

# eXciteOSA® Product Information

## Payer Summary Reference

### Description

eXciteOSA® is a tongue neuromuscular electrical stimulation (NMES) device for Obstructive Sleep Apnea (OSA) with adjustable stimulation manufactured by Signifier Medical Technologies, LLC.

The complete device includes 5 parts:



1. **Mouthpiece** – a universal-sized silicone disposable mouthpiece with 4 electrodes, which must be replaced every 90 days. Single patient use only.



2. **Control unit (with Bluetooth)** – a durable control unit with life expectancy of at least 36 months, which can be cleaned and refurbished for use by multiple successive patients.



3. **eXciteOSA application download instructions** - QR code and instructions to download and install eXciteOSA app onto your smartphone.



4. **USB-C charging cable** – connects to the control unit via USB connection.



5. **Cleaning cap** – cap to cover the USB port while cleaning the mouthpiece.



### FDA Status

The eXciteOSA® is a Class II device, with special controls. It received FDA De Novo classification, DEN200018, on February 5, 2021 and is listed as a neuromuscular tongue muscle stimulator for the reduction of snoring and obstructive sleep apnea under 21 CFR 872.5575.

This is a prescription device that complies with 21 CFR 801.109 and has met all applicable other requirements, including, but not limited to: registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), medical device reporting (21 CFR Part 807), good manufacturing practices (21 CFR Part 820), and as applicable, electronic product radiation control provisions (Sections 31- 542 of the FD&C Act), and general and specific standards according to 21 CFR 1000-1050.

### eXciteOSA® Coding

Healthcare Common Procedure Coding System (HCPCS) Level II Codes for Durable Medical Equipment, Prosthetic, Orthotics, and Supplies (DMEPOS) applies to medical devices used in the home.

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### Medicare Coding and Billing<sup>1-2</sup>:

The Centers for Medicare & Medicaid Services (CMS) is responsible for creating new HCPCS codes. CMS established the following Level II HCPCS codes to describe eXciteOSA, which became effective on January 10, 2024:

HCPCS Code	Description
E0492	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application.
E0493	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply.

*Per your User Guide, eXciteOSA is a single person device and should not be shared or used by other individuals. 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.*

The current IFU clarifies that the Control Unit can be used by multiple successive patients when refurbished.

### Other Payer Coding and Billing<sup>2</sup>:

Each individual insurance payer(s) may develop their own coding and coverage guidance for novel technologies not currently recognized by a unique HCPCS code.

The International Classification of Diseases uses the following codes to identify known diseases and other health problems.

2022 ICD-10-CM Diagnosis Code	Description
G47.30	Sleep apnea unspecified
G47.33	Obstructive sleep apnea (adult) (pediatric)

<sup>1</sup> PDAC verified code for EXCITEOSA effective April 23, 2021. Accessed at [www.dmepdac.com](http://www.dmepdac.com).

<sup>2</sup> Coding may be subject to revision based on additional information or alpha-numeric system changes.

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### Product Specific Codes:

Medicare's Pricing Data and Analysis Contractor (PDAC) has verified the new codes effective January 10, 2024.

Part Number	Product Description	HCPCS Codes*
13010	eXciteOSA starter kit includes a mouthpiece, control unit, eXciteOSA app download instructions, USB-C charging cable, and cleaning cap	E0492
16000	Replacement Mouthpiece	E0493

\*Verified by DME PDAC. It is DME Supplier's responsibility to bill correct codes.

### Warranty

Signifier Medical Technologies, LLC provides a warranty to the original purchaser confirming the product will be free from defects in the material, components, and workmanship for the period listed below.

1. Mouthpiece – 3 months.
2. Control unit (with Bluetooth) – 1 year.

The warranty does not include any misuse, abuse, or tampering with the unit. This warranty does not apply to "wear and tear" that would normally occur with usage.

### Indications for Use

eXciteOSA® is a removable tongue muscle stimulation device that delivers neuromuscular stimulation to the tongue in order to reduce snoring and mild OSA (AHI<15) for patients that are 18 years or older.

### Contraindications

Do not use eXciteOSA® if:

- You are pregnant or may be pregnant.
- You have a pacemaker or implanted electrodes.
- You have dental jewelry in the mouth.
- You are suffering from mouth ulcers.

Have or are suspected of having an AHI  $\geq 15$  as determined by evaluation by a Sleep Health Professional with a sleep study.

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### Precaution

Consult a Doctor/Dentist in these situations:

- Have gum disease or have bleeding from your gums or other oral conditions.
- Experience pain, numbness or bleeding after using this product.
- Have any medical concerns.

This device should not be used:

- While asleep (the device should only be used when awake)
- In contact with your head, neck, spine, chest, eyes, ears or any other parts of the body other than inside the mouth as instructed.
- The device has not been tested for MRI compatibility and should not be used in the vicinity of an MRI device.

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