remedē® System

Transvenous Phrenic Nerve Stimulation for Central Sleep Apnea

ZOLL®

PHYSICIAN BILLING GUIDE

2024

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 2024 **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

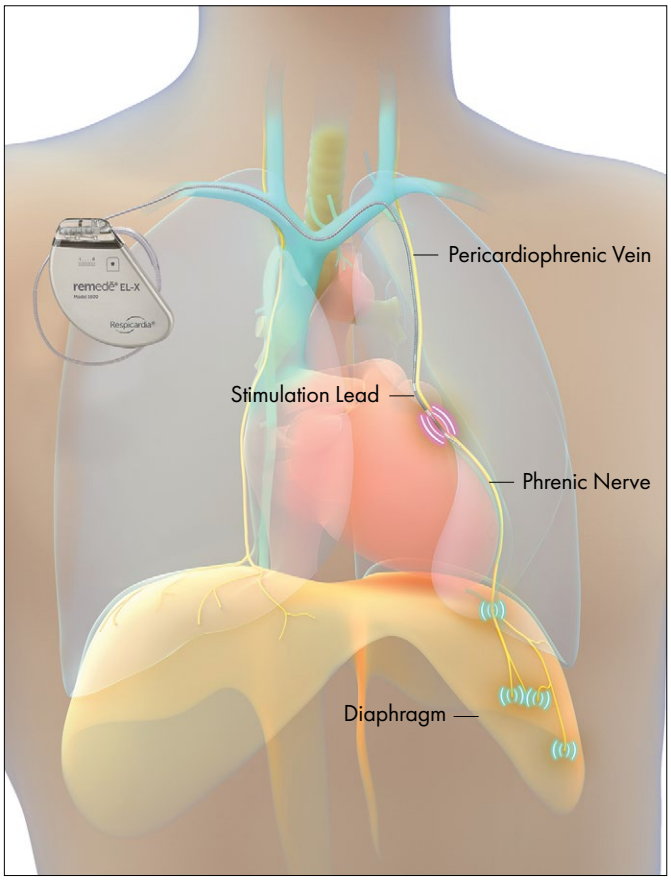
The **rem**edē® System is an implantable system that safely and effectively treats moderate to severe Central Sleep Apnea (CSA) in adult patients.[1] CSA is a serious breathing disorder that disrupts the normal breathing pattern during sleep and has been shown to negatively impact quality of life and 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:

- 96% reduction in Central Apnea Index[3]
- 95% of patients reported they would "elect to have the medical procedure again"[4]
- 78% of patients reported improved quality of life[4]
- Significant reduction in arousals and improvement in sleep architecture[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 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 **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

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 **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[5]	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

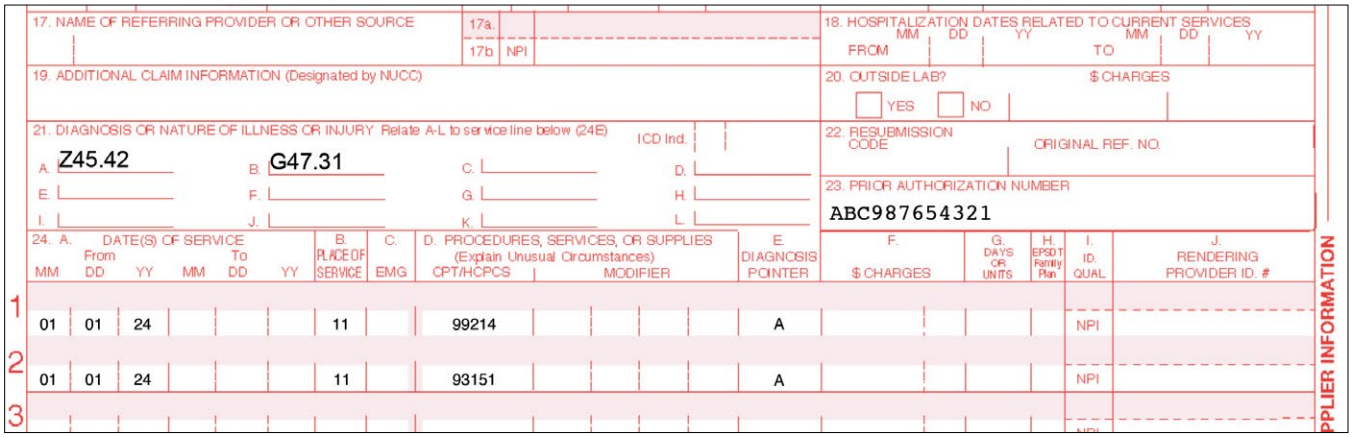
CPT® Codes and Physician Billing Table

		RVUS[7]		2024 MEDICARE NATIONAL AVERAGE PAYMENT[7]	
CPT® CODE[6]	DESCRIPTION	WORK	FACILITY	WORK	FACILITY
Insertion/Replacement					
33276	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed	9.50	17.05	$311.07	$558.29
33277	Insertion of phrenic nerve stimulator transvenous sensing lead	5.43	8.92	$177.80	$292.08
Removal without Replacement					
33278	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)	9.55	16.97	$312.71	$555.67
33279	Transvenous stimulation or sensing lead(s) only	5.42	10.26	$177.47	$335.96
33280	pulse generator only	3.04	6.17	$99.54	$202.03
Removal and Replacement					
33287	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance and interrogation and programming, when performed; pulse generator	6.05	11.44	$198.10	$374.59
33288	Transvenous stimulation or sensing lead(s) only	8.51	15.08	$278.65	$493.78
Repositioning					
33281	Repositioning of phrenic nerve stimulator transvenous lead(s)	6.00	11.09	$196.47	$363.13

		RVUS[7]			2024 MEDICARE NATIONAL AVERAGE PAYMENT[7]		
CPT® CODE[6]	DESCRIPTION	WORK	FACILITY	NON-FACILITY	WORK	FACILITY	NON-FACILITY
Programming							
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 without programming of implanted phrenic nerve stimulator system	0.43	0.64	1.55	$14.08	$20.96	$50.75
93151	Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system	0.80	1.19	2.61	$26.20	$38.97	$85.46
93152	Interrogation and programming of implanted phrenic nerve stimulator system during polysomnography	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. | 17b NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? ☐ YES ☐ NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. Z45.42 B. G47.31 C. D.
E. F. G. H.
I. J. K. L.

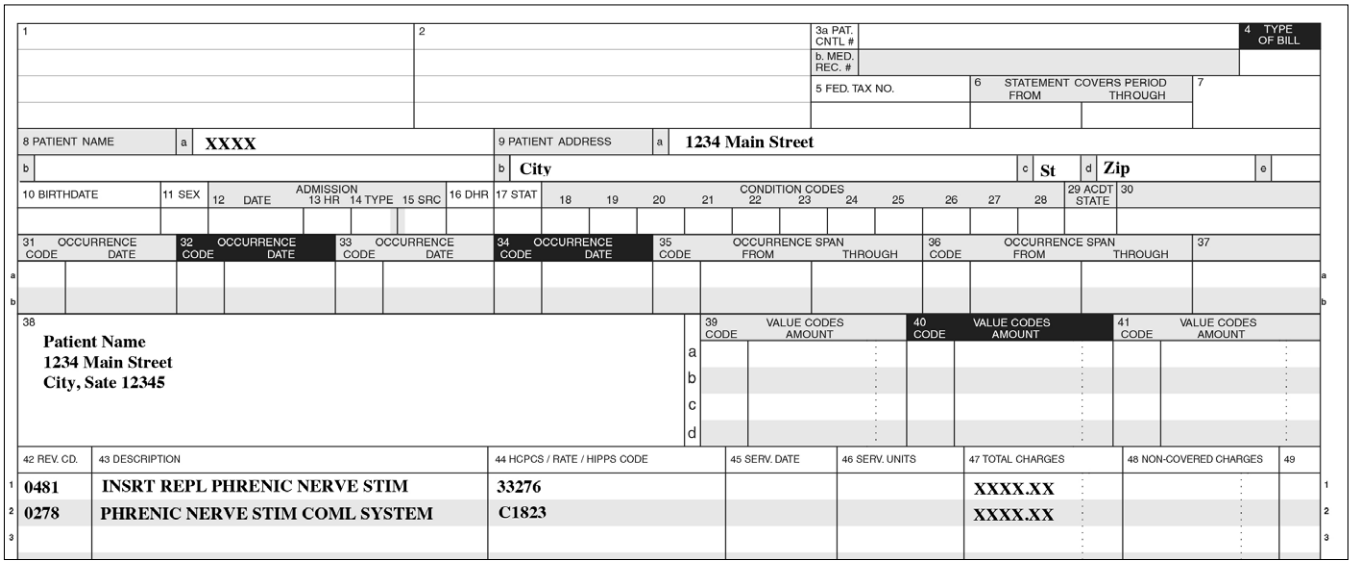
22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER ABC987654321

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT 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														NPI	

PPLIER INFORMATION

Physician Billing Example: Implant procedure



1 | 2 | 3a PAT. CNTL # | b. MED. REC. # | 4 TYPE OF BILL

5 FED. TAX NO. | 6 STATEMENT COVERS PERIOD FROM THROUGH | 7

8 PATIENT NAME a XXXX | 9 PATIENT ADDRESS a 1234 Main Street

b | b City | c St | d Zip | e

10 BIRTHDATE | 11 SEX | 12 ADMISSION DATE | 13 HR | 14 TYPE | 15 SRC | 16 DHR | 17 STAT | 18 | 19 | 20 | 21 | CONDITION CODES 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 CODE FROM THROUGH | 36 OCCURRENCE SPAN CODE FROM THROUGH | 37

a
b

38
Patient Name
1234 Main Street
City, Sate 12345

39 VALUE CODES CODE	AMOUNT	40 VALUE CODES CODE	AMOUNT	41 VALUE CODES CODE	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

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 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.
[4] 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.
[5] ICD-10-CM Expert for Physicians and Hospitals, 2024. AAPC.
[6] Current Procedural Terminology (CPT®) Professional Edition 2024.
[7] CY 2024 MPFS CMS-1784-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. The **rem**edē® 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 **rem**edē System MRI guidelines manual. 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 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. **Contraindications:** The **rem**edē 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 **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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