Payment Policy | Phrenic Nerve Stimulation for Central Sleep Apnea

EFFECTIVE DATE: 07|01|2022
POLICY LAST UPDATED: 03|16|2022

OVERVIEW
Central sleep apnea (CSA) is characterized by sleep-disordered breathing due to diminished or absent respiratory effort. Central sleep apnea 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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
The use of phrenic nerve stimulation for central sleep apnea is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
The use of phrenic nerve stimulation for central sleep apnea is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable not medically necessary benefits/coverage.

BACKGROUND
Central Sleep Apnea
Central sleep apnea (CSA) is characterized by repetitive cessation or decrease in both airflow and ventilatory effort during sleep. Central sleep apnea 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 individuals with heart failure (HF) or who have had strokes, and account for about half of the population with CSA. Central sleep apnea 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, and 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 individuals with hyperventilation-related CSA, continuous positive airway pressure (CPAP) is considered first-line therapy. Due to CPAP discomfort, individual compliance may become an issue. Supplemental oxygen during sleep may be considered for individuals experiencing hypoxia during sleep or who cannot tolerate CPAP. Individuals with CSA due to HF 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 2 pressure settings, 1 for inhalation and 1 for exhalation. Adaptive servo-ventilation 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 individuals with CSA due to HF and with an ejection fraction <45%,2, and therefore, ASV is not recommended for this group.

For individuals with hypoventilation-related CSA, first-line therapy is bilevel positive airway pressure.

Pharmacologic therapy with a respiratory stimulant may be recommended to individuals 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 individuals who are ventilator dependent. These systems stimulate the phrenic nerve in the chest, which sends signals to the diaphragm to restore a normal breathing pattern. Currently, there is 1 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 2 leads, 1 to stimulate a phrenic nerve (either the left pericardiophrenic or right brachiocephalic vein) and 1 to sense breathing. The device runs on an algorithm that activates automatically at night when the individual is in a sleeping position, and suspends therapy when the individual sits up. Individual-specific changes in programming can be conducted externally by a programmer.

Regulatory Status
In October 2017, the FDA approved 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.

CODING

The following code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

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
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

For the following code(s), please refer to the Related Policy Removal of Implantable Devices.
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

The following code is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products for the replacement. The removal is considered medically necessary when the medical criteria found in the Removal of Implantable Devices policy are met:
0431T Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only

RELATED POLICIES
Removal of Implantable Devices

PUBLISHED
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