Patient Reimbursement Guide for eXCITE OSA

Patient Reimbursement Guide for eXciteOSA®

Table of Contents

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SECTION ONE: PATIENT INTRODUCTION

Dear eXciteOSA® user,

We are excited that you have chosen to eXciteOSA®- the world's first, daytime treatment for sleep disordered breathing. eXciteOSA is a novel neuromuscular stimulation device that strengthens weak tongue and upper airway muscles to addresses the root cause of mild obstructive sleep apnea (OSA) and snoring.

Whether you've tried other OSA treatments or are new to treatment, congratulations for taking your first step towards better sleep. Clinical studies show a significant improvement in sleep apnea, oxygen desaturation, snoring, as well as sleep quality and daytime sleepiness.

Because eXciteOSA® is new to the market, coverage and payment have yet to be established on a national level. This simply means that all devices will be handled in a case by case basis if a claim is submitted to your health insurance payer. It will also require patience with the paperwork process. Your first step would be to have a conversation with your prescribing health care provider to discuss your options. This conversation would identify your case for medical necessity and what happens if the device is not covered.

In this Patient Reimbursement Guide, we will give you an overview of the insurance process as well as provide tips specific to eXciteOSA®. One of the most important strategies is to work closely with your support team – physicians, medical suppliers, billers, and support staff specialists to understand timing and deadlines in the process and how you can be involved as an advocate. You may not always imagine the health insurance and patient relationship as a client relationship, but it is. Be involved and you can become an informed partner, making the most of every decision for your health and wellbeing.

Sincerely,

Travis Nieman
Managing Director
Signifier Medical Technologies

SECTION TWO: PRODUCT INFORMATION OVERVIEW, eXciteOSA® FOR MILD OSA

A. Product Description

eXciteOSA® is a non-invasive tongue neuromuscular electrical stimulation (NMES) device. It targets the intrinsic and extrinsic tongue and upper airway muscles with electrodes placed above and below the tongue. The in-home device includes a control unit, a washable mouthpiece with electrodes (replaced every 90 days), wash cap, and USB-C cable for charging. An App is downloaded to a smartphone to guide the patient through therapy and control the intensity. It provides users with educational information, technical support, usage data, and compliance reminders. The App can also communicate with a physician portal to allow for virtual consultation.

Neuromuscular electrical stimulation (NMES) has been used widely across medical disciplines for several decades. However, eXciteOSA® is the first NMES device on the market to treat OSA.

B. How does it Work?

eXciteOSA® uses an electrical current to stimulate and improve muscle function of the tongue. A common cause of OSA is excessive relaxation of the tongue musculature. The improved responsiveness of these muscles prevents the tongue from collapsing, maintaining an open upper airway.

The prescribed therapy is similar to endurance muscle training, like a long-distance runner.

C. Who can receive eXciteOSA?

eXciteOSA® is a prescription device indicated to reduce snoring and mild obstructive sleep apnea for patients that are 18 years or older. Either one or both of these diagnoses [mild OSA or snoring] by a physician will qualify a person for the device; however, it is common for health insurers to pay for devices to treat OSA. Devices to treat snoring may not be considered a medical benefit.

It is important to discuss your diagnosis(es) and symptoms with your physician and call your health insurance provider to ask questions about coverage. See *Pre-Work, Questions to Ask Your Health Insurer* in this guide to help you navigate a conversation with your health insurance provider.

The device is not for people who are pregnant or may become pregnant, have a pacemaker that includes implanted electrodes, have temporary or permanent metal implants, dental braces, intraoral metal prosthesis/restorations/appliances or dental jewelry, those who suffer from mouth ulcers, or those who have moderate to severe OSA.

D. FDA Status

Under FDA's regulations, the eXciteOSA® neuromuscular stimulator is a class II device, with De Novo classification (DEN200018). This classification applies to new, novel devices whose classification type has not previously been classified. Your physician will determine if you meet the eXciteOSA indications.

E. Coding Status

An HCPCS (pronounced HICK-PICKS) code is the language health insurance companies use to describe medical devices, like Durable Medical Eqiupment (DME). Medicare's Pricing, Data Analysis and Coding (PDAC) Contractor assigns existing HCPCS codes to new DME items. The HCPCS code assigned by PDAC to Signifier's eXciteOSA on April 23, 2021 is A9270. The descriptor for A9270 is non-covered item or service.

So, what does this mean for your reimbursement of eXciteOSA?

For Medicare patients, the DME supplier is required to submit a claim with the non-covered code, A9270. Medicare will likely deny payment; therefore, the financial responsibility will transfer to the patient. There is an option to appeal the denial after a device is delivered, by asking for a coverage exception to this non-covered determination. This process can take many months with uncertainty relative to timelines. See Section 6, *Appealing when a submission has been denied*.

For non-Medicare patients, PDAC code assignments may or may not apply, depending on individual health insurance plans. Commercial payers have not issued guidance on alternative coding for eXciteOSA® so your support team should consult with your insurance provider to identify appropriate coding. A DME Supplier can use the *Payer Summary Reference* tool to help describe eXciteOSA® to the plan.

F. Coverage Status

A coverage policy is how health insurance companies define whether a medical procedure, diagnostic test or a device, like eXciteOSA® is reasonable and necessary for specific patient categories. Since eXciteOSA® is new, there are no guidelines established on a national level. Expect that your insurer may be unaware of eXciteOSA® device for mild OSA and thus will likely not have a coverage policy. Insurers will likely request additional information or documentation to make a case-by-case determination.

SECTION THREE: STEPS IN THE INSURANCE PROCESS

Here are the steps you can take while working alongside your healthcare team. Note some steps may occur in simultaneously and some sequentially.

1. **Pre-Work: gathering information from your plan**
2. **Working with your Physician**
    a. Physician documents medical necessity
    b. Physician writes eXciteOSA® prescription
    c. Physician provides documents to supplier
3. **Working with your Supplier**
    a. Supplier will verify your insurance benefits for eXciteOSA®
    b. Supplier will submit Pre-Determination of Benefits or a Pre-authorization, if applicable.
        i. Health insurance plan issues authorization or a denial.
    c. Supplier delivers eXciteOSA® to patient
    d. Supplier submits claim to health insurance plan
        i. Health insurance plan issues payment or denial to supplier.

Your Supplier will work with the health insurer on your behalf to bill for eXciteOSA®. Your provider and DME supplier will collect your insurance card information to verify current insurance benefits, inquire about co-insurance, co-pays, deductibles, and coding and coverage information. This is called the **Verification of Benefits** step. This can prevent billing issues and surprise billing.

With some **Commercial** and **Medicaid Plans**, pre-authorization, sometimes called pre-determination or pre-certification, may be required for certain codes or products and services of certain monetary value before you receive them. **Pre-authorization** allows your health insurer or plan to review medical documentation and information about a product to make a determination that a service or product is medically necessary.

Take note, preauthorization is not a promise your health insurance or plan will cover the cost. If a pre-authorization has been denied, your provider can appeal to see if your case can be overturned. Traditional **Medicare** does not pre-authorize products and services. Your health care provider will need to review everything in your medical chart to verify that eXciteOSA is medically necessary for you before you are able to move through the insurance process and receive your eXciteOSA® starter kit.

After your supplier confirms insurance benefits, and patient responsibility, you may schedule your eXciteOSA® delivery. Next, your DME supplier will work on your behalf to file a **claim** to your health insurer, which is a request for payment for items or services. Depending on the code and requirements for the code, the health insurer could proceed with payment, request additional information, or deny the claim. Since eXciteOSA® does not have a unique code, the post-delivery and post-claim submission may not have a typical timeline or result. If your health insurer allows your DME supplier or physician to pre-authorize your device, this can take some of the uncertainty out of the process, but does not guarantee payment or a smooth process.

Bold terms in this section can also be found in ***SECTION SIX: DEFINITIONS***.

SECTION FOUR: PRE-WORK, QUESTIONS TO ASK YOUR HEALTH INSURER

Navigating insurance and trying to find out specific information about coverage of supplies or devices can be complex and confusing, even for longstanding therapies with established reimbursement. No novel device starts with an established and recognized HCPCS code. If it meets the definition of an existing code, it means that it is not the first of its kind to be sold in the marketplace.

As an early adopter, you will be part of a group who will pave the road towards the potential of eXciteOSA® coverage.

We encourage you to be informed as possible, and you can start by collecting basic information from your health insurer.

What to expect when calling your insurance provider:

Ask a lot of questions and yet understand that some answers will not include direct answers. Customer service representatives at your health plan are trained to give general answers. When a device is completely new and there's no public policy, the representative will be trained to direct you to policies that may guide the decision process. Note that your case will likely be reviewed by a next level specialist who has more experience than the person trained to answer the phone. This specialist can be a coder, medical review employee with a medical license, or someone who has been trained in reviewing these non-typical cases.

Script: Explaining eXciteOSA® to your commercial insurance provider or Medicaid plan

(this only applies to non-Medicare insurance, as HCPCS code A9270 applies to Medicare claims)

eXciteOSA® is a non-invasive tongue neuromuscular electrical stimulation (NMES) device to treat mild OSA. It is a prescription device that has been cleared by the FDA, but it does not have a unique HCPCS code to describe its function and treatment indication. There are no neuromuscular electrical stimulation HCPCS codes specific for the tongue muscles or to treat mild OSA. [Pause if necessary] eXciteOSA® has three components: a controller that is durable, a removable mouthpiece that is replaced every 90 days, and a smart phone application that monitors and administers the electrical stimulation therapy. The controller can be rented and used for successive patients as necessary or purchased. I've discussed this treatment option with my physician and I would like to find out information about my insurance benefits and the process to determine if the eXciteOSA® neuromuscular electrical stimulation device is covered.

Follow-up coding questions:

1. What is the process for determining the correct code that the supplier should bill for the device my physician has prescribed?
2. Do you reference PDAC for coding decisions?
3. Are there any cases where you would not allow a miscellaneous code to be billed for a new device on the market?

Follow-up Prior Authorization questions:

1. Do these codes: E1399 or A9279 require pre-authorization or pre-determination?

For reference:

HCPCS Codes	Type of Code	Short Descriptions	Notes
E1399	Miscellaneous code	Durable Medical Equipment, miscellaneous	Payer determines the appropriateness of using code and product coverage on case by case basis
A9279	Not Otherwise Classified Code	Monitoring feature/device	Payer determines code coverage

Follow-up Coverage questions:

This device meets Medicare's Durable Medical Equipment definition.

> *Durable medical equipment is equipment which (a) can withstand repeated use (i.e., can be rented), (b) for items classified as DME after January 1, 2012, has an expected life of at least three years, (c) is primarily and customarily used to serve a medical purpose, (d) generally is not useful to a person in the absence of an illness or injury, and (e) is appropriate for use in the home.*[14]

1. Do you have a medical coverage policy for **Durable Medical Equipment and Supplies** or a general medical coverage policy on **Neuromuscular Electrical Stimulation** devices? Which policy would be more applicable? Please send me these documents.
2. What documents are required for my supplier to document medical necessity? Does this include documentation required with my claim when submitting a miscellaneous code?
3. If coverage is denied, will you direct me to the process for appealing?

As a reminder, your DME supplier can ask these or similar questions if you are seeking reimbursement from your health insurer. Only a select group of suppliers may have a contract with Signifier Medical Technologies to dispense eXciteOSA®. Some may have a policy to offer it for cash pay and some may work with you to submit it to insurance.

Written Policies:

Your health plan is likely to have a Durable Medical Equipment (DME) policy that would be the guide for your coverage unless other policies supersede this. These coverage policies can also be found in either your Plan Summary Document or your Summary of Benefit and Coverage.

Plan Summary Document A document that health insurance participants what the plan provides and how it operates. It provides information on when an employee can begin to participate in the plan and how to file a claim for benefits. If a plan is changed, participants must be informed, either through a revised summary plan description, or in a separate document, called a summary of material modifications.

Summary of Benefits and Coverage A uniform template that uses clear, plan language to summarize key features of the plan, such as covered benefits, cost-sharing provisions and coverage limitations.

Common Coverage Policy Search Terms from the Plan Summary Document or Summary of Benefits and Coverage:

- Durable Medical Equipment (DME)
- Neuromuscular electrical stimulation device (NMES)

- Treatments for Sleep Apnea

You can look for these written policies, but sometimes they can be hard to find. This is why you may find it easier to call the health insurer directly.

Bold terms in this section can also be found in ***SECTION SIX: DEFINITIONS***

SECTION FIVE: WORKING WITH YOUR PHYSICIAN TO GATHER MEDICAL NECESSITY

Gathering documentation from your medical record, or medical necessity, is a very important part of the process for health insurance coverage and payment. The justification needed will vary by payer. Medicare and other payers have not yet established a policy for eXciteOSA®'s neuromuscular electrical stimulation device. Outlined here is a generic checklist based on other OSA coverage policies, so that you can follow along in the process. Your DME supplier and physician will work behind the scenes to gather chart notes from office visits, lab/test reports, and other applicable records. Work with your treating physician to understand the appointments that need to be scheduled in order to support your case for eXciteOSA®.

It is important to note that if your insurance allows pre-authorization, a letter called a Letter of Medical Necessity (LMN) authored by your physician, is an efficient way to package everything that will be submitted to insurance. However, the trend is that insurers may not accept an LMN on its own – you will want to include relevant medical records. Ideally, the LMN acts as a cover letter to your relevant medical records specific to OSA.

Documents that a supplier will gather:

(A supplier can be a DME supplier or a physician's office, if your commercial plan allows your physician to also be your medical equipment supplier)

1. Prescription for eXciteOSA® to treat mild OSA
    - For Medicare, the prescription must be signed by the physician who treats you and is managing your mild OSA symptoms.
2. Documentation of co-morbidities and symptoms accompanying OSA
    - Your plan may require that you document co-morbidities (the presence of another medical condition, which all together may affect the care and treatment of the primary condition) or other symptoms like the following: snoring, daytime sleepiness, difficulty breathing during sleep – gasping/choking/interruptions in breathing patterns, morning headaches, moodiness, impaired cognition, insomnia, hypertension, history of stroke or heart disease etc.
3. Dental Exam to rule out cavities, dental implants, metal prosthesis, metal braces, dental appliances, and intraoral metallic jewelry/piercings.
4. Physical Exam addressing the diagnosis of mild OSA
    - Includes: Cardiopulmonary and upper airway evaluation, Evaluation of the physical anatomy of the upper airway (tongue, mouth, nasal passageway, neck etc.), Body Mass Index etc.
    - Because this is a neuromuscular stimulation device, it may be also important to confirm via a history that you do not have any neurological contributors to your OSA. For example, you have a degenerative nerve disease that would affect the nerve supply to the mouth/tongue. A stimulation device in this case, may not be able to address the root cause of your OSA.

- Your physician would also document the duration of your symptoms, what has been tried in the past, if it has worked or failed. If you have tried other treatments (prescription drugs, CPAP, oral appliances, or lifestyle changes) help your physician by giving clear and complete narrative while using these treatments.

5. A Sleep test, done at a facility or at home with a portable monitoring device
6. Your treating physician will need to document receipt of the sleep test & the interpretation (results)
7. Treatment Plan from a treating physician with the recommendation for eXciteOSA®

If you have specific questions about the eXciteOSA® device and your medical condition please contact your physician.

SECTION SIX: APPEALING WHEN A SUBMISSION HAS BEEN DENIED

Always work with your DME supplier and physician to coordinate efforts if your pre-authorization or claim has been denied. A physician authoring an appeal cover letter can add value because they add additional medical perspective, professional learnings, and rationales to the case. Your medical records as outlined above will be the main justification for the device.

Cases with strong patient involvement (calling your insurance to check status or writing a personal appeal letter) have higher success rates. Even if you find that you are the one who will need to appeal and carry the process forward, your health care team is still a great resource since that have had experience with the appeal process before.

A. Do your research

You may have received an **Explanation of Benefits (EOB)**. If you do not also receive a copy of the denial sent to the DME Supplier, request a written copy of the reason your health insurer is denying your claim. This can be done by contacting your insurance provider's customer service department. The representative should be able to provide you with the specific reason that your claim was denied, but you should also request that a copy of the written denial be sent to you for your files. You may find that the written denial will contain additional explanations for the denial not discussed over the phone. Additionally, it will likely provide you with steps for appealing that decision.

Document the following:

Why was it denied?

1. If documentation was missing, what was missing?
2. If it was deemed not **Medically Necessary**:
    a. Ask why it was deemed not medically necessary.
    b. Were there records that need to be submitted that was not submitted?
    c. Ask what documentation you will need to send them in order to receive a favorable decision.
3. If it was determined that the device was "**experimental/investigational**", ask for their definition of experimental or investigational.

Collecting the timeline and next steps:

Verify the appeal process and specific deadlines on either the Explanation of Benefits (EOB) or the written denial.

1. You must submit each appeal within the stated timeframe or you may forgo (voluntary give-up) your rights to appeal.
2. If you don't receive instructions, contact your insurance provider as soon as possible to avoid missing deadlines.

Generally, you will be allowed up to 3 appeals with the insurance company depending on your plan. The first two are reviewed within the health insurer by different reviewers and the third can be an external review, meaning that the review is done by an independent party, not employed by the health insurer. Appellants find that this highest level of appeal is where there is more consideration for the individual patient case, especially if other interventions have been tried and failed or failed to meet the patient's treatment goals. Be patient. Getting to a third round of appeal can be a waiting game that takes persistence. After a third round of appeal there may be additional levels that involve the court system, for example, if you have Medicare plan, but your case will have to meet certain standards and monetary amounts to be considered.

Even if your device has been deemed as non-covered on the first submission, consider that this may be a boiler plate response to a device that doesn't have an official coverage policy due to the current coding situation. . Take the case argument to an advanced level (figuratively) and challenge their interpretation of the situation. Perhaps, they did not understand how this is a new technology category for which they may not have developed coverage policies. . Challenge the denial by appealing, especially if you have no other options to treat your condition.

Another option in the appeals process is called a peer-to-peer review. This can take the place of a written appeal and it is a scheduled phone call between your physician and a physician at your health plan. This can be a helpful for a physician to talk to a physician, especially if the denial was due to medical necessity. If it is another type of denial for example that it was not covered by the plan- you'd likely want your DME supplier representative also on the call, as they may direct detailed questions about the code, which is a supplier question, or specific clinical studies, which can catch anyone off guard at times if not recently reviewed from the *eXciteOSA® Clinical Dossier*.

B. Making a Strategy

After you are informed about services your insurer will pay for and will not pay for, who to contact if you have a dispute about coverage, the procedures for settling disputes about coverage, and the time limits on appealing a plan's decision, it's time to make a strategy.

If you are taking on this responsibility of appealing, request copies of your medical records from your health care providers (general physician, sleep physician, ENT physician, Otolaryngologist, sleep technician) as outlined in *Working with your Physician to Gather Medical Necessity* Section.

Be persistent and don't give up. Use the following strategies according to the reason for denial as outlined below.

C. Types of Denials

There can be various reasons for your eXciteOSA® pre-authorization or post-claim submission denial. It is important to understand the basis for the denial to make sure you are using your time and resources wisely to meet your appeal deadline. Your opportunities for appeal may also be limited by nuances, like did you sign an **Advanced Beneficiary Notice of Non-coverage (ABN)** or a **Notice of Financial Responsibility** document prior to receiving your device? In this case, you may still proceed with an appeal, but the probability of overturning a denial may be less likely. Documents such as ABNs or the equivalent are when your DME supplier has good reason to believe that your health insurer will not cover eXciteOSA® or that you may not have all the medical records to show medical necessity. If you have any questions on why your health insurer may not cover the device, be sure to understand the supplier's perspective, including any of the following: conversations they have had with your insurance, outcome of a pre-authorization submission, and history of experiences working with your insurance plan.

1. Medically Necessary Denial

Denials stating that a therapy like eXciteOSA® are "not medically necessary" are all about your medical records (tests, physical exams, evaluations, treatment plans) to support your need for eXciteOSA® and the rationale regarding use of eXciteOSA® over other alternative treatments or therapies. It will be helpful to confirm with your health provider what medical records were made available to the health insurer. Identify if the health insurer believes that anything was missing. Use the section *Working with your Physician to Gather Medical Necessity* in this guide, to make sure you've gathered a throughout and complete list of medical records/chart notes to attached to your appeal cover letter.

2. Experimental and Investigational Denials

Each health insurer may have different coverage standards for new or novel devices. Some may have very stringent evidence requirements before coverage is allowed on a widespread scale. The strategy with experimental and investigational denials is to obtain the health insurer's definition.

Next, work with your physician to see if there are grounds to show that eXciteOSA® is not experimental per their definition. Since most definitions will have to either do with clinical evidence or widespread acceptance, your physician has the best background to review the evidence interpretation. In the appeal, include the *Payer Summary Reference* document and the *eXciteOSA® Dossier*. The *Payer Summary Reference* gives the health insurer facts that explain the product in terms they understand for a quick, but through check. The *eXciteOSA® Dossier* explains the evidence on eXciteOSA® and comparable treatments.

3. Non-Covered Denials, Not a Covered Item or Benefit

A new durable medical equipment device, like eXciteOSA®, is not expected to have a medical policy to tell whether or not the device will be covered by the health insurance plan. Some insurers may have strict guidelines for adoption new therapies or products.

If the denial is based on interpretation of coverage, the lack of third party coverage references, or the fact that PDAC has listed the device with a non-covered code – it can be tough fighting a denial. The insurer may review your benefit plan and determine it is not covered. This is not a conclusion that the device is not medical necessary for your treatment, but that for some reason they have chosen not to cover eXciteOSA® as a routine health insurance benefit. It best to find out why, but sometimes a specific reason may not be well explained.

Unless you find an explanation that directs the focus of your appeal letter, you'll want to appeal using two main strategies.

1. Explaining why eXciteOSA® is a safe, effective, and a reputable alternative OSA device AND
2. *Ask for an exception to their policy based on your unique medical necessity.*

Explaining why eXciteOSA® is a safe, effective, and prescribed alternative OSA treatment

An optional rationale like the following can be used.

eXciteOSA® is safe

eXciteOSA® is FDA cleared class II prescription device that delivers neuromuscular stimulation to the tongue to reduce snoring and mild obstructive sleep apnea for patients that are 18 years or older. A Class II device is typically non-invasive. There have been no serious adverse effects observed in trials and any nonserious effects [excessive salivation, tooth and tongue discomfort, tongue-tingling, filling sensitivity, metallic taste, gagging, and mouth tightness] are transient, resolving after the 20-minute eXciteOSA® therapy is completed. Events tended to occur more commonly in the first few weeks of therapy and then reduced as the participants became familiar with the device.

Neuromuscular Electrical Stimulation (NMES) as a technology has been used for decades for various diagnoses and treatments.

eXciteOSA® is effective

The device has been tested in multiple clinical trials, which show a significant improvement in sleep apnea indices such as the Apnea-Hypopnea Index (AHI), the Oxygen Desaturation Index (ODI), Objective Snoring, as well as sleep quality and daytime sleepiness.

	Wesselleck et al *Somnologie*, 2018	**Nokes et al** *JCM*, Est 2021	**Kotecha et al** *Sleep & Breathing*, 2021	**Baptista et al** J. of Clinical Medicine 2021	**Nokes et al** *J. Applied Physiology* 2021
Change in AHI (events/hr)	Not captured	Mild OSA: -3.4 (from 10.2 to 6.8) In 79% of pts: -52%	Mild OSA: -5.1 (from 9.8 to 4.7)	Not captured	OSA: -11.3 from 19.7 (7.9) to 8.4 (2.2)
Change in ODI events/hr	Not captured	Mild OSA: -2.5 (from 8.4 to 5.9) In 79% of pts: -50%	Mild OSA: -3.5 (from 7.8 to 4.3)	Not captured	Not captured
Change in ESS units	Not captured	Mild OSA: -3.4 (from 8.7 to 5.3) In 79% of pts: -3.9	Mild OSA: -3.9 (from 9.0 to 5.1)	Not captured	OSA: -0.3 (from 5.5 to 5.2)
VAS	Mild OSA: -3, from 6.6 to 3.6) Snorers: - 3.7 (from 6.4 to 2.7)	Mild OSA: -2.39 (from 6.28 to 3.89)	Snorers/Mild OSA:-1.90 (from 5.88 to 3.98)	• VAS score reduced in 89% of the participants	PSQI: OSA: -0.8 (from 5.7 to 4.9)
Objective snoring*	Not captured	Not captured	Not captured	• Reduced in 90% of participants, with average reduction of 46%	Not captured
Partner reported snoring	Reduced by 52%	Not captured	Not captured	• Reduced in 89% of participants, with an average reduction of 45%	Not captured
Adherence	Not captured	83%	Not captured	83%	81%

1. Wessolleck E, Bernd #, Dockter S, et al. Intraoral electrical muscle stimulation in the treatment of snoring. *Somnologie(Berl).* 2018;22(Suppl 2): S47-S52. Doi:10.1007/s11818-018-0179-z

2. Nokes B, Kotcha B, Wong PY, et al. Transoral awake state neuromuscular therapy for mild obstructive sleep apena. 2021, submitted for publication.
3. Kotecha B, Wong PY, Zhang, H. et al. A novel intraoral neuromuscular stimulation device for treating sleep-disordered breathing. [published online ahead of print, 2021 Mar 26] *Sleep Breath.* 2021; 10.1007/s11325-021-02355-7 https://doi.org/10.1007/s11325-021-02355-7
4. Baptista PM, Martinez 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 Apean. *J Clin Med*. 2021: 10(9): 1883. Published 2021 Apr 27. Doi: 10.330-/jcm10091883.
4. Nokes B, Schmickl C, Brena R, et al. The impact of daytime transoral neuromuscular stimulation on upper airway physiology in snoring and mild OSA. in review by Journal of Applied Physiology.

eXciteOSA® is a prescribed alternative to treat OSA

Not every patient may benefit from the current treatments for mild OSA.

Oral appliances are considered suitable, as their primary action is to advance the mandible and, in effect, reposition the tongue, thus enhancing the caliber of the retroglossal airway. Such MADs can be offered to patients to improve mild to moderate OSA. There is also evidence suggesting that oral appliances improve subjective sleepiness and SDB, compared with controls[1]. Oral appliances do have their downsides, however, including discomfort while wearing and cost of customization, and thus prescription or compliance to therapy is low.

Currently, CPAP is seen as the gold standard of treatment for moderate to severe OSA. However, CPAP can also be used in mild OSA patients that experience additional symptoms or comorbidities. For those who can tolerate CPAP, it is a highly effective treatment for OSA[1]. However, some people find CPAP masks difficult to tolerate because of high-pressure levels and other symptoms, such as aerophagia, nasal congestion, claustrophobia, and dryness of the mouth. Switching to machines that vary the level of air pressure required to reduce sleep disturbance could increase comfort and promote more regular use[2]. Still, CPAP's impact on normal life and normal sleep is considered high by most patients, especially for those with mild to moderate symptoms, and thus compliance is low.

Tongue muscle training using eXciteOSA® requires 'no night-time wearable' like a mouth or nasal mask for patients and overcomes many of the risks and disadvantages associated with the currently available treatment options. It also does not require setup or off-the-shelf/custom fitting of the device. eXciteOSA's® has adherence rates between 81-83%, which is a high adherence rate for a medical device. Two studies show a reduction of 52% reduction in AHI and 45% reduction in ODI.[3,4]

1. Oral appliances for obstructive sleep apnoea. Lim J, Lasserson TJ, Fleetham J, et al. 2006, Cochrane Database of Syst Rev, Vol. 4, p. CD004435. doi.org/10.1002/14651858.CD004435.pub2. 1465-858.

2. Pressure modification or humidification for improving usage of continuous positive airway pressure machines in adults with obstructive sleep apnoea. Kennedy B, Lasserson TJ, Wozniak DR, et al. 2019, Cochrane Database of Syst Rev, Vol. 12(12), p. CD003531. doi.org/10.1002/14651858.CD003531.

3. Transoral awake state neuromuscular therapy for mild obstructive sleep apnea. Nokes B, Kotecha B, Wong PY, et al. 2021, Journal of Clinical Medicine (submitted for publication).

4. A novel intraoral neuromuscular stimulation device for treating sleep-disordered breathing. Kotecha, B., Wong, P.Y., Zhang, H. et al. 2021, Sleep & Breathing. https://doi.org/10.1007/s11325-021-02355-7

Asking for an Exception to your Coverage Policy

Typically when asking for exception to the coverage policy or for individual consideration, the appeal will go directly to a medical director. You will have a better chance for an exception if there is documentation of other products failing and/or there is a unique medical need (e.g. co-morbidities of sleepiness and the symptoms

have a threat to job safety or the serious concern affecting work/home life). You now have a responsibility to work with your physician and gather the medical record to fully detail the rationale and history of your medical need.

Formulate the argument for your specific need to justify why it is in their best interest to allow an exception. After all, they cover DME devices all the time that are equal to the cost of eXciteOSA®. Plus, NMES devices have been around for decades, exhibiting that the technology is safe.

What if your insurance plan is an employee administered plan and I need to ask for an Exception to the Coverage Policy?

An employee administered plan is more common when you work for a large employer. The employer contracts with a commercial insurance, but they do not purchase the typical commercial plans. They choose to manage their own health insurance funds and leave the administration to the commercial plan. This type of insurance plan influences what health insurance claims are paid and who decides in the case that a product or service is denied. It's not uncommon for the first few denials to be processed through the commercial plan, but on the 3rd level of an appeal, typically an external review, to be brought in-house for a formal decision or reviewed by board appointed by the employer.

The denial letter from the health insurance plan or the Employee Handbook are two places that you can look for steps outlining the full appeal process. You can also go to your HR department that wrote the contract and purchased the plan to get more information about the process of appeal.

1. Ask if the company would be willing to make an exception

- Ask them what is the process for making an exception or appealing
- Ask them to create a rider to the policy
    - A rider is an addendum to the insurance contract that is used to add specific detail and conditions to the original contract.
    - This may take more time than your appeals process will allow

4. Prior Use of a CPAP or custom oral appliance device (e.g. Somnodent Herbst Classic, Flex, or Advanced Flex etc.) needed

While there is no medical society recommendation that requires prior use of a CPAP or oral appliance device, this denial reason may be used by your health insurer to limit coverage. CPAP is considered the Standard of Care treatment for OSA, as it is widely studied and recommended by medical societies.

In this case that you have not had a history with a CPAP or custom oral appliance device, have your physician write why you are not a candidate for these devices. Perhaps, you have a specific medical situation where these devices would not meet your treatment goals or these devices would be contra-indicated. Is there a lifestyle consideration where you would not be able to be compliant with sleep time routine? If so, use these reasons in an appeal.

At the end if you have exhausted all appeals and options, do have other treatment options that your physician has indicated? You may need to make a choice at this time if you are willing to try them first. If they don't work, you could always request the eXciteOSA® again after your trial with the other devices.

D. How to write an Appeal

When putting together an appeal cover letter you want to follow a basic format:

- Restate the reason why the claim was denied
- State why you disagree with the determination using their terms
- Give your narrative of your diagnosis of mild OSA, your symptoms, what you have tried for treatment, and why you believe use of eXciteOSA® will help treat your mild OSA.
- If you already have experience using the device, you can narrate any observations, improvements, and changes you have experienced.
- Lead them down the path of proof of why you think the claim should be paid.
- Include a bulleted list of medical records attached.

To download sample appeal templates that will require your customization, see the eXciteOSA® website page, https://exciteosa.com/support-hub/reimbursement/.

Conclusion

Again, be persistent in advocating for yourself and don't be afraid to ask for assistance in every step of the way – from your medical team to a trusted person who can proofread your appeal.

Bold terms in this section can also be found in ***SECTION SIX: DEFINITIONS***.

SECTION SEVEN: PATIENT FREQUENTLY ASKED QUESTIONS / FREQUENT SITUATIONS

Question: What HCPCS code should be used to report the eXciteOSA® device?

Answer: Your health insurance billing support team should check with the insurance payer for appropriate HCPCS codes to be billed. If your DME supplier disagrees with a HCPCS code an insurance provider suggests, they can make their case to the health insurance company. With eXciteOSA® being a new product on the market to treat OSA, it is not uncommon to need to explain the device in detail. Insurance plans may vary in the HCPCS codes they determine to be appropriate, because there is no unique code to describe a tongue neuromuscular stimulation control unit and mouthpiece for the treatment of OSA. Some may reference Medicare's verified code, A9270, on www.dmepdac.com and some may make their own determination.

Question: **What diagnosis is indicated for the eXciteOSA® device?**

Answer: You may have either one or both of the following diagnoses you would meet the FDA indications for eXciteOSA®.

ICD-10-CM Diagnosis Code[1]	Description
G47.33	Obstructive sleep apnea (adult) (pediatric)[2]
R06.83	Snoring[3]

1. Diagnosis codes should be reported to the highest level of specificity available – a code is invalid if it has not been coded to the full number of digits required for that code.

2. eXciteOSA® is only indicated for mild obstructive sleep apnea, which is an AHI between 4 and 15. It is also only indicated for adults (18 years and older).

3. If you do not have a diagnosis of obstructive sleep apnea, but have a diagnosis of snoring, check with your health insurance provider if snoring devices are covered under your plan. If your health insurance does not cover snoring devices, a health savings account plan may allow you to purchase prescription devices.

Question: What if my supplier asks me to pay for the eXciteOSA® device upfront?

Answer: Your supplier may ask for payment upfront or for a credit card to charge in the case your insurance payer does not cover or pay for the eXciteOSA® device. Partner with your medical support team and request they research what your plan may or may not cover. Basic questions like what code is appropriate, does your insurance require prior authorization, what are your payment responsibilities (co-pays, deductibles, and out-of-pocket), and best and worse-case scenario should be part of the discussion. If they are unwilling to partner with you in this research or if they only sell eXciteOSA® as a cash item, you may have to initiate this research yourself. *First*, call your insurance plan and ask the questions in the *Pre-Work, Questions to ask your Health Insurer* section. *Second*, ask if you can submit a patient claim to your insurance or if it is required to have a supplier bill on your behalf. The actual claim submission happens post-purchase. If you do not have the ability to submit a patient claim – ask the supplier referral if they will submit one for you. They may be willing to do so – but you may need to work with your physician to ensure that there is documentation for medical necessity and to be the advocate in the case of a denial. *Last*, in the case of a denial, see the section, *Appealing when a submission has been denied.*

Question: May I use my HSA or FSA account to pay for the eXciteOSA® device?

Answer: Typically, HSA or FSA plans allow use of pre-tax dollars for medical expenses prescribed by a physician. However, tax rules change and plans may have specific exclusions. Please confirm any rules or restrictions with your plan administrator.

SECTION SIX: DEFINITIONS

Medical Definitions

Sleep-Disordered Breathing *often referred to as Obstructive Sleep Apnea (OSA), is characterized by frequent episodes of hypopnea or apnea during sleep. Multiple detrimental physiologic changes may result from these hypopneic and apneic episodes.*[4]

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]

Insurance Definitions

Advanced Beneficiary Notice of Non-Coverage for Medicare or Notice of Financial Responsibility for Commercial Plans: An Advance Beneficiary Notice of Non-Coverage is a written notice a supplier gives to a beneficiary before provided an item and/or service. It is issued when the supplier/health care provider believes that Medicare may not pay for an item and is expected to be denied by Medicare based on lack of medical necessity or the fact that Medicare does not usually pay for this service.[9]

Allowed Amount: The maximum amount a plan will pay for a covered health care service. May also be called "eligible expense", "payment allowance," or "negotiated rate."[10]

Appeal: A request for your health insurance company to review a decision that denies a benefit or payment. [10]

Attestation: To attest to the truth of the information provided by signing a statement or a form. [10]

Authorized Representative: Someone who you choose to act on your behalf, like a family member or other trusted person. Some authorized representatives may have legal authority to act on your behalf. [10]

Benefits: The health care items or services covered under a health insurance plan. Covered benefits and excluded services are defined in the health insurance plan's coverage documents. [10]

Claim: A request for payment that you or your health care provider submits to your health insurer when you get items or services you think are covered. [10]

Coinsurance: The percentage of costs of a covered health care service you pay (for example 20% with Medicare) after you've paid your deductible. [10]

Commercial Health Insurance: Health insurance provided and administered by non-governmental entities. Plan offerings, to a degree, are often regulated and overseen by each state. [9]

Coordination of Benefits: A way to figure out who pays first when 2 or more health insurance plans are responsible for paying the same medical claim. [10]

Copayment or Co-pay: A fixed amount ($20, for example) you pay for a covered health care service after you've paid your deductible. [10]

Deductible: The amount you pay for covered health care services before you insurance plan starts to pay. With a $2,000 deductible, for example, you pay the first $2,000 of covered services yourself. [10]

Durable Medical Equipment (DME): Equipment and supplies ordered by a health care provider for everyday or extended use. Examples include, oxygen equipment, wheelchairs, or crutches. [10]

ERISA: is the abbreviation for the Employee Retirement Income Security Act of 1974. It is a federal law that sets minimum standards for the most voluntarily established retirement and health plans in private industry to provide protection for individuals in these plans. ERISA has established minimum requirements for plan processes and interactions with participants.[12]

Excluded Services: Health care services that your health insurance or plan doesn't pay for or cover. [10]

Exemption: Granted in circumstances where typically other rules and procedures would apply and dictate other outcomes. [10]

Experimental/Investigational Device: The terms "unproven, experimental or investigational" are generically defined as: A supply, procedure, therapy or device whose effectiveness has not been demonstrated by required scientific evidence and properly authorized by governing entities in order to be acknowledged as medically effective for the improvement of function for specific conditions or treatment. [9]

Explanation of Benefits (EOB): A summary of the total charges for your visit/product/service and how much your health plan will pay. An EOB is not a bill. [9]

External Review: A review of a plan's decision to deny coverage for or payment of a service by an independent third-party no related to the plan. If the plan denies an appeal, an external review can be requested. External review is available when the plan denies treatment based on medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, when the plan determines that the care is experimental and/or investigational, or for rescissions of coverage. An external review either upholds the plan's decision or overturns all or some of the plan's decision. The plan must accept this decision. [10]

Fee for Service: A method in which doctors and other health care providers are paid for each service performed. Examples of services include tests and office visits. [10]

Group Health Plan: In general, a health plan offered by an employer or employee organization that provides health coverage to employees and their families. [10]

HCPCS codes (pronounced HICK-PICKS): HCPCS is a standardized coding system necessary for medical providers to submit health claims to Medicare and other health insurance in a consistent and order manner. HCPCS Level II codes sets is used primarily to identify products, supplies, and services such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office.[13]

Health Coverage: Legal entitlement to payment or reimbursement for your health care costs, generally under a contract with a health insurance company, a group health plan offered in connection with employment, or a government program like Medicare, Medicaid, or the Children's Health Insurance Program (CHIP). [10]

Health Insurance: A contract that requires your health insurer to pay some or all of your health care costs in exchange for a premium. [10]

Health Maintenance Organization (HMO): A type of health insurance plan that usually limits coverage to care from doctors who work for or contract with the HMO. It generally won't cover out-of-network care except in an emergency. HMOs often provide integrated care and focus on prevention and wellness. [10]

Health Savings Account (HSA): A type of savings account that lets you set aside money on a pre-tax basis to pay for qualified medical expenses. By using untaxed dollars in a Health Savings Account (HSA) to pay for deductibles, copayments, coinsurance, and some other expenses, you may be able to lower your overall health care costs. HAS funds generally may not be used to pay premiums. While you can use the funds in an HSA at any time to pay for qualified medical expenses, you may contribute to an HAS only if you have a High Deductible Health Plan (HDHP) that only covers preventive services before the deductible.[10]

High Deductible Health Plan (HDHP): A plan with a higher deductible than a traditional insurance plan. The monthly premium is usually lower, but you pay more health care costs yourself before the insurance company starts to pay its share (your deductible). A high deductible plan (HDHP) can be combined with a health savings account (HAS), allowing you to pay for certain medical expenses with money free from federal taxes. [10]

Individual Health Insurance Policy: Policies for people that aren't connected to job-based coverage. Individual health insurance policies are regulated under state law. [10]

Medicaid: Insurance program that provides free or low-cost health coverage to low-income people, families and children, pregnant women, the elderly, and people with disabilities. [10]

Medically Necessary: Health care services or supplies needed to diagnose or treat an illness, injury, condition, disease or tis symptoms and that meet accepted standards of medicine. [10]

Medicare: A federal health insurance program for people 65 and older and certain younger people with disabilities. It also covers people with End-Stage Renal Disease (ESRD). [10]

Network: The facilities, providers and suppliers your health insurer or plan has contracted with to provide health care services. [10]

Non-preferred provider: A provider who doesn't have a contract with your health insurer or plan to provide services to you. You'll pay more to see a non-preferred provider. Check your policy to see if you can go to all providers who have contracted with your health insurance or plan, of if your health insurance or plan has a "tiered" network and you must pay extra to see some providers. [10]

Out-of-Pocket Costs: Your expenses for medical care that aren't reimbursement by insurance. Out-of-pocket costs include deductibles, coinsurance, and copayments for covered services plus all costs for services that aren't covered. [10]

Plan: A benefit your employer, union or other group sponsor provides to you to pay for your health care services.[10]

Plan Summary Document: A document that health insurance participants what the plan provides and how it operates. It provides information on when an employee can begin to participate in the plan and how to file a claim for benefits. If a plan is changed, participants must be informed, either through a revised summary plan description, or in a separate document, called a summary of material modifications.[11]

Preauthorization or Predetermination: A decision by your health insurer or plan that a health care service, treatment plan, prescription drug or durable medical equipment is medically necessary. Sometimes called prior authorization, prior approval or precertification. Your health insurance or plan may require preauthorization for certain services before you receive them, except in an emergency. Preauthorization isn't a promise your health insurance or plan will cover the cost. [10]

Preferred Provider: A provider who has a contract with your health insurer or plan to provide services to you at a discount. Check your policy to see if you can see all preferred providers or if your health insurance or plan has a "tiered" network and you must pay extra to see some providers. Your health insurance or plan may have preferred providers who are also "participating" providers. Participating providers also contract with your health insurer or plan, but the discount may not be as great, and you may have to pay more. [10]

Prior Authorization: Approval from a health plan that may be required before you get a service or fill a prescription in order for the service or prescription to be covered by your plan. [10]

Rider: A rider is an amendment to an insurance policy. Some riders add coverage. [10]

Self-Insured Plan: Type of plan usually present in larger companies where the employer itself collect premiums from enrollees and takes on responsibility of paying employee' and dependents' medical claims. These employers can contract for insurance services such as enrollment, claims processing, and provider networks with a third party administrator, or they can be self-administered. [10]

Summary of Benefits and Coverage: A uniform template that uses clear, plan language to summarize key features of the plan, such as covered benefits, cost-sharing provisions and coverage limitations.[11]

Verification of Benefits: The process of verifying the patient's active medical benefits with the insurance company. This can prevent billing issues and surprise billing.[9]

SECTION SEVEN: REFERENCES

1. 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.
2. 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.
3. 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.
4. Centers for Medicare and Medicaid Services. Medicare Coverage Database. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Surgical Treatment of Obstructive Sleep Apnea (OSA) (L34526). Accessed from https://www.cms.gov/medicare-coverage-database/new-search/search.aspx on July 20th, 2021.

5. CGS Administrators, LLC. Durable Medical Equipment Medicare Administrative Contractor (DMEMAC) Jurisdiction C. DMEPOS Requiring Claim Narratives Chart. Revised February 22, 2021. Accessed from https://www.cgsmedicare.com/pdf/dme/dme_claims_narratives_chart.pdf on July 20th, 2021.
6. Palmetto GBA LLC. PDAC – Medicare Contractor for Pricing, Data Analysis and Coding of HCPCS Level II DMEPOS Codes. Durable Medical Equipment Coding System (DMECS) Product Classification List. Accessed from https://www4.palmettogba.com/pdac_dmecs/initProductClassificationResults.do on July 20th, 2021.
7. Palmetto GBA LLC. Pricing, Data Analysis and Coding (PDAC) Contractor. HCPCS Award Letter for eXciteOSA. July 3, 2021.
8. 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
9. Centers for Medicare and Medicaid Services. General Definition Search. www.cms.gov
10. Centers for Medicare and Medicaid Services. Programs and Initiatives. Consumer Information and Insurance Oversight. Marketplace Resources. www.healthcare.gov
11. U.S. Department of Labor. Health Plan and Benefits. Plan information. https://www.dol.gov/general/topic/health-plans/planinformation
12. U.S. Department of Labor. Health Plan and Benefits. ERISA. https://www.dol.gov/general/topic/health-plans/planinformation
13. American Academy of Professional Coders. Codify. HCPCS. https://www.aapc.com/codes/hcpcs-codes-range/
14. CGS Administrators, LLC. DME MAC Jurisdiction C Supplier Manual. Coverage and Medical Policy Chapter 9. DMEPOS Benefit Categories. Durable Medical Equipment (DME). Accessed from https://cgsmedicare.com/jc/pubs/pdf/dme_jc_supman_full_summer2021.pdf on August 3, 2021.

SECTION EIGHT: ADDITIONAL SUPPORT

For additional assistance please contact Signifier Medical Technologies via email at **reimbursement @signifiermedical.com** or call **844-MILDOSA** to talk to a representative that will direct you to a reimbursement specialist. You can access additional reimbursement tools at https://exciteosa.com/support-hub/reimbursement/ and additional sample template letters may be available upon request.

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HCPCS disclaimer: HCPCS codes and their descriptions do not reflect or guarantee coverage or payment. Just because a HCPCS code exists, payment for the service it describes is not guaranteed. Coverage and payment policies of governmental and private payers vary from time to time and for different areas of the country. Questions regarding coverage and payment by a Payer should be directed to that Payer. It is the DME supplier's responsibility to accurately code eXciteOSA®. HCPCS codes may be subject to revision based on alpha-numeric system changes or additional information.