Prior Authorization Review Panel
MCO Policy Submission

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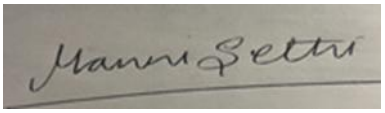
Plan: AmeriHealth Caritas Pennsylvania Community HealthChoices/Keystone First Community HealthChoices	Submission Date: 7/1/2026
Policy Number: CCP.1559	Effective Date: 7/1/2026 Revision Date:
Policy Name: Tongue neurostimulation for snoring and mild obstructive sleep apnea	

Type of Submission:

☒ New Policy	☒ Prior Authorization Policy
☐ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Keystone First
Community HealthChoices

Tongue neurostimulation for snoring and mild obstructive sleep apnea

Clinical Policy ID: CCP.1559

Recent review date: 6/2026

Next review date: 10/2027

Policy contains: tongue neurostimulation, eXciteOSA, snoring, mild obstructive sleep apnea, obstructive sleep apnea, OSA, apnea-hypopnea index, intraoral neuromuscular stimulation

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First Community HealthChoices, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

Tongue neurostimulation, including eXciteOSA, for the treatment of snoring or mild obstructive sleep apnea is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

No alternative covered services were identified during the writing of this policy.

Background

Tongue neurostimulation is a removable daytime oral neuromuscular stimulation therapy intended for adults with primary snoring or mild obstructive sleep apnea. In the eXciteOSA labeling, mild obstructive sleep apnea is defined by an apnea-hypopnea index less than 15 events per hour. The intervention differs from devices worn during sleep because the individual uses it while awake to train tongue muscles that contribute to upper airway patency during sleep (Food and Drug Administration, 2021; Kotecha, 2021).

The device consists of a flexible mouthpiece with electrodes positioned above and below the tongue, a rechargeable control unit, and a remote control or smartphone application. During treatment, the device delivers neuromuscular electrical stimulation to intrinsic and extrinsic tongue muscles, including the genioglossus muscle. The proposed mechanism is increased tongue muscle tone during sleep, with reduced posterior tongue relaxation and reduced upper airway narrowing. Clinical study protocols and regulatory materials describe use for 20 minutes during wakefulness for six weeks (Food and Drug Administration, 2021; Kotecha, 2021; Moffa, 2023).

The Food and Drug Administration granted De Novo classification for eXciteOSA on February 5, 2021 (DEN200018, request received March 24, 2020), as a Class II neuromuscular tongue muscle stimulator under Title 21 of the Code of Federal Regulations, section 872.5575, product code QNO. The Food and Drug Administration subsequently cleared eXciteOSA with and without remote control under 510(k) K223446 on January 18, 2023, under the same regulation and product code, and on September 3, 2024 codified the device classification and associated special controls at 21 CFR 872.5575 by final order (89 FR 71153). The indicated population is adults age 18 years or older with snoring or mild obstructive sleep apnea. Labeling describes prescription use, awake use only, dental assessment before use, repeat sleep testing, and regular follow-up with dental and sleep health professionals. Labeling also identifies precautions and contraindications, including pregnancy, pacemakers or implanted electrodes, certain intraoral metallic objects or appliances, mouth ulceration, and suspected apnea-hypopnea index 15 or greater (Food and Drug Administration, 2021; Food and Drug Administration, 2023; Food and Drug Administration, 2024).

Snoring and mild obstructive sleep apnea exist on a spectrum of sleep-disordered breathing. In this setting, tongue neurostimulation is intended to address tongue-related upper airway collapsibility rather than to provide airway splinting during sleep. Other approaches used in clinical care include lifestyle measures, mandibular advancement devices, positive airway pressure therapy, and surgical procedures, depending on disease severity, anatomy, symptoms, and treatment tolerance (Kotecha, 2021; Moffa, 2023).

Findings

The direct evidence base for tongue neurostimulation is small and mostly noncomparative. Two systematic reviews have synthesized the available studies: Moffa (2023) identified four studies of noninvasive electrical stimulation devices for snoring and obstructive sleep apnea, and Awan (2025) identified four studies of noninvasive oral-cavity neuroelectric stimulation enrolling 154 participants. Both reviews report heterogeneous participants, devices, outcomes, and follow-up schedules. Only one included study used a randomized placebo-controlled design, and that study evaluated an older device rather than eXciteOSA. Most eXciteOSA evidence comes from prospective cohorts or multicenter observational studies. The absence of sham-controlled, blinded, adequately powered trials limits causal inference (Moffa, 2023; Awan, 2025).

Clinical effectiveness

The Moffa (2023) systematic review identified four clinical studies of awake tongue or tongue-related electrical stimulation, including three studies of eXciteOSA and one older single-channel device. Across the included studies, snoring outcomes generally improved by approximately 50%, but apnea-hypopnea index findings were inconsistent. The older randomized placebo-controlled study did not show improvement in apnea-hypopnea index, although snoring epochs decreased. Two eXciteOSA studies reported statistically significant apnea-hypopnea index reductions in participants with mild obstructive sleep apnea, though the multicenter eXciteOSA

study characterized its apnea-hypopnea index change as statistically but not clinically significant; another smaller eXciteOSA study did not show an apnea-hypopnea index effect (Baptista, 2021; Moffa, 2023).

The largest directly relevant prospective cohort (Kotecha, 2021) included 70 participants with primary snoring or mild obstructive sleep apnea. After 20 minutes of daily treatment for six weeks, objective snoring reduction was reported in 95% of participants, with a mean snoring time reduction of 48%. In the subgroup with mild obstructive sleep apnea (n = 38), apnea-hypopnea index decreased from 9.8 to 4.7 events per hour, oxygen desaturation index decreased from 7.8 to 4.3 events per hour, and Epworth Sleepiness Scale decreased from 9.0 to 5.1 (Kotecha, 2021).

A multicenter prospective eXciteOSA study (Baptista, 2021) enrolled 125 participants and reported outcomes in the 115 who completed treatment, including 50 with primary snoring and 65 with mild obstructive sleep apnea. The study reported improvement in objective snoring time in 90% of participants, with a mean reduction in total snoring time of 41%, a mean reduction in time snoring louder than 45 dB of 52%, and bed partner-reported snoring reduction of 39%. It also reported an apnea-hypopnea index reduction from 6.85 to 5.03 events per hour and an oxygen desaturation index reduction from 5.68 to 4.33 events per hour; the authors characterized the apnea-hypopnea index reduction as statistically significant but not clinically significant (Baptista, 2021; Moffa, 2023).

Meta-analyses of implanted hypoglossal nerve stimulation, submental electrical stimulation, and transcutaneous electrical stimulation report improvements in respiratory indices in selected obstructive sleep apnea populations, but those sources are indirect for removable daytime tongue neurostimulation because they involve different devices, stimulation sites, treatment timing, and disease severity. A 2023 randomized phase III trial of domiciliary transcutaneous electrical stimulation in adults with obstructive sleep apnea and limited continuous positive airway pressure adherence (Ratneswaran, 2023) and a 2025 feasibility study of sequential 4-channel neuromuscular electrical stimulation (Lim, 2025) similarly evaluate non-eXciteOSA devices and protocols, and are reported here for context only (Ratneswaran, 2021; Ratneswaran, 2023; Serghani, 2024; Lim, 2025; Wang, 2025).

Safety

The Moffa (2023) systematic review found no significant complications across the included noninvasive tongue stimulation studies. Minor adverse events included excessive salivation, tongue or tooth discomfort, tongue tingling, dental filling sensitivity, metallic taste, gagging, and tight jaw. Tooth discomfort and filling sensitivity were generally associated with higher stimulation intensity and were reported to improve with mouthpiece repositioning or lower intensity (Moffa, 2023). The Kotecha (2021) prospective cohort similarly described adverse effects as minimal, short-lived, and without long-term or permanent effects.

Durability and adherence

Durability evidence is limited. The Kotecha (2021) and Baptista (2021) studies evaluated outcomes shortly after a six-week treatment period, and the Moffa (2023) systematic review noted the need for larger studies with longer follow-up to determine whether effects persist after treatment discontinuation. The Kotecha (2021) cohort included only short post-treatment observation and stated that longer three-month and six-month follow-up evaluations were planned. The published direct evidence does not establish the durability of a twice-weekly maintenance regimen.

Adherence evidence is also limited. The Moffa (2023) systematic review reported eXciteOSA adherence greater than 80% (drawn primarily from the Baptista 2021 multicenter study) but noted that only one short-term tolerability study was available. Because eXciteOSA is used during the daytime rather than during sleep, adherence cannot be directly compared with nightly oral appliance or positive airway pressure adherence using the same measurement framework. The regulatory labeling also emphasizes repeat sleep testing and follow-up with dental and sleep health professionals, which limits reliance on symptoms alone to judge ongoing treatment response (Food and Drug Administration, 2021; Moffa, 2023).

References

On 5/15/2026, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were: ("tongue neurostimulation" OR "tongue muscle stimulation" OR "neuromuscular electrical stimulation" OR NMES OR "intraoral electrical stimulation" OR "daytime electrical stimulation" OR eXciteOSA OR "upper airway stimulation") AND (snoring OR "primary snoring" OR "obstructive sleep apnea" OR OSA OR "sleep-disordered breathing" OR "mild obstructive sleep apnea" OR "apnea hypopnea index"). We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

Awan MO, Arif A, Adeel M, Ahmed S, Iftikhar H. Effect of non-invasive neuroelectric stimulation of oral cavity for obstructive sleep apnoea: a systematic review. World J Otorhinolaryngol Head Neck Surg. 2025;11(2):290-297. Doi: 10.1002/wjo2.220

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. Doi: 10.3390/jcm10091883

Kotecha B, Wong PY, Zhang H, Hassaan A. A novel intraoral neuromuscular stimulation device for treating sleep-disordered breathing. Sleep Breath. 2021;25(4):2083-2090. Doi: 10.1007/s11325-021-02355-7

Lim J, Suh JH, Lee SU, et al. Restorative effect of sequential 4-channel neuromuscular electrical stimulation in obstructive sleep apnea: a feasibility study. Sleep Breath. 2025;29:300. Doi: 10.1007/s11325-025-03465-2

Moffa A, Giorgi L, Carnuccio L, et al. New non-invasive electrical stimulation devices for treatment of snoring and obstructive sleep apnoea: a systematic review. Sleep Breath. 2023;27(1):103-108. Doi: 10.1007/s11325-022-02615-0

Ratneswaran D, Guni A, Pengo MF, et al. Electrical stimulation as a therapeutic approach in obstructive sleep apnea: a meta-analysis. Sleep Breath. 2021;25(1):207-218. Doi: 10.1007/s11325-020-02069-2

Ratneswaran D, Cheng M, Nasser E, et al. Domiciliary transcutaneous electrical stimulation in patients with obstructive sleep apnoea and limited adherence to continuous positive airway pressure therapy: a single-centre, open-label, randomised, controlled phase III trial. eClinicalMedicine. 2023;62:102112. Doi: 10.1016/j.eclinm.2023.102112

Serghani MM, Heiser C, Schwartz AR, Amatoury J. Exploring hypoglossal nerve stimulation therapy for obstructive sleep apnea: a comprehensive review of clinical and physiological upper airway outcomes. Sleep Med Rev. 2024;76:101947. Doi: 10.1016/j.smrv.2024.101947

Wang M, Yin X, Liang Y, et al. Comparative efficacy of electrical stimulation therapies for obstructive sleep apnea: a network meta-analysis of randomized controlled trials. Medicine (Baltimore). 2025;104(35):e44103. Doi: 10.1097/MD.0000000000044103.

U.S. Food and Drug Administration. 510(k) Premarket Notification K223446: eXciteOSA with Remote Control (6000); eXciteOSA without Remote Control (3000). Decision date January 18, 2023. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K223446.

U.S. Food and Drug Administration. Medical Devices; Dental Devices; Classification of the Neuromuscular Tongue Muscle Stimulator for the Reduction of Snoring and Obstructive Sleep Apnea. Final order. Federal Register. September 3, 2024;89(170):71153-71155. Available from: https://www.federalregister.gov/d/2024-19725.

U.S. Food and Drug Administration. De Novo Classification Request for eXciteOSA with Remote and eXciteOSA without Remote. DEN200018. Decision date February 5, 2021. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN200018.

Policy updates

Initial review date: 5/2026 and clinical policy effective date: 6/2026

6/2026: Policy created.

Related codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1559. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code description
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.
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified.