**DATE**

**Insurance**

**Fax**

Re: Request for Prior Authorization for **[HCPCS Code]**, eXciteOSA

**Patient:**

**Policy number:**

**Claim number:**

**Diagnosis:**

Dear Utilization Review Manager:

I am writing on behalf of my patient, **NAME**, to appeal **INSURANCE** denial for pre- authorization for the use of the FDA approved **eXciteOSA** for the treatment of **DIAGNOSIS** and deemed not medically necessary on **DATE.**

Information related to the patient’s medical history, prognosis and treatment rationale are summarized below:

**[Insert a narrative of the patient’s medical history, including:**

* **Patient’s diagnosis, condition, and treatment history**
* **Previous therapies the patient has undergone for the disease symptoms**
* **Patient’s response to past tried and failed therapies**
* **Brief description of the patient’s recent symptoms and conditions]**

**[Summarize your professional opinion of the patient’s likely prognosis or disease progression without treatment with eXciteOSA]**

Given **[patient name]**’s medical history and the indications for the eXciteOSA, I am confident that you will agree that the use of eXciteOSA is medically necessary for my patient. Please do not hesitate to contact me at **[physician’s telephone number]** if you require any further information to approve this request.

eXciteOSA is an FDA approved non-invasive intraoral neuromuscular electrical stimulation (NMES) device indicated for the treatment of mild OSA. The device received De Novo clearance on February 5, 2021 due to its novel design and use as a daytime treatment option for OSA. eXciteOSA is used for 20 minutes daily over a six-week period and after the initial six weeks the device is used once per week. OSA patients experience a reduction in tongue muscle tone and loss of upper airway muscle endurance that results in excessive relaxation and obstruction. Unlike other treatment options for OSA, eXciteOSA targets a root cause of the apnea—the genioglossus (tongue) and upper airway musculature—with NMES to gain lasting improvements in the tongue’s endurance.1 eXciteOSA offers a safe and effective treatment option for mild OSA patients who are often left untreated.2-4

eXciteOSA offers the following patient benefits:

* **Improved Patient Outcomes** – demonstrated reduction in excessive daytime sleepiness2-4
* **Therapy Flexibility** – a daytime treatment option that only requires a daily 20-minute session, eXciteOSA’s physiological effect lasts even when not in use. The device is highly portable and discreet
* **Comfort** – eXciteOSA fits comfortably in the patient’s mouth at their convenience during the day while other sleep apnea treatment options require night-time wearables often not well tolerated
* **Burden Reduction** – eXciteOSA does not require setup or fitting of the device, there are fewer parts, and adherence is easily monitored via the eXciteOSA app and physician portal
* Greater **adherence** – eXciteOSA’s advantage can be attributed to the features listed above. Published literature reports a patient adherence rate of 83%2-3

The following peer reviewed publications will assist you in your evaluation of eXciteOSA:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Patient #** | 27  Mild OSA | n = 70  (38 Mild OSA) | n = 115  Snoring | n = 65  Mild OSA | n = 20  Mild OSA |
| **Objective** | VAS w Bed Partner Response | Single Center  Mild OSA & Snoring, Home Sleep Tests  AHI, ODI, ESS, PSQI & VAS | Multi-Center  Mild OSA & Snoring, Home Sleep Tests  AHI, ODI, ESS, PSQI & VAS | Multi-Center  Mild OSA & Snoring, Home Sleep Tests  AHI, ODI, ESS, PSQI & VAS | UCSD  Mechanstic Trial  Prove mechanism of action |
| **Publication date** | 09-2018 | 02-2021 | 04-2021 | Est 07-2021 | Est 08-2021 |
| **Journal** | Somnologie | Sleep & Breathing | Journal of Clinical Medicine | Journal of Clinical Sleep Medicine | Journal of Applied Physiology |

Sincerely,

**PHYSICIAN**

**FACILITY**

**Enclosures:**

Chart notes including imaging reports and test results

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1 Signifier Medical Technologies (SMT). eXciteOSA® Non-invasive intraoral neuromuscular stimulation device with clinically proven reduction of mild obstructive sleep apnea and primary snoring. 2020, White Paper (internal publication by SMT for FDA submission).

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

3 Baptista PM, Martínez Ruiz de Apodaca P, Carrasco M, et al. Daytime Neuromuscular Electrical Therapy of Tongue Muscles in Improving Snoring in Individuals with Primary Snoring and Mild Obstructive Sleep Apnea. J Clin Med. 2021;10(9):1883. Published 2021 Apr 27. doi:10.3390/jcm10091883.

4 Nokes B, Kotecha B, Wong PY, et al. Transoral awake state neuromuscular therapy for mild obstructive sleep apnea. 2021, Journal of Clinical Sleep Medicine (in review for publication, available upon request).

5 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*.

6 Wessolleck E, Bernd E, Dockter S, et al. Intraoral electrical muscle stimulation in the treatment of snoring. Somnologie, 2018. Vol. 22(Suppl 2), pp. S47–S52.