To Whom It May Concern:

As a practicing (**Physician type**), I am writing on behalf of my patient, (**Patient name**), to request that (**Name of Insurance Company**), approve coverage of eXciteOSA® -- Primary Mild Sleep Apnea Therapy.

**Patient Summary**

On (**Date**), (**Patient’s name**), an (**Age, Sex**) was diagnosed with Obstructive Sleep Apnea (OSA). OSA is a sleep-related breathing disorder that is characterized by recurrent episodes of complete or partial obstruction of the upper airway. The repetitive airway obstruction results in patients experiencing nocturnal asphyxia, fragmented sleep, major fluctuations in their blood pressure, and increased sympathetic nervous system activity [1].

OSA typically occurs when muscles around the airways weaken thereby leading to restriction or obstruction of airflow. A large body of research suggests that OSA is a progressive condition and left untreated (**Patient name**) would be at higher risk of developing other health complications such as:

* Secondary hypertension [2, 3]
* Stroke [4, 5]
* Heart failure [5]
* Cardiac arrhythmias [6]
* Atrial Fibrillation [5]
* Diabetes [7,8]

**Progression of OSA**

OSA is a chronic condition that is potentially progressive [9, 10, 11]. Left untreated, mild-to-moderate OSA can advance in scope and severity. Numerous studies suggest that it is essential to focus on the early diagnosis and active treatment of even a mild degree of OSA [9]. Doing so may prevent disease progression and the development of other more serious health complications.

According to one study, severe OSA confers a 2.6x increased risk of incident myocardial infarction, coronary revascularization and cardiovascular death after controlling for confounders such as body mass index [12]. The risk of ischemic stroke is also increased in patients with untreated OSA, particularly in men with an apnea–hypopnea index (AHI) of more than 19 events per hour or women with an AHI of more than 25 events per hour [12].

**eXciteOSA® Device Description Summary**

Conventional treatments for OSA attempt to alleviate the sleep-related airway obstruction episodes (Apnea or Hypopnea) that are the hallmark of OSA. However, treatments such as CPAP, a first-line option for the management of OSA do not modify the underlying disease and the treatment modality suffers from poor patient compliance and adherence. Other treatment options such as lifestyle changes or dental appliances are equally challenging to adhere to over time.

eXciteOSA® is a neuromuscular electrical stimulation (NMES) therapy device that targets the intrinsic and extrinsic tongue muscles by delivering low frequency stimulation to the tongue muscles and interlinked upper airway musculature. The device increases muscle endurance and prevents excessive relaxation of the tongue and airway during sleep.

Patients use eXciteOSA® by placing the mouthpiece onto the tongue. With two electrodes located on the superior and inferior surfaces of the tongue, the therapy consists of a series of pulse bursts with rest periods. It is used for 20 minutes during wakeful state for a therapy period of 6-weeks, followed by twice per week as a muscle maintenance program. eXciteOSA® provides a targeted retraining tool to stimulate the biggest dilatory muscle of the airway—the genioglossus muscle.

With daily use of eXciteOSA®, tongue and upper airway muscle function is improved. This prevents the tongue from collapsing backward and obstructing the airway during sleep. For patients that experience mild OSA, eXciteOSA® may be used as a first line treatment option or as an adjunct to support night-time device compliance [1].

In addition, for individuals where CPAP is not a suitable option, treatment with eXciteOSA® provides a lower-cost, minimally invasive alternative than the next step treatment options such as oral appliances or surgery.

**Clinical Efficacy**

Three peer-reviewed publications have validated the safety and effectiveness of eXciteOSA® for treating snoring and mild OSA. These studies show that eXciteOSA® works across a range of OSA metrics (AHI), body mass index (BMI), age, gender, and race. Highlights of the published results are summarized below:

**Significant Reduction in Apnea-Hypopnea Index (AHI) and Oxygen Desaturation Index (ODI)**

* Two trials using pre & post-therapy sleep studies demonstrated similar patient outcomes:
  1. Kotecha et al, n = 38 (of 70 snoring patients), AHI reduction from mean 9.8 to 4.7 (p<0.001) and ODI dropped from 7.8 to 4.3 [13]
  2. Nokes et al, n = 65 (of 115 snoring patients), AHI reduction from mean 10.3 to 4.9 (p<0.001) in 79% of participants; and ODI dropped from 8.6 to 4.3 [15]

**Significant Reduction in Snoring Using Objective Assessments**

* + - * In a 115 patient multi-center trial with eXciteOSA® using sleep study recorded snoring sound, objective snoring sound (all snoring above 40dB) was reduced on average 39% across 80% of participants. (p<0.001) [14]

**Significant Reduction in Snoring Using A Bedpartner-Reported Visual Analogue Scale (VAS)**

* All trials included VAS scores, from the proof of concept (n = 27) to the multi-center (n = 115):

1. Mean Bed Partner Snoring score reduced by 39% from 6.1 to 3.7 (p<0.001) with over 80% declaring a reduction of >40% in the reported snoring [**14**]
2. Primary Snorers VAS reduced from 6.4 to 2.7 (p<0.001), Mild OSA patients reduced from 6.6 to 3.6 (p<0.001) [**14**]
3. VAS remained stable for the 2-weeks after stopping the therapy suggesting a sustained change in muscle physiology but over time returned to baseline [**14, 17**]

**Significant Improvement in Pittsburgh Sleep Quality Index (PSQI)**

* + - * Sleep quality, sleep efficacy, sleep disturbance and global score measured by PSQI, statistically and significantly showed improvement in 4 of 8 components, supporting a concurrent improvement in the snorer’s sleep quality with the use of the device [**14**]

**Significant Improvement in Subjective Daytime Sleepiness**

1. Epworth Sleepiness Scale (ESS) scores were significantly reduced after 6-weeks of eXciteOSA® use from 8.1 to 5.3 [**14**]
2. In patients with increased sleepiness, 83% of patients with Mild excessive daytime sleepiness (ESS 10-12) became normal, whilst moderate to severe sleepiness (ESS 13 to 24) reduced from 28% to 6%) [**14**]

**Treatment Longevity and High Level of Compliance by Patient Report**

1. VAS remained stable for the 2-weeks after stopping the therapy (mean VAS 3.3) suggesting a sustained change in muscle physiology. [**14, 17**]
2. eXciteOSA treatment was acceptable to 99% of patients in the trial with an adherence rate to once daily therapy of 83% over the 6-week treatment period [**14**]

**Safety**

1. No serious device related adverse events have been reported [13 - **17**]
2. The most frequently reported events include (n=115) excess salivation (12), tongue (11) or tooth (7) discomfort, tongue tingling (7), metallic taste (3) (XX). [14]

**Summary**

As numerous peer-reviewed studies suggest, the progressive nature of OSA puts patients at risk for developing comorbidities and long-lasting effects to their health. I believe that eXciteOSA® would help prevent the worsening of (**Patient’s name**) OSA and potentially mitigate the compounding effects of an untreated condition on their future health status.

eXciteOSA® is clinically proven for use in patients with snoring and mild OSA and may be considered as an adjunctive therapy with a night-time OSA device. It also reduces the likelihood of adverse events associated with snoring and OSA.

For these reasons, I believe that eXciteOSA® is medically necessary for (**Patient name**). It would be a valuable investment in their current and long-term health.

Attached for your reference, please find additional information about the device, including illustrations and a prescription.

If you have any further questions or comments, please feel free to call me at **xxx-xxx-xxxx**, to discuss. Thank you for your immediate attention to this request.

Sincerely,

***[Signature Treating Physician]*****[Provider name] [Degree] [Provider Identification Number]**

**Enclosures:**

Chart notes including imaging reports and test results

**References**:

1) Signifier Medical Technologies. (2020). eXciteOSA® Non-Invasive Intraoral Neuromuscular Stimulation Device with Clinically Proven Reduction of Primary Snoring And Mild Obstructive Sleep Apnea. Whitepaper.

2) Dopp, J. M., Reichmuth, K. J., & Morgan, B. J. (2007). Obstructive sleep apnea and hypertension: mechanisms, evaluation, and management. Current hypertension reports, 9(6), 529. <https://pubmed.ncbi.nlm.nih.gov/18367017/>

3) Parish, J. M., & Somers, V. K. (2004, August). Obstructive sleep apnea and cardiovascular disease. In Mayo Clinic Proceedings (Vol. 79, No. 8, pp. 1036-1046). Elsevier. <https://www.sciencedirect.com/science/article/abs/pii/S0025619611625792>

4) Loke, Y. K., Brown, J. W. L., Kwok, C. S., Niruban, A., & Myint, P. K. (2012). Association of obstructive sleep apnea with risk of serious cardiovascular events: a systematic review and meta-analysis. Circulation: Cardiovascular Quality and Outcomes, 5(5), 720-728. <https://pubmed.ncbi.nlm.nih.gov/22828826/>

5) Bauters, F., Rietzschel, E. R., Hertegonne, K. B., & Chirinos, J. A. (2016). The link between obstructive sleep apnea and cardiovascular disease. Current atherosclerosis reports, 18(1), 1. <https://link.springer.com/article/10.1007/s11883-015-0556-z>

6) Geovanini, G. R., & Lorenzi-Filho, G. (2018). Cardiac rhythm disorders in obstructive sleep apnea. Journal of thoracic disease, 10(Suppl 34), S4221–S4230. https://doi.org/10.21037/jtd.2018.12.63 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6321897/>

7) Wang, X. I. A., Bi, Y., Zhang, Q., & Pan, F. (2013). Obstructive sleep apnoea and the risk of type 2 diabetes: a meta‐analysis of prospective cohort studies. Respirology, 18(1), 140-146.

<https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1440-1843.2012.02267.x>

8) Kendzerska, T., Gershon, A. S., Hawker, G., Tomlinson, G., & Leung, R. S. (2014). Obstructive sleep apnea and incident diabetes. A historical cohort study. American journal of respiratory and critical care medicine, 190(2), 218-225. <https://www.atsjournals.org/doi/abs/10.1164/rccm.201312-2209OC>

9) Sahlman, J., Pukkila, M., Seppä, J., & Tuomilehto, H. (2007). Evolution of mild obstructive sleep apnea after different treatments. The Laryngoscope, 117(6), 1107-1111. <https://onlinelibrary.wiley.com/doi/abs/10.1097/MLG.0b013e3180514d08>

10) Svanborgy, E., & Larsson, H. (1993). Development of nocturnal respiratory disturbance in untreated patients with obstructive sleep apnea syndrome. Chest, 104(2), 340-343. <https://www.sciencedirect.com/science/article/abs/pii/S0012369216353375>

11) Pendlebury, S. T., Pepin, J. L., Veale, D., & Levy, P. (1997). Natural evolution of moderate sleep apnoea syndrome: significant progression over a mean of 17 months. Thorax, 52(10), 872. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1758423/>

12) Laratta, C. R., Ayas, N. T., Povitz, M., & Pendharkar, S. R. (2017). Diagnosis and treatment of obstructive sleep apnea in adults. CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne, 189(48), E1481–E1488. <https://doi.org/10.1503/cmaj.170296> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5714700/>

13) 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>

14) 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. <https://www.mdpi.com/2077-0383/10/9/1883>

15) 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).

16) 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*.

17) 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.