Corporate Medical Policy

Phrenic Nerve Stimulation for Central Sleep Apnea

File Name: phrenic_nerve_stimulation_for_central_sleep_apnea
Origination: 7/2019
Last Review: 3/2024

Description of Procedure or Service

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 Cheyne-Stokes breathing, a medical condition, 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. Risk factors for CSA include age (>65 years), male gender, history of heart failure, 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 heart failure 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 heart failure 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 heart failure 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 (Zoll Medical). 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.

Regulatory Status

In October 2017, the Food and Drug Administration granted approval for the remede System (Respicardia, Inc; Minnetonka, MN) through the premarket approval application process. The approved indication is for treatment of moderate to severe CSA in adults. Follow-up will continue for 5 years in the post-approval study. FDA product code: PSR.

Related Policies:
Sleep Apnea: Diagnosis and Medical Management
Surgery for Obstructive Sleep Apnea and Upper Airway Resistance Syndrome

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

The use of phrenic nerve stimulation for central sleep apnea is considered investigational in all situations. **BCBSNC does not provide coverage for investigational services or procedures.**

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When phrenic nerve stimulation for central sleep apnea is covered

Not applicable.

When phrenic nerve stimulation for central sleep apnea is not covered

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

Policy Guidelines

For individuals with CSA who receive phrenic nerve stimulation, the evidence includes 1 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 1 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 analysis 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 that the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 33276, 33277, 33278, 33279, 33280, 33281, 33287, 33288, 93150, 93151, 93152, 93153, C1823

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.33, 5/2/2019

Aurora, RR, Chowdhuri, SS, Ramar, KK, Bista, SS, Casey, KK, Lamm, CC, Kristo, DD, Mallea, JJ, Rowley, JJ, Zak, RR, Tracy, SS. The treatment of central sleep apnea syndromes in adults: practice parameters with an evidence-based literature review and meta-analyses. Sleep, 2012 Jan 5;35(1). PMID 22215916

Specialty Matched Consultant Advisory Panel review 3/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.33, 5/21/2020

Costanzo MR, Javaheri S, Ponikowski P, et al; remedē®System Pivotal Trial Study Group. Transvenous Phrenic Nerve Stimulation for Treatment of Central Sleep Apnea: Five-Year Safety and Efficacy Outcomes. Nat Sci Sleep. 2021 Apr 29;13:515-526.

Schwartz AR, Goldberg LR, McKane S, et al. Transvenous phrenic nerve stimulation improves central sleep apnea, sleep quality, and quality of life regardless of prior positive airway pressure treatment. Sleep Breath. 2021 Mar 20. doi: 10.1007/s11325-021-02335-x. Epub ahead of print.

Specialty Matched Consultant Advisory Panel rev\iew 3/2021

Medical Director review 4/2021

Specialty Matched Consultant Advisory Panel review 3/2022

Medical Director review 3/2022

Donovan LM, Kapur VK. Prevalence and Characteristics of Central Compared to Obstructive Sleep Apnea: Analyses from the Sleep Heart Health Study Cohort. Sleep. Jul 01 2016; 39(7): 1353-9. PMID 27166235

Specialty Matched Consultant Advisory Panel review 3/2023

Medical Director review 3/2023

Specialty Matched Consultant Advisory Panel Review 3/2024

Medical Director review 3/2024

Policy Implementation/Update Information

7/1/19	New policy developed. The use of phrenic nerve stimulation for central sleep apnea is considered investigational in all situations. (sk)
4/28/20	References updated. Specialty Matched Consultant Advisory Panel 3/31/2020. No changes to policy statement. (eel)
7/1/21	Description section updated. References added. Specialty Matched Consultant Advisory Panel 3/2021. Medical Director review 4/2021. No changes to policy statement. (bb)
3/31/22	Related policies added. References added. Specialty Matched Consultant Advisory Panel 3/2022. Medical Director review 3/2022. No changes to policy statement. (tt)
3/31/23	Description and policy guidelines updated. References added. Specialty Matched Consultant Advisory Panel 3/2023. Medical Director review 3/2023. No changes to policy statement. (tt)
12/29/23	Removed the following CPT codes from Billing/Coding section: 0424T, 0425T, 0426T, 0427T, 0428T, 0429T, 0430T, 0431T, 0432T, 0433T, 0434T, 0435T, 0436T, Added the following CPT codes to Billing/Coding section, effective 1/1/2024: 33276, 33277, 33278, 33279, 33280, 33281, 33287, 33288, 93150, 93151, 93152, 93153. (tt)
4/1/24	Description and References updated. Specialty Matched Consultant Advisory Panel 3/2024. Medical Director review 3/2024. No changes to policy statement. (tt)