remedē® System

Transvenous Phrenic Nerve Stimulation for Central Sleep Apnea

HOSPITAL BILLING GUIDE
2021

Respicardia®

The remedē® System Hospital Billing Guide

This guide contains hospital coding and reimbursement information for procedures associated with the placement of the **rem**edē System to treat moderate to severe central sleep apnea.

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.

Respicardia provides reimbursement case management and hotline services in order to support patient access to the **rem**edē System therapy. We provide 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 Respicardia Reimbursement Hotline at **1-952-540-4470** or email questions to **reimbursement@respicardia.com.**

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

CONTENTS

TRANSVENOUS PHRENIC NERVE STIMULATION FOR CENTRAL SLEEP APNEA

Therapy Overview

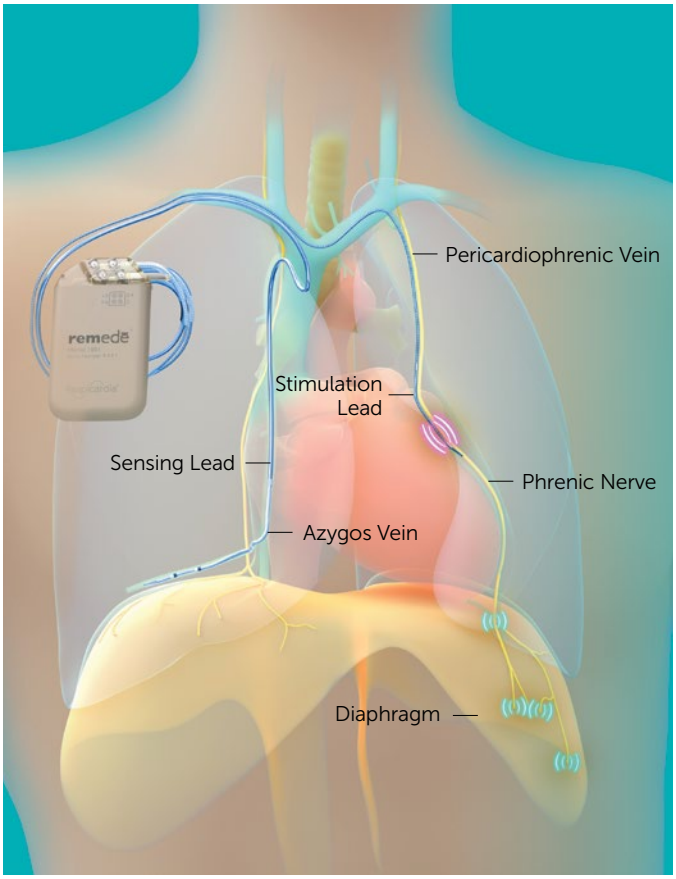
The **rem**edē® System is an implantable system that safely and effectively treats moderate to severe central sleep apnea (CSA) in adult patients.[1] CSA is a serious breathing disorder that disrupts the normal breathing pattern during sleep and has been shown to negatively impact quality of life and 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 two small thin wires (leads), one to deliver the therapy (stimulation lead) and one to sense breathing (sensing lead). The stimulation lead stimulates the phrenic nerve and the sensing lead gathers transthoracic impedance data.



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.

Although CMS granted the **rem**edē System the Transitional APC Pass-Through Status, payment policy decisions are separate from coverage policies for a new technology.

Private Payer Coverage

Commercial insurance coverage policies vary and a prior authorization is recommended even if it is not required by the payer. Proceeding without a prior authorization may result in a claim denial and non-payment. We encourage health care professionals (HCPs) to contact payer(s) directly with questions regarding coverage policies or guidelines for the **rem**edē System.

Respicardia 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.[4] 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 Provider Manual. The **rem**edē Patient Access Program can assist you with this process. Contact the Respicardia 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 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	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

Hospital Outpatient Codes

Hospitals report outpatient procedures using CPT® codes. 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.

For hospital outpatient payments, Medicare assigns each CPT code to a specific Ambulatory Payment Classification (APC). Each APC has a fixed payment amount which includes the cost of any devices. The Status Indicator (SI) "J1" indicates the primary code and all other procedures performed are considered adjunctive and included in the single C-APC payment rate. Codes with Status Indicator "S" means that the code is not subject to a reduction in payment when submitted with another higher-ranked code but do not receive separate payment when included on a claim with another J1 code. Regardless of whether a code receives separate payment, all appropriate HCPCS and CPT codes that correctly describe procedures performed and documented may be billed.

Medicare Payment Status Indicators, Ambulatory Payment Classifications (APC), and national average payments are provided below for procedures commonly associated with the **rem**edē System. The Medicare fee schedules listed are a national average and have not been geographically or wage adjusted.

Hospital Outpatient Codes

CPT® CODE[4]	DESCRIPTION	OPPS APC[7]	OPPS STATUS INDICATOR[7]	2021 MEDICARE NATIONAL AVERAGE PAYMENT[7]
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)	5465	J1	$29,444.52
0425T	sensing lead only	5463	J1	$11,236.21
0426T	stimulation lead only	5463	J1	$11,236.21
0427T	pulse generator only	5465	J1	$29,444.52
Removal				
0428T	Removal of neurostimulator system for treatment of central sleep apnea; pulse generator only	5461	J1	$3,275.30
0429T	sensing lead only	5461	J1	$3,275.30
0430T	stimulation lead only	5461	J1	$3,275.30
0431T	Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only	5465	J1	$29,444.52
Repositioning				
0432T	Repositioning of neurostimulator system for treatment of central sleep apnea; stimulation lead only	5461	J1	$3,275.30
0433T	sensing lead only	5461	J1	$3,275.30
Programming				
0434T	Interrogation device evaluation implanted neurostimulator pulse generator system for central sleep apnea	5742	S	$100.31
0435T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session	5742	S	$100.31
0436T	during sleep session	5724	S	$919.82

Hospitals use HCPCS Level I (eg, CPT®) and HCPCS Level II codes to report hospital outpatient services. CPT codes are assigned for the implant procedure and HCPCS II codes are assigned to identify the device itself. Level II HCPCS codes are reported by facilities when they have purchased and supplied the device and are required to be reported to Medicare. The following HCPCS Level II C-codes may be appropriate for Medicare hospital outpatient reporting. Some non-Medicare payers recognize HCPCS Level II L-codes and the following HCPCS Level II L-codes may be appropriate for non-Medicare payers. In general, C-codes are used for billing Medicare and L-codes are used for billing private payers, although some private payers may also accept C-codes.

HCPCS Level II Device Crosswalk

DEVICE CATEGORY	DEVICE DESCRIPTION	MODEL NUMBER(S)	HCPCS C-CODE(S)[8]	HCPCS L-CODE(S)[8]
IPG	Implantable Pulse Generator (IPG)	1001	C1823	L8686
Stimulation Lead	LQS Stimulation Lead	4065, 4165	C1823	L8680
	R Stimulation Lead	3102, 3103		
Delivery System	Guide Catheter	7120-S	C1887	n/a
Programmer	System Programmer & Wand	1002A/1004A/1004A-F	C1787	L8681

NOTE: Medicare hospital outpatient cases involving the use of the **rem**edē® System are eligible for Transitional Pass-Through Payment (TPT). These cases should identify the **rem**edē System leads and IPG with the HCPCS code C1823 to be eligible for Transitional Pass-Through Payment.[9] See page 11 for more details on the TPT program.

HCPCS Level II Device Descriptions

HCPCS CODE	HCPCS LONG DESCRIPTION[8]
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads.
C1887	Catheter, guiding
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only

Hospital Inpatient Codes

ICD-10-PCS procedure codes are used by hospitals to report inpatient procedures. Each major component of the procedure is coded separately. Procedures involving the **rem**edē® System may involve the following codes:

Hospital Inpatient ICD-10-PCS Codes

ICD-10-PCS CODE[5]	DESCRIPTION
0JH60DZ	Insertion of multiple array stimulator generator into chest subcutaneous tissue
05H33MZ	Insertion of neurostimulator lead into right innominate (brachiocephalic) vein
05H43MZ	Insertion of neurostimulator lead into left innominate (brachiocephalic) vein
05H03MZ	Insertion of neurostimulator lead into azygos vein

Medicare uses MS-DRG codes to reimburse hospitals for inpatient admissions. Each inpatient stay is assigned to a specific diagnosis-related group (DRG) based on the ICD-10-CM diagnosis codes and ICD-10-PCS procedure codes. Only one MS-DRG is assigned for each inpatient stay, regardless of the number of procedures performed. When more than one procedure is coded, DRG assignment is based on the highest-ranked code. Each MS-DRG has a fixed payment amount which includes the cost of any devices.

While an inpatient procedure may be unlikely, a hospital inpatient procedure involving the **rem**edē System may involve the following DRG codes:

DRG Classification[9]

DRG	DESCRIPTOR
040	Peripheral/Cranial Nerve & other nervous system procedures with a major complication or comorbidity (MCC)
041	Peripheral/Cranial Nerve & other nervous system procedures with a complication or comorbidity (CC) or Peripheral Neurostimulator
042	Peripheral/Cranial Nerve & other nervous system procedures without a CC or MCC
05H03MZ	Insertion of neurostimulator lead into azygos vein

Ambulatory Surgical Center Codes

Procedures involving the **rem**edē System may also be performed in Ambulatory Surgery Centers (ASC). ASCs report CPT® codes, but they are assigned to individual fee schedules. The following CPT codes may be used as a guide for Ambulatory Surgery Center (ASC) reporting. The actual code(s) billed should reflect the services provided to each individual patient. The Medicare fee schedules listed below are a national average and have not been geographically or wage adjusted.

Device interrogation and programming are nonsurgical procedures that are not payable by Medicare and most commercial payers in an ASC. The ASC should not report these codes to Medicare. If the physician performs device programming, they may report those codes on the physician claim. For more guidance, please see the 2021 **rem**edē System Physician Billing Guide.

ASC Codes

CPT® CODE[4]	DESCRIPTION	ASC PAYMENT INDICATOR[10]	2021 MEDICARE NATIONAL AVERAGE PAYMENT[10]
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)	G2	$13,111.88
0425T	sensing lead only	G2	$6,087.43
0426T	stimulation lead only	G2	$6,087.43
0427T	pulse generator only	J8	$23,251.20
Removal			
0428T	Removal of neurostimulator system for treatment of central sleep apnea; pulse generator only	G2	$1,840.75
0429T	sensing lead only	G2	$1,840.75
0430T	stimulation lead only	G2	$1,840.75
0431T	Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only	J8	$23,413.79
Repositioning			
0432T	Repositioning of neurostimulator system for treatment of central sleep apnea; stimulation lead only	G2	$1,840.75
0433T	sensing lead only	G2	$1,840.75

ASC Status Indicator

DRG CODE	ASC PAYMENT STATUS
J8	Device-intensive procedure; paid at adjusted rate
G2	Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight.

MEDICARE BILLING AND PAYMENT

Billing Considerations

For hospital inpatient and outpatient procedures, device category HCPCS codes (i.e. C-codes) for implantable devices, along with the associated charge for the device may be reported. Complete and accurate reporting of implantable devices and the associated HCPCS codes assures accurate payment and provides necessary data for the reimbursement system.

CMS Transitional Pass-Through Payment (TPT)

The Transitional APC Pass-through Payment Status provides incremental payment (in addition to the APC payment) for outpatient procedures with qualified technologies. To qualify for a TPT requires a submission to CMS that assesses the technology's eligibility based on four criteria:

- New, novel, breakthrough technology
- Above a minimum cost threshold
- "Substantial clinical improvement" over current standard of care
- Clinically reasonable and necessary

CMS determined that all of these criteria were met for the **rem**edē® System and granted the Pass-Through Payment for outpatient discharges occurring on and after January 1, 2019. The payment is available for up to 3 years.

The Medicare administrative contractor (MAC) will calculate the TPT based on the CPT procedure code 0424T (APC 5465) and cases identifying the **rem**edē System leads and implantable pulse generator (IPG) with the HCPCS code C1823. The Transitional Pass-Through Payment is intended to fully reimburse hospitals and ASCs for the cost of the **rem**edē System when that cost exceeds the current device-related portion of the APC payment.[11] The TPT payment amount is determined based on hospital charges for the **rem**edē System and the hospital's cost-to-charge (CCR) ratio. Contact the Respicardia Reimbursement Hotline for more details on the TPT program and illustrative examples of the incremental payment calculation.

Medical Unlikely Edit (MUE) Biling Guidance

The **rem**edē System consists of an Implantable Pulse Generator (IPG), a stimulation lead and a sensing lead. All device components are reported under the same HCPCS code, C1823. The HCPCS code C1823 describes the entire **rem**edē System and CMS has established a medically unlikely edit (MUE) of one for this code. Therefore, when a quantity greater than one is reported on the hospital UB04 claim form, CMS may not process the pass-through payment.

Hospitals should combine all of the individual charges for **rem**edē System components into a single charge line as shown below with a quantity of one (1). This comprehensive charge should be inclusive of all implantable medical device components for the system, including a sensing lead from another manufacturer, if used.

Example:

Recommended: Charges as they should be reported on the UB04 for pass-through eligibility.

MODEL NUMBER	DEVICE DESCRIPTION	HCPCS CODE	QUANTITY	HOSPITAL CHARGES
1001	**rem**edē System, Complete System	C1823	1	$125,700

Example:

Not Recommended: Unadjusted hospital charges generated from operating room/supply documentation system.

MODEL NUMBER	DEVICE DESCRIPTION	HCPCS CODE	QUANTITY	HOSPITAL CHARGES
1001	Pulse Generator, Non-rechargeable **rem**edē System	C1823	1	$107,300
4165	Left Stimulation Lead, **rem**edē System	C1823	1	$9,200
3102	Right Stimulation Lead	C1823	1	$9,200

APPEALING A DENIED CLAIM OR PRIOR AUTHORIZATION REQUEST

Because the **rem**edē System is a novel therapy with a CPT® III code, a payor's appeal process may need to be utilized in order to obtain payment or authorization for patient care. Respicardia 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 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 denied Medicare or post-service claims, the **rem**edē Patient Access Program can also support the provider or the patient with the appeal process. Contact the Respicardia 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 Respicardia 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 Respicardia Reimbursement Hotline at

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

FREQUENTLY ASKED QUESTIONS

Q: Why does the remedē® System have a Category III code or "T" code? Will it change?

As a novel therapy offering, the **rem**edē System is currently classified a CPT® Category III code by the American Medical Association (AMA) and indicated by the alphanumeric indicator "T" at the end of each code. CPT Category III codes are a set of temporary codes that allow data collection for emerging technology, services, and procedures. As therapy adoption increases, therapies with a Category III code may meet the requirements to transition to a Category I code. Respicardia will continue to actively engage with the appropriate physician societies and the AMA to determine the most appropriate code category for the **rem**edē System.

Q: What is the remedē Patient Access Program?

Respicardia has partnered with an external firm called PRIA to provide the **rem**edē Patient Access Program. PRIA is a healthcare management firm determined to bring the latest medical devices, treatments, and procedures to physicians and patients nationwide. PRIA fights on behalf of the patient by executing on prior authorizations and patient-based appeals of denied care.

Q: Can I enroll my patient case in the remedē Patient Access Program after our practice submitted the case and received a prior authorization denial or a Medicare claim denial?

Yes. The **rem**edē System Patient Access program leverages the patient's legally protected right to appeal an adverse benefit determination and can be used at any time, even after a claim or appeal submitted by a provider is denied. PRIA will work on behalf of patients until all avenues in the appeal process are exhausted. By working directly on behalf of the patient, additional avenues of appeal may be utilized that are not always available to providers. However, PRIA will also work on behalf of the provider to appeal a post-service denial.

Learn more at **respicardia.com**

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6. CMS-1763-FC; Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. CY2021 NFRM Addendum B. Effective through December 31, 2021.
7. 2021 Alpha-Numeric HCPCS File.
8. ICD-10-PCS Expert for Hospitals, 2021.
9. 2021 Medicare Inpatient Prospective Payment System (IPPS) Final Rule.
10. CMS-1763-FC; Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. CY2021 NFRM Addendum AA. Effective through December 31, 2021.
11. Exact reimbursement amount is determined for each case based on actual hospital charges and the hospitals cost-to-charge ratio (CCR) as determined from its cost report.

Important Safety Information

The **rem**edē® System is indicated for moderate to severe Central Sleep Apnea 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 www.respicardia.com, call +1-952-540-4470 or email info@respicardia.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 has received FDA and CE Mark approvals.

RMB1722, Rev C