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

Last Approval: 10/12/2022
Next Review Due By: October 2023

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, and other symptoms such as 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 (Mashaqi et al. 2021).

A positive airway pressure (PAP) machine is the first-line treatment for OSA. In general, the two types of PAP indicated in most OSA patients are continuous PAP (CPAP) and auto-adjusting PAP (APAP). CPAP is usually the first-line therapy option for most adult patients with moderate to severe OSA; however, a considerable proportion of patients are nonadherent to PAP due to low patient tolerance. Patients who do not prefer or do not respond to CPAP may benefit from oral appliances therapy, the primary non-surgical, non-CPAP treatment for individuals with OSA and may be considered for less severe OSA or CPAP intolerance. 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, genioglossusm, during apnea, resulting in protrusion of the tongue and alleviation of the obstruction. The eXciteOSA, the first OSA treatment device to be used while awake, 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 apnea episodes.

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) 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 gadget 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.

Regulatory Status

The FDA granted marketing clearance for the eXciteOSA device to reduce snoring and mild OSA apnea (apnea-hypopnea index [AHI] < 15) in adults (FDA, 2021).
FDA de novo marketing classification granted. Class II (product code QNO)
**De Novo premarket review: a regulatory pathway for low- to moderate-risk devices of a new type.*

COVERAGE POLICY

Daytime neuromuscular stimulation of the tongue (e.g., eXciteOSA) **is considered experimental and investigational** for the treatment of OSA or snoring because the effectiveness of these approaches has not been established.

There is a paucity of high-quality evidence demonstrating the safety and efficacy of nonsurgical electrical muscle stimulation for OSA. There are currently no controlled trials for eXciteOSA. Two prospective, single-arm trials involving patients with primary snoring or mild OSA provide the supporting evidence. Current evidence suggests that the treatment may reduce snoring when used for 20 minutes per day over a period of 6 weeks. The effects on Apnea Hypopnea Index (AHI) were not clinically significant in the general population. The improvement in AHI remained modest in these uncontrolled studies for the subset of persons with mild OSA. Additional trials that include comparison groups assessing safety, efficacy, and long-term results are required.

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, which was assessed in 115 patients with snoring, including 48 patients with snoring and mild sleep apnea (AHI less than 15). All patients used the device once a day for 20 minutes for six weeks, then discontinued use for two weeks before being reevaluated. Two successive WatchPAT night sleep tests were used to record objective snoring and respiratory data both before and after using the device. Overall, in 87 of the 115 patients, the percentage of time spent snoring at decibel levels greater than 40dB was decreased by more than 20%. The average AHI decreased by 48%, from 10.21 to 5.27, in 41 out of 48 patients in a subset of 48 patients who had mild OSA and snoring. The most common side effects reported were excessive salivation, soreness in the tongue or teeth, tongue tingling, sensitivity to dental fillings, metallic taste, choking, and tightness in the jaw (FDA, 2021).

Baptista et al. (2021), in a multicenter prospective study, assessed 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) and 50 participants had an AHI of less than 5 and were considered primary snorers. 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), in a Cochrane Review, 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 address the use of the eXciteOSA system for 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.**

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 Scoring Manual, 2020).

The AASM provides the following updated definitions of OSA severity:

- 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. HGNS reduces airway collapsibility and alleviates obstruction at both the level of the soft palate and tongue base.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
K1028	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application
K1029	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 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

9/8/2022 New policy. IRO Peer Review. Oct 2020. Practicing physician. Board-certified in Sleep Medicine.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: "local coverage determination hypoglossal nerve stimulation for the treatment of obstructive sleep apnea" – includes LCDs: L38528, L38398, L38307, L38276, L38385, L38312, L38310, L38387). Available from CMS. Accessed September 16, 2021.

2. ClinicalTrials.gov
   - Intraoral tongue stimulation for treatment of primary snoring. ClinicalTrials.gov Identifier: NCT03829956. Available from ClinicalTrials.
   - Efficacy of intra-oral neuromuscular stimulation training on snoring and mild sleep apnea. ClinicalTrials.gov Identifier: NCT04392765. Available from ClinicalTrials.
3. United States Food and Drug Administration (FDA)
   - FDA news release. FDA authorizes marketing of novel device to reduce snoring and mild obstructive sleep apnea in patients 18 Years and older. Available from FDA. FDA Notice of Approval: 02/05/2021. Accessed September 8, 2022.
   - De novo classification summary. 21 CFR 872.5575. February 5, 2021. Available from FDA. Accessed on May 20, 2021.

Manufacturer/Labeling
1. Signifier Medical Technologies, LLC. eXciteOSA user guide. Boston, MA: Signifier Medical Technologies; 2021. Available here. Accessed September 2022.
2. Signifier Medical Technologies, LLC. Signifier Medical ushers in new era of treatment for sleep apnea and snoring with FDA approval of eXciteOSA device. Press Release: Business Wire [online]. Boston, MA: Signifier Medical Technologies; February 8, 2021.

Other Evidence Based Reviews and Publications
1. DynaMed. Oral appliances in the treatment of sleep-disordered breathing. Available from DynaMed. Accessed September 8, 2022. Registration and login required.
2. DynaMed. Obstructive sleep apnea (OSA) in adults. Available from DynaMed. Accessed September 8, 2022. Registration and login required.
3. DynaMed. Surgical management of obstructive sleep apnea (OSA) in adults. Available from DynaMed. Accessed September 8, 2022. Registration and login required.
4. Hayes. Emerging technology report: eXciteOSA device for mild obstructive sleep apnea. Available from Hayes. Updated February 2021. Archived February 23, 2022. Registration and login required.

Peer Reviewed Publications
1. Baptista PM, Martínez Ruiz de Apodaca P, Carrasco M, et al. Daytime neuromuscular electrical therapy of tongue muscles in improving snoring in individuals with primary snoring and mild obstructive sleep apnea. J Clin Med. 2021 Apr 27;10(9):1883. doi: 10.3390/jcm10091883. PMID: 33925376; PMCID: PMC8123870.
2. Kotecha B, Wong PY, Zhang H, Hassaan A. A novel intraoral neuromuscular stimulation device for treating sleep-disordered breathing. Sleep Breath. 2021 Dec;25(4):2083-2090. doi: 10.1007/s11325-021-02355-7. Epub 2021 Mar 26. PMID: 33772397; PMCID: PMC8590646.
3. Rueda JR, Mugueta-Aguinaga I, Vilaró J, Rueda-Etxebarria M. Myofunctional therapy (oropharyngeal exercises) for obstructive sleep apnoea. Cochrane Database Syst Rev. 2020; 11(11):CD013449. DOI: 10.1002/14651858.CD013449.pub2.

National and Specialty Organizations
1. Ramar K, Dort LC, Katz SG, Lettieri CJ, et al. American Academy of Sleep Medicine (AASM) and American Academy of Dental Sleep Medicine (AADSM) clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: An update for 2015. J Clin Sleep Med. 2015 Jul 15;11(7):773-827. doi: 10.5664/jcsm.4858. PMID: 26094920; PMCID: PMC4481062.

Other Peer Reviewed and National Organization Publications (used in the development of this policy)
1. Mashaqi S, Patel SI, Combs D, Estep L, Helmick S, Machamer J, Parthasarathy S. The hypoglossal nerve stimulation as a novel therapy for treating obstructive sleep apnea: A literature review. Int J Environ Res Public Health. 2021 Feb 9;18(4):1642. doi: 10.3390/ijerph18041642. PMID: 33572156; PMCID: PMC7914469.

APPENDIX

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