Anthem

Medical Policy

Subject: Electronic Positional Devices for the Treatment of Obstructive Sleep Apnea
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Description/Scope

This document addresses electronic devices used in the treatment of positional obstructive sleep apnea (POSA). Positional therapy prevents individuals from sleeping in the supine position and can decrease or eliminate obstructive events in POSA. A new generation of electronic positional therapy devices have been suggested as an alternative to the current treatments. At least two devices are currently available on the market, including the NightBalance Lunoa system (Philips; Cambridge, MA) or Night Shift (Advanced Brain Monitoring, Carlsbad, CA).

Position Statement

Investigational and Not Medically Necessary:

Electronic positional therapy devices are considered **investigational and not medically necessary** in the treatment of obstructive sleep apnea.

Rationale

A number of studies have explored the use, effectiveness and compliance of positional therapy in the treatment of mild to moderate OSA. These studies have reported on the effect of positional sleep therapy using sleep position modification devices to prevent supine sleeping and improve sleep-disordered breathing. While the studies seem to indicate that these devices may be effective in the short term (12 months or less) and improve short term compliance, there is no evidence regarding long term effectiveness and adherence (Benoist, 2019; Bignold, 2009; Oksenberg, 2006). Long-term evidence is needed to assess clinical outcomes associated when these devices are used to treat this chronic condition (Beyers, 2018; Buyse, 2019; Jackson, 2015; van Maanen, 2014).

A Cochrane review (Srijithesh, 2019) compared the efficacy of positional therapy to either CPAP or an inactive control. A total of eight randomized, controlled trials (RCTs) comprised of 323 participants were included. Positional therapy was administered using physical positioning devices in five studies and vibration alarm devices in three of the studies. The authors concluded that while positional therapy demonstrated improved apnea-hypopnea index (AHI) and Epworth Sleepiness Scale (ESS) over inactive controls, CPAP therapy resulted in improved AHI results when compared to positional therapy. The duration of a majority of the studies ranged from 2 nights to 4 weeks; the exception being one study which lasted 6 months. Given the limited follow-up in these studies, no conclusions about long-term efficacy can be made from them.

Benoist and associates (2017) conducted an RCT to evaluate equivalence regarding the efficacy and effectiveness of oral appliance therapy (OAT) compared to positional therapy using the electronic device the sleep position trainer (SPT). The efficacy of treatment was determined by the actual reduction in apneic events when treatment was followed, while effectiveness includes both efficacy and adherence. Individuals with mild to moderate POSA were randomized to receive either custom-made OAT or SPT (n=99). The primary outcome measure was AHI, but mean disease alleviation (MDA) and adherence were also addressed. Approximately 82% of the participants (81/99) completed the study and the 3-month follow-up. At 3 months follow-up, both groups showed similar improvement in respiratory indices. The median AHI decreased from 12.7 to 6.8 in the SPT group and from 12.9 to 6.9 in the OAT group. Both groups showed similar outcomes in mean adherence and MDA in the per-protocol analysis. A total of 18 participants dropped out of the study. The majority of the dropouts occurred in the OAT group and accounted for one-third of the OAT group. The authors note that the delay in manufacturing and titration of the device may have partially accounted for the high dropout rate. Both the high dropout rate and the limited follow-up term (3 months) limit the generalizability of these findings.

De Ruiter and associates (2018) compared SPT and OAT therapy in the treatment of mild to moderate POSA (AHI 5-30 events/hour). In this prospective, multicenter trial, 99 individuals were randomized to receive either SPT or OAT therapy. Subjects were followed for 12 months after randomization. Researchers designated change in OSA severity from baseline through 12 months as the primary endpoint. OSA severity was based on AHI and oxygen desaturation index (ODI). A total of 58 participants completed the study, 29 in each group. At 12 months, the AHI and ODI were significantly reduced from baseline, with no significant between-group differences. The AHI was reduced by more than half in 51.7% and 55.2% in the SPT and OAT groups respectively. Both groups reported similar average usage per night (SPT: 5.2 hours; OAT: 5.0 hours) and mean adherence to treatment (SPT: 100.0%; OAT: 97.0%). The OAT therapy group reported more adverse events (AEs), however more individuals in the SPT group dropped out due to AEs between the 3-12-month period. The authors note that the study is limited by a higher than anticipated dropout rate.

Eijsvogel and colleagues (2015) conducted a prospective randomized study which compared positional therapy using the tennis ball technique with an electronic positional device. Individuals with mild to moderate POSA were randomized to parallel arms. One group received an SPT device (n=29) and the other group used the tennis ball technique (TBT) (n=26). TBT therapy consisted of attaching airbags between the shoulders using an elastic band. Sleep studies were obtained at baseline and after 1 month. Compliance was objectively measured in both groups using built-in sensors. A total of 7 individuals, 5 in the TBT group and 2 in the SPT group dropped out of the study prior to the 1-month sleep study. Following 1 month of therapy, both groups reported significantly decreased median AHI with no significant difference between the groups. In addition, there was no clinically significant difference in the ESS or the Quebec Sleep Questionnaire (QSQ) scores. Compliance, defined as usage for at least 4 hours a day for at least 5 days a week, was significantly higher in the SPT group compared to the TBT group (75.9% [22/29] versus 42.3% [11/26]; respectively). Both groups were trending towards decreased compliance over the 1-month period. There are several limitations associated with this study. The small size of the study limits its generalizability. At baseline, several parameters were significantly worse in the SPT group. While compliance in the SPT group was significantly higher, the ESS scores, which is an index of daytime sleepiness, were not significantly different.

Ravesloot and colleagues (2017) examined the efficacy of positional therapy using electronic devices as well as assessing compliance. This meta-analysis included three prospective cohort studies and four RCTs. An analysis of the pooled data notes that the mean AHI was significantly reduced from 21.8 ± 7.2 to 9.9 ± 10.6 (53.6%). In addition, the mean time spent in the supine position, which is directly related to the severity of disease in POSA, was reduced by 83.8%. The authors note that while the early studies

show promising results in short term follow-up, follow-up data is lacking and further long-term study with a more diverse group of participants is needed.

In a prospective, multicenter, randomized, crossover trial, Berry and colleagues (2019) compared the efficacy of NightBalance SPT and auto-adjusting positive airway pressure (APAP) in the treatment of POSA. Individuals were eligible for the study if they had an AHI of 15 events/hour or between 10 and 15 events/hour with an ESS of greater than 10. Study eligibility required that the supine AHI was at least twice the non-supine AHI and that at least 30% of sleep time was spent in both supine and non-supine positions. Participants were randomized to either the SPT group (n=58) or the APAP group (n=59). Following 6 weeks of therapy, participants were crossed over to the second device for an additional 6 weeks of therapy. The authors chose noninferiority co-primary endpoints: AHI analysis by polysomnography and objective adherence as quantified by average nightly minutes of use. Following 6 weeks of device use, the treatment AHI on SPT was significantly greater than on APAP (mean 7.29 versus 3.71 events/hour). The authors noted that the mean difference in AHI between the devices was within the prestudy noninferiority difference. A number of indices, including total sleep time, sleep efficiency, sleep latency, wake after sleep onset, or the duration of sleep stages as a percentage of total sleep time did not show significantly different outcomes between the devices. Nightly adherence was significantly higher during SPT use compared to APAP (345.3 ± 111.22 minutes versus 286.98 ± 128.9 minutes). Participants reported that the SPT devices were more comfortable and easier to use, but that the APAP device treated their OSA better. Previous studies suggest that adherence to both APAP and SPT decreases over time. Longer studies with larger numbers of subjects are needed to establish the relative effectiveness of these treatments.

In the first published study comparing the gold standard of CPAP to positional devices, Mok and associates (2020) reported on the results of a crossover RCT which compared the treatment effects of a vibratory positional therapy (PT) to CPAP in POSA. Participants were randomized to first receive CPAP (n=21) or a Night Shift positional device (n=20) for 8 weeks. Following the initial phase and a 1-week washout period, participants received the alternative treatment for 8 weeks. The difference in ESS between the treatments was selected as the primary endpoint, with a minimal clinically significant change in ESS calculated to be 1.5, which was designated as the non-inferiority endpoint. The study also included an evaluation of polysomnogram parameters, which was performed at the end of each 8-week period. The non-inferiority endpoint for PT compared with CPAP was not met in this study; the difference in ESS score following the treatment phase (PT minus CPAP) was 2.0 (95% confidence interval [CI], 0.68 to 3.32). The AHI on CPAP was significantly lower compared to AHI on PT (4.0 ± 3.2 versus 13.0 ± 13.8 events/hour, respectively). After completion of the study, participants were asked about treatment preference. A majority of participants preferred the CPAP (60%) compared to PT (20%), the remaining 20% preferred neither device. The majority of those who preferred CPAP cited better sleep and more energy while those who preferred PT cited ease of use. While this is the first study to directly compare CPAP therapy and PT, the study is limited by a small participant population and a limited study period. The authors recommended that CPAP remain the first line treatment for individuals with POSA and significant daytime sleepiness.

In summary, several factors influence the success of treatments for POSA. These include the AHI in the non-supine position as well as the residual time spent in the supine position. Overall, the benefits reported in these devices are significantly less than the CPAP benefit (Jackson, 2015). While the benefits appear to be similar to OAT therapy, the current studies are limited in terms of follow-up to 12 months or less. In addition, many of the studies report excessive dropout rates (De Vries 2015; Laub, 2017). There is insufficient published data to show that use of electronic positional therapy devices is as effective as more established treatments for POSA.

Background/Overview

OSA occurs when the upper airway repeatedly collapses during sleep, causing an airflow obstruction. One clinically common phenotype of OSA is the positional OSA. POSA can be defined as an apnea-hypopnea index (AHI) at least twice as high in supine position as in other positions (de Vries, 2015). Due to the effects of gravity on the upper airway structures, the airflow obstruction is more likely in the supine position. Individuals with POSA tend to differ anatomically from those with non-positional OSA, with features that result in a greater lateral diameter and elliptoid shape of the upper airway. While individuals with POSA or non-POSA both have reduced anterior-posterior diameter due to the gravitational effect in the supine position, individuals with POSA have a larger lateral diameter in the non-supine position. For this reason, airway space is preserved in the non-supine position (Ravesloot, 2017).

Sleep disordered breathing is a common disorder affecting an estimated 24% of middle-aged men and 9% of middle-aged women. Approximately 6 to 7% of affected individuals are considered as having severe OSA (Beyers, 2019; Srijithesh, 2019). Approximately 50% of those individuals diagnosed with OSA have POSA; those with mild to moderate OSA reporting even higher percentages, with an estimated of 70-80% of those with POSA categorized as having mild to moderate OSA (de Vries, 2015; Ravesloot, 2017).

Standard treatment can involve CPAP or a custom-made OAT device. While CPAP has been shown to be more effective in reducing AHI, OAT has reported better usage rates. The non-adherence rate among CPAP users ranges from 29-83%, while OAT non-adherence rates have generally been reported at less than 20% (Benoist, 2017). An alternative treatment, positional therapy, focuses on preventing affected individuals from sleeping in the supine position. There are several positional therapy techniques, including devices which physically restrict movement into the supine position, such as pillows behind the back or tennis balls in a backpack or sown into the back of sleeping garments. New generation vibrational devices, which are worn around the chest or neck, are also used to discourage sleeping in the supine position. These devices provide a vibrating stimulus when the supine position is identified by a built-in monitor. Over time, some of these devices claim to train the individual to sleep in a non-supine position (Benoist, 2017).

Definitions

Apnea: Complete collapse of the airway during sleep

Hypopnea: Partial collapse of the airway during sleep

Obstructive sleep apnea classification:

- Mild: Apnea-hypopnea index (AHI) of 5-15 events/hour
- Moderate: AHI of 15-30/hour
- Severe: AHI of greater than 30/hour

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

For the following procedure code; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

HCPCS

E0530	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

1. Benoist L, de Ruiter M, de Lange J, de Vries N. A randomized, controlled trial of positional therapy versus oral appliance therapy for position-dependent sleep apnea. Sleep Med. 2017; 34:109-117.
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9. de Vries GE, Hoekema A, Doff MH, et al. Usage of positional therapy in adults with obstructive sleep apnea. J Clin Sleep Med. 2015; 11(2):131-137.
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12. Jackson M, Collins A, Berlowitz D, et al. Efficacy of sleep position modification to treat positional obstructive sleep apnea. Sleep Med. 2015; 16(4):545-552.
13. Laub RR, Tønnesen P, Jennum PJ. A Sleep Position Trainer for positional sleep apnea: a randomized, controlled trial. J Sleep Res. 2017; 26(5):641-650.
14. Mok Y, Tan A, Hsu PP, et al. Comparing treatment effects of a convenient vibratory positional device to CPAP in positional OSA: a crossover randomised controlled trial. Thorax. 2020; 75(4):331-337.
15. Oksenberg A, Silverberg D, Offenbach D, Arons E. Positional therapy for obstructive sleep apnea patients: 6-month follow-up study. Laryngoscope. 2006; 116(11):1995-2000.
16. Ravesloot MJL, White D, Heinzer R, et al. Efficacy of the new generation of devices for positional therapy for patients with positional obstructive sleep apnea: a systematic review of the literature and meta-analysis. J Clin Sleep Med. 2017; 13(6):813-824.
17. 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):1209-1215.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Morgenthaler TI, Kapen S, Lee-Chiong T, et al; Standards of Practice Committee; American Academy of Sleep Medicine. Practice parameters for the medical therapy of obstructive sleep apnea. Sleep. 2006; 29(8):1031-1035. .
2. Srijithesh PR, Aghoram R, Goel A, Dhanya J. Positional therapy for obstructive sleep apnoea. Cochrane Database Syst Rev. 2019;(5):CD010990.
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    - Night Balance Lunoa System. K180608. June 5, 2018.
    - Night Shift Sleep Positioner. K140190. May 29, 2014.

Websites for Additional Information

1. National Institute of Neurological Disorders and Stroke. Sleep Apnea Information Page. Last reviewed January 20, 2023. Available at: https://www.ninds.nih.gov/disorders/all-disorders/sleep-apnea-information-page. Accessed on March 19, 2023.
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Night Shift Sleep Trainer
Phillips Night Balance Lunoa system

The use of specific product names is illustrative 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.

Document History

Status	Date	Action
	12/28/2023	Updated Coding section with 01/01/2024 HCPCS changes, added E0530 replacing K1001 deleted as of 01/01/2024.

Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections.
Reviewed	05/12/2022	MPTAC review. Updated Rationale and References sections.
Reviewed	05/13/2021	MPTAC review. Updated Rationale, Background and References sections.
New	05/14/2020	MPTAC review. Initial document development.

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