Molina Clinical Policy
Neuromuscular Electrical Training for the Treatment of Obstructive Sleep Apnea or Snoring (eXciteOSA)
Policy No. 422

Last Approval: 10/08/2025
Next Review Due By: October 2026

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplement ation 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

Obstructive Sleep Apnea (OSA) is a chronic disorder characterized by an intermittent cessation of breathing that occurs when the upper airway collapses during sleep. The repetitive complete or partial collapse of the oropharyngeal airway during sleep results in obstructive apneas, hypopneas, and/or respiratory effort-related arousals. Patients will present with complaints of snoring, excessive daytime sleepiness, nocturnal choking, morning headaches, and fatigue. Multiple comorbidities are associated with untreated OSA, including an increased risk of cardiovascular disease, arrhythmias, hypertension, and mortality. OSA is diagnosed using in-laboratory polysomnography or validated home sleep apnea testing, with severity classified by the apnea-hypopnea index in conjunction with clinical symptoms (AASM 2023).

Positive airway pressure (PAP) therapy remains the first-line treatment for OSA. In general, the most common type of PAP therapy for OSA patients is continuous PAP (CPAP). Bilevel PAP (BiPAP) therapy is prescribed for patients with OSA that also have an underlying disease process that may affect normal ventilation, such as chronic hypercapnic respiratory failure. Less commonly used is average volume-assured pressure support (AVAPS). A considerable proportion of patients are nonadherent to PAP due to low patient tolerance. Patients who do not prefer or do not respond to PAP therapy may benefit from oral appliance therapy. Oral appliances used to treat sleep-disordered breathing include mandibular advancement/retention devices, tongue retention devices, and soft palate lifters. An alternative is the implantable hypoglossal nerve stimulator, which stimulates the upper airway dilator muscle during apnea, resulting in protrusion of the tongue and alleviation of the obstruction. The eXciteOSA is the first OSA treatment device to be used while awake and provides an additional noninvasive treatment for patients with snoring and OSA. The goal of therapy is to improve the tone, tension, endurance, and mobility of the oropharyngeal muscles and soft tissues, which collapse during sleep, leading to apneic events (Cistulli 2025; Suurna 2025; Brown & Lee 2024).

The **eXciteOSA device** (Signifier Medical Technologies) targets the intrinsic and extrinsic tongue muscles by delivering neuromuscular electrical stimulation to the back of the tongue with the purpose of increasing muscle tone with daily use and preventing excessive relaxation thereby preventing the tongue from collapsing backwards and obstructing the airway during sleep. The intraoral neuromuscular stimulation device consists of three components: 1) a washable flexible mouthpiece with electrode array that fits onto the tongue (the mouthpiece has four electrodes: two located above the tongue and two located below the tongue), 2) a rechargeable control unit that attaches to the mouthpiece via a USB-C connection, and 3) a smartphone app that manages the functions of the device. The device provides electrical muscle stimulation action in sessions that consist of a series of electrical pulses with rest periods in between. The recommended duration of use for the device is 20 minutes per day during a wakeful state for six weeks, followed by weekly use thereafter. The most common adverse events observed were excessive salivation, tongue or tooth discomfort, tongue tingling, dental filling sensitivity, metallic taste, gagging, and tight jaw (Hayes 2024).

Regulatory Status

The FDA granted de novo marketing clearance as a class II device for the eXciteOSA device to reduce snoring and mild OSA apnea (apnea-hypopnea index [AHI] < 15) in adults (FDA 2021). The eXciteOSA devices (with and without

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remote control) received FDA 510(k) approval on January 18, 2023 (FDA 2023). Additional FDA approvals may be found by searching the 510(k)-database using product code "QNO".

COVERAGE POLICY

Daytime neuromuscular stimulation of the tongue (e.g., eXciteOSA) is considered **experimental, investigational, and unproven** for the treatment of OSA or snoring 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

Systematic Reviews and Meta-Analyses
Rueda et al. (2020) compared the efficacy of myofunctional therapy as a treatment for OSA with other treatment options. The systematic review included 9 studies that randomized a total of 425 participants and analyzed 347 participants. There were no studies involving neuromuscular electrical training devices were included in the review and the results did not support the assumption that toning and strengthening oropharyngeal muscles enhanced clinical outcomes. The authors concluded that there is no objective evidence that myofunctional treatment improves OSA and compared to CPAP therapy, myofunctional therapy demonstrated minimal to no effect in daytime sleepiness and may increase AHI.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence
Baptista et al. (2021) performed a multicenter prospective study to assess the effectiveness of daytime neuromuscular electrical training (NMES) of the tongue in adults with primary snoring and mild OSA (apnea-hypopnea index [AHI] < 15). A total of 115 participants (mean age 46 years; 73 male, 42 female) completed the six-week study. Fifty participants were Primary Snorers (AHI < 5) and 65 had Mild OSA (AHI 5-15). Patients were eligible if they were 18 or older, had a live-in partner able to document snoring, at least 6 months of habitual snoring on more than 5 nights per week, and had an AHI < 15 confirmed by the Watch-PAT 200 device. Exclusions included Patients a BMI > 35 kg/m^2, symptomatic nasal pathology, tonsil hypertrophy (tonsil size of grade 3 or greater), tongue or lip piercing, pacemaker or other implanted medical device, prior snoring surgery, facial skeletal abnormalities, or significant oral disease/conditions. Participants used the eXciteOSA device for 20 minutes daily which awake for six weeks, with adherence tracked through a smartphone app. Mean time spent in moderate or greater snoring fell from 30.4 % to 17.9 % (41 % reduction), and partner-reported snoring scores dropped from 6.1 to 3.7 (39 % reduction). Epworth Sleepiness Scale scores improved from 8.4 to 5.8, and Pittsburgh Sleep Quality Index scores improved for both participants (7.16 → 5.75) and their partners (6.87 → 5.94). Mean AHI decreased from 6.85 to 5.03, a statistically significant but clinically modest change. Daytime NMES was well tolerated, with no serious adverse events; the most common side effect, reported in about 15 % of participants, was excess salivation. The investigators concluded that eXciteOSA reduced both objective and subjective measures of snoring and improved sleep quality and daytime alertness. They emphasized, however, that the study lacked randomization, a comparator arm, and long-term follow-up. Designing a sham-controlled trial is particularly challenging because the device acts while the patient is awake and delivers perceptible stimulation, but the authors suggested that future studies compare NMES with established treatments such as mandibular advancement devices and incorporate extended follow-up to address these limitations and align with research priorities highlighted by the American Thoracic Society.

Kotecha et al. (2021) conducted a prospective cohort study of 70 adults with primary snoring or mild OSA (AHI < 15) to evaluate the eXciteOSA device. Participants had to be habitaual snorers for at least 6 months (more than 5 out of 7 nights per week) and lived with a partner. Patients were excluded if they had a BMI > 35, AHI > 15, symptomatic nasal pathology, tonsillar hypertrophy ≥ grade 3, tongue piercing, pacemakers or implanted electrical devices, prior oral

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surgery for snoring, or significant facial skeletal abnormalities. Each patient used the device for 20 minutes over six weeks. Pre- and post-treatment assessments included objective snoring time and intensity, AHI, oxygen desaturation index (ODI), and respiratory disturbance index via two-night WatchPat studies, along with subjective measures such as ESS, PSQI (for both participant and partner), participant sleep quality, partner-rated snoring on a visual analog scale (VAS), and adverse events. Among the 70 participants that completed the study, 95% experienced an objective reduction in snoring, with average snoring time reduced by 48%. Bed-partner VAS scores indicated a 40% decrease in snoring in 95% of subjects. Mean AHI declined from 5.94 to 5.37 events/hour overall. In the subgroup with mild OSA (n = 38), AHI fell from 9.8 to 4.7 events/hour (52% reduction), ODI from 7.8 to 4.3 (45% reduction), and ESS from 9.0 to 5.1. Compliance averaged 83%. Adverse effects were minimal. The authors concluded that eXciteOSA produced notable improvements in both objective and subjective measures of snoring and mild OSA. However, the study lacked a control group, used non-standardized snoring criteria, had a small sample size, and provided no long-term follow-up.

National and Specialty Organizations

The **National Institute for Health and Care Excellence (NICE)** published recommendations for the treatment of OSA using daytime intraoral neuromuscular electrical tongue stimulation (NICE 2023). NICE does not recommend these devices due to a lack of evidence for their safety and effectiveness.

The **American Academy of Sleep Medicine (AASM) and American Academy of Dental Sleep Medicine (AADSM)** clinical guideline for the treatment of OSA and snoring recommend the use of oral appliances rather than no therapy for adult patients who request treatment of primary snoring (without OSA); however, the use of the eXciteOSA technology for snoring or OSA treatment was not specifically mentioned (Ramar et al. 2015).

SUPPLEMENTAL INFORMATION

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).

The American Academy of Sleep Medicine provides the following updated definitions of OSA severity (AASM 2023):

- Mild OSA: AHI of 5-15, involuntary sleepiness during activities that require little attention, such as watching TV or reading.
- Moderate OSA: AHI of 15-30, involuntary sleepiness during activities that require some attention, such as meetings or presentations.
- Severe OSA: AHI > 30: involuntary sleepiness during activities that require more active attention, such as talking or driving.

The hypoglossal nerve (cranial nerve XII) innervates the genioglossus muscle. Stimulation of the nerve causes anterior movement and stiffening of the tongue and dilation of the pharynx. Hypoglossal nerve stimulation reduces airway collapsibility and alleviates obstruction at both the level of the soft palate and tongue base.

CODING & BILLING INFORMATION

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
E0492	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application.
E0493	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply.

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

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APPROVAL HISTORY

10/08/2025	Policy reviewed. No changes to coverage criteria. Updated Summary of Medical Evidence and References.
10/09/2024	Policy reviewed, no changes to criteria.
12/13/2023	Coding and Billing section updated. Annual review scheduled for October 2024.
10/12/2023	Policy reviewed, no changes to criteria. Updated Overview, Summary of Medical Evidence, and References.
09/08/2022	New policy. IRO Peer Review on September 8, 2022, by a practicing, board-certified physician with a specialty in Sleep Medicine.

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