Medical Policy

Phrenic Nerve Stimulation for Central Sleep Apnea

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- Policy: Medicare
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Policy Number: 955
BCBSA Reference Number: 2.02.33
NCD/LCD: Local Coverage Determination (LCD): Transvenous Phrenic Nerve Stimulation in the Treatment of Central Sleep Apnea (L37929)

Related Policies
Diaphragmatic/Phrenic Nerve Stimulation and Diaphragm Pacing Systems, #593

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

The use of phrenic nerve stimulation for central sleep apnea is considered INVESTIGATIONAL in all situations.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance for Medicare Advantage members living in Massachusetts can be found through the link below.

Local Coverage Determinations (LCDs) for National Government Services, Inc.

Local Coverage Determination (LCD): Transvenous Phrenic Nerve Stimulation in the Treatment of Central Sleep Apnea (L37929)

Note: To review the specific LCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

For medical necessity criteria and coding guidance for Medicare Advantage members living outside of Massachusetts, please see the Centers for Medicare and Medicaid Services website at https://www.cms.gov for information regarding your specific jurisdiction.

Prior Authorization Information

Inpatient
- For services described in this policy, precertification/preauthorization IS REQUIRED for all products if the procedure is performed INPATIENT.
Outpatient

For services described in this policy, see below for products where prior authorization might be required if the procedure is performed outpatient.

<table>
<thead>
<tr>
<th>Outpatient</th>
<th>Commercial Managed Care (HMO and POS)</th>
<th>This is not a covered service.</th>
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</thead>
<tbody>
<tr>
<td>Commercial PPO and Indemnity</td>
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<tr>
<td>Medicare HMO BlueSM</td>
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<tr>
<td>Medicare PPO BlueSM</td>
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</table>

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT and HCPCS codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0424T</td>
<td>Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)</td>
</tr>
<tr>
<td>0425T</td>
<td>Insertion or replacement of neurostimulator system for treatment of central sleep apnea; sensing lead only</td>
</tr>
<tr>
<td>0426T</td>
<td>Insertion or replacement of neurostimulator system for treatment of central sleep apnea; stimulation lead only</td>
</tr>
<tr>
<td>0427T</td>
<td>Insertion or replacement of neurostimulator system for treatment of central sleep apnea; pulse generator only</td>
</tr>
<tr>
<td>0428T</td>
<td>Removal of neurostimulator system for treatment of central sleep apnea; pulse generator only</td>
</tr>
<tr>
<td>0429T</td>
<td>Removal of neurostimulator system for treatment of central sleep apnea; sensing lead only</td>
</tr>
<tr>
<td>0430T</td>
<td>Removal of neurostimulator system for treatment of central sleep apnea; stimulation lead only</td>
</tr>
<tr>
<td>0431T</td>
<td>Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only</td>
</tr>
<tr>
<td>0432T</td>
<td>Repositioning of neurostimulator system for treatment of central sleep apnea; stimulation lead only</td>
</tr>
<tr>
<td>0433T</td>
<td>Repositioning of neurostimulator system for treatment of central sleep apnea; sensing lead only</td>
</tr>
<tr>
<td>0434T</td>
<td>Interrogation device evaluation implanted neurostimulator pulse generator system for central sleep apnea</td>
</tr>
<tr>
<td>0435T</td>
<td>Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session</td>
</tr>
<tr>
<td>0436T</td>
<td>Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; during sleep study</td>
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HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>C1823</td>
<td>Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads</td>
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</table>

**Description**

**Central Sleep Apnea**

CSA is characterized by repetitive cessation or decrease in both airflow and ventilatory effort during sleep. CSA may be idiopathic or secondary (associated with Cheyne-Stokes breathing, a medical condition, drugs, or high altitude breathing. Cheyne-Stokes breathing is common among patients with heart failure (HF) or who have had strokes, and accounts for about half of the population with CSA. CSA is less common than obstructive sleep apnea. Based on analyses of a large community-based cohort in the Sleep Heart Health Study, the estimated prevalence of CSA and obstructive sleep apnea are 0.9% and 47.6%, respectively. Risk factors for CSA include age (>65 years), male gender, history of HF, history of stroke, other medical conditions (acromegaly, renal failure, atrial fibrillation, low cervical tetraplegia, and primary mitochondrial diseases), and opioid use. Individuals with CSA have difficulty maintaining sleep and therefore experience excessive daytime sleepiness, poor concentration, morning headaches, and are at higher risk for accidents and injuries.

**Treatment**

The goal of treatment is to normalize sleep-related breathing patterns. Because most cases of CSA are secondary to an underlying condition, central nervous system pathology, or medication side effects, treatment of the underlying condition or removal of the medication, may improve CSA.

Treatment recommendations differ depending on the classification of CSA as either hyperventilation-related (most common, including primary CSA and those relating to HF or high altitude breathing) or hypoventilation-related (less common, relating to central nervous system diseases or use of nervous system suppressing drugs such as opioids).

For patients with hyperventilation-related CSA, continuous positive airway pressure (CPAP) is considered first-line therapy. Due to CPAP discomfort, patient compliance may become an issue. Supplemental oxygen during sleep may be considered for patients experiencing hypoxia during sleep or who cannot tolerate CPAP. Patients with CSA due to HF and with an ejection fraction >45% and who are not responding with CPAP and oxygen therapy, may consider bilevel positive airway pressure or adaptive servo-ventilation (ASV) as second-line therapy. Bilevel positive airway pressure devices have two pressure settings, one for inhalation and one for exhalation. ASV uses both inspiratory and expiratory pressure and titrates the pressure to maintain adequate air movement. However, a clinical trial reported increased cardiovascular mortality with ASV in patients with CSA due to HF and with an ejection fraction <45%, and therefore, ASV is not recommended for this group.

For patients with hypoventilation-related CSA, first-line therapy is bilevel positive airway pressure. Pharmacologic therapy with a respiratory stimulant may be recommended to patients with hyper- or hypoventilation CSA who do not benefit from positive airway pressure devices, though close monitoring is necessary due to the potential for adverse effects such as rapid heart rate, high blood pressure, and panic attacks.

**Phrenic Nerve Stimulation**

Currently, there is one phrenic nerve stimulation device approved by the Food and Drug Administration, the remede System (Respicardia, Inc.). The remede System is an implantable device that stimulates the phrenic nerve in the chest which sends signals to the diaphragm to restore a normal breathing pattern. A cardiologist implants the battery powered device under the skin in the right or left pectoral region. The procedure is conducted using local anesthesia. The device has two leads, one to stimulate a phrenic nerve (either the left pericardiophrenic or right brachiocephalic vein) and one to sense breathing. The device runs on an algorithm that activates automatically at night when the patient is in a sleeping position.
and suspends therapy when the patient sits up. Patient-specific changes in programming can be conducted externally by a programmer.

**Summary**

Central sleep apnea (CSA) is characterized by sleep-disordered breathing due to diminished or absent respiratory effort. CSA may be idiopathic or secondary (associated with Cheyne-Stokes breathing, a medical condition, drugs, or high altitude breathing). The use of positive airway pressure devices is currently the most common form of therapy for CSA. An implantable device that stimulates the phrenic nerve in the chest is a potential alternative treatment. The battery-powered device sends signals to the diaphragm in order to stimulate breathing and normalize sleep-related breathing patterns.

For individuals with CSA who receive phrenic nerve stimulation, the evidence includes one randomized controlled trial (RCT) and observational studies. The relevant outcomes are change in disease status, functional outcomes, and quality of life (QOS). The RCT compared the use of phrenic nerve stimulation to no treatment among patients with CSA of various etiologies. All patients received implantation of the phrenic nerve stimulation system, with activation of the system after one month in the intervention group and activation after six months in the control group. Activation is delayed one month after implantation to allow for lead healing. At six months follow-up, the patients with the activated device experienced significant improvements in several sleep metrics and QOS measures. At 12 months follow-up, patients in the activated device arm showed sustained significant improvements from baseline in sleep metrics and QOL. A subgroup analysis of patients with heart failure combined 6- and 12-month data from patients in the intervention group and 12- and 18-month data from the control group. Results from this subgroup analyses showed significant improvements in sleep metrics and QOL at 12 months compared with baseline. Results from observational studies supported the results of the RCT. No RCTs were identified in which phrenic nerve stimulation was compared with the current standard of care, positive airway pressure or respiratory stimulant medication. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>7/2019</td>
<td>Ongoing investigational statement on phrenic nerve stimulation for the treatment of central sleep apnea was transferred from policy #593.</td>
</tr>
<tr>
<td>9/2017</td>
<td>MPA literature review. Policy statements unchanged.</td>
</tr>
<tr>
<td>8/2015</td>
<td>Coding information clarified.</td>
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**Information Pertaining to All Blue Cross Blue Shield Medical Policies**

Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

**References**

3. Costanzo, MM, Augustini, RR, Goldberg, LL, Ponikowski, PP, Stellbrink, CC, Javaheri, SS. Design of the remedâ“- System Pivotal Trial: A Prospective, Randomized Study in the Use of Respiratory
Rhythm Management to Treat Central Sleep Apnea. J. Card. Fail., 2015 Oct 4;21(11). PMID 26432647


11. Aurora, RR, Bista, SS, Casey, KK, Chowdhuri, SS, Kristo, DD, Mallea, JJ, Ramar, KK, Rowley, JJ, Zak, RR, Heald, JJ. Updated Adaptive Servo-Ventilation Recommendations for the 2012 AASM Guideline: