Molina Clinical Policy
Implantable Neurostimulator (remedē System) for Central Sleep Apnea
Policy No. 340

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Next Review Due By: December 2026

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Central sleep apnea (CSA) encompasses a diverse range of sleep-related breathing disorders characterized by diminished or absent central respiratory drive. CSA episodes occur through two pathophysiologic patterns: either post-hyperventilation or post-hypoventilation ([1]Badr 2025). CSA may be primary (idiopathic) or secondary, associated with an underlying medical condition ([1-2]Badr 2025). The third edition of the *International Classification of Sleep Disorders-Text Revision* categorizes seven CSA disorders affecting adults, including primary CSA, CSA with Cheyne-Stokes breathing, CSA due to high-altitude periodic breathing, CSA related to a medical disorder without Cheyne-Stokes breathing, CSA due to medication or substances, and treatment-emergent CSA (formerly known as complex sleep apnea) (Judd & Sateia 2023). The latest classification update specifies that diagnosing treatment-emergent CSA now requires both clinical signs or symptoms and central apnea events on polysomnography (Judd & Sateia 2023).

CSA is relatively rare in the general population, but rates are higher among older adults, males, and those with certain comorbid conditions, such as heart failure or stroke ([2]Badr 2025). Diagnosis of CSA typically involves overnight polysomnography, which assesses both sleep and breathing metrics. This in-laboratory sleep study is recommended for patients with daytime sleepiness plus CSA risk factors (e.g., heart failure, stroke, or long-acting opioid use) or with multiple CSA symptoms (e.g., insomnia, morning headaches, witnessed breathing pauses) ([2]Badr 2025). Polysomnography helps distinguish CSA from obstructive sleep apnea, with CSA marked by an absence of respiratory effort, unlike obstructive sleep apnea, where effort is present. CSA diagnosis requires evidence of five or more central apneas per hour of sleep along with symptoms such as insomnia, excessive daytime sleepiness, frequent awakenings, or daytime hypersomnolence ([2]Badr 2025). The apnea-hypopnea index (AHI), which measures apnea and hypopnea events per hour, indicates CSA severity: <5 events per hour is normal, 5–14 is mild, 15–30 is moderate, and >30 is severe.

The primary therapeutic goals for CSA are to normalize breathing during sleep, eliminating central apneas and oxygen desaturation, thereby enhancing sleep quality and daytime function ([1]Badr 2025). Treatment options include positive airway pressure therapies, such as continuous positive airway pressure (CPAP), bilevel positive airway pressure, adaptive servo ventilation, supplemental oxygen, and medications including acetazolamide, theophylline, and sedative-hypnotic agents. For patients unresponsive to these therapies, phrenic nerve stimulation is a potential treatment option ([1]Badr 2025; Hayes 2023).

Regulatory Status

The remedē System provides phrenic nerve stimulation to promote normal diaphragm contractions, thereby improving sleep in CSA patients (Respicardia Inc, Minnetonka, MN) ([1]Badr 2025). The remedē System was FDA approved on October 6, 2017, for moderate-to-severe CSA in adults (FDA 2017). The system functions similar to an implantable pacemaker with a battery pack and wires placed under the skin in the upper chest area. It continuously monitors respiratory signals and stimulates the phrenic nerve to restore normal breathing by activating the diaphragm (FDA 2017). The device is not intended for use in patients with obstructive sleep apnea ([1]Badr 2025).

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The FDA classifies the remedē System as a Class III implanted phrenic nerve stimulation device for CSA, under the product code PSR (FDA 2018). A newer model of the remedē System (remedē EL-X System) was approved on July 28, 2021, with a smaller design and about 40% longer battery life that is much smaller in size and has approximately 40% improved battery life (FDA 2021; Hayes 2023).

COVERAGE POLICY

Implantable neurostimulators for the treatment of central sleep apnea (e.g., remedē System) are considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Overall, the quality of evidence evaluating the clinical impact of the phrenic nerve stimulation with the remedē System in adults with central sleep apnea (CSA) is low. Further large, randomized, comparative, controlled studies are needed to determine safety and efficacy, define optimal patient selection, and assess long-term effect of phrenic nerve stimulation on CSA-related morbidity and mortality.

Randomized Controlled Trials

Costanzo et al. (2016) conducted a pivotal, industry-supported, multicenter, prospective randomized controlled trial to support FDA approval of the remedē System. The study aimed to assess the safety and effectiveness of the remedē System in reducing the apnea-hypopnea index (AHI) among patients with moderate to severe central sleep apnea (CSA), defined by an AHI of at least 20 events per hour as recorded by polysomnography. The trial included 151 adult participants (mean age 65, 89% male, 95% Caucasian), all of whom had been stable on appropriate guideline-based therapies for at least 30 days. Participants received the remedē System implanted in the pectoral region and were randomly assigned to either the treatment group (n=73) with active stimulation or the control group (n=78) without stimulation for the first 6 months. After 6 months, the control group's devices were activated. The primary endpoint was the proportion of participants in each group achieving a 50% or greater reduction in AHI. At 6 months, 51% of participants in the treatment group met this threshold ($p < 0.0001$), compared to 11% in the control group. Neurostimulation significantly improved several metrics, including central apnea index, arousal index, oxygen desaturation levels, sleepiness scores, and health-related quality of life after 6 months. The most common adverse events were interactions with other devices, implant site infections, and local tissue issues such as swelling or pocket erosion. Thirteen participants experienced serious adverse events, including pocket erosion, implant site infections, lead dislodgement, device interaction, elevated transaminase, unintended stimulation, hematoma, lead component failure, lead displacement, and non-cardiac chest pain. The remedē System is not recommended for patients with active infections or those requiring MRI. Study limitations included a low proportion of female participants, potential referral bias, and loss to follow-up.

Costanzo et al. (2018) reported on the 12-month outcomes of the Costanzo et al. (2016) pivotal trial. At the 12-month mark, the treatment group (n=54) had experienced active device stimulation for the full year, while the control group (n=65) had received 6 months of active treatment after initial control. Results showed that 67% of participants in the treatment group achieved a ≥ 50% reduction in AHI from baseline. In the control group, 55% of participants saw a ≥ 50% reduction in AHI from baseline after 6 months of stimulation. Participants in the treatment group also demonstrated ongoing improvements in sleep-related metrics, oxygenation levels, and overall quality of life. Among the entire study population, 91% were free from serious adverse events at the 12-month mark. The authors concluded that the remedē System provides significant improvements in sleep quality and metrics, with maintained safety over at least a year of treatment.

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Costanzo et al. (2021) provided 5-year safety and efficacy outcomes from the initial pivotal trial conducted by Costanzo et al. (2016). Out of the original 151 participants, 53 were available at the 5-year mark, with 42 included in the final analysis. Participants underwent overnight polysomnography at baseline and at 1, 2, and 5 years, with a home polysomnography study conducted for the 3-year follow-up. Results showed sustained improvements across all sleep-related breathing events, particularly in metrics such as the apnea-hypopnea index (AHI), central apnea index, 4% oxygen desaturation index, minutes of sleep with oxygen saturation below 90%, and the percentage of rapid eye movement (REM) sleep. The AHI decreased from 46 at baseline to 18, 16, 14, and 17 at 1, 2, 3, and 5 years, respectively ($p < 0.001$). The central apnea index improved from 23 at baseline to 1 at each follow-up ($p < 0.001$). The 4% oxygen desaturation index dropped from 39 at baseline to 15 at 5 years ($p < 0.001$). Sleep time with oxygen saturation below 90% decreased from 31 minutes at baseline to 11, 13, and 11 minutes at 1, 2, and 5 years, respectively ($p=0.134$). REM sleep percentage increased from 10% at baseline to 14%, 17%, and 21% at the 1-, 2-, and 5-year marks ($p=0.001$). Between years 2 and 3, no serious adverse events were recorded. From years 3 to 5, there were four serious adverse events, including one case of lead dislocation requiring multiple procedures, two cases of lead component failure necessitating hospital stays for replacements, and one implant site infection that led to device removal and hospitalization. No deaths were reported. These long-term results support the ongoing safety and efficacy of phrenic nerve stimulation as a treatment for CSA.

Systematic Reviews and Meta-Analyses

Wang et al. (2023) conducted a meta-analysis to evaluate the effectiveness of phrenic nerve stimulation for treating CSA. The analysis included 10 studies with a combined total of 580 participants, examining outcomes such as AHI, central apnea index, arousal index, percentage of sleep with oxygen saturation below 90%, Epworth Sleepiness Scale, and sleep efficiency. The results showed significant reductions in AHI ($p < 0.00001$), central apnea index ($p < 0.00001$), and arousal index ($p = 0.0002$) following phrenic nerve stimulation therapy. implantation and therapy via phrenic nerve stimulation. However, sleep efficiency, Epworth Sleepiness Scale scores, and the percentage of sleep time with oxygen saturation below 90% did not show significant changes following implantation ($p > 0.05$). Researchers concluded that phrenic nerve stimulation appears to be a safe and feasible treatment for CSA, though they emphasized the need for larger, independent randomized controlled trials to further evaluate its effectiveness, particularly regarding sleepiness and oxygen saturation during sleep.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Potratz et al. (2021) conducted a single-center, prospective, open-label study to assess how phrenic nerve stimulation affects functional physical capacity and hypoxemic burden in patients with both heart failure and CSA. Inclusion criteria included participants with heart failure (either preserved or reduced ejection fraction) who had received optimal heart failure therapy for at least six months prior to phrenic nerve stimulator implantation. Exclusion criteria were use of mask-based therapies for CSA, any active cancer requiring treatment, end-stage renal disease or dialysis, and hemodynamically significant heart valve disease. Eligibility for implantation required an apnea-hypopnea index (AHI) of ≥ 20, with central apneas comprising ≥ 50% of events, a central apnea index ≥ 30, and obstructive apneas comprising ≤ 20% of events. The study's primary outcome was the change in a symptom-limited 6-minute walk test and hypoxemic burden before and six months after implantation. Secondary outcomes included left ventricular ejection fraction, total central respiratory events, central apnea index, AHI, hypopnea index, obstructive apnea index, and hypoxemic burden (time with oxygen saturation < 90% during polysomnography) pre- and post-stimulation. Twenty-four participants were enrolled, with 15 in NYHA class II heart failure and 9 in class III. Initial AHI was 38.1±17.9, and the average 6-minute walk distance was 369.5±163.5 meters. After six months, AHI decreased significantly to 17.3±9.4, and the walk test distance improved to 410±169.7 meters ($p = 0.035$). Total central respiratory events decreased from 109.5±102.5 to 38.6±53.5 ($p = 0.027$), and the central apnea index dropped from 18±16.8 to 7.2±10 ($p = 0.02$). Hypoxemic burden also showed a significant reduction, from 81±55.7 minutes to 27.8±42.7 minutes ($p < 0.01$). Left ventricular ejection fraction remained relatively unchanged, at 42.4±13.4% baseline versus 41.9±14.7% at six months. The study had limitations, including small sample size, the lack of a control group, and limited generalizability to smaller treatment centers. Despite these limitations, significant improvements were observed in physical capacity, hypoxemic burden, and AHI following phrenic nerve stimulation. Although specific heart failure-related benefits were not established, the findings indicate notable gains in functional performance and reductions in respiratory events and oxygen desaturation time. Feasibility was determined by the success rate of implantation and therapy delivery, while safety was monitored through device- and procedure-related adverse events. Efficacy was assessed by changes in AHI at 3 months, showing a significant reduction of 55% in AHI from baseline (49.5 ± 14.6 episodes/hour to 22.4 ± 13.6 episodes/hour, $p < 0.0001$; 95% confidence interval: -32.3 to -21.9). Additional improvements were observed in the central apnea index,

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oxygenation levels, and arousal frequency. Quality of life was evaluated at 6 months using the Epworth Sleepiness Scale (ESS), the Patient Global Assessment, and, for heart failure patients, the Minnesota Living with Heart Failure Questionnaire. ESS scores improved, and heart failure patients showed an average 10-point improvement in quality of life ($p = 0.0009$).

Abraham et al. (2015) conducted a prospective, multicenter, non-randomized study to evaluate the feasibility, safety, and efficacy of transvenous unilateral phrenic nerve stimulation for treating central sleep apnea (CSA). The study included 57 patients with CSA who underwent baseline polysomnography, device implantation, and follow-up. Eligible patients had an apnea-hypopnea index (AHI) of at least 20, with at least half of the events being central in origin, while those with more than 20% obstructive events were excluded. Device- or procedure-related serious adverse events occurred in 26% of patients within the first 6 months, primarily due to early lead repositioning issues. Despite these events, therapy was well tolerated, and efficacy was maintained at 6 months. Study limitations included a small sample size, absence of a control arm, short follow-up period, and potential for referral bias. The authors concluded that transvenous unilateral phrenic nerve stimulation appears to be a safe and effective approach for CSA, with recommendations for a larger, randomized, controlled trial (NCT01124370) to confirm these findings.

Jagielski et al. (2016) evaluated 12-month outcomes from the study Abraham et al. (2015), in which 47 patients with CSA were treated with the remedē System for at least 3 months. Polysomnography was used to assess sleep-disordered breathing parameters at 3, 6, and 12 months. Sleep symptoms and quality of life were also evaluated, with 41 patients completing all follow-up polysomnograms and included in the analysis. At the 12-month follow-up, significant improvements were sustained from baseline in several key metrics: the AHI (49.9 ± 15.1 vs. 27.5 ± 18.3 events/hour, $p < 0.001$), central apnea index (28.2 ± 15.0 vs. 6.0 ± 9.2 events/hour, $p < 0.001$), oxygen desaturation index (46.1 ± 19.1 vs. 26.9 ± 18.0 events/hour, $p < 0.001$), rapid eye movement (REM) sleep (11.4 ± 6.1% vs. 17.1 ± 8.0%, $p < 0.001$), and sleep efficiency (69.3 ± 16.9% vs. 75.6 ± 17.1%, $p = 0.024$). Additionally, there were sustained improvements in sleepiness and quality of life. Over the 12-month follow-up period, three deaths unrelated to the remedē System and five serious adverse events occurred. The authors highlighted the study's limitations, including the non-randomized, open-label design, small sample size, low female representation, and loss to follow-up. They concluded that larger, randomized, controlled trials are needed to validate these findings.

National/Specialty Organizations

The **American Thoracic Society (ATS)** published a research statement for research priorities for patients with heart failure and CSA (Orr et al. 2021). The research statement mentions the documented improvements in AHI and central apnea index associated with phrenic nerve stimulation for short-term outcomes (≤ 1 year). The statement concludes that additional research is needed with a focus on long-term outcomes.

The **American Academy of Sleep Medicine (AASM)** published updated clinical practice guidelines for the management of central sleep apnea in adults (Badr et al. 2025). The guideline issued a conditional recommendation with very low certainty for the use of transvenous phrenic nerve stimulation (TPNS). The guideline advises that TPNS may be considered only in adults with primary CSA or CSA due to heart failure, and after other, less invasive treatment options have been tried without adequate benefit. The AASM also emphasizes that TPNS is an invasive and resource-intensive therapy requiring specialized expertise and should therefore be reserved for carefully selected refractory patients.

SUPPLEMENTAL INFORMATION

Apnea: cessation of airflow for > 10 seconds

Central Apnea Index: the number of central sleep apnea episodes per hour of sleep

Apnea Hypopnea Index (AHI): The number of apneas plus the number of hypopneas during the entire sleeping period, times 60, divided by total sleep time in minutes; unit: event per hour (AASM 2023).

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CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
33276	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed
33277	Insertion of phrenic nerve stimulator transvenous sensing lead (List separately in addition to code for primary procedure)
33278	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)
33279	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only
33280	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only
33281	Repositioning of phrenic nerve stimulator transvenous lead(s)
33287	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator
33288	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s)
93150	Therapy activation of implanted phrenic nerve stimulator system, including all interrogation and programming
93151	Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system
93152	Interrogation and programming of implanted phrenic nerve stimulator system during polysomnography
93153	Interrogation without programming of implanted phrenic nerve stimulator system

HCPCS (Healthcare Common Procedure Coding)

Code	Description
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/10/2025	Policy reviewed. No changes to coverage criteria. Updated Summary of Medical Evidence and References.
12/11/2024	Policy reviewed, no changes to coverage criteria. Updated Overview, Summary of Medical Evidence, and References.
02/14/2024	Coding and billing section updated.
12/13/2023	Policy reviewed, no changes to criteria. Updated Overview, Summary of Medical Evidence, Supplemental Information, and References. IRO Peer Review on November 7, 2023, by a practicing, board-certified physician with specialties in Sleep Medicine and Neurology.
12/14/2022	Policy reviewed, no changes to criteria.
02/08/2021	Policy reviewed, no changes to criteria.
04/23/2020	Policy reviewed, no changes.
03/11/2019	New policy. IRO Peer Review on January 24, 2019, by a practicing, board-certified physician with specialties in Internal Medicine and Pulmonary Disease.

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