KAISER PERMANENTE® Mid-Atlantic States	**Phrenic Nerve Stimulator (remedē System) for Treatment of Adult Central Sleep Apnea Medical Coverage Policy**

UTILIZATION * ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- For Medicare members, please consult the Medicare Coverage Database.
- Note: After searching the Medicare Coverage Database, if no NCD/LCD/LCA is found, then use the policy referenced above for coverage guidelines

I. Procedure: **Phrenic Nerve Stimulator** for treatment of adult central sleep apnea
The remedē System (see VII) currently is the only FDA approved treatment of moderate-to-severe central sleep apnea in adult patients.

II. Specialties**:** Implant, Sleep Medicine, Pulmonary Medicine, Cardiology, Neurology

III. Clinical Indications for Referral

A. Phrenic nerve stimulator is medically necessary for selected patients who meet **ALL** of the following criteria:
   1. Age: 18 years and older;
   2. Diagnosis of moderate to severe central sleep apnea through sleep study and polysomnography;
   3. Failed or unresponsive to conventional treatments for central sleep apnea:
      a. Address associated medical problems;
      b. Reduction of opioid medications;
      c. Pharmacotherapy (e.g., acetazolamide or theophylline),
      d. Supplemental oxygen therapy
      e. Adaptive servo-ventilation (ASV); and
      f. Masked-based therapies (e.g., bi-level positive airway pressure or continuous positive airway pressure).
   4. Evidence of intact diaphragm and sufficient bilateral phrenic nerve function through electromyography recordings and nerve conduction studies;
   5. Careful evaluation of the patient as a candidate for remedē System including clearance from exclusions and contraindications. See section IV and V;

      Concomitant active implantable devices. Patients with active implanted devices (such as pacemaker or defibrillator) must be tested prior to initiating therapy with the phrenic neurostimulator to ensure that the other implantable pacing devices are not unintentionally interacting with the phrenic neurostimulator.

6. Patient demonstrated a normal level of consciousness and cognitive ability to understand, comprehend, participate, and complete the training and rehabilitation associated with the use of the device including lifestyle adjustments, expectations and precautionary measures associated with the neurostimulator therapy; and
7. The patient is compliant with treatment.

IV. Exclusion

Phrenic nerve stimulator is not medically necessary for the following condition as it's safety and effectiveness have not been established:

A. Treatment of other conditions other than moderate to severe central apnea;
B. Evidence of phrenic nerve palsy;
C. Obstructive sleep apnea;, unless there also evidence of moderate to severe central sleep apnea;
D. Pediatric use; and
E. During pregnancy

V. Contraindication

A. Patient-related contraindication:

1. Patient with active infection;
2. Patient who are known to require:
   a. Magnetic Resonance Imaging (MRI); and
   b. Diathermy therapies

B. Therapy-related contraindication:

1. Wi-Fi must not be used or enabled on the remedē System programmer to protect the system from cybersecurity risks.
2. The use of modified components with the remedē System is not allowed and may result in damaged components, unintended operation, or increased risks to the patient.

C. Exposure-related contraindication:

1. Exposure to the following is absolutely contraindicated as unintended interference from these can result in severe damage to the neurostimulator and severe injury, even death to the patient.
   a. Extremely strong sources of Electro-Magnetic-Interference (EMI); and
   b. Diathermy (such as shortwave diathermy, microwave diathermy or therapeutic ultrasound)
2. Contact or exposure to the following must be avoided to prevent serious harm to the patient.
3. If the patient does not have other option and necessary to use or be exposed to these elements,

it is critical that the neurostimulator is inactive or turned off during use or exposure to these elements otherwise exposure to these can trigger interference with the normal operation and/or damage to the neurostimulator system and cause serious harm to the patient such as induce arrhythmia, permanent tissue damage at the location of the implant, and even death.

a. Direct contact between radiofrequency ablation or cryoballoon catheter and the implanted remedē System
b. Therapeutic radiation (such as ionizing radiation produced by cobalt machines or linear accelerators)
c. Electrocautery;
d. Computed Tomography (CT) imaging;
e. High ultrasonic frequencies such as therapeutic ultrasound;
f. Energy from external defibrillator;
g. Patient monitoring equipment including automated external defibrillators;
h. Electrical current leakage from patient contact with grounded equipment during neurostimulator implant procedure;
i. High powered electric fields;
j. Magnetic, electrical and electromagnetic signals;
k. Cellular phones - a minimum separation of 25 cm (10 in) must be maintained between the cellular phone and the remedē System, even if the cellular phone is not on;
l. Electronic article surveillance equipment such as retail theft prevention systems;
m. Airport metal detectors;
n. Common radiofrequency sources such as Radio Frequency Identification Device (RFID) technology that uses radio waves;
o. Static magnetic fields greater than 10 gauss or 1 mT; and
p. The remedē System programmer must be grounded to a power source when operating the device under AC power to prevent the risk of electric shock.

VI. Description

The **remedē System** is the only FDA approved transvenous phrenic nerve stimulator for the treatment of adult patients with moderate to severe central sleep apnea. The system comprises of a battery powered device, surgically placed under the skin in the right or left pectoral region and two small leads, inserted into the blood vessels in the chest near the phrenic nerve that stimulates breathing. The neurostimulator delivers electrical pulse to the phrenic nerve through a series of low amplitude (3-4 mAmp) pulses delivered over a very short duration (0.15 msec) at a rapid rate (20 Hz). The sensing lead senses the patient's breathing while the stimulation lead delivers the therapy making it possible for the system to monitor the patient's respiratory signals during sleep. These stimulations selectively stimulate the phrenic nerve and create a smooth, physiologic diaphragm contraction and restore normal breathing and sleep quality.

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The remedē System (manufactured by Respicardia, Inc. now Zoll Medical) was approved by the FDA on October 2017 for the treatment of moderate to severe CSA in adults through the pre-market approval application process. In Oct. 20, 2020, the 5-year result from the remedē System Post Approval Study was released, assessing the safety and efficacy of transvenous phrenic nerve stimulation for the treatment of moderate to severe central sleep apnea. The 5-year data showed sustained improvements from baseline that were highly consistent with the previously published 6, 12, 24, and 36-month results.

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Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC	Date of Implementation
10/25/2023	10/25/2023
10/28/2024	10/28/2024

*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of

circumstances for an individual member.