Medica Coverage Policy

Policy Name:	**Phrenic Nerve Stimulation for Central Sleep Apnea**
Effective Date:	**9/18/2023**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Phrenic nerve stimulation for central sleep apnea is considered investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

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 or who have had strokes, and accounts for about half of the population with CSA. CSA is less common than obstructive sleep apnea (OSA). 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.

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.

For patients with hyperventilation-related CSA, continuous positive airway pressure (CPAP) is considered first- line therapy. 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 (BPAP) or adaptive servo-ventilation (ASV) as second-line therapy. For patients with hypoventilation-related CSA, first-line therapy is BPAP.

Phrenic nerve stimulation (PNS) for moderate to severe CSA is a treatment alternative that uses an implantable device (e.g., Remedē® System) that purportedly delivers unilateral transvenous stimulation to deliver diaphragmatic contraction that mimics normal breathing patterns. This approach is believed to help restore normal breathing patterns by stimulating the phrenic nerve, which innervates the diaphragm, allowing better oxygenation and improving sleep. However, not much is known about its comparative efficacy to standard treatments.

FDA Approval

The remedē® System (ZOLL Medical Corporation, Minnetonka, MN; formerly Respicardia, Inc., Minnetonka, MN) received FDA premarket approval (PMA) October 2017. Since the original approval, FDA has approved five supplements for updates in the tablet, stimulation lead models, and software and changes in the approval protocol and manufacturing process.The most recent labeled indication reads: "The remedē® System is an implantable phrenic nerve stimulator indicated for the treatment of moderate to severe central sleep apnea (CSA) in adult patients." Follow-up will continue for 5 years in the post-approval study. FDA product code: PSR.

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

HCPCS Codes

- **C1823 –** Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads

Original Effective Date: 9/18/2023

Re-Review Date(s): 9/28/2023 – administrative update; coding