Anthem

Medical Policy

Subject: Neuromuscular Electrical Training for the Treatment of Obstructive Sleep Apnea or Snoring
Document #: DME.00043 **Publish Date:** 12/28/2023
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Description/Scope

This document addresses the use of neuromuscular electrical training of the tongue muscles as a treatment of obstructive sleep apnea (OSA) or snoring. The eXciteOSA® (Signifier Medical Technologies, Needham, MA) is the first OSA treatment device to be used while awake and is intended to improve tongue function.

Position Statement

Investigational and Not Medically Necessary:

The use of a neuromuscular electrical training device is considered**investigational and not medically necessary** for the treatment of obstructive sleep apnea or snoring.

Rationale

In February 2021, the U.S. Food and Drug Administration (FDA) authorized marketing of the eXciteOSA device, formerly known as the Snoozeal device, as a treatment of snoring and mild OSA. The authorization was approved based on the Baptista study (2021). The device was reviewed through the De Novo premarket review pathway. The FDA identified this device as:

> Neuromuscular tongue muscle stimulator for the reduction of snoring and obstructive sleep apnea. A neuromuscular tongue muscle stimulator for the reduction of snoring and obstructive sleep apnea consists of a removable intraoral mouthpiece that uses electrodes to deliver neuromuscular stimulation to the tongue to strengthen tongue musculature to reduce snoring and obstructive sleep apnea.

During sleep, there is a reduction in muscle tone and increased collapsibility in the throat and tongue. Neuromuscular electrical training is proposed to treat OSA based on the premise that transcutaneous electrical stimulation can improve tone and function in dysfunctional skeletal muscles (Baptista, 2021). Myofunctional therapy, isotonic and isometric exercises involving muscles of the mouth, pharynx and upper respiratory tract to improve the function of the upper airway dilator muscles, has been investigated as a non-invasive, non-pharmacological technique to treat OSA. Therapy is meant to increase tone, tension, endurance and mobility of the oropharyngeal muscles and soft tissues that collapse during apnea episodes (Rueda, 2020). In a systematic review of nine randomized, controlled trials (RCTs), Reuda (2020) found no objective evidence that myofunctional therapy improves OSA. Compared to CPAP therapy, myofunctional therapy showed little to no difference in daytime sleepiness and a possible increase in apnea-hypopnea index (AHI). While the review did not include any studies which used neuromuscular electrical training devices, the results did not show that treatment focusing on toning and strengthening the oropharyngeal muscles improved clinical outcomes.

In an industry sponsored pilot study, Wessolleck and colleagues (2018) evaluated whether electrical stimulation of the intraoral musculature, using an intraoral stimulation training device (eXciteOSA), decreases snoring in those without OSA or with mild OSA (apnea-hypopnea index [AHI] < 15). Snoring intensity before, during, and 2 weeks post-treatment was reported by bed partners who documented the intensity according to a visual analog scale (VAS). While 16 participants were initially included, only 13 participants completed the study. The participants' bed partners reported a significantly reduced snoring intensity from baseline up to 2 weeks following treatment. While the participants underwent sleep testing prior to participation to check for the presence of OSA and the level of severity based on AHI, there was no further testing of AHI following treatment. No conclusions can be drawn regarding the treatment of clinically significant OSA based on this small, short-term case series which focused on subjectively-reported snoring intensity.

An industry sponsored, multicenter, prospective study by Baptista and colleagues (2021) evaluated the use of daytime neuromuscular electrical training (NMES) of tongue muscles to treat primary snoring with mild sleep apnea. Participants included those with documented snoring (n=125). A segment of this population also had a mild OSA diagnosis (n=48). Prior to inclusion in the study, individuals underwent a screening sleep test to confirm an AHI < 15. In addition, participants needed to have a consistent daily bed partner to report snoring intensity using VAS. Participants used the device for 6 weeks, then discontinued use for 2 weeks before reassessment using a home sleep study. The partner began reporting 2 weeks prior the 6-week treatment phase and ended 2 weeks following the treatment phase. The change in the proportion of time snoring at levels > 40dB, the primary endpoint, showed a mean reduction of 41% at the second sleep study. Approximately 90% of participants demonstrated some level of reduction in their objective snoring time. While the mean AHI was statistically significantly improved from 6.85 to 5.03, the improvement was not clinically meaningful. Subjective measures such as partner reported VAS, Epworth Sleepiness Scale (ESS), and Pittsburgh Sleep Quality Index (PSQI) were improved from baseline compared to the end of the study results. While this study incorporated objective outcome measurements, this small study was limited by no comparison group and short-term follow-up. Finally, the study was not adequately powered to detect a 20% reduction in snoring time with 80% power.

In another industry sponsored prospective cohort study, Kotecha and associates (2021) evaluated the usefulness of an intraoral neuromuscular stimulation device in treating individuals with primary snoring or mild OSA. Several features of both conditions were assessed, including: % of time snoring, different loudness levels, AHI, oxygen desaturation index (ODI) and oxygen saturations. Sleep studies were performed before and following the 6-week treatment period. A total of 75 participants were included and 70 completed the trial; 32 of those who completed the trial had a diagnosis of snoring and 38 had mild OSA. The group with a primary diagnosis of snoring reported an average 41% reduction in all snoring above 40dB. In participants with mild OSA, the AHI and ODI posttreatment levels were reduced compared to pretreatment levels: 9.8 compared to 4.7 events/hour (52% reduction) and 7.8 compared to 4.3 events/hour (45% reduction), respectively. As in earlier studies, the results are limited by its small size, lack of a control group and the short follow-up period.

The remaining evidence regarding the efficacy of neuromuscular electrical training devices is limited to a few additional small, short studies with unfavorable efficacy results, particularly in the treatment of OSA (Chwieśko-Minarowska, 2016; Randerath, 2004). No medical societies address the use of a neuromuscular electrical training device in the treatment of OSA.

Background/Overview

Both OSA and snoring are considered types of sleep disordered breathing disorders. OSA affects approximately 2 to 9% of individuals in the United States, with 60% categorized as mild OSA. Habitual snoring can indicate a susceptibility to and a precursor for OSA. The treatment of snoring and mild OSA is considered controversial (Baptista, 2021).

The eXciteOSA device is a removable neuromuscular stimulation device which delivers stimulation to the tongue. The use of the device once a day is intended to improve tongue muscle function and, over time, theorized to prevent the tongue from collapsing backwards and obstructing the airway during sleep. Once the mouthpiece is inserted into the mouth, 4 electrodes located above and below the tongue deliver consecutive electrical muscle stimulation sessions with rest periods in between. A smartphone application controls therapy intensity and monitors usage. The device is intended to be used once a day for 20 minutes for 6 weeks then decreasing to once a week after the initial active treatment phase. The device is not intended to be used in individuals with OSA and an AHI of 15 and higher.

Definitions

Apnea: A transient period where breathing ceases.

Apnea-Hypopnea index (AHI): A measure of apnea severity defined by the total number of episodes of apnea or hypopnea during a full period of sleep divided by the number of hours asleep.

Obstructive sleep apnea (OSA): This is a form of sleep disturbance, which occurs as the result of a physical occlusion of the upper airway during sleep, which interferes with normal breathing. The occlusion is usually in the back of the tongue and/or flabby tissue in the upper airway. This condition is associated with frequent awakening and often with daytime sleepiness.

According to the American Academy of Sleep Medicine (AASM), updated definitions of OSA severity are provided as follows:

- 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 of more than 30, involuntary sleepiness during activities that require more active attention, such as talking or driving (AASM, 2008).

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

HCPCS	
E0490	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote
E0491	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply
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

ICD-10 Diagnosis	
	All diagnoses, including but not limited to
G47.00-G47.9	Sleep disorders
R06.83	Snoring

References

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; 10(9):1883.
2. Chwieśko-Minarowska S, Minarowski Ł, Szewczak WA, et al. Efficacy of daytime transcutaneous electrical stimulation of the genioglossus muscle in patients with obstructive sleep apnea syndrome: short report. Eur Arch Otorhinolaryngol. 2016; 273(11):3891-3895.
3. 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.
4. Nokes B, Baptista PM, de Apodaca PMR, et al. Transoral awake state neuromuscular electrical stimulation therapy for mild obstructive sleep apnea. Sleep Breath. 2023; 27(2):527-534.
5. Randerath WJ, Galetke W, Domanski U, et al. Tongue-muscle training by intraoral electrical neurostimulation in patients with obstructive sleep apnea. Sleep. 2004; 27(2):254-259.
6. Torres-Castro R, Vasconcello-Castillo L, Puppo H, et al. Effects of exercise in patients with obstructive sleep apnoea. Clocks Sleep. 2021; 3(1):227-235.
7. Wessolleck E, Bernd E, Dockter S, et al. Intraoral electrical muscle stimulation in the treatment of snoring. Somnologie (Berl). 2018; 22(Suppl 2):47-52.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Epstein LJ, Kristo D, Strollo PJ Jr, et al.; Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. J Clin Sleep Med. 2009; 5(3):263-276.
2. 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.
3. United States Food and Drug Administration (FDA). De Novo Classification Summary. 21 CFR 872.5575. February 5, 2021. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200018.pdf. Accessed on June 20, 2023.

Websites for Additional Information

1. American Academy of Otolaryngology-Head and Neck Surgery. ENThealth. Snoring, Sleeping Disorders, and Sleep Apnea. Last reviewed August 2018. Available at: https://www.enthealth.org/conditions/snoring-sleeping-disorders-and-sleep-apnea/. Accessed on June 20, 2023.
2. U.S. National Library of Medicine. MedlinePlus. Obstructive Sleep Apnea. Reviewed March 1, 2018. Available at: https://medlineplus.gov/genetics/condition/obstructive-sleep-apnea/#synonyms. Accessed on June 20, 2023.
3. U.S. National Library of Medicine. MedlinePlus. Snoring. Reviewed August 4, 2016. Available at: https://medlineplus.gov/snoring.html. Accessed on June 20, 2023.

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
	12/28/2023	Updated Coding section with 01/01/2024 HCPCS changes, added E0492, E0493 replacing K1028, K1029 deleted as of 01/01/2024.
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, References and Index sections. Updated Coding section with 10/01/2023 HCPCS changes; added E0490 and E0491, revised descriptor for K1028.
Reviewed	08/11/2022	MPTAC review. Updated Rationale, References and Websites sections. Updated Coding section to correct ICD-10-CM code to G47.00.
	04/01/2022	Updated Coding section with 04/01/2022 HCPCS changes; added K1028, K1029 replacing NOC code E1399.
New	08/12/2021	MPTAC review. Initial document development.