



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 08/01/23
LAST REVIEW DATE: 08/06/24
CURRENT EFFECTIVE DATE: 08/06/24
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NEXT ANNUAL REVIEW DATE: 3RD QTR 2025

DEVICES FOR THE MEDICAL MANAGEMENT OF OBSTRUCTIVE SLEEP APNEA

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. Conventional medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of continuous positive airway pressure (CPAP) during sleep. Novel treatments include nasal expiratory positive airway pressure (EPAP) and oral pressure therapy.

A positional sleep therapy device (i.e., NightBalance) has been developed for individuals who have positional obstructive sleep apnea. The positional sleep trainer is worn with an elasticized chest strap and is intended to keep individuals from sleeping in the supine position. The device vibrates when it detects a supine position and the vibration increases gradually until the individual changes position.

A neuromuscular stimulation device (i.e., eXciteOSA[®]) is designed to deliver daytime stimulation of the tongue to strengthen the tongue in order to reduce snoring and mild sleep apnea. It is used for 20 minutes once a day for a period of 6 weeks, and once a week thereafter.

FDA approved novel devices include NightBalance Lunoa System and eXciteOSA[®].

Criteria:

- The use of a sleep positioning trainer with vibration for the treatment of positional obstructive sleep apnea is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
 5. Insufficient evidence to support improvement outside the investigational setting

These devices include, *but are not limited to:*

- NightBalance Lunoa System

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- The use of neuromuscular electrical tongue stimulation for the treatment of obstructive sleep apnea is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
 5. Insufficient evidence to support improvement outside the investigational setting

These devices include, *but are not limited to*:

- eXciteOSA®

Resources:

Literature reviewed 08/06/24. We do not include marketing materials, poster boards and non-published literature in our review

Resources prior to 08/06/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Abreu AR, Stefanovski D, Patil SP, et al. Neuromuscular electrical stimulation for obstructive sleep apnoea: comparing adherence to active and sham therapy. *ERJ Open Res*. Nov 2023;9(6):doi:10.1183/23120541.00474-2023
2. American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Treatment of obstructive sleep apnea. 2021. Accessed May 9, 2024. <https://www.entnet.org/resource/position-statement-treatment-of-obstructive-sleep-apnea/>
3. Balk EM, Moorthy D, Obadan NO, et al. AHRQ Comparative Effectiveness Reviews. *Diagnosis and Treatment of Obstructive Sleep Apnea in Adults*. Agency for Healthcare Research and Quality (US); 2011.
4. 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*. Apr 27 2021;10(9):doi:10.3390/jcm10091883
5. Belkhode V, Godbole S, Nimonkar S, Pisulkar S, Nimonkar P. Comparative evaluation of the efficacy of customized maxillary oral appliance with mandibular advancement appliance as a treatment modality for moderate obstructive sleep apnea patients-a randomized controlled trial. *Trials*. Feb 1 2023;24(1):73. doi:10.1186/s13063-022-07054-6

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11. Buyse B, Ciordas S, Hoet F, Belge C, Testelmans D. Positional obstructive sleep apnoea: challenging findings in consecutive patients treated with a vibrating position trainer. *Acta Clin Belg*. Dec 2019;74(6):405-413. doi:10.1080/17843286.2018.1545374
12. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA) (240.4). 2008. Accessed May 2, 2024. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=226&ver=3>
13. Centers for Medicare & Medicaid Services (CMS). CMS Manual System: Pub 100-03 Medicare National Coverage Determinations. Transmittal 96. Change request 6048. 2008. Accessed May 9, 2024. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r96ncd.pdf>
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15. Clinical practice guideline: diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*. Apr 2002;109(4):704-12. doi:10.1542/peds.109.4.704
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25. Krakow B, Ulibarri V, Melendrez D, Kikta S, Togami L, Haynes P. A daytime, abbreviated cardio-respiratory sleep study (CPT 95807-52) to acclimate insomnia patients with sleep disordered breathing to positive airway pressure (PAP-NAP). *J Clin Sleep Med*. Jun 15 2008;4(3):212-22.
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Coding:

HCPCS: E0490, E0491, E0492, E0493, E0530, E1399, K1001, K1028, K1029



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<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Medical Policy Panel	08/06/24	Review with revisions
Medical Policy Panel	08/01/23	Approved guideline

Policy Revisions:

08/06/24	Added:	HCPCS codes: E0490, E0491
08/06/24	Revised:	Criteria statement “The use of daytime electrical stimulation of the tongue for the treatment of obstructive sleep apnea is considered experimental or investigational” to “The use of neuromuscular electrical tongue stimulation for the treatment of obstructive sleep apnea is considered experimental or investigational”
08/06/24	Updated:	Resource section
02/14/24	Added:	HCPCS codes: E0492, E0493, E0530



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idilkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idilkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowotgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojį' bich'į' hodilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

