan considers occipital nerve stimulation for any indication to be experimental and investigational.

Limitations

This service is considered experimental and investigational.

Definitions

**Occipital Neuralgia:** A rare neurological disorder characterized by piercing or throbbing pain in the upper neck, back of the head, and behind the ears, usually on one side of the head. Typically, the pain begins in the neck and spreads upwards. Some individuals also experience pain in the scalp, forehead, and behind the eyes. The location of pain is related to the course of the greater and lesser occipital nerves, which runs from the site at which the spinal cord meets the skull, up to the scalp at the back of the head. Occipital neuralgia can occur due to irritation or injury of the occipital nerve; however, in many cases the cause is unknown.

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 Stated 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 notice.

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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 Considered Experimental and Investigational</th>
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<tbody>
<tr>
<td>64555</td>
<td>Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)</td>
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<tr>
<td>64575</td>
<td>Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)</td>
</tr>
<tr>
<td>64585</td>
<td>Revision or removal of peripheral neurostimulator electrode array</td>
</tr>
<tr>
<td>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling</td>
</tr>
<tr>
<td>64595</td>
<td>Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver</td>
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Clinical Background Information

Occipital nerve stimulation has been proposed for patients with intractable headache that cannot be managed by alternative treatments. The procedure involves implanting electrodes under the skin in the suboccipital region of the scalp that deliver the electrical stimulus, and subcutaneous placement of the pulse generator in the chest wall or abdomen. The electrodes deliver electrical impulses near the occipital nerves through insulated wires, which are tunneled under the skin and connected to the pulse generator. The electrical stimulus interferes with the neural transmission of the pain sensations back to the brain. Usually a trial of stimulation is done for several days to assess the response to pain before permanent implantation.

Complications related to this procedure include lead migration (which may require removal and replacement), power depletion in the pulse generator, and the possibility of infection. At the current time occipital nerve stimulation is considered experimental and investigational for all indications because its effectiveness has not been established. The devices used to perform electrical stimulation are regulated by the U.S. Food and Drug Administration (FDA) with the 510(k) premarket approval process; examples of FDA-approved peripheral nerve stimulators include but may not be limited to the

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Synergy® (Medtronic Inc.) and the Renew™ Quattrode® (Advanced Neuromodulation Systems Inc.) devices, although none are specifically approved for occipital nerve stimulation.

At the time of the Plan’s most recent policy review, no clinical guidelines were found from the Centers for Medicare & Medicaid Services (CMS) for occipital nerve stimulation for the treatment of intractable occipital neuralgia, cluster headaches, migraines, or for any other indication. Verify the applicable CMS criteria in effect for this service in a national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request for a Senior Care Options member. According to the Medicare Benefit Policy Manual (Rev. 198, 11/06/14), medical devices that are not approved for marketing by the FDA are considered investigational by Medicare and are not considered medically necessary for the diagnosis or treatment of illness or injury, or to improve functioning. Occipital nerve stimulation devices are not FDA approved but may be covered by Medicare when used in the context of an FDA-approved investigational device exemption (IDE) trial when Medicare-specified criteria are met. For other types of peripheral nerve stimulators (excluding occipital nerve stimulation), review the CMS criteria included in the NCD for Electrical Nerve Stimulators (160.7) and the NCD for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1).

References


<table>
<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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<tbody>
<tr>
<td>Regulatory Approval: N/A</td>
<td>12/06/05 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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*Effective Date for the BMC HealthNet 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 Senior Care Options Product(s): 01/01/16

Effective 06/01/13, this policy replaced Spinal Cord and Occipital Nerve Stimulation for Chronic Pain policy, policy number OCA 3.50.

Occipital Nerve Stimulation

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<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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<tbody>
<tr>
<td>02/06/07</td>
<td>Updated template and references.</td>
<td>Version 2</td>
<td>02/06/07: Q&amp;CMC</td>
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<tr>
<td>02/19/08</td>
<td>Revised clinical criteria. Revisions effective 07/01/08.</td>
<td>07/01/08 Version 3</td>
<td>02/19/08: MPCTAC 02/26/08: Utilization Management Committee (UMC) 03/12/08: QIC</td>
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<tr>
<td>01/27/09</td>
<td>No changes to the clinical criteria. Updated codes.</td>
<td>Version 4</td>
<td>01/27/09: MPCTAC 01/27/09: UMC 02/25/09: QIC</td>
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<tr>
<td>12/21/09</td>
<td>No changes to the clinical criteria. Updated references.</td>
<td>Version 5</td>
<td>12/23/09: MPCTAC 02/24/10: QIC</td>
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<tr>
<td>12/01/10</td>
<td>Updated references. No changes to criteria.</td>
<td>Version 6</td>
<td>12/28/10: MPCTAC 01/26/11: QIC</td>
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<tr>
<td>12/01/11</td>
<td>Added occipital nerve stimulation for migraines as experimental. Updated title, summary, clinical criteria, background information, references, and coding sections.</td>
<td>Version 7</td>
<td>12/12/11: MPCTAC 12/20/11: QIC</td>
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<tr>
<td>07/30/12</td>
<td>Off cycle review for Well Sense Health Plan. Revised Summary statement, reformatted Medical Policy Statement, revised Definitions, revised Limitations, and updated code list.</td>
<td>Version 8</td>
<td>08/13/12: MPCTAC 09/06/12: QIC</td>
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<tr>
<td>02/01/13</td>
<td>Review for effective date 06/01/13. Separated occipital nerve stimulation and spinal cord stimulation into two separate policies; policy formerly titled Spinal Cord and Occipital Nerve Stimulation for Chronic Pain (formerly 3.50). Revised title and re-numbered policy. Updated language in Summary, Description of Item or Service, Medical Policy Statement (formerly named the Clinical Guideline Statement), Definitions, Limitations, and Clinical Background Information sections. Changed name of policy category from “Clinical Coverage Guidelines” to “Medical Policy.” Revised applicable code list and updated language in introductory paragraph of Applicable Coding section. Updated and added references.</td>
<td>06/01/13 Version 9</td>
<td>02/20/13: MPCTAC 03/21/13: QIC</td>
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<td>08/14/13</td>
<td>Off cycle review for Well Sense Health Plan and</td>
<td>Version 10</td>
<td>08/14/13: MPCTAC</td>
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Policy Revisions History

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Policy Revisions History

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<tr>
<th>Date</th>
<th>Description</th>
<th>Version</th>
<th>Date</th>
<th>Approving Entity</th>
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<tr>
<td>08/15/13</td>
<td>merged policy format. Incorporate policy revisions dated 02/01/13 (as specified above) for the Well Sense Health Plan product; these policy revisions were approved by MPCTAC on 02/20/13 and QIC on 03/21/13 for applicable Plan products.</td>
<td></td>
<td>(electronic vote)</td>
<td>08/15/13: QIC</td>
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<tr>
<td>02/01/14</td>
<td>Review for effective date 03/01/14. Updated references. Revised Description of Item or Service section and Clinical Background Information section.</td>
<td>03/01/14 Version 11</td>
<td>02/19/14: MPCTAC 02/26/14: QIC</td>
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<tr>
<td>02/01/15</td>
<td>Review for effective date 04/01/15. Updated References section. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available.</td>
<td>04/01/15 Version 12</td>
<td>02/18/15: MPCTAC 03/11/15: QIC</td>
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<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 Version 13</td>
<td>11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC</td>
<td></td>
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<tr>
<td>02/01/16</td>
<td>Review for effective date 04/01/16. Updated Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections.</td>
<td>04/01/16 Version 14</td>
<td>02/17/16: MPCTAC 03/09/16: QIC</td>
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Last Review Date

02/01/16

Next Review Date

02/01/17

Authorizing Entity

QIC

Other Applicable Policies

Medical Policy - *Experimental and Investigational Treatment*, policy number OCA 3.12

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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.

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