MASSACHUSETTS

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Medical Policy

# Phrenic Nerve Stimulation for Central Sleep Apnea

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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 Blue[SM] and Medicare PPO Blue[SM] 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**.

| | Outpatient |
|---|---|
| **Commercial Managed Care (HMO and POS)** | This is **not** a covered service. |
| **Commercial PPO and Indemnity** | This is **not** a covered service. |
| **Medicare HMO Blue℠** | This is **not** a covered service. |
| **Medicare PPO Blue℠** | This is **not** a covered service. |

## 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

| CPT codes: | Code Description |
|---|---|
| 0424T | 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) |
| 0425T | Insertion or replacement of neurostimulator system for treatment of central sleep apnea; sensing lead only |
| 0426T | Insertion or replacement of neurostimulator system for treatment of central sleep apnea; stimulation lead only |
| 0427T | Insertion or replacement of neurostimulator system for treatment of central sleep apnea; pulse generator only |
| 0428T | Removal of neurostimulator system for treatment of central sleep apnea; pulse generator only |
| 0429T | Removal of neurostimulator system for treatment of central sleep apnea; sensing lead only |
| 0430T | Removal of neurostimulator system for treatment of central sleep apnea; stimulation lead only |
| 0431T | Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only |
| 0432T | Repositioning of neurostimulator system for treatment of central sleep apnea; stimulation lead only |
| 0433T | Repositioning of neurostimulator system for treatment of central sleep apnea; sensing lead only |
| 0434T | Interrogation device evaluation implanted neurostimulator pulse generator system for central sleep apnea |
| 0435T | Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session |
| 0436T | Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; during sleep study |

## HCPCS Codes

| HCPCS codes: | Code Description |
|---|---|
| C1823 | Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads |

## Description

**Central Sleep Apnea**

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 a medical condition such as congestive heart failure, drugs, or high altitude breathing). Apneas associated with Cheyne-Stokes respiration are 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 of participants 40 years of age and older in the Sleep Heart Health Study, the estimated prevalence of CSA and obstructive sleep apnea are 0.9% and 47.6%, respectively.[1,] 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%,[2,] 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**

Several phrenic nerve stimulation systems are available for patients who are ventilator dependent. They stimulate the phrenic nerve in the chest which sends signals to the diaphragm to restore a normal breathing pattern. Currently, there is one phrenic nerve stimulation device approved by the U.S. Food and Drug Administration (FDA) for CSA, the remede System (Respicardia, Inc.). A cardiologist implants the battery powered device under the skin in the right or left pectoral region 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 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. Relevant outcomes are change in disease status, functional outcomes, and quality of life. 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 1 month in the intervention group and activation after 6 months in the control group. Activation is delayed one month after implantation to allow for lead healing. At 6 months follow-up, the patients with the activated device experienced significant improvements in several sleep metrics and quality of life measures. At 12 months follow-up, patients in the activated device arm showed sustained significant improvements from baseline in sleep metrics and quality of life. 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 quality of life at 12 months compared with baseline. Results from observational studies supported the results of the RCT. An invasive procedure would typically be considered only if non-surgical treatments had failed, but there is limited data in which phrenic nerve stimulation was evaluated in patients who had failed 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

| Date | Action |
|---|---|
| 7/2020 | BCBSA National medical policy review. Description, summary and references updated. Policy statement(s) unchanged. |
| 7/2019 | Ongoing investigational statement on phrenic nerve stimulation for the treatment of central sleep apnea was transferred from policy #593. |
| 11/2018 | MPA literature review. Investigational policy statements clarified. Policy statements unchanged. |
| 9/2017 | MPA literature review. Policy statements unchanged. |
| 8/2015 | Coding information clarified. |
| 9/2013 | New policy describing investigational indications. Effective 9/1/2013. |

## 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


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13. Centers for Medicare and Medicaid Services. Local Coverage Determination: Transvenous Phrenic Nerve Stimulation in the Treatment of Central Sleep Apnea (A57548) 2019 https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37929. Last Accessed April 2, 2020