Medicare Documentation Guide

Physician Checklist

Medicare Documentation Requirements for DMEPOS medical devices may be considered more stringent than other health insurance providers. The following is provided to serve as a guide, as no Medicare coverage guidelines have been established on a national basis for eXciteOSA®. Recently, the Medicare coding contractor, PDAC, reviewed eXciteOSA® and determined that a non-covered HCPCS code is appropriate for the device. This was based on an unclear claim in the IFU that has since been updated. However, the code still remains active in reference to the device.

In many cases due to the HCPCS code, DME suppliers may choose to issue an Advance Beneficiary Notice (ABN) to the patient, transferring financial responsibility. For those patients who will desire to appeal despite the HCPCS code, thorough documentation of medical necessity in the patient's medical record is important. An investment in the initial justification will save time in the case of a denial/appeal. It is also important to note that a letter of medical necessity or a pre-made evaluation template with checklists will not stand on its own with Medicare.

eXciteOSA®

eXciteOSA® is a prescription only, non-invasive tongue muscle stimulation device that delivers neuromuscular electrical stimulation in order to reduce snoring and mild obstructive sleep apnea (OSA) (AHI<15) for patients that are 18 years or older. It strengthens weak tongue and upper airway muscles to address a common root cause of mild OSA and snoring.

Before you Start: the Basics

Medicare Coding: PDAC has verified code A9270 for eXciteOSA.
This determination was based on a retired IFU which listed eXciteOSA® as a single patient use device. The current IFU clarifies that eXciteOSA can be used by multiple successive patients when refurbished between patients. No updates have been made to the DMECS classification list on the PDAC website since the IFU was updated.

Medicare Documentation of Mild OSA must include documentation of the following symptoms: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, or history of stroke.

Dispensing as Rental or a Purchase: *Durable medical equipment, as defined in Social Security Act (SSA) Sections 1861 (n) and (s)(6), and National Coverage Determination 280.1, must be able to withstand repeated use i.e. could normally be rented and used by successive patients*.

This definition applies to the eXciteOSA® Control Unit, which can be used by successive patients in a rental agreement. If a patient would like the option to purchase the Control Unit over renting it, the appropriate billing code to describe the eXciteOSA® Control Unit is A9270, to designate a non-covered item that would be billed to the patient if proper documentation is supplied.

This checklist is based upon Medicare's coverage policies for OSA devices, like CPAP and oral appliances, because Medicare has not yet established a policy for eXciteOSA's NMES device. If Medicare or other payers establish a policy, it could establish coverage criteria different from the items listed in this checklist.

Initial Claim

Standard Written Order (SWO)

☐ **1.** The SWO contains all of the following elements:

- ☐ a. Beneficiary's name or Medicare Beneficiary Identifier (MBI)
- ☐ b. Order Date
- ☐ c. General description of the product (choose 1 of the following):
  - Product Narrative:
    - Tongue neuromuscular electrical stimulation control unit for OSA, with adjustable stimulation.
    - Mouthpiece for tongue neuromuscular electrical stimulation with 4 electrodes.
    - Monitoring Device / Feature
  - General Description: eXciteOSA controller & mouthpiece w/ monitoring application
  - Product /model number and description:

13010 eXciteOSA Starter Kit includes the following		
Quantity	Part Number	Description
1	800600000	eXciteOSA control unit
1	801300000	eXciteOSA mouthpiece
1	0809700000	eXciteOSA app IOS
1	0809800000	eXciteOSA app Android

☐ **2.** Treating Practitioners Name or NPI

☐ **3.** Treating Practitioner's signature

Examples of signatures that meet CMS requirements:

- If Legible can be:
  - full signature
  - first initial and last name
- If Illegible can be:

- signature over a typed or printed name
- letterhead or information on the page the identity of the signatory
- accompanied by signature log or attestation statement

- Electronic Signature accompanied by date stamp

Note: Signature on File or an unsigned document with typed name does not meet CMS signature requirements.

Medical Necessity Documentation

☐ **1.** Face to Face Physician's Examination

☐ a. History of Diagnosis (Dx)

G47.33	**Obstructive sleep apnea (adult) (pediatric)**

☐ b. Signs and symptoms of sleep disordered breathing including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches

☐ c. Duration of symptoms

☐ d. Epworth Sleepiness Scale inventory or equivalent validated sleep questionnaire

☐ e. Physical Exam focused on diagnosis including highlighting:

☐ Cardiopulmonary and upper airway system evaluation

☐ Evaluation of tongue/mouth/nasal passageway noting abnormality or potential contributors to collapse of oropharyngeal walls and obstruction of airflow

☐ Neck circumference

☐ Body Mass index

☐ Confirmation that the nerve supply to the tongue is intact

☐ f. Prognosis

☐ g. Treatment Goals

☐ h. Verify clinical evaluation was completed prior to the sleep test

☐ **2.** Facility Sleep Test (Type I) – A sleep test is an objective study to measure AHI and confirm sleep apnea. If a test, whether at a facility or at home, is not standard practice for the referring physician for a symptom-based mild OSA diagnosis, consider that Medicare requires a sleep or home test for standard OSA treatment devices.

☐ a. Verify test was performed at a facility-based sleep laboratory

- ☐ b. Verify test was ordered by the beneficiary's treating practitioner
- ☐ c. Test was conducted by an entity that qualifies a s a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements
- ☐ d. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
  - ☐ Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; **OR**,
  - ☐ Hypertension, ischemic heart disease, or history of stroke.

OR

☐ **2.** Home Sleep Test (Type II, III, IV or other) – A home sleep test is an objective study to measure AHI and confirm sleep apnea. If a test, whether at a facility or at home, is not standard practice for the referring physician for a symptom-based mild OSA diagnosis, consider that Medicare requires a facility sleep or home test for standard OSA treatment devices.

- ☐ a. Test was ordered by patient's treating practitioner.
- ☐ b. Test was conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements.
- ☐ c. Documentation that the patient received instruction on how to properly apply the portable sleep monitoring devices from the entity conducting the home sleep test of the patient, may include face to face demonstration or video/telephonic instruction with 24 hour access to qualified personnel to answer questions or troubleshoot the device.
- ☐ d. No aspect of the Home Sleep Test, including delivery and/or pickup of the device was performed by the DME supplier.
- ☐ e. The portable monitoring device used to conduct the Home Sleep Study met criteria for one of the following devices (see NCD 240.4.1):
  - ☐ Type II: minimum of 7 channels, monitors sleep staging so AHI can be calculated
  - ☐ Type III: minimum of 4 channels including ventilation or airflow, heartrate or ECG, and oxygen saturation
  - ☐ Type IV: measure 1, 2, or 3 or more channels, which 1 is airflow, but do not meet all the criteria of a higher category device
  - ☐ Other: measure 3 or more channels that include actigraphy, oximetry, and peripheral arterial tone.

- ☐ f. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
  - ☐ Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; **OR**,
  - ☐ Hypertension, ischemic heart disease, or history of stroke.

☐ **3.** If other OSA devices or therapies have been tried, document:

- ☐ a. Type of interventions (Sleeping on side, diet management, exercise, avoid tobacco etc.) or type of device (CPAP, Custom fabricated mandibular advancement oral appliance etc.)
- ☐ b. Duration of intervention
- ☐ c. Whether the intervention worked, partially worked, or didn't work and the results

CPAP Examples (not all inclusive):

- Patient did not respond to CPAP, i.e. AHI did not decrease, symptoms did not improve, or patient requires better intervention for medical reason.
- Patient was not compliant (> than 4 hours a night for 70% of the nights in a consecutive 30 day period) during CPAP trial, explain
- Lifestyle consideration: patient does not tolerate wearing mouthpiece or nasal appliance at night, appliance negatively interferes with sleep, or other specific medical consideration

Note: Medicare coverage criteria for CPAP and custom Mandibular Advancement Appliances are the same. Some physicians may opt to prescribe a CPAP first before an Oral Appliances, but in the case the Medicare it is not required.

Other Intervention Examples (not all inclusive):

- Patient was on weight management program for "x" amount of time and saw minimal improvements. Various interventions tried. According to your medical expertise it is time to try another intervention.

☐ **4.** Recommendation for treatment with eXciteOSA tongue neuromuscular electrical stimulation device and rationale of treatment over alternatives:

Examples (not all inclusive):

- Your experience with eXciteOSA has shown high compliance, explain rationale why you believe patient would be compliant based on motivation and patient willingness to use eXciteOSA.
- Patient refused other intervention and in your opinion needs an intervention based on co-morbidities.
- Last resort for treating mild OSA.

Note: Leverage your professional knowledge to build a chain of arguments specific to your patient where coverage would be appropriate.

Medical Necessity For Subsequent Claims

For Continued Use & Continued Coverage (past 6 weeks)[1]

☐ **1.** A treating physician who is following patient's treatment should download and evaluate the patient's data from the eXciteOSA App. The following should be confirmed:

- ☐ a. The patient is using the device consistently. Evidence of adherence may include data from the eXciteOSA App or include a patient narrative summarizing the use of the device. This compliance data should be added to the patient's medical record.
- ☐ b. The patient is benefiting from the eXciteOSA therapy. This can be done is a variety of ways: a patient follow-up call, a telemedicine visit, or a face to face exam.

Documentation may include any of the following:

- ☐ Improvement in the symptoms of obstructive sleep apnea as narrated by patient or patient's family members.
- ☐ Improvement in Epworth Sleepiness Scale inventory or equivalent validated sleep questionnaire
- ☐ A Re-evaluation, Physical Exam, or observational improvements are documented and detailed in the beneficiary's medical chart
- ☐ Documentation of improvement in AHI

Note: follow-up visit and evaluation may be recorded at the time the physician determines is most appropriate. It may not always occur during the switch from Phase 1 to Phase 2 therapy.

[1] Per the IFU, Phase I therapy is recommended every day for 6 weeks and twice a week thereafter for Phase 2. A physician may prescribe a different therapy treatment plan customized to the individual patient needs and adjusted based on data from the eXciteOSA App by Signifier Medical Technologies Limited.

For Continued Need

☐ **1.** Every 90 days with a reorder of the mouthpiece: A refill prescription by the treating practitioner would justify continued need documentation. Also, medical record from the treating practitioner would document continued usage qualifies. Per the IFU, the mouthpiece is recommended to be replaced every 90 days regardless of the frequency of use. This maintains the functioning of the electrodes when exposed to the tongue mucosa.

☐ **2.** Every 12 months: a prescription, refill order, or medical record documenting usage of eXciteOSA from the treating practitioner would show continued need.

Break in Need

A Break in Need refers to a break in the capped rental period due to medical necessity of the patient. For example, if the patient develops a mouth ulcer or another condition that is contra-indicated per the IFU or if a condition develops where the treating physician has recommended stopping use of eXciteOSA for a period, this would constitute a break in need.

☐ **1.** If the break in medical need is at least 60 days, a new capped rental period can begin:

- ☐ Document justification and reason for the break in need in patient's records

Replacement of Device or Supplies

Replacement of a device that is functional may only occur after the Medicare Reasonable Useful Lifetime (RUL), which in general is established as 5 years for DME devices, 42 CFR 414.210(f). Computation of the RUL is based on when the equipment is delivered to the beneficiary, not the age of the equipment. The RUL is used to determine how often it is reasonable for Medicare to pay for the replacement of DME under the Medicare program and is not explicitly set forth as a minimum lifetime standard.

In order to meet the definition of Durable Medicare Equipment, a device must meet the Minimum Lifetime Requirement (MLR), which is the 3-year duration for repeated use (durability). Repeated rental requires full functionality over the entire MLR period. eXciteOSA control unit has been tested to last at least 3 years.

Determine which of the following replacement situations applies to the patient and record the following documentation:

1. Replacement of **Control Unit** During Reasonable Useful Lifetime Due to Loss, Theft, or Irreparable Damage

☐ a. Documentation that verifies the reason for the replacement (police report, insurance report, fire report)

2. Replacement of **Control Unit** following 5 year Reasonable Useful Lifetime

☐ a. A prescription for the device (See Standard Written Order Section of this guide)

☐ b. An in-person evaluation by the treating practitioner that documents the beneficiary continues to use and benefit from the device.

☐ c. Documentation of the condition of the device.

3. Repair or Replacement of **Control Unit** Following 3 years, but before 5 year Reasonable Useful Lifetime

☐ a. Documentation of the condition of the device by the manufacturer or supplier.

☐ b. Invoice for the repairs and what was done.

NOTE: Replacement of Device due to manufacturer's defects or malfunction not caused by tampering or misuse/abuse within 3 years must be resolved with the manufacturer.

4. Refill of **Mouthpiece** (Non-Consumable Supply)

☐ a. A prescription for the refill supply will need to be updated in accordance to state laws.

☐ b. Beneficiary's name or Medicare Beneficiary Identifier (MBI)

☐ c. Order Date

☐ d. A description of the devices is needed:

- eXciteOSA mouthpiece OR
- Mouthpiece for tongue neuromuscular electrical stimulation with 4 electrodes.

☐ e. Treating practitioners name or NPI

☐ f. Treating practitioners signature

Medicare Definitions

Sleep-Disordered Breathing *often referred to as Obstructive Sleep Apnea, is characterized by frequent episodes of hypopnea or apnea during sleep. Multiple detrimental physiologic changes may result from these hypopneic and apneic episodes.*[6]

Obstructive sleep apnea (OSA) *is the collapse of the oropharyngeal walls and the obstruction of airflow occurring during sleep.*[3]

Apnea-hypopnea index (AHI) *is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device. Sleep time can only be measured in a Type 1 (facility based polysomnogram) or Type II sleep study.* [1, 2]

> ***Apnea*** *is the cessation of airflow for at least 10 seconds.* [1, 2]
>
> ***Hypopnea*** *is an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.* [1, 2]

Respiratory disturbance index (RD) *is defined as the average number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure device. The RDI is reported in Type II, Type IV and Other home sleep studies.* [1, 2]

Ineffective CPAP trial *is defined as documented failure to meet therapeutic goals using an E0601 during the titration portion of a facility-based study of during home use despite optimal therapy (i.e. proper mask selection and fitting and appropriate pressure settings)* [1, 2]

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Disclaimers

Medicare Documentation Guide and Coverage: This document was prepared as an educational tool and is intended to be a general summary based on Medicare's testing and coverage requirements for equipment and supplies to treat OSA. It was based on the most current information available at the time this tool was created. Since there is no Medicare Coverage, National Coverage Guidelines, or Local Coverage Guidelines for tongue neuromuscular electrical stimulation devices, there is no way to know what documentation Medicare will actually require for eXciteOSA medical necessity. Medicare coverage policies, regulations, and definitions whether written or by interpretation are subject to change. This is not intended to take the place of written references including: statutes, laws, regulations, or other policy materials. The DME MAC supplier is encouraged to consult with their local DME MAC contractor and DME MAC and/or CMS Manuals.

HCPCS Coding: The responsibility for accurate coding lies with the DME supplier who bills eXciteOSA. Medicare's Pricing, Data Analysis, and Coding Contractor (PDAC), is the official source for the Medicare Durable Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) product code verification and assignment. This coding verification is a voluntary process that allows manufacturers to request a coding decision on a DMEPOS item. Once a verification is submitted to PDAC, it is the responsibility of the PDAC to review the DMEPOS product(s) to determine the appropriate HCPCS code for Medicare billing. eXciteOSA was verified with HCPCS code A9270 effective April 23, 2021.

HCPCS coding narratives are based on reasonable judgment and are not recommended to replace the DME Supplier's judgment.

These recommendations may be subject to revision based on alpha-numeric system changes or additional information.

MSRP: The 2021 Manufacturer's Suggested Retail Price (MSRP) is a suggested retail price only and is subject to change. Signifier Medical Technologies LLC has provided the suggested MSRP in the event that a third-party or federal healthcare insurers request it for reimbursement purposes. A DME Supplier is not required to use the MSRP to determine their usual and customary charges when submitting claims to health insurers for payment.

The ultimate responsibility for the correct submission of claims lies with the DME Supplier who bills eXciteOSA.