**SAMPLE LETTER OF MEDICAL NECESSITY/PRIOR AUTHORIZATION FOR THE rem**edē**® SYSTEM
Device (IPG) Replacement/Battery Change**

**DISCLAIMER:** This sample template letter is provided as a courtesy by ZOLL Respicardia, Inc. Please do not include statements that do not apply to your patient and edit this letter to fit your unique experience. ZOLL Respicardia is not responsible for any edits made to the letter, makes no representations or warranties with respect to the contents of this letter, and disclaims any liability associated with the use of this letter. You are responsible for providing true, accurate, and complete information concerning the applicable diagnosis and procedure codes and the patient’s medical record and ensuring the medical necessity of the procedure.

This document is for informational purposes only and is not legal advice or official guidance from payors. It is not intended to increase or maximize reimbursement by any payor. Hospitals and physicians are solely responsible for being in compliance with Medicare and other payor rules and requirements for the information submitted with all claims and appeals. ZOLL Respicardia does not warrant or guarantee that the use of this information will result in coverage or payment. Before any claims or appeals are submitted, hospitals and physicians should review official payor instructions and requirements, should confirm the accuracy of their coding or billing practices with these payors and should use independent judgment when selecting codes that most appropriately describe the services or supplies provided to a patient. Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements. ZOLL Respicardia recommends that you consult with your payers, reimbursement specialists and/or legal counsel regarding coding, coverage, and reimbursement matters.

**Instructions for completing the sample letter:**

1. Please customize the template based on the medical appropriateness of the **rem**edē® System for your patient. Fields required for customization are highlighted in yellow. Notes/instructions are provided in red text.
2. It is important to provide the most complete information to assist with the prior authorization process.
3. After you have customized the letter, please make sure to delete any specific instructions for completion that are provided in red text and remove the yellow highlights throughout the letter, so the health plan does not misinterpret this as a form letter.
4. If you have questions, please contact 1-952-540-4470 or email reimbursement@remede.zoll.com.

**LETTER OF MEDICAL NECESSITY/PRIOR AUTHORIZATION REQUEST**

[Date]

To: [Payer Name]

Prior Authorizations

[Address or Fax]

**Re: Request for coverage for surgical removal and replacement of transvenous phrenic nerve stimulator to treat central sleep apnea**

Patient Name: [Patient Name]

Group/policy number: [Policy Number]

Member ID number: [Member ID Number]

Requesting Physician: [Physician full name and credentials]

NPI: [physician NPI]

Tax ID: [physician Tax ID #]

Facility: [facility name]

Facility NPI: [facility NPI]

Diagnosis: **Central Sleep Apnea, G47.31** [adjust diagnosis code as appropriate]

Procedure Code:

**33287** - Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator

Dear Utilization Review Manager:

I am requesting a predetermination of coverage and/or prior authorization for insurance coverage on behalf of my patient, [Patient Name], to undergo surgical intervention to remove and replace a previously implanted neurostimulator pulse generator (the **rem**edē System). The **rem**edē System is an implantable system that safely and effectively treats moderate to severe Central Sleep Apnea (CSA) in adult patients.

**PLEASE NOTE:** [Patient Name] underwent insertion of the **rem**edē® Phrenic Neurostimulator on [date of implant] and has demonstrated meaningful clinically improvement in [his/her] CSA. The coverage for placement of the **rem**edē System (CPT code 33276) was approved on [Date of approval of implant surgery] and the authorization code for the initial surgery is [insert initial implant auth code] [if available]. My medical judgment is that [Patient Name] will benefit greatly from ***continued phrenic nerve stimulation therapy***. Replacement of the device is therefore medically necessary to ensure continuity of the therapy and to maintain the patient’s CSA symptoms and overall health outcomes.

Since being treated with phrenic nerve stimulation, [he / she] has shown marked improvement in [his / her] CSA symptoms and a significant improvement in their overall quality of life as documented by sleep apnea study measures including: [central apneas /hour reduction / hypopneas /hour reduction]. Without treatment [he / she] is at risk for severe comorbid medical conditions including [heart failure / atrial fibrillation, increased risk of motor vehicle accident and reduced daytime productivity due to chronic fatigue]. [edit as appropriate].

In order to maintain this therapy benefit, the **rem**edē implantable pulse generator requires replacement due to the [battery status indicator OR elective replacement indicator (ERI) OR end of life indicator (EOL)] shown on the device interrogation report. [Although battery EOL has not yet been reached, I anticipate that it will be reached in the extremely near future and am requesting authorization to avoid potential gaps in therapy]. According to the **rem**edē System Clinician Use Manual, the **rem**edē IPG replacement should occur as soon as possible given only an estimated 3 weeks of normal operation remain once the ERI is triggered. When the EOL indicator is shown, stimulation therapy has been disabled, and the patient will not receive any therapy until the remedē IPG is replaced. The patient continues to meet all clinical indications for this therapy. Replacement is essential to maintain treatment effectiveness and prevent disease recurrence or progression.

**The** **rem**edē**® Phrenic Nerve Stimulation System**

The **rem**edē Systemis the ***only*** device approved by the FDA (PMA P160039, October 2017) as a transvenous implantable phrenic nerve stimulator **indicated to treat moderate to severe CSA** in adult patients.

The **rem**edē System consists of an implantable neurostimulator of the phrenic nerve that is designed to stabilize the breathing pattern and restore sleep throughout the night for patients with CSA. The system activates automatically at night removing compliance issues and the need for patient interaction. By stimulating the nerve that controls the diaphragm, it utilizes a physiologic mechanism similar to natural breathing.

Key features of the **rem**edēTransvenous Phrenic Nerve Stimulationsystem include:

* In an randomized controlled trial, the **rem**edē system showed clinically meaningful results in AHI (apnea-hypopnea index) reduction and a range of important sleep metrics for CSA patients.[[1]](#endnote-2)
* The treatment effects are clearly durable over time, with clinical data demonstrating sustained treatment effect to 12, 24, 36 and 60 months.[[2]](#endnote-3),4,5
* Nightly compliance is assured by automatic therapy activation and a high rate of tolerance as suggested by 95% of patients reporting they would “elect to have the medical procedure again.”
* The remedē system has shown to produce comparable treatment effects in CSA patients with and without HF.[[3]](#endnote-4)
* There is a strong safety profile.[[4]](#endnote-5)

The recently updated American Academy of Sleep Medicine (AASM) CSA guidelines recommend transvenous phrenic nerve stimulation as a treatment option, [[5]](#endnote-6), noting that it demonstrated clinically significant improvements in excessive sleepiness, disease severity, and cardiovascular disease.

**Clinical & Economic Value Evidence**

This therapy was evaluated in the **rem**edē pivotal trial, a randomized controlled trial evaluating the safety and effectiveness of phrenic nerve stimulation in patients with CSA. In the clinical study, the **rem**edē system was shown to effectively treat sleep disorder breathing with a 93% mean reduction in the central apnea index (CAI), and 91% of patients experienced a reduction in their overall AHI from baseline to 12 months. Additionally, 82% of patients experienced an improvement in their quality of life and 95% of implanted patients would elect to have the procedure again. Improvements in sleep and quality of life are sustained over time and the improvements were similar when the control group was activated.4

There was a 91% freedom from serious adverse effects related to the implant procedure, the **rem**edē system, or delivered therapy at 12 months.1 The implant success rate was high (97%) and serious implant procedure related complications, including lead dislodgements, were low and comparable to those of other implantable transvenous systems.1 Long-term, the safety profile and beneficial effects of the **rem**edē System were maintained through 5 years post implant.[[6]](#endnote-7)

The **rem**edē System offers clear and substantial benefit in patients with CSA including improvements in AHI, CAI, oxygenation, arousals, and sleep quality with these improvements leading to a significant improvement in patient quality of life.

Thank you for taking the time to review this request on behalf of my patient. Please contact me should you require any additional information.

Sincerely,

[Physician Name]

[Contact Information]

Enclosures: [adjust as appropriate]

Sleep Study Results, Clinical Notes

Device Interrogation Report

FDA Letter

Clinical Fact Sheet/Evidence Table

1. Costanzo MR, Ponikowski P, Javaheri S, et al. Transvenous neurostimulation for central sleep apnoea: a randomised controlled trial. *Lancet* 2016;388(10048):974–982. [↑](#endnote-ref-2)
2. Fox H, Oldenberg O, Costanzo MR, et al. Long-term efficacy and safety of phrenic nerve stimulation for the treatment of

central sleep apnea outcomes of phrenic nerve stimulation for central sleep apnea. *Sleep* 2019;42(11): zsz158. [↑](#endnote-ref-3)
3. Costanzo MR, Ponikowski P, Coats A, et al. Phrenic nerve stimulation to treat patients with central sleep apnoea and heart failure. *Eur J Heart Fail* 2018;20:1746-1754. [↑](#endnote-ref-4)
4. Costanzo MR, Ponikowski P, Javaheri S, et al. remedē System Pivotal Trial Study Group. Sustained 12 month benefit of phrenic nerve stimulation for central sleep apnea. *Am J Cardiol* 2018; 121:1400-1408. [↑](#endnote-ref-5)
5. Badr MS, Khayat RN, Allam JS, et al. Treatment of central sleep apnea in adults: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med* 2025; <https://doi.org/10.5664/jcsm.11858>. [↑](#endnote-ref-6)
6. Costanzo MR 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.. [↑](#endnote-ref-7)