Commercial Documentation Guide

DME Supplier & Physician Checklist

Some Commercial Plans allow Physicians or DME suppliers to deliver DME under the appropriate circumstances. The following is a general documentation guide based on several coverage policies for devices to treat obstructive sleep apnea (OSA), because there is no nationally established policy for the 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.

It is best practice to always first check with the individual health insurance plan for medical necessity coverage requirements before proceeding with the submission of a claim. Following comprehensive documentation guidelines may provide a basis for a systemized process in collecting medical necessity documentation; however, it does not guarantee coverage.

It is expected the beneficiary's medical records will reflect the need for the care provided. This would include medical records from the treating physician as well as specialty medical providers, available upon request.

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

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 made to the DMECS classification list on the PDAC website since the IFU was updated.

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 in order to designate a non-covered item that would be billed to the patient if proper documentation is supplied.

Initial Claim

Written Order

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

- ☐ a. Beneficiary's name or Patient ID
- ☐ b. Order Date
- ☐ c. General description of the product (choose 1 of the following):
  - HCPCS Code:
    - A9270 NON-COVERED ITEM OR SERVICE (HCPCS code for Medicare, published on PDAC)
    - A9279 MONITORING FEATURE/DEVICE, STAND-ALONE OR INTEGRATED, ANY TYPE , INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED
  - 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 acceptable signatures:
- 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

Medical Necessity Documentation

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

☐ a. History of Diagnosis (Dx)

G47.33	**Obstructive sleep apnea (adult) (pediatric)**		
Potential ICD10-CM Accompanying Symptoms: Symptoms required for Medicare coverage may not have a diagnosis code. Documentation must come from the medical record.			
R40.0	Somnolence. *Drowsiness*	I10	Essential (primary) hypertension
F34.81	Disruptive mood dysregulation disorder	I15.0	Renovascular hypertension
F34.89	Other specified persistent mood disorders	I15.1	Hypertension secondary to other renal disorders
F34.9	Persistent mood [affective] disorder, unspecified	I15.2	Hypertension secondary to endocrine disorders
F39	Unspecified mood [affective] disorder	I15.8	Other secondary hypertension
G47.00	Insomnia, unspecified	I15.9	Secondary hypertension, unspecified
G47.01	Insomnia due to medical condition	I27.0	Primary pulmonary hypertension
G47.09	Other insomnia	I27.20	Pulmonary hypertension, unspecified
I24.8	Other forms of acute ischemic heart disease	I27.21	Secondary pulmonary arterial hypertension
I24.9	Acute ischemic heart disease, unspecified	I27.22	Pulmonary hypertension due to left heart disease
I25.5	Ischemic cardiomyophathy	I27.23	Pulmonary hypertension due to lung diseases and hypoxia
I25.6	Silent myocardial ischemia	I27.24	Chronic thromboembolic pulmonary hypertension
I25.89	Other forms of chronic ischemic heart disease	I27.29	Other secondary pulmonary hypertension
I25.9	Chronic ischemic heart disease, unspecified	Z86.73	History of Stroke
I27.0	Primary pulmonary hypertension		

☐ 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: onset, duration, and frequency

☐ d. Documentation of daytime sleepiness by:

- ☐ Epworth Sleepiness Scale inventory or equivalent validate sleep questionnaire g.
- ☐ Interference with daily activities or work (e. causes safety issues, or threatens to cause conflict with work requirements) i.

☐ e. Physical Exam focused on diagnosis including highlighting: f.

- ☐ 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.

☐ g. Treatment Goals h.

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

☐ **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 – 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 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*:
  *some policies may not require the documentation below
  - ☐ 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

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.** Rationale for recommending eXciteOSA tongue neuromuscular electrical stimulation device over alternatives:

Examples (not all inclusive):

- Physician's 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.

☐ **5.** Documentation that the beneficiary and/or their caregiver received instructions from the supplier of eXciteOSA device and supplies in the proper use and care of the equipment.

Examples (not all inclusive):

- Patient received written Instructions for Use (User Guide).
- Patient was directed to video explaining use and care of the device.
- Patient received verbal instructions from a representative.
- Patient signed document acknowledging the receipt of instructions.

Proof of Delivery / Delivery Ticket

If shipped to patient (must have means to track package):

- ☐ **1.** Shipping invoice
  - ☐ a. Beneficiary's name
  - ☐ b. Delivery address
  - ☐ c. Description of the item (see order checklist)
  - ☐ d. Quantity shipped
- ☐ **2.** Tracking slip
  - ☐ a. References each package (if shipped in multiple packages)
  - ☐ b. Delivery address
  - ☐ c. Package ID number, i.e. tracking number
  - ☐ d. Date shipped
  - ☐ e. Date delivered
- ☐ **3.** Common reference number e.g. PO#, order #, tracking # - links the invoice and tracking slip to each other

Delivery directly to the patient or authorized representative (e.g. picked up by patient):

- ☐ **1.** Patient's name
- ☐ **2.** Delivery address
- ☐ **3.** Quantity delivered
- ☐ **4.** Description of the item(s) (see order checklist)
- ☐ **5.** Date delivered
- ☐ **6.** Signature of patient or designee. If a designee signs, must document relationship to patient.

Optional: Advance Beneficiary Notice (ABN) or Notice of Financial Responsibility

An ABN or Notice of Financial Responsibility is a written notice that advises a beneficiary before items or services are furnished that the health insurer is likely to deny payment.

ABNs or Notice of Financial Responsibility allow beneficiaries to make informed consumer decisions about items or service for which they may have to pay out-of-pocket.

- ☐ **1.** The item not covered is clearly identified
- ☐ **2.** Specify the reason for expected denial
- ☐ **3.** Give a reasonable estimate cost of the non-covered item and/or service
- ☐ **4.** Must be signed and dated by the patient

  Currently flexibilities for delivering notices during the COVID-19 Public Health Emergency (PHE)

  - ☐ **Hard copy.** If person delivering ABN is unable to answer questions the patient has a contact phone number must be provided **OR**
  - ☐ **Email.** Annotate the circumstances of delivery, including the when and to whom the email was sent and from what email address. **OR**
  - ☐ **Telephone.** Notice may be delivered via telephone to patient or patient representative. Annotate the circumstances including the person delivering the notice via telephone, the time of the call, and who received the phone call.

Note: When there is an expectation of a medical necessity denial, supplies must enter GA on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or GZ if they have not obtained a valid ABN, but coverage is not expected.

Billing Reminders and Modifier Checklist

- ☐ **1.** Bill A9270 Quantity 1 for both the Control Unit and the Mouthpiece

	24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES		G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	XX	XX	XX	XX	XX	XX	12		A9270	XX		XXX	XX	1		NPI	XXXXXXXXXX
2	XX	XX	XX	XX	XX	XX	12		A9270	XX		XXX	XX	1		NPI	XXXXXXXXXX

- **2.** Do you have an ABN? Include a GA or GZ modifier after the HCPCS code.

  GA = valid ABN on file

  GZ = no ABN obtained

- ☐ **3.** Add a narrative line note for unspecified codes (A9270) as you would an unlisted procedure code or NOC code. While you are not required to add a narrative, it will clarify what device you are billing.

A narrative goes in the NTE Note segment of an electronic claim, loop 2300, or Item 19 of the CMS-1500 claim form. It typically has a character limit of 80 characters.

Suggested narrative per line item (80 characters each):

Control Unit	800600000 TONGUE NMES CTRL UNIT FOR OSA ADJ STIMULATION MDR SIGNIFIER MSRP $1500
Mouthpiece	801300000 TONGUE NMES MOUTHPIECE FOR OSA W/ 4 ELECTRODES MDR SIGNIFIER MSRP $150

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:

[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.

- ☐ 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

☐ **2.** The DME Supplier may also verify continued use before a supply refill request is shipped. Document that the patient is using the device and record the frequency that the patient is using the device. This can be done via a phone conversation or sometimes documented electronically via a re-order form (i.e. check box or attestation from the patient that the patient continues to routinely use the device).

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.

Billing Reminder: It is not appropriate to bill capped rental months when the patient is not using the device. Confirmation that the patient is using the device on a continual basis is necessary for coverage and payment.

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
  - ☐ On the claim, include a narrative to explain the new rental period

Break in Service

A Break in Service is defined as break in the capped rental period not due to medical necessity. This could be the device was returned to be serviced, a recall was issued, or that the patient for whatever reason stopped using the device for a period of time and then started using it again.

- ☐ **1.** Submit claim as normal, but include a narrative explaining that there has been a break in service. Request an extension of the capped rental period for the remainder of the rental months if necessary.
- ☐ **2.** If billing has continued automatically while there has been a break in service, a corrected claim(s) will need to be submitted so that the DOS match the actual occurrence.

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 SWO (prescription) for the device (see SWO section above)

☐ 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)

Refill record, shipped to the patient:

☐ a. Beneficiary's name or authorized representative if different from the beneficiary

☐ b. A description of the item being requested.

☐ c. Date of the refill request.

☐ d. Functional condition of the non-consumable supply item

Documentation of a request to refill:

☐ a. A written document received from the beneficiary, can also be electronic.

☐ b. A contemporaneous written record of a phone conversation/contact between the supplier and beneficiary.

☐ c. Must occur and be documented before shipment.

AASM Definitions

Obstructive sleep apnea (OSA) sleep related breathing disorder that involves a decrease or complete halt in airflow despite an ongoing effort to breathe.

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.*

> ***Apnea*** *is the cessation of airflow (≥ 90% decrease in airflow compared to baseline) for at least 10 seconds.*
>
> ***Hypopnea*** *is an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in airflow and with at least a 3% decrease in oxygen saturation from pre-event baseline or the event is associated with an arousal.*

Respiratory disturbance index (RDI) *number of apneas plus number of hypopneas plus the number of Respiratory Effort-Related Arousals during the entire sleeping period, time 60, divided by total sleep time in minutes. Unit = events per hour*

References

1. Centers for Medicare and Medicaid Services. Medicare Coverage Database. Proposed Local Coverage Determination (LCD): Positive Airway Pressure (PAP) Devices for the Treatment of OSA (DL33719). Accessed from https://www.cms.gov/medicare-coverage-database/new-search/search.aspx on July 20th, 2021.

2. Centers for Medicare and Medicaid Services. Medicare Coverage Database. Local Coverage Determination (LCD): Positive Airway Pressure (PAP) Devices for the Treatment of OSA (L33718). Accessed from https://www.cms.gov/medicare-coverage-database/new-search/search.aspx on July 20th, 2021.

3. Centers for Medicare and Medicaid Services. Medicare Coverage Database. National Coverage Determination for Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA) (240.4). Accessed from https://www.cms.gov/medicare-coverage-database/new-search/search.aspx on July 20th, 2021.

4. Centers for Medicare and Medicaid Services. Medicare Coverage Database. Proposed Local Coverage Determination (LCD): Oral Appliances for Obstructive Sleep Apnea (DL33611). Accessed from https://www.cms.gov/medicare-coverage-database/new-search/search.aspx on July 20th, 2021.

5. Centers for Medicare and Medicaid Services. Medicare Coverage Database. Local Coverage Determination (LCD): Oral Appliances for Obstructive Sleep Apnea (L33611). Accessed from https://www.cms.gov/medicare-coverage-database/new-search/search.aspx on July 20th, 2021.

6. UnitedHealthcare. United Healthcare Commercial Medical Policy. Obstructive Sleep Apnea Treatment. Various Guideline Numbers.

7. Aetna. Obstructive Sleep Apnea in Adults. Clinical Policy Bulletins 0004. Accessed from http://www.aetna.com/cpb/medical/data/1_99/0004.html on July 29, 2021.

8. Palmetto GBA LLC. Pricing, Data Analysis and Coding (PDAC) Contractor. HCPCS Award Letter for eXciteOSA. July 3, 2021.

9. U.S. Food and Drug Administration, Center for Devices and Radiological Health (CDRH). eXciteOSA without remote control, eXciteOSA with remote control DEN2000018 De Novo classification letter, February 5, 2021. Accessed from https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200018.pdf on July 23, 2021

Disclaimers

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. 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.