SAMPLE LETTER OF MEDICAL NECESSITY/PRIOR AUTHORIZATION FOR THE remedē**® SYSTEM PROCEDURE**

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Instructions for completing the sample appeal letter:

1. Please customize the appeals template based on the medical appropriateness of the **rem**edē® System for your patient. Fields required for customization are **highlighted in red text**.

2. It is important to provide the most complete information to assist with the appeals process.

3. After you have customized the appeals letter, please make sure to delete any specific instructions for completion that are highlighted in red text 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 FOR THE remedē® SYSTEM

Date

To: Insurance
Re: Request for Coverage for transvenous phrenic nerve stimulation
Patient Name: Patient Name
Group/policy number: Policy Number
Diagnosis: **Central Sleep Apnea, G47.31**
Procedure Code (s): 33276

Dear Utilization Review Manager:

I am requesting prior authorization for insurance coverage on behalf of my patient, Patient Name, for transvenous phrenic nerve stimulation as medically necessary for the treatment of ***central sleep apnea***.

Patient Name is age years old and suffers from

- Chronic fatigue/lack of energy
- Excessive daytime sleepiness
- Memory/concentration problems
- Mood changes, such as depression or irritability
- Headaches
- Nighttime gasping

My patient has attempted but failed conventional treatment including

- supplemental oxygen therapy
- pharmacotherapy
- CPAP /mask desensitization
- BiPAP

and symptoms persist that interfere with his/her safety, wellbeing and quality of life. Without treatment he/she is at risk for severe comorbid medical conditions, increased risk of motor vehicle accident and reduced daytime productivity due to life altering chronic fatigue.

My patient also

- is not suitable for CPAP ONLY KEEP IF PATIENT HAS NOT TRIED CPAP
- is not suitable for ASV due to heart failure
- suffers from atrial fibrillation
- suffers from congestive heart failure

In discussion with my patient, we have decided to opt for implantation of the **remedē Phrenic Nerve Stimulation System** to address this condition.

Demonstration of Medical Necessity

The following clinical documentation supports the medical necessity of this procedure:

- Symptoms of Central Sleep Apnea:
  - Chronic fatigue/lack of energy
  - Excessive daytime sleepiness
  - Memory/concentration problems
  - Mood changes (i.e. depression or irritability)

- Headaches Nighttime gasping

- Sleep Study Results:
  - AHI ≥ 15 with > 50% Central Events
  - Central Apneas/Hour
  - Mixed Apneas/Hour
  - Hypopneas/Hour
  - Oxygen Desaturation Events/Hour
  - Patient was not receiving treatment during the sleep study
  - Patient was receiving the following treatment during the sleep study: □ CPAP □ BiPAP □ ASV □ Oxygen
- Ejection Fraction % (LVEF) _____%
- NYHA Heart Failure Classification (Function Capacity): [ ] I [ ] II [ ] III [ ] IV

Advanced Features of the remedē® Phrenic Nerve Stimulation System

The **rem**edē System is the ***only*** device approved by the FDA (PMA P160039, October 2017) as a transvenous implantable phrenic nerve stimulator **indicated to treat moderate to severe central sleep apnea (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**edē **Transvenous Phrenic Nerve Stimulation** system include:

- In an RCT, 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]
- The treatment effects are clearly durable over time, with clinical data demonstrating sustained treatment effect to 12, 24, 36 and 60 months.[2,4,5]
- 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 **rem**edē system has shown to produce comparable treatment effects in CSA patients with and without HF.[3]
- There is a strong safety profile.[4]

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, and 91% of patients experienced a reduction in their overall apnea/hypopnea index 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.[5]

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

Enclosures:
Sleep Study Results, Clinical Notes
FDA Letter
Clinical Fact Sheet/Evidence Table

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[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.

[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 apneaSleep. doi.org/10.1093/sleep/zsz158.

[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.

[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

[5] 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.