remedē® System

Transvenous Phrenic Nerve Stimulation for Central Sleep Apnea

ZOLL®

PHYSICIAN BILLING GUIDE

2022

The remedē® System Physician Billing Guide

This guide contains physician and hospital coding and reimbursement information for procedures associated with the **rem**edē System to treat moderate to severe central sleep apnea. For more information on hospital billing, the 2022 **rem**edē System Hospital Billing Guide is available online at **remede.zoll.com/reimbursement** or by contacting the **rem**edē Reimbursement Hotline.

Disclaimer: The information provided in this guide is general reimbursement information only; it is not legal advice, nor is it advice about how to code, complete or submit any claim for payment, nor is it intended to increase or maximize reimbursement by any third-party payer. All coding and reimbursement information is subject to change without notice. The content provided by the Center for Medicare and Medicaid Services is updated frequently. It is the responsibility of the health services provider to confirm the appropriate coding required by their local Medicare carriers, fiscal intermediaries, and commercial payers.

ZOLL provides reimbursement case management and hotline services in order to support patient access to the **rem**edē System therapy. We provide hands-on assistance with prior authorizations and appeals through our **rem**edē Patient Access Program. We also provide reimbursement support of billing, coding, and coverage related activities.

- Prior authorizations
- Prior authorization appeals/peer-to-peers
- Claim appeals
- Billing/coding/coverage questions

For questions or case management support, please call the **rem**edē Reimbursement Hotline at**1-952-540-4470** or email questions to **reimbursement@remede.zoll.com.**

This guide and all supporting documents are available for download at **remede.zoll.com/reimbursement.**

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TRANSVENOUS PHRENIC NERVE STIMULATION FOR CENTRAL SLEEP APNEA

Therapy Overview

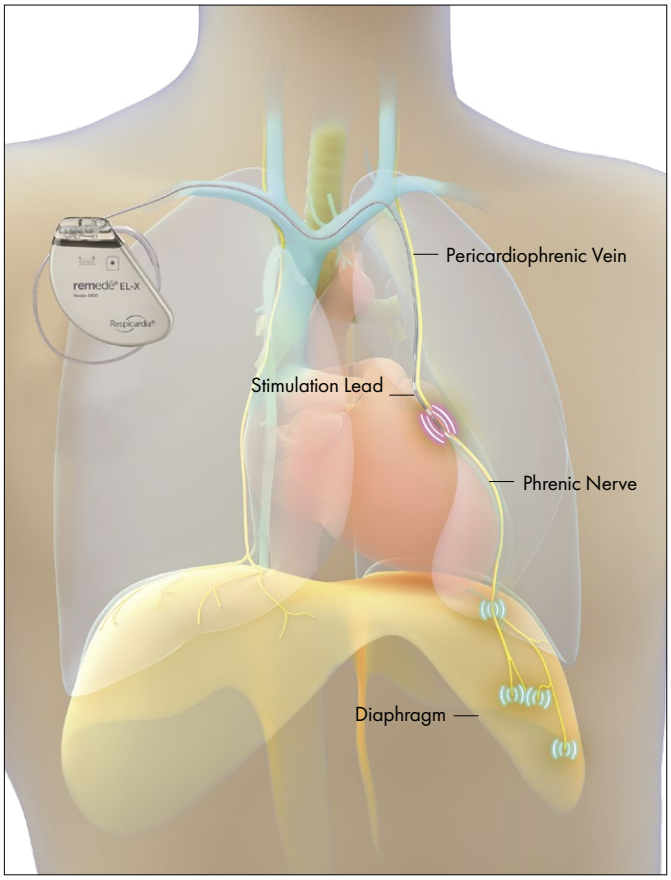
The **rem**edē® System is an implantable system that safely and effectively treats moderate to severe Central Sleep Apnea (CSA) in adult patients.[1] CSA is a serious breathing disorder that disrupts the normal breathing pattern during sleep and has been shown to negatively impact quality of life and cardiovascular health.[2] The **rem**edē System is an implantable system that stimulates a nerve in the chest (the phrenic nerve) to send signals to the large muscle that controls breathing (the diaphragm).

In a clinical study, the **rem**edē System has been shown to significantly improve CSA patient outcomes:

- 91% of patients had a reduction in the number of sleep apnea events per hour at 12 months[3]
- 82% of patients had an improvement in quality of life[3]
- 95% of patients would get **rem**edē again[3]

Device and Implant Procedure

The **rem**edē System is placed during a minimally invasive procedure. The system consists of a battery powered Implantable Pulse Generator (IPG) device placed under the skin in the upper chest area with one or two small thin wires (leads). One lead delivers the therapy to stimulate the phrenic nerve (stimulation lead). For select models, an optional sensing lead may be used for diagnostic purposes to sense breathing (sensing lead).



Postoperative Care

Postoperative care is recommended to optimize therapy with the **rem**edē System. Regular patient follow-up should be scheduled every 3-6 months to monitor the condition of the IPG battery and to confirm that therapy settings are appropriately programmed.

The IPG should be replaced when the IPG battery has been depleted and either the Elective Replacement Indicator (ERI) or End of Life (EOL) indicator is displayed on the **rem**edē System programmer.

The decision to remove the **rem**edē System is the responsibility of the physician and patient, and should be determined on a case-by-case basis.

COVERAGE

FDA Approval

The **rem**edē® System received Premarket Approval (PMA) from the FDA on October 6, 2017. The FDA-approved indications for use are as follows:

Indications for use: The **rem**edē System is an implantable phrenic nerve stimulator indicated for the treatment of moderate to severe Central Sleep Apnea (CSA) in adult patients.

Contraindications: The **rem**edē System is contraindicated for the following:

- Patients with an active infection
- Patients known to require Magnetic Resonance Imaging (MRI)

The Instructions for Use document provides further information regarding the procedure, indications for use, contraindications, warnings, precautions, and potential adverse events. The FDA has posted 1) the Summary of Safety and Effectiveness Data (SSED), 2) the FDA Approval Letter, 3) the Implant System Directions for Use (Physician Labeling), and 4) the Patient Guide (Patient Labeling) on its website located at:
https://www.fda.gov/medical-devices/recently-approved-devices/remeder-system-p160039

Medicare Coverage

Currently, there is no National Coverage Determination (NCD) related to the **rem**edē System. Check with your local Medicare Administrative Contractor (MAC) regarding any Local Coverage Determinations (LCDs) related to the **rem**edē System. Medicare may cover the **rem**edē System on a case-by-case basis, with evidence of medical necessity. While traditional Medicare does not require or allow prior authorization or prior approval for procedures, Medicare Advantage plans are managed by commercial payers who may require prior authorization for Medicare Advantage patients. Check with your plan administrator for any prior authorization requirements.

Private Payer Coverage

Commercial insurance coverage policies vary and many require prior authorization for an elective procedure such as the **rem**edē System. We encourage Health Care Professionals (HCPs) to contact payer(s) directly with questions regarding coverage policies or guidelines for the **rem**edē System.

ZOLL offers the **rem**edē Patient Access Program which can assist in determining the availability of coverage for your patients and facilitating prior authorization support services.

Reimbursement Denials

The **rem**edē System is currently classified with CPT® Category III codes by the American Medical Association. CPT Category III codes are a set of temporary codes that allow data collection for emerging technologies, services, procedures, and service paradigms. Many payers initially deny therapies with a CPT III code as investigational or experimental and an appeal may be required to obtain a successful prior authorization or claim approval for the **rem**edē System. Most commercial health plans have a method by which denials can be appealed through a process documented in the Provider Manual. Contact the **rem**edē Reimbursement Hotline for additional information and resources to support your patient case appeal process.

CODING AND PHYSICIAN BILLING

This coding information is provided for general reimbursement information purposes only. It is not intended to provide advice about how to code, complete or submit any claim for payment, nor is it intended to increase or maximize reimbursement by any third-party payer. It is the responsibility of the health services provider to confirm the appropriate coding required by their local Medicare carriers, fiscal intermediaries, and commercial payers.

Diagnosis Codes

The **rem**edē System is used to treat moderate to severe Central Sleep Apnea (CSA) in adult patients. Diagnosis coding for Central Sleep Apnea may include the following codes:

ICD-10-CM Diagnosis Codes

ICD-10-CM CODE[4]	DESCRIPTION
Insertion/Replacement/Removal	
G47.31	Primary Central Sleep Apnea
G47.32	Central Sleep Apnea due to high altitude periodic breathing
G47.37	Central sleep apnea in conditions classified elsewhere
Procedure or Device Follow-up Care	
Z45.42	Encounter for adjustment and management of neuropacemaker; brain, peripheral nerve, spinal cord

CPT® Procedure Codes and Physician Billing

Hospitals report outpatient procedures using CPT codes which are used for physician billing. The **rem**edē System is currently classified as a CPT Category III code, which is indicated by the alphanumeric indicator "T" at the end of each code. As a Category III therapy, the **rem**edē System has not yet been assigned a Relative Value Unit (RVU) amount. This is indicated in the Medicare Physician Fee Schedule (MPFS) status indicator "C", which means commercial payers and MACs will establish the RVU and payment amounts for these services at their discretion .

The following is not legal or coding advice. See important disclaimer on page 2. Providing a comparable CPT code may assist payers in processing claims that include an unlisted procedure. Industry practice has evolved, based on the expectation from many U.S. commercial insurers and MACs, that a comparable established CPT code may be provided that best approximates the effort associated with the unlisted procedure. This may help the payer better understand what was performed for the unlisted procedure and value it accordingly. The comparable CPT code should be provided in the accompanying documentation when billing the procedure and include a concise description of an "unlisted procedure code" or a "NOC" code in Box 19 of the physician's claim form.

For additional information on RVU and payment crosswalk examples, contact your payer and/or the **rem**edē Reimbursement Hotline.

CPT® Codes and Physician Billing Table

CPT CODE[5]	DESCRIPTION	MPFS STATUS INDICATOR[6]	RVU	2022 MEDICARE NATIONAL AVERAGE PAYMENT
Insertion/Replacement				
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)	C	Not Available	Carrier Priced
0425T	sensing lead only			
0426T	stimulation lead only			
0427T	pulse generator only			
Removal				
0428T	Removal of neurostimulator system for treatment of central sleep apnea; pulse generator only	C	Not Available	Carrier Priced
0429T	sensing lead only			
0430T	stimulation lead only			
0431T	Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only			
Repositioning				
0432T	Repositioning of neurostimulator system for treatment of central sleep apnea; stimulation lead only	C	Not Available	Carrier Priced
0433T	sensing lead only			
Device Interrogation and Programming				
0434T	Interrogation device evaluation implanted neurostimulator pulse generator system for central sleep apnea	C	Not Available	Carrier Priced
0435T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session			
0436T	during sleep session			

For information on RVU and payment crosswalk examples, contact your payer and/or the **rem**edē Reimbursement Hotline.

Appealing a denied claim or prior authorization request

Because the **rem**edē® System is a novel therapy with a CPT® III code, a payers' appeal process may need to be utilized in order to obtain payment or authorization for patient care. ZOLL offers the **rem**edē Patient Access Program that advocates on behalf of patients who qualify for the **rem**edē System to exhaust all avenues in the prior-authorization appeal process. This program is available for procedural prior-authorization and claim appeals as well as the related physician services billed. Contact the **rem**edē Reimbursement Hotline for more information on how to enroll your patient case in the **rem**edē Patient Access Program.

We have found that successfully responding to a claim denial requires evaluating why the claim was denied, presenting the clinical need for the therapy, and citing the relevant evidence to convince the reviewer. We can provide letter templates and recommend you include the following details in your appeal:

1. Evaluate the Denial

- What was the stated rationale for denial? Take time to understand the specific points listed in the denial notice (i.e. reason codes, remark codes and denial codes)
- What is the appeal process? Most insurers have a defined process with deadlines and specific requests; be sure to adhere to this process
- What is the background and specialty of the peer reviewer? Assess the reviewer's relevant experience in order to best tailor an argument to that person's background

2. Present the Clinical Need

- Highlight the patient CSA symptoms and relevant comorbidities: Describe how long the patient has suffered from CSA, and how CSA has reduced the patient's quality of life (e.g. Severe fatigue, cognitive decline, inability to hold a job or participate regularly in activities, mood changes, frequent night-time arousals and abrupt awakenings accompanied by shortness of breath, describe any relevant comorbidities that may be worsened by the disease, including heart failure, atrial fibrillation, and stroke-risk)
- Use relevant sleep metrics to demonstrate the severity of the disease: Share the Apnea-hypopnea Index (AHI), average length of apnea, and/or number of arousals per hour. These statistics often highlight how much time the patient spends without active breathing during the night.
- Share other relevant treatment options previously attempted by the patient: Mention if the patient has tried and failed CPAP, ASV, oxygen, pharmaceutical, or any other therapies often attempted. If the patient could not tolerate a PAP-based therapy, share reasons why.
- Provide clinical rationale for the decision to implant the **rem**edē System: Explain why the **rem**edē System was the best or only available treatment option, e.g.
  - ASV was contraindicated because patient had reduced ejection fraction
  - Patient was unable to tolerate PAP therapies
  - Patient had attempted PAP therapy but symptoms did not improve
  - Physician perceived a mortality risk for positive airway pressure therapy
  - Patient cognitive decline made it necessary to utilize a therapy that did not require patient compliance

3. Cite Clinical Evidence

Contact the **rem**edē Reimbursement Hotline for an extensive list of publications related to Central Sleep Apnea and the **rem**edē System as well as sample appeal letter templates.

For questions or case management support, please call the **rem**edē Reimbursement Hotline at

1-952-540-4470 or email questions to **reimbursement@remede.zoll.com.**

[1] Costanzo M, et al. Transvenous neurostimulation for central sleep apnoea: a randomised controlled trial. *The Lancet.* 2016; 388: 974–82.
[2] Costanzo MR, Khayat R, Ponikowski P, et al. State-of-the-art review: Mechanisms and clinical consequences of untreated central sleep apnea in heart failure. *J Am Coll Cardiol* 2015;65:72-84.
[3] Costanzo M, et al. Sustained Twelve Month Benefit of Phrenic Nerve Stimulation for Central Sleep Apnea. *Am J Cardiol* 2018;121:1400-8.
[4] ICD-10-CM Expert for Physicians and Hospitals, 2021. AAPC.
[5] Current Procedural Terminology (CPT®) Professional Edition 2022. Copyright 2018 American Medical Association. All rights reserved.
[6] 2022 MPFS CMS-1751-F, Addendum B.

Important Safety Information
The **rem**edē® System is indicated for moderate to severe Central Sleep Apnea (CSA) in adult patients. A doctor will need to evaluate the patient's condition to determine if the **rem**edē System is appropriate. Patients will not be able to have an MRI or diathermy (special heat therapies) if the **rem**edē System is implanted. The **rem**edē System may be used with another stimulation device such as a heart pacemaker or defibrillator; special testing will be needed to ensure the devices are not interacting. As with any surgically implanted device, there are risks related to the surgical procedure itself which may include, but are not limited to, pain, swelling, and infection. Once the therapy is turned on, some patients may experience discomfort from stimulation and/or from the presence of the device. The majority of these events are resolved either on their own or by adjusting the therapy settings. The **rem**edē System may not work for everyone. There are additional risks associated with removing the system. If it is decided to remove the system, another surgery will be required. Be sure to understand all of the risks and benefits associated with the implantation of the **rem**edē System. For further information please visit remede.zoll.com, call 952-540-4470 or email info@remede.zoll.com. **Indication for use:** The **rem**edē System is an implantable phrenic nerve stimulator indicated for the treatment of moderate to severe Central Sleep Apnea (CSA) in adult patients. **Contraindications:** The **rem**edē System is contraindicated for use in patients with an active infection or patients known to require magnetic resonance imaging (MRI). See the Instructions for Use for complete information regarding the procedure, indications for use, contraindications, warnings, precautions, and potential adverse events.
Rx Only. The **rem**edē® System, **rem**edē® EL System, and **rem**edē® EL-X System have received FDA approval.
The **rem**edē® System model 1001 has received CE Mark approval.

ZOLL MEDICAL CORPORATION

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For subsidiary addresses and fax numbers, as well as other global locations, please go to www.zoll.com/contacts.

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