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

**Last Approval: 12/13/2023**
**Next Review Due By: October 2024**

## 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

**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 based on the existence or absence of associated symptoms and the frequency of respiratory episodes during sleep.

Positive airway pressure (PAP) therapy is the first-line treatment for OSA. In general, the most common type of PAP therapy indicated in most OSA patients is continuous PAP (CPAP). Bilevel PAP (BPAP) 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 (Brown et al. 2022). Newer home CPAP and BPAP units have the option for auto-adjusting pressures with set lower and upper limits for CPAP and BPAP (Brown et al. 2022). Less commonly used is average volume-assured pressure support (AVAPS) (Brown et al. 2022)). A considerable proportion of patients are nonadherent to PAP due to low patient tolerance (Cistulli 2023). Patients who do not prefer or do not respond to PAP therapy may benefit from oral appliance therapy (Cistulli 2023). Oral appliances used to treat sleep-disordered breathing include mandibular advancement/retention devices, tongue retention devices, and soft palate lifters (Cistulli 2023). An alternative is the implantable hypoglossal nerve stimulator, which stimulates the upper airway dilator muscle, genioglossusm, during apnea, resulting in protrusion of the tongue and alleviation of the obstruction (Surrna 2023). 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.

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 (Hayes 2022). 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 (Hayes 2022). The most common adverse events observed were excessive salivation, tongue or tooth discomfort, tongue tingling, dental filling sensitivity, metallic taste, gagging, and tight jaw.

### 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 remote control) received FDA 510(k) approval on January 18, 2023 (FDA 2023).

## COVERAGE POLICY

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

The FDA approval was based on the safety and efficacy of the eXciteOSA (formerly Snoozeal) device as assessed in the Baptista et al. (2021) study summarized below. Current evidence for the eXciteOSA device is limited and relevant studies are summarized below.

Baptista et al. (2021) performed a multicenter prospective study to assess the effectiveness of daytime neuromuscular electrical training (NMES) of tongue muscles in 125 adults with primary snoring and mild OSA. The participants had a complaint of snoring and an AHI less than 15 (no more than mild OSA). Only 1 participant withdrew due to inability to tolerate the treatment (gag reflex), and 115 participants (73 male; 42 female) completed the trial (92%) with an average mean age of 46 years. Of the 115 snorers, 50 patients 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 who could record snoring, had a history of at least 6 months of habitual snoring on more than 5 days per week, and had an AHI less than 15 according to the Watch-PAT 200 device.
- Patients were excluded if they had a BMI of more than 35 kg/m$^2$, symptomatic nasal pathology, tonsil hypertrophy (tonsil size of grade 3 or greater), tongue or lip piercing, pacemaker or implanted medical electrical devices, previous snoring surgery, relevant facial skeletal abnormalities, or significant oral disease/conditions. The live-in partner was instructed to rate their partner's snoring using the Visual Analogue Scale (VAS) for two weeks prior to the trial.

At the conclusion of the two-week period, both the partner and participant completed sleep quality questionnaires, including the Pittsburgh Sleep Quality Index (PSQI) and Epworth Sleepiness Scale (ESS). Each participant was given the eXciteOSA device and instructions on how to utilize it at the start of the trial. Participants were instructed to utilize the device for 20 minutes once each day for a total of 6 weeks, recording daily assessments of any side effects or adverse occurrences. The smartphone application was used to remotely validate patient adherence to the therapy. The mean reduction In the proportion of time with moderate or greater snoring decreased from 30.41% to 17.87% (41% reduction). Bed-partner-reported snoring decreased from 6.1 to 3.7 (39% reduction). ESS improved from 8.4 to 5.8 and the PSQI improved for both the participants (7.16 to 5.75) and bed partners (6.87 to 5.94). While the mean AHI decreased statistically significantly from 6.85 to 5.03, the improvement was not clinically significant. Subjective measures such partner reported VAS, ESS, and PSQI improved from baseline to study conclusion.

The authors concluded that daytime NMES using the eXciteOSA device was effective at reducing objective and subjective snoring, as well as improving sleep quality and daytime somnolence in the patient. However, while the device resulted in reduction in AHI and demonstrated that NMES was well-tolerated *(*no serious adverse events reported with the most common side effect in 15% of patients was oral salivation*)*, there were notable limitations, including the need for randomization and a comparator group, its short duration and follow-up, and the absence of long-term outcomes. The authors noted that "there are inherent challenges in designing a study of a device with an

awake stage mode of action on one of the bodys primary sensory organs and presents challenges in creating appropriate blinding. Whilst it would be technically possible to provide users with a deactivated device that does not produce an electrical signal, it may be relatively easy for users to deduce if they are receiving sham or active therapy. Randomizing and conducting comparative analysis against [mandibular advancement devices] might be a more appropriate future trial design. Another limitation of this study was the limited duration of follow-up, a common issue with many early trials of emerging technologies. The official research statement by the American Thoracic society identified many gaps in the current literature related to mild OSA therapy options and makes recommendations on the research priorities and need for further studies. Further studies are planned to capture long-term outcomes and follow guidance set by the task force."

Kotecha et al. (2021) assessed the efficacy of eXciteOSA in a prospective cohort study in 70 adult patients with mild OSA and/or primary snoring (AHI <15). Participants had to snore habitually (more than 5 out of 7 nights per week) for at least 6 months and required to have a live-in partner. Patients were excluded if they had a BMI greater than 35, AHI greater than 15, had symptomatic nasal pathology, tonsillar hypertrophy at grade 3 or above, had tongue piercing, pacemakers or implanted electrical medical devices. Patients who had previous oral surgery for snoring and those with relevant facial skeletal abnormalities were also excluded. The study evaluated objective snoring (% time snoring, different loudness levels) and respiratory parameters (AHI, ODI, and oxygen saturations) with two consecutive night sleep studies (WatchPat 200) before and after the use of the device. The eXciteOSA device was used for 20-minutes, once a day for a 6-week period. Primary outcome measures included reduction in snoring levels at greater than 40 dB. Objective parameters assessed were snoring duration and intensity, AHI, ODI and RDI as evaluated by the WatchPat sleep study apparatus. Subjective parameters studied included ESS, PSQI (for participant and bed partner), participant subjective sleep quality, bed partner snoring record VAS as well as any adverse effect encountered whilst using the device.

- For the 70 patients who completed the study: On the sleep studies, 95% of subjects had an objective reduction in snoring, with a reduction in the average snoring time (as measured by the Watch-PAT) of 48%. Subjectively, the VAS reported by bed partners showed an average reduction of 40% in snoring in 95% of the patients.
- Mean AHI decreased from 5.94 to 5.37 events per hour. In addition, after treatment, the ODI decreased from 4.92 to 4.73. In a subset of 38 patients with mild OSA, AHI reduced from 9.8 to 4.7 events per hour (52% reduction), ODI 7.8 to 4.3/h (45% reduction), and ESS from 9.0 to 5.1. Compliance with the protocol as measured by the app ranged from 59.5% to 95.2% (mean utilization 83.3%). Adverse effects encountered were minimal.

The authors concluded a notable improvement in both objective and subjective parameters of snoring and mild OSA in both simple snorers and patients with mild OSA. However, the study is constrained by a lack of a control group, a lack of *standardized snoring criteria, a small sample size, and the absence of long-term effects. *Snoring criteria: There are no agreed or published guidelines on which parameters of snoring that should be measured or what degree of change can be considered clinically relevant.

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.

**National and Specialty Organizations**

No guidelines were identified that specifically address the use of the eXciteOSA system for the management of snoring or OSA.

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 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

**CPT (Current Procedural Terminology) Codes**

| CPT | Description |
|---|---|
| **E0492** | Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application. (Replacement code for K1028 and will be effective on 01/01/2024) |
| **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. (Replacement code for K1029 and will be effective on 01/01/2024) |

**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

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|---|---|
| **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. |

## REFERENCES

**Government Agencies**

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## APPENDIX

***Reserved for State specific information.*** *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*