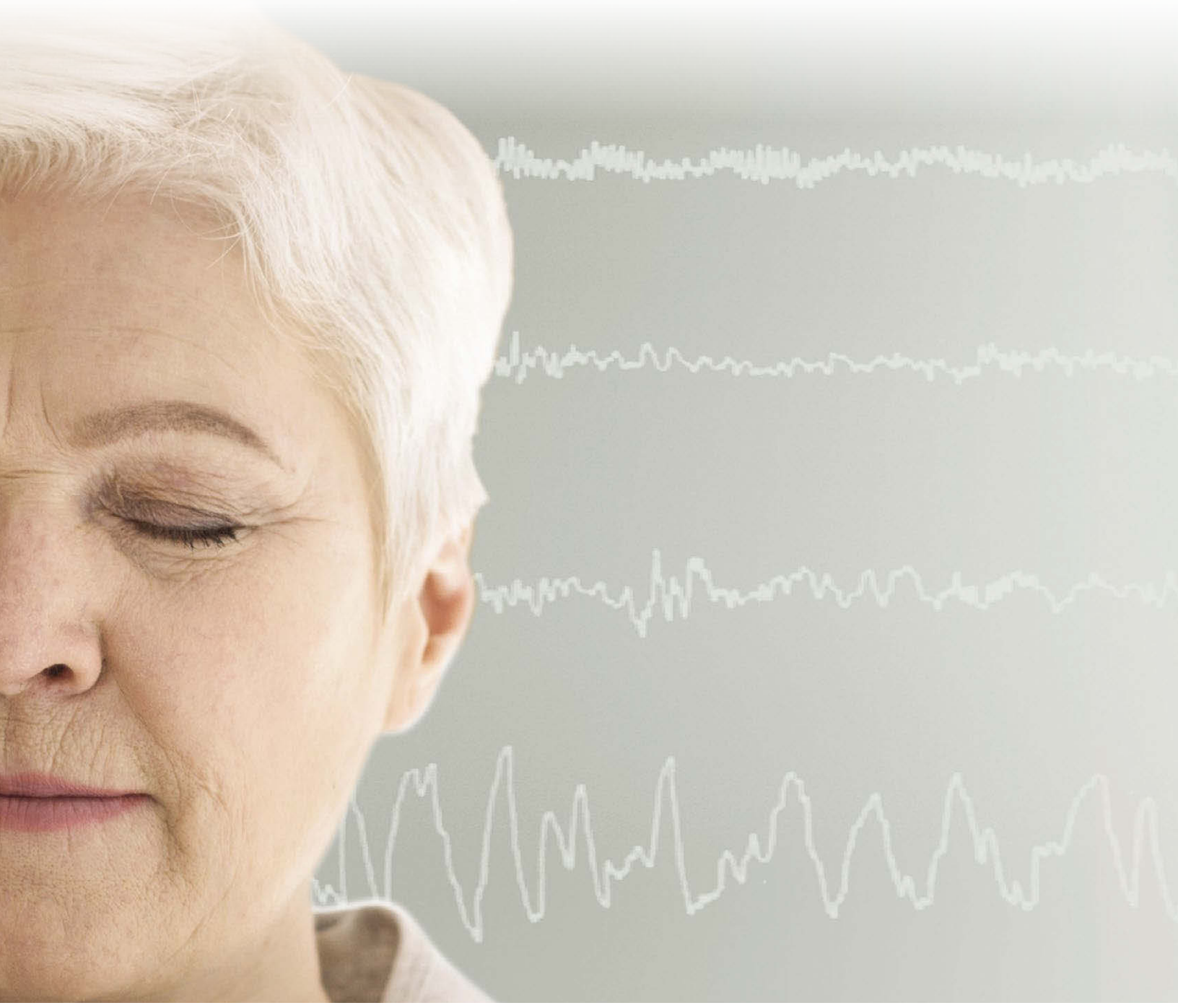
remedē® System

Transvenous Phrenic Nerve Stimulation for Central Sleep Apnea

ZOLL®



SLEEP SERVICES BILLING GUIDE

2022

The remedē® System Sleep Services Billing Guide

This guide contains coding and reimbursement information for sleep procedures associated with the **rem**edē System to treat moderate to severe central sleep apnea. For more information on billing for the **rem**edē System implant procedure and related services, the 2022 **rem**edē System Hospital and Physician Billing Guides are 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 offer hands-on assistance to physicians and hospitals 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

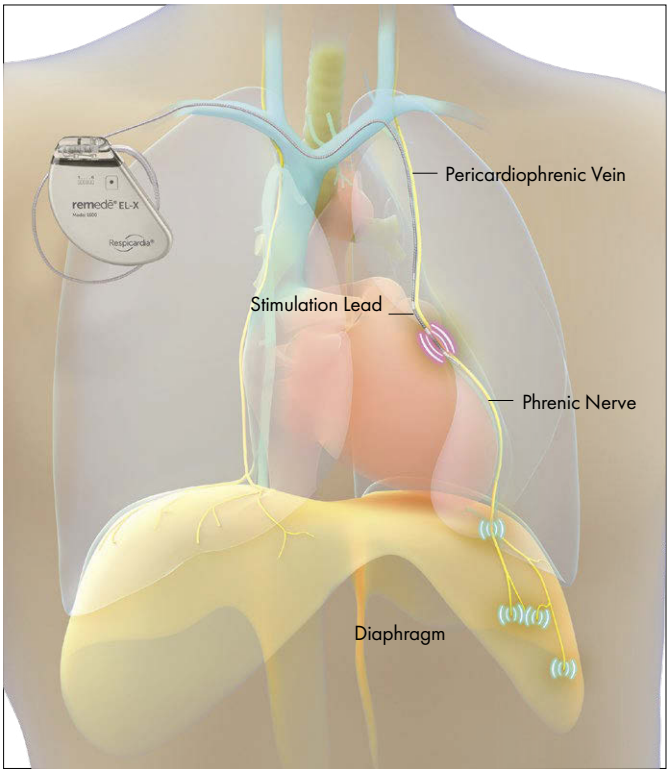
The **rem**edē® System is an implantable system that safely and effectively treats moderate to severe Central Sleep Apnea (CSA) in adult patients.[1] CSA is a serious breathing disorder that disrupts the normal breathing pattern during sleep and has been shown to negatively impact quality of life and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



Programming & Analysis

There are three different types of programming sessions that occur for patients with the **rem**edē System.

The **Therapy Activation** session is the first programming session when the device stimulation is activated and often occurs 4-6 weeks after the implant procedure. During this visit, the device data is reviewed and initial device programming occurs. Patient education also occurs.

The **Device Optimization** session occurs 6 weeks after therapy initiation and/or every 6-12 weeks until therapy delivery is stable. During this visit, the device data is reviewed and programming changes are made, as needed, to optimize therapy response and patient comfort. A subjective assessment is completed with the patient. This visit is often 30-45 minutes and most patients will require at least one iteration of adjustment and customization of program settings.

When individualized programming has been optimized, Chronic Follow-up is recommended every 3-6 months. During these visits, the device data is reviewed and minor programming changes are made, as needed, to optimize therapy response and patient comfort. A subjective assessment is completed with the patient which will determine the timing for the next visit. This visit is often 15-20 minutes.

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 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. However, Medicare may cover the **rem**edē System on a case-by-case basis, with evidence of medical necessity. Check with your local Medicare Administrative Contractor (MAC) regarding any Local Coverage Determinations (LCDs) related to the **rem**edē System. While traditional Medicare does not require or allow prior authorization or prior approval, Medicare Advantage plans are managed by commercial payers who may require prior authorization for Medicare Advantage patients. Check with your billing and coding staff for any prior authorization requirements.

Private Payer Coverage

Unlike traditional Medicare, private payers may require prior authorization for the Polysomnogram (PSG) or programming services. Before scheduling a PSG, the specific insurance requirements for sleep studies should be verified and authorized if required.

Commercial insurance coverage policies vary and many require prior authorization for an elective procedure or services 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.

Sleep Studies

It is also important to understand coverage regarding sleep studies for patients with the **rem**edē System. For Medicare beneficiaries, a single diagnostic and a single titration PSG are generally considered reasonable and necessary once per year.[4] Any repeat diagnostic or titration studies will require justification of medical necessity for the additional services.

For Commercial Payers, sleep studies typically require prior authorization. A repeat sleep study may be considered medically necessary up to twice a year to assess the treatment response or as a result of persistent or new symptoms. However, commercial plans vary and it is important to confirm coverage with your plan administrator.

Coverage differences may also exist for split-night, full-night and home sleep studies.

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 plan's Provider Manual. Contact the **rem**edē Reimbursement Hotline for additional information and resources to support your patient's appeal process.

CODING

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 CSA in adult patients. Hospitals report outpatient procedures using CPT codes. The **rem**edē System is currently classified with CPT Category III codes, which is indicated by the alphanumeric indicator "T" at the end of each code.

Diagnosis coding for CSA may include the following codes:

ICD-10-CM Diagnosis Codes

*Diagnosis coding for the **rem**edē System procedures may involve the following codes:*

ICD 10 CM CODE[5]	DESCRIPTOR
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

Diagnosis coding for routine interrogation and reprogramming may involve the following code:

ICD 10 CM CODE[5]	DESCRIPTOR
Device Follow-up Care	
Z45.42	Encounter for adjustment and management of neuropacemaker; brain, peripheral nerve, spinal cord

Qualifying Polysomnogram or Home Sleep Test

It is recommended that patients have a Polysomnogram (PSG) or Home Sleep Test (HST) documenting their CSA diagnosis within 24 months of consultation for the **rem**edē System. Keep in mind that certain sleep study technologies also do not separately identify mixed apneas from central and obstructive apneas which is a critical metric in determining a patient's CSA diagnosis and eligibility for the **rem**edē System.

If medically necessary, the sleep physician may order a sleep test every 6-12 months to monitor the device and optimize therapy. CPT coding for the PSG/HST may involve the following codes:

CPT®	DESCRIPTOR	RVU[6]	EXAMPLE[7]
95810	Polysomnography; sleep staging with 4 or more additional parameters of sleep, attended by a technologist.	17.57	In-lab PSG
95800	HST; Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time.	4.74	WatchPAT
95801	HST; Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (e.g., by airflow or peripheral arterial tone)	2.68	ResMed Apnea Link w/Oximetry
95806	HST; Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)	2.70	ResMed ApneaLink Air and Apnea Link Plus
G0398	Home sleep study test (HST) with type II portable monitor; unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort, and oxygen saturation	Carrier Priced	
G0399	Home sleep test (HST) with type III portable monitor; unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation	Carrier Priced	ResMed ApneaLink Air and Apnea Link Plus
G0400	Home sleep test (HST) with type IV portable monitor; unattended; minimum of 3 channels	Carrier Priced	WatchPAT, Resmed Apnea Link w/ Oximetry

Daytime Clinic Visits

After the **rem**edē System is implanted, it is common for the office visit to be billed along with the device activation or programming. In order to bill for the clinic visit, the Evaluation & Management (E/M) criteria must be separate and identifiable from the device programming activity and modifier-25 may be used with the E/M CPT code.

Sample of Clinic Visit CPT Codes

CPT® CODE	DESCRIPTOR	2022 Medicare National Average Payment[9]	RVU[6]
99204	New patient office visit, Level 4	$170.98	4.90
99205	New patient office visit, Level 5	$226.11	6.48
99214	Established patient office visit, Level 4	$130.85	3.75
99215	Established patient office visit, Level 5	$184.58	5.29

Therapy Activation

The Therapy Activation session is the first programming session when the device stimulation is activated and often occurs 4-6 weeks after the implant procedure. This initial visit includes patient education and is an extended session of approximately 45 min-1 hour. Therapy activation requires patient participation to optimize therapy comfort and should not be done during a PSG, it is most often done as a clinic visit.

Therapy Activation

CPT® CODE	DESCRIPTION	OPPS APC	OPPS STATUS INDICATOR[8]	2022 MEDICARE NATIONAL AVERAGE PAYMENT[9]	RVU
Device Interrogation and Programming					
0435T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session	5742	S	$102.53	Carrier Priced

Device Optimization & Ongoing Follow-up

After therapy activation occurs, additional clinic visits may be needed every 6-12 weeks to optimize the therapy delivery and patient comfort. During these evaluations, the device data will be review and any appropriate programming changes will occur. CPT code 0435T should be used when these changes occur during a clinic visit or CPT code 0436T if conducted during a PSG. CPT code 0434T should be used if only an interrogation occurs without any programming and it should not be combined with CPT code 0435T or 0436T.

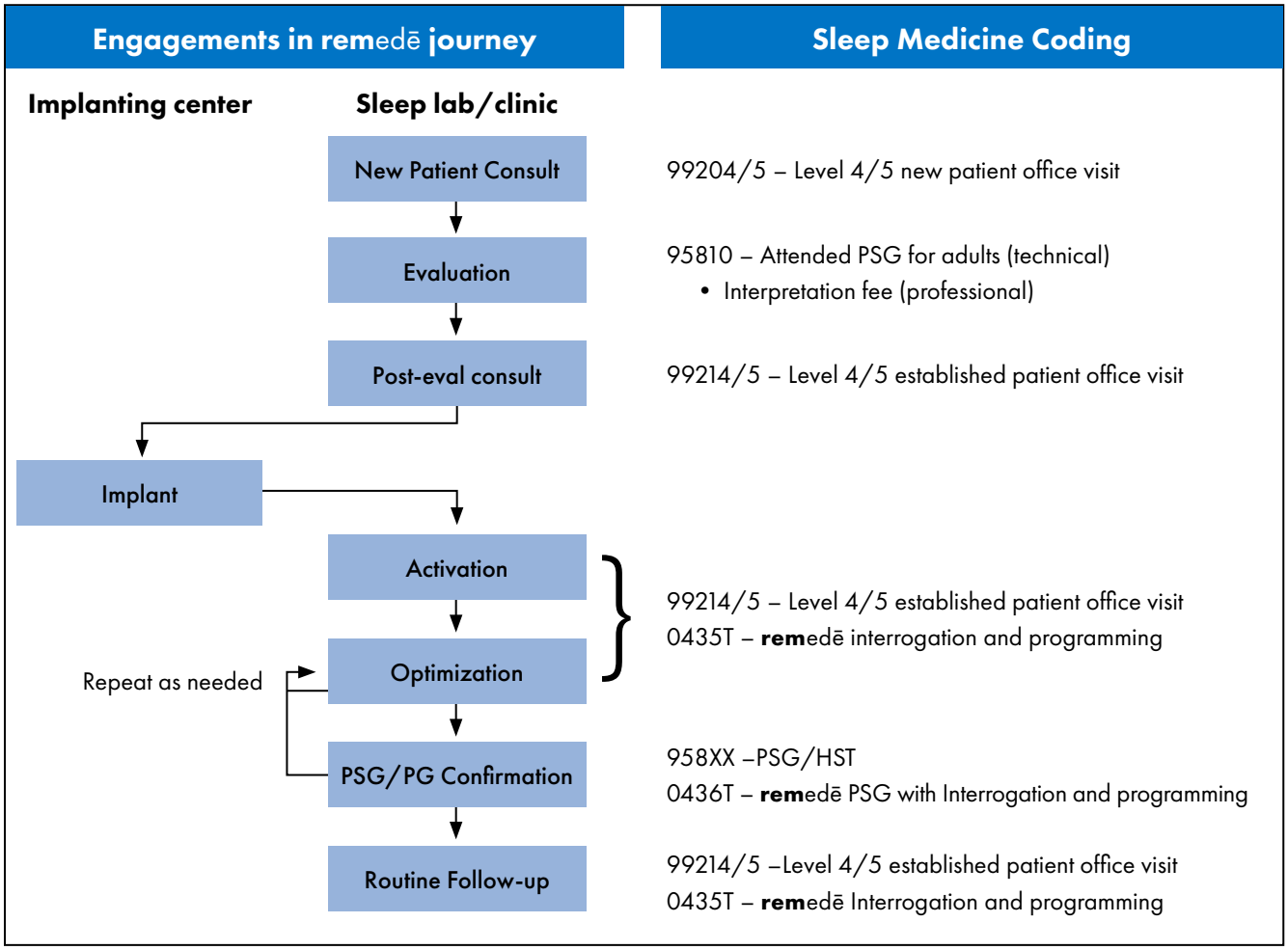
When therapy optimization has been attained, chronic follow-up should continue every 3-6 months based on individual patient needs. If medically necessary, these visits often include a patient assessment, device data review and minor programming changes.

Therapy Optimization and Follow-up

CPT® CODE	DESCRIPTION	OPPS APC	OPPS STATUS INDICATOR[8]	2022 MEDICARE NATIONAL AVERAGE PAYMENT[9]	RVU
Device Interrogation and Programming					
0434T	Interrogation device evaluation implanted neurostimulator pulse generator system for central sleep apnea	5742	S	$102.53	Carrier Priced
0435T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session	5742	S	$102.53	Carrier Priced
0436T	during sleep session	5724	S	$939.61	Carrier Priced

Example Pathway and Coding

See below for an illustrative example of a **rem**edē patient pathway in Sleep Medicine and some of the commonly used CPT codes.



BILLING AND PAYMENT

Billing Considerations

Given the Category III CPT codes for the services associated with the **rem**edē System, it is important to include the prior authorization number for commercial payers when submitting the claim. It may also be beneficial to include the prior authorization number for the initially device implant procedure.

Payers have different billing requirements for programming and polysomnograms. Check with the payer at Prior Authorization.

CLAIM FORM ITEM	VALUES	NOTES
Item 21A	Diagnosis (primary)	Enter the primary ICD-10-CM diagnosis Codes (see page 7)
Item 23	Prior Authorization Number	Enter the payer's prior authorization number for patients with commercial and Medicare Advantage
Item 24D	Procedures, Services, or Supplies	Enter the CPT code for each procedure or service provided with one CPT code in each line

Physician Billing

The **rem**edē System is currently assigned CPT Category III Codes by the American Medical Association. As a Category III CPT code, the **rem**edē System has not yet been assigned a Relative Value Unit (RVU) amount for the physician services performed. This means that Medicare and most commercial payers will establish the RVU and payment amount for these services at their discretion. It is a best practice when billing Category III CPT codes to include supporting documentation that addresses medical necessity for the procedure and describes the services performed.

Providing a comparable CPT code can assist payers in processing claims that do not have an established RVU. The comparable to an established Category I CPT code can serve as helpful proxies (i.e., "crosswalks") to characterize the work and practice expense associated with the **rem**edē System procedure. This information should be clearly documented in the patient's record for the payer to review and may include the detailed operative report, patient Letter of Medical Necessity, and FDA documentation. Ultimately, each physician is responsible for determining the appropriate crosswalk code, the appropriate charges for the **rem**edē System components used, and providing supporting documentation for all claims submitted involving the **rem**edē System.

When submitting a claim for a Category III CPT code, providers should include a "special report" with detailed medical notes that contain the following patient-specific information:

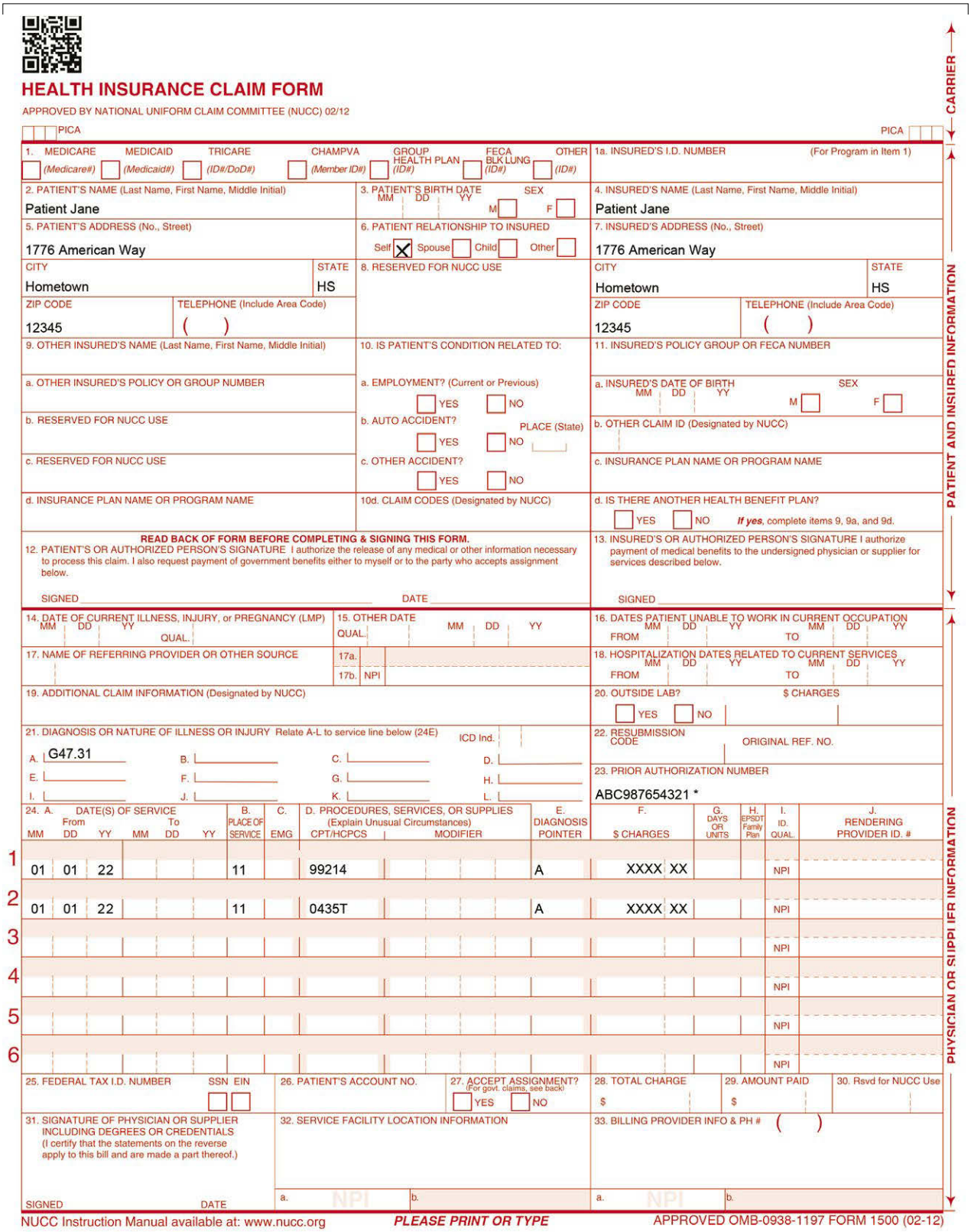
- Procedural information documenting the time required for the procedure.
- Level of the complexity of the physician work associated with providing the service based on the severity of the patient's medical condition.
- Rationale for why this specific treatment was selected for this patient.
- Any other information that would support the payment requested for the procedure.

Please note that the Category I proxy code should NOT be reported on the claim form. The appropriate Category III CPT code representative of the specific **rem**edē System procedure must always be submitted. The Category I crosswalk code should only be referenced in the special report or any documentation sent to the payer to reference as a proxy procedure to establish payment and justify charges. The determination of all charges and selection of reference codes is at the discretion of the provider.

Contact the Reimbursement Hotline for a template "Special Report" letter and additional resources when utilizing a crosswalk code.

Physician CMS-1500 Programming Billing Example

See below for an illustrative example of a Physician Claim.



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Patient Jane

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Patient Jane

5. PATIENT'S ADDRESS (No., Street): 1776 American Way

6. PATIENT RELATIONSHIP TO INSURED: Self [X] Spouse Child Other

7. INSURED'S ADDRESS (No., Street): 1776 American Way

CITY: Hometown STATE: HS

8. RESERVED FOR NUCC USE

CITY: Hometown STATE: HS

ZIP CODE: 12345 TELEPHONE (Include Area Code): ( )

ZIP CODE: 12345 TELEPHONE (Include Area Code): ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

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. G47.31 B. 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	22			11		99214		A	XXXX XX			NPI	
2	01	01	22			11		0435T		A	XXXX XX			NPI	
3														NPI	
4														NPI	
5														NPI	
6														NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org **PLEASE PRINT OR TYPE** APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

CLAIM AND PRIOR AUTHORIZATION APPEALS

Because the **rem**edē System is a novel therapy utilizing Category III CPT codes, a payor's appeal process may need to be utilized in order to obtain payment or authorization for patient care. Contact the Reimbursement Hotline for appeal letter templates and additional resources.

Appealing a Prior Authorization or Post-Service Claim Denial

ZOLL offers a Patient Access Program that works on behalf of patients who qualify for the **rem**edē System to exhaust all avenues in the prior-authorization and appeal process. By working on behalf of the patient directly, additional avenues of appeal can be utilized that are not always available to providers. For post-service claim denials, the Reimbursement Hotline can provide appeal letter templates and supporting documentation.

Appealing a Denied Claim or Low Payment for the Physician Services

If the claim for the physician services is denied, it is recommended that additional documentation is submitted including a Special Report that addresses the medical necessity for the procedure and describes the services performed. Contact the Reimbursement Hotline for letter template examples.

If the payment received for the claim is lower than expected, a Low Pay Claim Appeal letter should be submitted to the Payer that provides a comparable CPT code to assist the payment valuation given the **rem**edē System codes do not have an established RVUs. The comparison to an established Category I CPT code can serve as helpful proxies (i.e., "crosswalks") to characterize the work and practice expense associated with the **rem**edē System procedure.

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] CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 70
[5] ICD-10 PCS Expert for Hospitals, 2021.
[6] Total Non-Facility RVU's; CY2022 Physician Fee Schedule Finale Rule, CMS 1751-F. Addendum B.
[7] ResMed and Itamar Medical company website; accessed October 26, 2021.
[8] OPPS Payment Status Indicators for CY 2019, Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Final Rule, Federal Register Volume 83, Number 248.
[9] CMS-1753-F; Changes to Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. CY2022 NFRM 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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