



## Medical Policy Manual **Approved New: Do Not Implement Until 4/2/25**

### Oral Negative Pressure Therapy Devices for The Treatment of Sleep Apnea

#### DESCRIPTION

Alternative therapies for newly diagnosed obstructive sleep apneas have been investigated ever since the recall of the Phillips continuous positive airway pressure (CPAP) machines and the CPAP shortages began. One alternative being proposed is negative pressure therapies delivered orally (e.g., iNAP, Winx Sleep therapy system)

The Winx Sleep Therapy System is an oral pressure system that received FDA clearance in 2012 but has been unavailable since 2017.

The iNAP sleep is a non-surgical device on the market that has been proposed as an alternative for the treatment of obstructive sleep apnea when positive airway pressure is not the preferred treatment of choice. Unlike the Winx system that uses continuous pressure, iNAP uses intermittent negative pressure with a soft flexible mouthpiece, thin tubing, and a battery powered console the size of a smartphone. It delivers a light vacuum in the oral cavity that moves the tongue forward and away from the airway. When it activates, a seal is established and set, iNAP's intermittent negative airway pressure then turns off to save the battery unless the tongue moves out of position it will provide negative pressure again to reposition the tongue and open the airway. There is an external light that indicates if the individual has a proper seal. This system received FDA clearance in May 2022.

#### POLICY

- Oral negative pressure therapy devices (e.g., iNAP, Winx,) for the treatment of obstructive sleep apnea is considered *investigational*.

#### IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g., statement.
- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

#### ADDITIONAL INFORMATION

There is currently not enough robust clinical data to prove the effectiveness of these negative pressure devices and there remains a need for more established medical evidence supporting their use.

#### SOURCES

American Academy of Sleep Medicine. (2009, March). *Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults*. Retrieved November 26, 2024 from [https://aasm.org/resources/clinicalguidelines/osa\\_adults.pdf](https://aasm.org/resources/clinicalguidelines/osa_adults.pdf).

Cheng, C-Y., Chen, C-C., Lo, M-T., Gulleminault, C., & Lin, C-M. (2021). Evaluation of efficacy and safety of intraoral negative air pressure device in adults with obstructive sleep apnea in taiwan. *Sleep Medicine*, 81, 163-168. (Level 3 evidence)



Hung, T-C., Liu, T-J., Hsieh, W-Y., Chen, B-N., Su, W-K., Sun, K-H., et al. (2019). A novel intermittent negative air pressure device ameliorates obstructive sleep apnea syndrome in adults. *Sleep and Breathing*, 23 (3), 849-856. Abstract retrieved November 20, 2024 from PubMed database.

Kuo, Y-H. Liu, T-J., Chiu, F-H., Chang, Y., Lin, C-M., Jacobowitz, O., et al. (2021). Novel intraoral negative airway pressure in drug-induced sleep endoscopy with target-controlled infusion. *Nature and Science of Sleep*, 13, 2087-2099. (Level 4 evidence)

Lorenzi-Filho, G., Almeida, F.R., & Strollo, P.J. (2017). Treating osa: current and emerging therapies beyond cpap. *Respirology*, 22 (8), 1500-1507. (Level 5 evidence)

National Institute for Health and Care Excellence. (NICE). (2021, August). *Obstructive sleep apnoea/hypopnea syndrome and obesity hypoventilation syndrome in over 16s*. Retrieved November 19, 2024 from <http://www.nice.org.uk>.

Nilius, G., Farid-Moayer, M., Lin, C-M., Knaack, L., Wang, Y-P., Dellweg, D., et al. (2024). Multi-center safety and efficacy study of a negative-pressure intraoral device in obstructive sleep apnea. *Sleep Medicine*, 119, 139-146. Abstract retrieved November 20, 2024 from PubMed database.

**EFFECTIVE DATE** 4/2/2025

ID\_BT