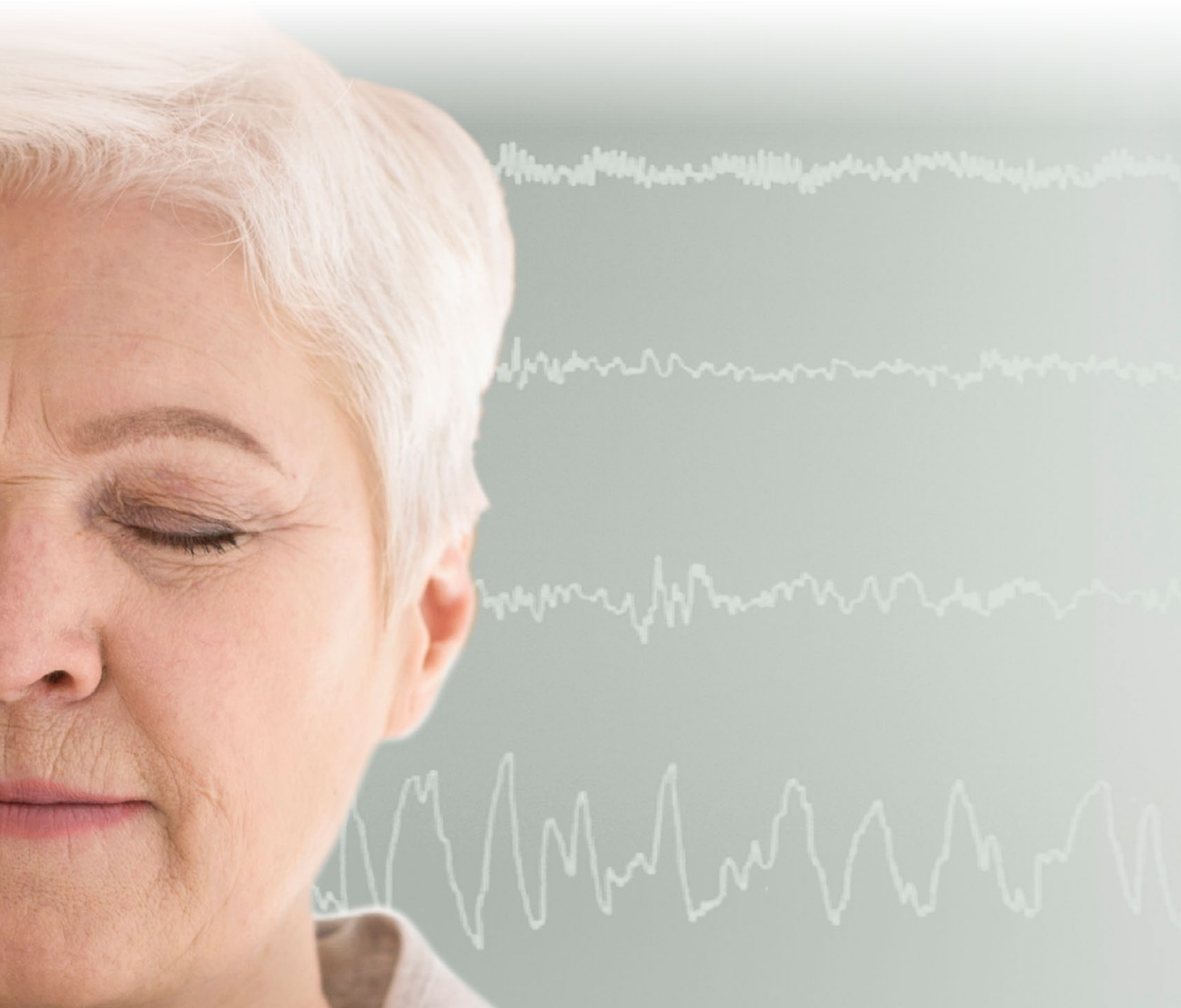


remedē[®] System

Transvenous Phrenic Nerve Stimulation for Central Sleep Apnea

ZOLL[®]



SLEEP SERVICES BILLING GUIDE

2023

The **remedē**® System Sleep Services Billing Guide

This guide contains coding and reimbursement information for sleep procedures associated with the **remedē** System to treat moderate to severe central sleep apnea. For more information on billing for the **remedē** System implant procedure and related services, the 2023 **remedē** System Hospital and Physician Billing Guides are available online at 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 offer hands-on assistance to physicians and hospitals 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.

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 **remedē**® 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 **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 Index³
- 95% of patients reported they would “elect to have the medical procedure again”⁴
- 78% of patients reported improved quality of life⁴
- Significant reduction in arousals and improvement in sleep architecture³

Device and Implant Procedure

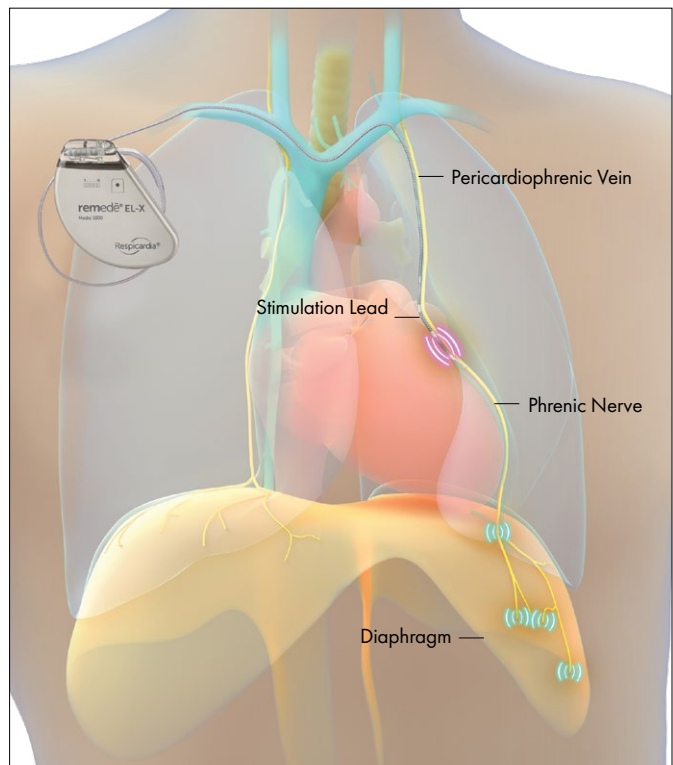
The **remedē** System is placed during a minimally invasive procedure. The system consists of a battery powered Implantable Pulse Generator (IPG) device placed under the skin in the upper chest area with one or two small thin wires (leads). One lead delivers the therapy to stimulate the phrenic nerve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

Programming & Analysis

There are three different types of programming sessions that occur for patients with the **remedē** 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 **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 CSA in adult patients.

Contraindications: The **remedē** 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 **remedē** System. However, Medicare may cover the **remedē** 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 **remedē** 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 **remedē** System. We encourage Health Care Professionals (HCPs) to contact payer(s) directly with questions regarding coverage policies or guidelines for the **remedē** System.

Sleep Studies

It is also important to understand coverage regarding sleep studies for patients with the **remedē** System. For Medicare beneficiaries, a single diagnostic and a single titration PSG are generally considered reasonable and necessary once per year.⁵ 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 **remedē** 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 **remedē** 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 **remedē** 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 **remedē** System is used to treat moderate to severe CSA in adult patients. Hospitals report outpatient procedures using CPT codes. The **remedē** 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 **remedē** System procedures may involve the following codes:*

| ICD-10-CM CODE ⁶ | 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 ⁶ | 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 **remedē** 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 **remedē** 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 ⁷ | EXAMPLE ⁸ |
|------------------|---|------------------|--|
| 95810 | Polysomnography; sleep staging with 4 or more additional parameters of sleep, attended by a technologist. | 18.15 | 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. | 4.45 | 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) | 2.77 | 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) | 2.74 | 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 **remedē** 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 | 2023 Medicare National Average Payment ⁹ | RVU ⁷ |
|-----------------------|---|---|------------------|
| 99204 | New patient office visit, Level 4 | \$170.98 | 4.94 |
| 99205 | New patient office visit, Level 5 | \$226.11 | 6.52 |
| 99214 | Established patient office visit, Level 4 | \$130.85 | 3.79 |
| 99215 | Established patient office visit, Level 5 | \$184.58 | 5.31 |

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 ⁹ | 2023 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 | \$ 99.81 | 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.

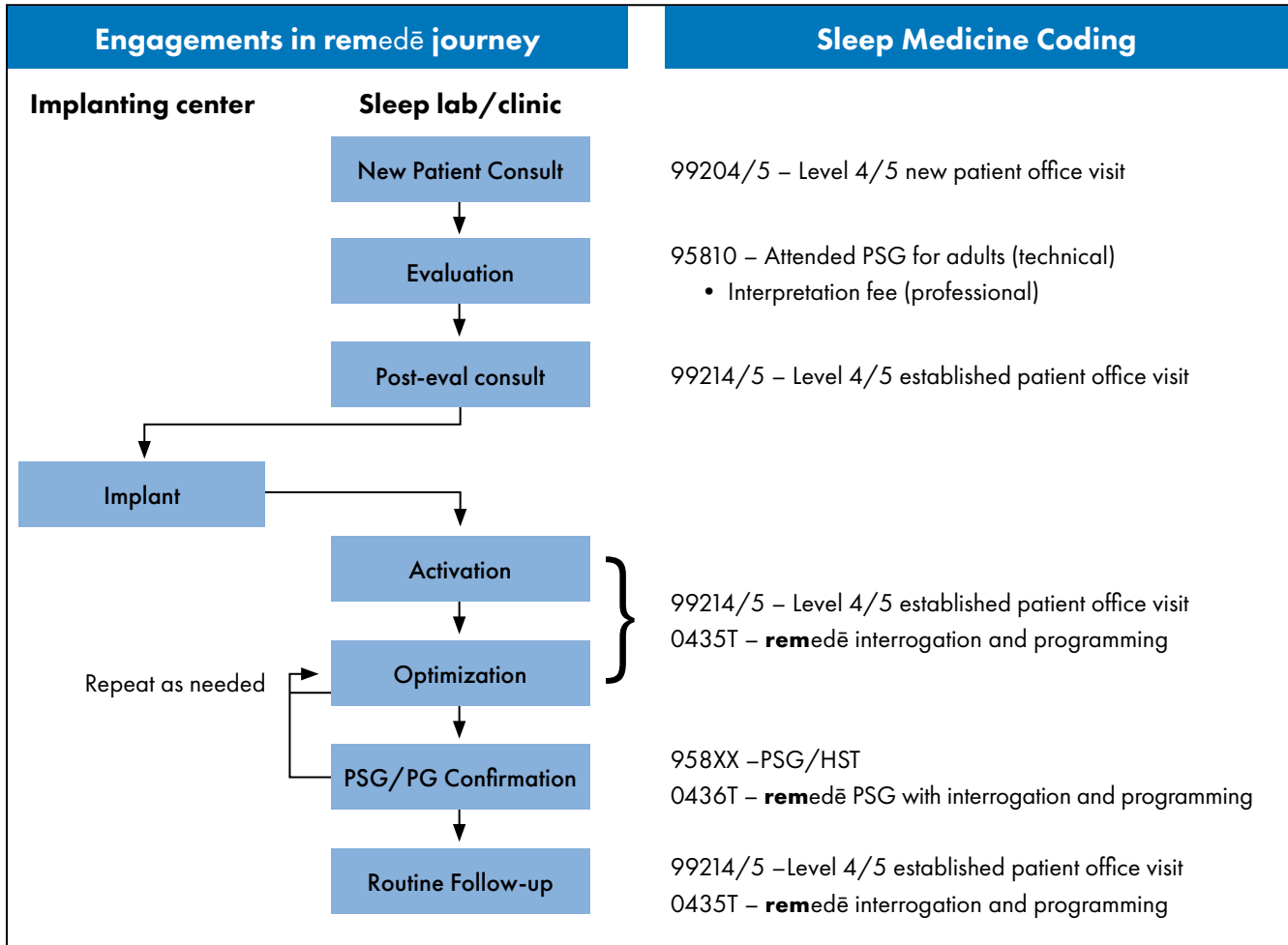
When therapy optimization has been attained, chronic follow-up should continue every 3-6 months based on individual patient needs. If medically necessary, these visits often include a patient assessment, device data review and minor programming changes.

Therapy Optimization and Follow-up

| CPT® CODE | DESCRIPTION | OPPS APC | OPPS STATUS INDICATOR ⁹ | 2023 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 | \$ 99.81 | Carrier Priced |
| 0435T | Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session | 5742 | S | \$ 99.81 | Carrier Priced |
| 0436T | during sleep session | 5724 | S | \$ 934.38 | Carrier Priced |

Example Pathway and Coding

See below for an illustrative example of a **remedē** 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 **remedē** 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 **remedē** System is currently assigned CPT Category III Codes by the American Medical Association. As a Category III CPT code, the **remedē** 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 **remedē** 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 **remedē** System components used, and providing supporting documentation for all claims submitted involving the **remedē** 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 **remedē** 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 <input type="checkbox"/> | | | | | PICA <input type="checkbox"/> | | | | |
| 1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA BLK LUNG <input type="checkbox"/> OTHER <input type="checkbox"/> | | | | | 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 <input type="checkbox"/> F <input type="checkbox"/> | | | | |
| 5. PATIENT'S ADDRESS (No., Street) 1776 American Way | | | | | 6. PATIENT RELATIONSHIP TO INSURED Self <input checked="" type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/> | | | | |
| 7. INSURED'S ADDRESS (No., Street) 1776 American Way | | | | | 8. RESERVED FOR NUCC USE | | | | |
| CITY Hometown STATE HS | | | | | 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: | | | | |
| a. OTHER INSURED'S POLICY OR GROUP NUMBER | | | | | a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/> | | | | |
| b. RESERVED FOR NUCC USE | | | | | b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State) _____ | | | | |
| c. RESERVED FOR NUCC USE | | | | | c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> | | | | |
| d. INSURANCE PLAN NAME OR PROGRAM NAME | | | | | 10d. CLAIM CODES (Designated by NUCC) | | | | |
| 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. | | | | | 11. INSURED'S POLICY GROUP OR FECA NUMBER | | | | |
| SIGNED _____ DATE _____ | | | | | a. INSURED'S DATE OF BIRTH MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/> | | | | |
| 13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below. | | | | | b. OTHER CLAIM ID (Designated by NUCC) | | | | |
| SIGNED _____ DATE _____ | | | | | c. INSURANCE PLAN NAME OR PROGRAM NAME | | | | |
| 14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL. | | | | | 15. OTHER DATE MM DD YY QUAL. | | | | |
| 17. NAME OF REFERRING PROVIDER OR OTHER SOURCE | | | | | 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY | | | | |
| 17a. _____ 17b. NPI _____ | | | | | 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY | | | | |
| 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) | | | | | 20. OUTSIDE LAB? YES <input type="checkbox"/> NO <input type="checkbox"/> \$ CHARGES _____ | | | | |
| 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. _____ | | | | | 22. RESUBMISSION CODE _____ ORIGINAL REF. NO. _____ | | | | |
| A. <u>Z45.42</u> B. <u>G47.31</u> C. _____ D. _____ | | | | | 23. PRIOR AUTHORIZATION NUMBER ABC987654321 * | | | | |
| E. _____ F. _____ G. _____ H. _____ | | | | | 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 23 11 99214 A XXXX XX NPI | | | | | 2 01 01 23 11 0435T A XXXX XX NPI | | | | |
| 3 _____ _____ _____ _____ _____ NPI | | | | | 4 _____ _____ _____ _____ _____ NPI | | | | |
| 5 _____ _____ _____ _____ _____ NPI | | | | | 6 _____ _____ _____ _____ _____ NPI | | | | |
| 25. FEDERAL TAX I.D. NUMBER _____ SSN EIN <input type="checkbox"/> <input type="checkbox"/> | | | | | 26. PATIENT'S ACCOUNT NO. _____ | | | | |
| 27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES <input type="checkbox"/> NO <input type="checkbox"/> | | | | | 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.) | | | | | 32. SERVICE FACILITY LOCATION INFORMATION | | | | |
| SIGNED _____ DATE _____ | | | | | 33. BILLING PROVIDER INFO & PH # () | | | | |
| a. NPI _____ b. _____ | | | | | a. NPI _____ b. _____ | | | | |

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CLAIM AND PRIOR AUTHORIZATION APPEALS

Because the **remedē** 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 **remedē** 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 **remedē** 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 **remedē** System procedure.

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.

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 CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 70

⁶ ICD-10 PCS Expert for Hospitals, 2022.

⁷ Total Non-Facility RVU's; CY2023 Physician Fee Schedule Final Rule, CMS-1770-F, Addendum B.

⁸ ResMed and Itamar Medical company website; accessed November 1, 2022.

⁹ CMS-1772-FC; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems. CY2023, 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. Patients will not be able to have an MRI or diathermy (special heat therapies) if the **remedē** System is implanted. 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 of the risks and benefits associated with the implantation of the **remedē** System. For further information please visit remede.zoll.com, call 952-540-4470 or email info@remede.zoll.com. **Indication 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 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 **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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For subsidiary addresses and fax numbers, as well as other global locations, please go to www.zoll.com/contacts.

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