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NOTE: This policy is not effective until January 1, 2027

Medical Policy Manual

Durable Medical Equipment, Policy No. 99

Sleep Position Trainer

Effective: January 1, 2027

Next Review: August 2027

Last Review: August 2026

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Sleep position trainers provide feedback (e.g., electronic vibration) whenever an individual with positional obstructive sleep apnea is sleeping on their back in order to trigger a change in body position.

MEDICAL POLICY CRITERIA

The use of a sleep position trainer (e.g., NightBalance Positional Sleep Therapy Device) is considered **investigational** for any indication.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. [Prefabricated Oral Appliances for Obstructive Sleep Apnea](#), Allied Health, Policy No. 36
2. [Surgeries for Snoring, Obstructive Sleep Apnea Syndrome, and Upper Airway Resistance Syndrome](#), Surgery, Policy No. 166
3. [Hypoglossal Nerve Stimulation](#), Surgery, Policy No. 215

BACKGROUND

Some people with obstructive sleep apnea (OSA) experience breathing problems (e.g., sleep apnea) when sleeping on their back. Sleep position trainers are devices designed to help these individuals avoid sleeping in this position. These trainers range from simple options, like tennis balls sewn into the back of pajamas, to electronic devices that deliver an electronic vibration. The NightBalance Positional Sleep Therapy Device (Philips Respironics, Inc) is one such device that vibrates whenever the person rolls onto their back during sleep. This vibration prompts them to shift to a different sleeping position, which can reduce sleep apnea events throughout the night.

REGULATORY STATUS

In 2021 the NightBalance Lunoa System (Philips Respironics, Inc) received U.S. Food and Drug Administration (FDA) approval (K180608) through the substantial equivalence pathway. The NightBalance Lunoa System is indicated for prescription use for the treatment of adult patients with positional OSA with a non-supine apnea-hypopnea index (AHI) < 20. It records position and movement so that positional changes in sleep quality can be assessed.

EVIDENCE SUMMARY

Systematic Reviews

A Cochrane review by Srijithesh (2019) evaluated positional therapy for OSA.⁴¹ The meta-analysis included three crossover studies with a vibration alarm and five with specially designed pillows or semi-rigid backpacks. The review found low to moderate evidence that continuous positive airway pressure (CPAP) was more effective than positional therapy in improving AHI (n = 72), but positional therapy was more effective than no treatment for improving outcomes (n = 251) and may have better adherence than CPAP. All of the studies were short-term and the long-term effect was uncertain.

Randomized Controlled Trials

Berry (2019) compared the NightBalance Sleep Position Trainer to auto-adjusting positive airway pressure (APAP) in a 6-week randomized crossover trial (POSActive) in treatment naive patients (N=117) with exclusive positional OSA.^[1] The investigators selected a non-inferiority margin of five events/hour for the AHI endpoint and 30 minutes for adherence. The sleep position trainer achieved non-inferiority with a difference of 3.58 events/hour. APAP was more effective than the Sleep Position Trainer in terms of the AHI (p < 0.001), but adherence was better with NightBalance (p < 0.001). There were no significant differences between the treatments for total sleep time, sleep efficiency, sleep latency, wake after sleep onset, or the duration of sleep stages. The Epworth Sleepiness Scale (ESS) was statistically better in the APAP phase, although this did not achieve clinical significance. Post-hoc analysis of participants who had a baseline ESS score of greater than 10 showed that while both treatments improved the ESS, APAP was more effective (final ESS: 9.5 vs. 11; p < 0.001). Patients reported that the NightBalance device was easier to use and more comfortable and would choose this device, but thought that APAP was more effective in treating sleep apnea.

de Ruiter (2018) evaluated 12-month efficacy of the NightBalance Sleep Position Trainer compared to oral appliance therapy in a multicenter randomized trial of participants with positional OSA.^[2] This was a follow-up to a previously published 3-month study. There were no

significant differences between the two groups in AHI, ESS, Functional Outcomes of Sleep Questionnaire (FOSQ), or the average hours of use per night. However, 41% of the participants dropped out of the study by the 12-month follow-up due to adverse events or lack of efficacy, and the results in the publication represent only those individuals who remained in the study. Sensitivity analysis with intention-to-treat (ITT) was reported in a supplement, and in the worst-case scenario, AHI decreased by one with NightBalance and by 5.5 with the oral appliance. With ITT and last observation carried forward, the average hours of use per night decreased to 3.1 for NightBalance and 2.7 for the oral appliance ($p = 0.522$).

Eijsvogel (2015) compared the first-generation sleep position trainer to "the tennis ball technique" with commercially available air pillows on the back in 55 participants.^[3] Both devices reduced supine position by a median of 100% and reduced the median supine AHI to 0 events/hour during the 1-month sleep study. There were no significant differences between the groups for the ESS, visual analog scale (VAS), and sleep-related quality of life (QOL) data. Objective compliance data for the entire month showed that the median hours used per night was numerically higher but did not achieve statistical significance due to variability (6.5 vs. 4.5; $p = 0.078$). There were significant increases in the percentage of patients who used the device every day (51.7% vs. 15.4%, $p = 0.005$) and in effective compliance, measured by use for at least 4 hours per night on at least 5 days per week (75.9% vs. 42.3%, $p = 0.011$). Compliance in both groups decreased over the month of the study. Continued use after the month trial was not evaluated, and the clinical significance of an increase in compliance without a difference in sleepiness or QOL is uncertain.

Nonrandomized Studies

Beyers (2018) invited patients to participate in a 1-month trial of the sleep position trainer as part of a standard clinical pathway at a university hospital.^[4] In order to qualify for the trial, patients were required to have an overall AHI of > 5 events/hour, a supine AHI at least twice as high as the non-supine AHI, and 10% to 90% of total sleep time spent in the supine position. Out of 101 patients, 79 (78%) completed the 28-day trial period. There were 45 responders who had an overall reduction in respiratory event index (REI) from 11.3 to 3.4 and a reduction in supine REI from 28.9 to 2.3. For the 44 patients (43% of 101) who decided to purchase the device, 27 (27% of total) were considered responders. Reasons for not purchasing the device included persistent daytime sleepiness, intolerance to the vibrations, and preference for other treatment options. Due to the relatively low percentage of patients who responded and chose to purchase the device, the investigators recommended a trial period. Treatment success over longer than the 1-month trial period was not evaluated. Similar findings were reported in a separate clinical study of 51 consecutive patients with positional OSA who had a 1-month trial of the NightBalance device.⁴⁷ About half of patients ($n = 27$) were considered adherent during the trial, and half of those ($n = 13$) wanted to purchase the device. Ten patients had a higher response to the vibrations and were considered cured.

Van Maanen (2014) conducted a prospective study in patients with mild to moderate positional OSA.^[5] There were 145 patients who were asked to use the Sleep Position Trainer for six months with the option to keep the device at the end of the study. However, the data could not be retrieved in 39 patients, leaving 106 with objective data. The time spent supine decreased from 21% at baseline to 3% in the 53 participants (36%) who provided objective measurements at 6 months. Subjective measures (median ESS 11 to 8; Pittsburgh Sleep Quality Index [PSQI] 8 to 6; and FOSQ 87 to 103) were significantly improved compared to baseline, but only 66 participants out of the 145 (45%) completed the questionnaires. Analysis

was per protocol rather than intent-to-treat, raising questions about the validity of the results. Objective Sleep Position Trainer compliance, defined as more than 4 hours of usage per night as an average over 168 nights, was 64.4%; regular use, defined as at least 4 hours per night over at least 5 nights, was 71.2% averaged over the trial period. Objective use of the device for at least 1 hour per night decreased from 106 patients at the start of the study to less than 60 by six months. It is uncertain whether the number of patients using the device would be as high as this outside of a trial.

Summary

The evidence on the NightBalance Sleep Positioning Trainer includes randomized controlled trials (RCTs) and single-arm studies. The RCTs suggest that the device may be as effective as oral appliances and more comfortable than positive airway pressure (PAP) in patients with positional OSA. However, the studies are limited by a high dropout rate and short follow-up. A 6-month prospective study found that 64% of patients used the sleep position trainer for more than four hours per night, but another observational study found that only about one-quarter of patients may be both able to tolerate the device and have a reduction in supine AHI in the short-term. Further study is needed to evaluate who may receive benefit and continue utilization after the trial period.

PRACTICE GUIDELINE SUMMARY

No clinical practice guidelines were identified which addressed the use of sleep position trainers for the treatment of obstructive sleep apnea.

SUMMARY

There is not enough research to show that sleep position trainers improve health outcomes. No clinical guidelines based on research recommend sleep position trainers. Therefore, sleep position trainers (e.g., NightBalance System) are considered investigational.

REFERENCES

1. Berry RB, Uhles ML, Abaluck BK, et al. NightBalance Sleep Position Treatment Device Versus Auto-Adjusting Positive Airway Pressure for Treatment of Positional Obstructive Sleep Apnea. *J Clin Sleep Med*. 2019;15(7):947-56. PMID: 31383231
2. de Ruiter MHT, Benoist LBL, de Vries N, et al. Durability of treatment effects of the Sleep Position Trainer versus oral appliance therapy in positional OSA: 12-month follow-up of a randomized controlled trial. *Sleep Breath*. 2018;22(2):441-50. PMID: 28913630
3. Eijsvogel MM, Ubbink R, Dekker J, et al. Sleep position trainer versus tennis ball technique in positional obstructive sleep apnea syndrome. *J Clin Sleep Med*. 2015;11(2):139-47. PMID: 25515276
4. Beyers J, Dieltjens M, Kastoer C, et al. Evaluation of a Trial Period With a Sleep Position Trainer in Patients With Positional Sleep Apnea. *J Clin Sleep Med*. 2018;14(4):575-83. PMID: 29609712

5. van Maanen JP, de Vries N. Long-term effectiveness and compliance of positional therapy with the sleep position trainer in the treatment of positional obstructive sleep apnea syndrome. *Sleep*. 2014;37(7):1209-15. PMID: 25061249

CODES

Codes	Number	Description
CPT	None	
HCPCS	E0530	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type

Date of Origin: August 2026