

**remedē<sup>®</sup> System**

Transvenous Phrenic Nerve Stimulation for Central Sleep Apnea

**ZOLL<sup>®</sup>**



# PHYSICIAN BILLING GUIDE **2024**

## The remedē<sup>®</sup> System Physician Billing Guide

This guide contains physician and hospital coding and reimbursement information for procedures associated with the remedē System to treat moderate to severe central sleep apnea. For more information on hospital billing, the 2024 remedē System Hospital Billing Guide is available online at [remede.zoll.com/reimbursement](https://remede.zoll.com/reimbursement) or by contacting the remedē 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 remedē System therapy. We provide hands-on assistance with prior authorizations and appeals through our remedē 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 remedē Reimbursement Hotline at **1-952-540-4470** or email questions to [reimbursement@remede.zoll.com](mailto:reimbursement@remede.zoll.com).

This guide and all supporting documents are available for download at [remede.zoll.com/reimbursement](https://remede.zoll.com/reimbursement).

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# TRANSVENOUS PHRENIC NERVE STIMULATION FOR CENTRAL SLEEP APNEA

## Therapy Overview

The **remedē**® System is an implantable system that safely and effectively treats moderate to severe Central Sleep Apnea (CSA) in adult patients.<sup>1</sup> 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.<sup>2</sup> The **remedē** 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 **remedē** System has been shown to significantly improve CSA patient outcomes:

- 96% reduction in Central Apnea Index<sup>3</sup>
- 95% of patients reported they would “elect to have the medical procedure again”<sup>4</sup>
- 78% of patients reported improved quality of life<sup>4</sup>
- Significant reduction in arousals and improvement in sleep architecture<sup>3</sup>

## Device and Implant Procedure

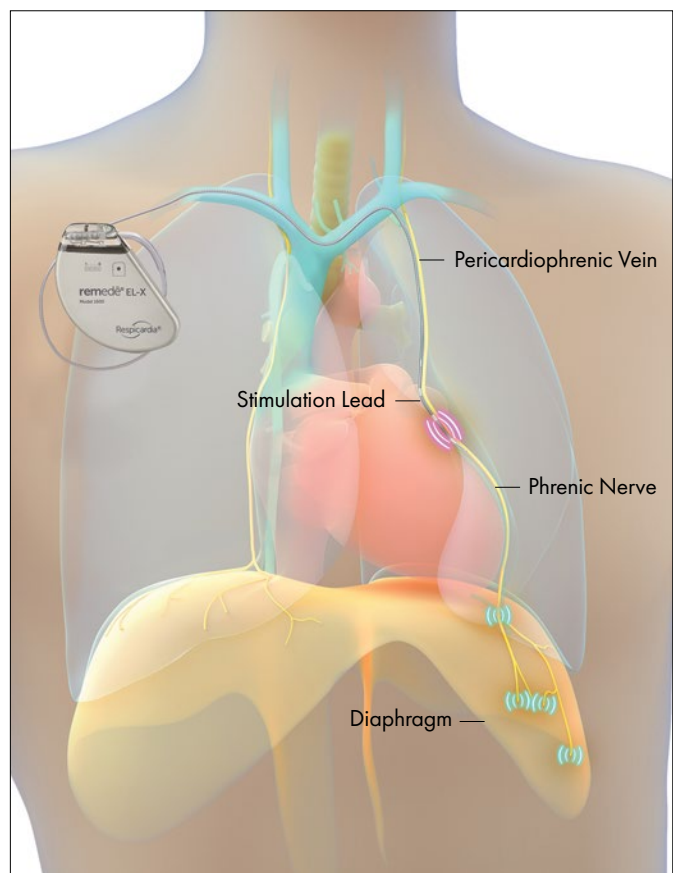
The **remedē** System is placed during a minimally invasive procedure. The system consists of a battery powered Implantable Pulse Generator (IPG) device placed under the skin in the upper chest area with one or two small thin wires (leads). One lead delivers the therapy to stimulate the phrenic nerve (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 **remedē** 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 **remedē** System programmer.

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



## COVERAGE

### FDA Approval

The **remedē**® 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 **remedē** System is an implantable phrenic nerve stimulator indicated for the treatment of moderate to severe Central Sleep Apnea (CSA) in adult patients.

**Contraindications:** The **remedē** System is contraindicated for patients with an active infection.

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 **remedē** System. Check with your local Medicare Administrative Contractor (MAC) regarding any Local Coverage Determinations (LCDs) related to the **remedē** System. Medicare may cover the **remedē** 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 **remedē** System. We encourage Health Care Professionals (HCPs) to contact payer(s) directly with questions regarding coverage policies or guidelines for the **remedē** System.

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

### Reimbursement Denials

Payers may not write a coverage policy initially, instead opting to review on a case by case basis for medical necessity. In some cases, an appeal may be required to obtain a successful prior authorization or claim approval for the **remedē** System. Most commercial health plans have a method by which denials can be appealed through a process documented in the Provider Manual. Contact the **remedē** 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 **remedē** 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 <sup>5</sup>	DESCRIPTION
<b>Insertion/Replacement/Removal</b>	
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
<b>Procedure or Device Follow-up Care</b>	
Z45.42	Encounter for adjustment and management of neuropacemaker; brain, peripheral nerve, spinal cord

### CPT® Procedure Codes

#### CPT® Codes and Physician Billing Table

CPT® CODE <sup>6</sup>	DESCRIPTION	RVUS <sup>7</sup>		2024 MEDICARE NATIONAL AVERAGE PAYMENT <sup>7</sup>	
		WORK	FACILITY	WORK	FACILITY
<b>Insertion/Replacement</b>					
33276	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)	9.50	17.05	\$311.07	\$558.29
33277	sensing lead only	5.43	8.92	\$177.80	\$292.08
<b>Removal without Replacement</b>					
33278	Removal of neurostimulator system for treatment of central sleep apnea	9.55	16.97	\$312.71	\$555.67
33279	stimulation or sensing lead only	5.42	10.26	\$177.47	\$335.96
33280	pulse generator only	3.04	6.17	\$99.54	\$202.03
<b>Removal and Replacement</b>					
33287	Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only	6.05	11.44	\$198.10	\$374.59
33288	Removal and replacement of neurostimulator system for treatment of central sleep apnea, stimulation or sensing lead only	8.51	15.08	\$278.65	\$493.78
<b>Repositioning</b>					
33281	Repositioning of neurostimulator system for treatment of central sleep apnea; stimulation lead only	6.00	11.09	\$196.47	\$363.13

CPT® CODE <sup>6</sup>	DESCRIPTION	RVUS <sup>7</sup>			2024 MEDICARE NATIONAL AVERAGE PAYMENT <sup>7</sup>		
		WORK	FACILITY	NON-FACILITY	WORK	FACILITY	NON-FACILITY
<b>Programming</b>							
93150	Therapy activation of implanted phrenic nerve stimulator system including all interrogation and programming	0.85	1.26	2.99	\$27.83	\$41.26	\$97.91
93153	Interrogation device evaluation implanted neurostimulator pulse generator system for central sleep apnea	0.43	0.64	1.55	\$14.08	\$20.96	\$50.75
93151	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session	0.80	1.19	2.61	\$26.20	\$38.97	\$85.46
93152	during sleep session	1.82	2.78	4.72	\$59.59	\$91.03	\$154.55

## Physician Billing Examples

### Physician Billing Example: In-Office Device Programming Session

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE																	17a		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES																
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)																	17b NPI		FROM MM DD YY TO MM DD YY																
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)																	ICD-10		20. OUTSIDE LAB? \$ CHARGES																
A <b>Z45.42</b> B <b>G47.31</b> C _____ D _____																			22. RESUBMISSION CODE ORIGINAL REF. NO.																
E _____ F _____ G _____ H _____																			23. PRIOR AUTHORIZATION NUMBER																
I _____ J _____ K _____ L _____																			<b>ABC987654321</b>																
24. A. DATE(S) OF SERVICE From To B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. EPSON Family Plan I. ID. QUAL. J. RENDERING PROVIDER ID. #																																			
1 01 01 24 11 99214 A																			NPI																
2 01 01 24 11 93151 A																			NPI																
3																																			

### Physician Billing Example: Implant procedure

1																	3a PAT. CNTL. #		4. TYPE OF BILL																
2																	b. MED. REC. #																		
																	5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM THROUGH 7																
8 PATIENT NAME a. <b>XXXX</b>																	9 PATIENT ADDRESS a. <b>1234 Main Street</b>																		
b. <b>City</b>																	c. <b>St</b> d. <b>Zip</b> e.																		
10 BIRTHDATE 11 SEX 12 DATE 13 HR 14 TYPE 15 SRC 16 DHR 17 STAT 18 19 20 21 22 23 24 25 26 27 28 29 ACDT STATE 30																																			
31 OCCURRENCE CODE DATE 32 OCCURRENCE CODE DATE 33 OCCURRENCE CODE DATE 34 OCCURRENCE CODE DATE 35 OCCURRENCE SPAN FROM THROUGH 36 OCCURRENCE SPAN FROM THROUGH 37																																			
38 Patient Name 1234 Main Street City, Sate 12345																	39 VALUE CODES AMOUNT 40 VALUE CODES AMOUNT 41 VALUE CODES AMOUNT																		
																	a b c d																		
42 REV. CD. 43 DESCRIPTION 44 HCPCS / RATE / HIPPS CODE 45 SERV. DATE 46 SERV. UNITS 47 TOTAL CHARGES 48 NON COVERED CHARGES 49																																			
1 0481 INSRT REPL PHRENIC NERVE STIM 33276 XXXX.XX																			1																
2 0278 PHRENIC NERVE STIM COML SYSTEM C1823 XXXX.XX																			2																
3																			3																

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- <sup>1</sup> Costanzo M, et al. Transvenous neurostimulation for central sleep apnoea: a randomised controlled trial. *The Lancet*. 2016; 388: 974–82.
- <sup>2</sup> 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.
- <sup>3</sup> Costanzo MR, Javaheri S, Ponikowski P, et al. Transvenous Phrenic Nerve Stimulation for Treatment of Central Sleep Apnea: Five-Year Safety and Efficacy Outcomes. *Nat Sci Sleep*. 2021;13:515-526.
- <sup>4</sup> Costanzo MR, Ponikowski P, Javaheri S, et al. Sustained Twelve Month Benefit of Phrenic Nerve Stimulation for Central Sleep Apnea. *Am J Cardiol*. 2018. pii: S0002-9149(18)30258-3. doi: 10.1016/j.amjcard.2018.02.022.
- <sup>5</sup> ICD-10-CM Expert for Physicians and Hospitals, 2024. AAPC.
- <sup>6</sup> Current Procedural Terminology (CPT®) Professional Edition 2024.
- <sup>7</sup> CY 2024 MPFS CMS-1784-F, Addendum B.

#### Important Safety Information

The **remedē**® 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 **remedē** System is appropriate. The **remedē**® System should not be implanted during an active infection and patients will not be able to have diathermy (special heat therapies). The device is MR Conditional. The conditions and precautions can be found in the **remedē** System MRI guidelines manual. The **remedē** 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 **remedē** 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 the risks and benefits associated with the implantation of the **remedē** System. For further information please visit [remede.zoll.com](http://remede.zoll.com), call 952-540-4470 or email [info@remede.zoll.com](mailto:info@remede.zoll.com). **Contraindications:** The **remedē** System is contraindicated for use in patients with an active infection. See the Instructions for Use for complete information regarding the procedure, indications for use, contraindications, warnings, precautions, and potential adverse events.

**Rx Only.** The **remedē**® System, **remedē**® EL System, and **remedē**® EL-X System have received FDA approval.

The **remedē**® System model 1001 has received CE Mark approval.

## ZOLL MEDICAL CORPORATION

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