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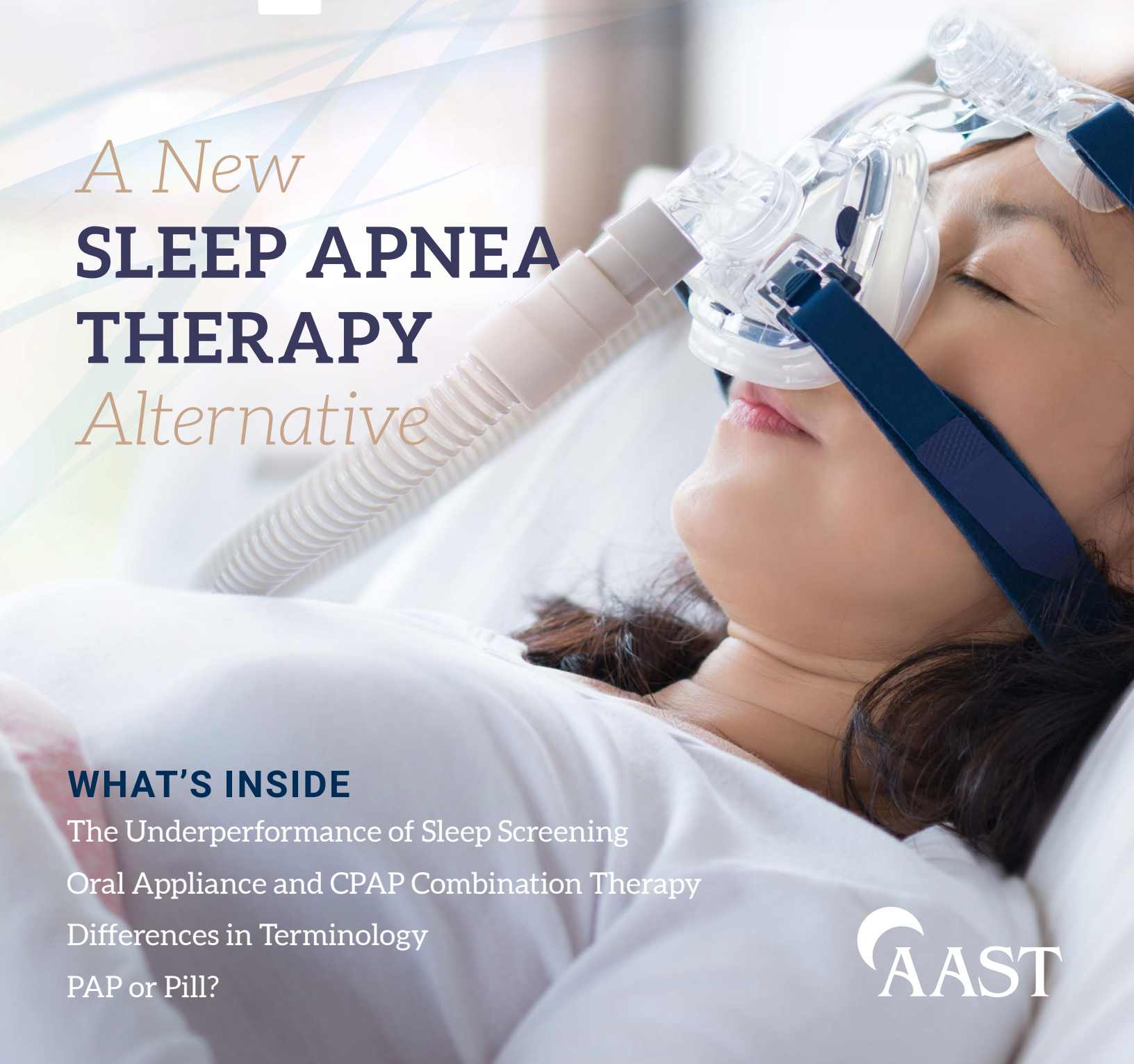

A New SLEEP APNEA THERAPY *Alternative*

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AAST

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A New Sleep Apnea Therapy Alternative

By Regina Patrick, RPSGT, RST

CPAP is the gold standard treatment for OSA but many patients are not compliant with treatment, seeking other methods such as oral appliances. While studies for a CPAP alternative that aims to strengthen the upper airway dilator muscles are fairly new, they show encouraging results.

DEPARTMENTS

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QUARTER TWO 2022
VOLUME 31 / NUMBER 02

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CONTRIBUTORS

AAST
330 N Wabash Suite 2000 Chicago, IL 60611
A2Zzz@aastweb.org | www.aastweb.org

AAST THANKS ITS PRESTIGE PARTNERS

From the Editor

Moving Into Summer....

By Rita Brooks, MEd, RPSGT, REEG/EPT, FAAST

As we move into the summer and toward a return to travel and in-person meetings, the Centers for Disease Control and Prevention (CDC) continues to recommend vaccinations and boosters for COVID-19. AAST recently held an in-person summit in Chicago at the AAST Headquarters and is actively planning two in-person Certification in Clinical Sleep Health (CCSH) Designated Education Programs in June and October this year. I hope you will feel confident enough to travel and take advantage of one of these programs, which are designed for health professionals who work directly with sleep medicine patients, families and other health care practitioners to coordinate and manage patient care and improve outcomes. The programs are also a great pathway for those seeking the CCSH credential.

For those who are not ready to travel yet, there are many excellent AAST educational offerings available online, including a CCSH Designated Education Program. Additional online educational modules include Advanced Pediatrics, Advanced Sleep Titration and the recently released Fundamentals of EKG and Fundamentals of Virtual Patient Monitoring. In addition, the new Advanced Pediatrics Workbook and e-book were just released. Visit the Learning Center on the AAST website to review all of the educational programs available.

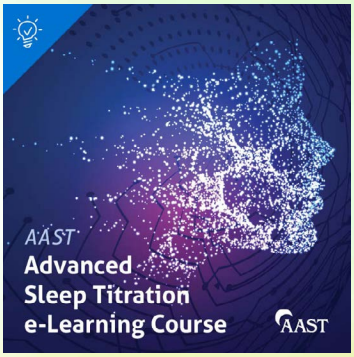
In this issue of *A$_2$Zzz*, we are focused on new ideas for improving screening for sleep disorders, and new and novel treatments for sleep disordered breathing using daytime treatments for obstructive sleep apnea (OSA), medications and advanced oral appliance therapies. One article delves into the difference between compliance and adherence and how the use of terminology can affect the success of positive airway pressure (PAP) therapy.

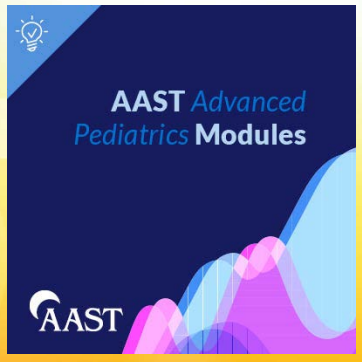
Laura Linley's Compliance Corner focuses on questions related to hypopnea scoring criteria required for qualification of PAP therapy for OSA. The questions currently seem to be related to commercial plans available for Medicare replacement plans and Aetna commercial plans; however, it is important for all to have an understanding of the OSA treatment criteria for all of our patients' plans.

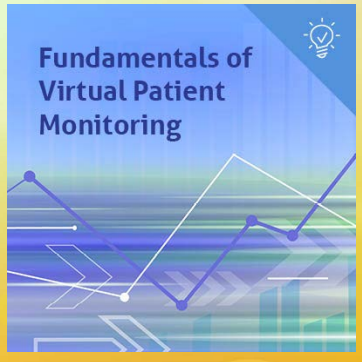
Have a wonderful summer! Remember to take advantage of the free continuing education credits that accompany your membership and the member discounts on our many excellent educational offerings to maintain and re-certify your credentials.

Sleep well!

Rita







President's Message

An Eventful Summer Ahead

By Laree J. Fordyce, RPSGT, RST, CCRP, CCSH, FAAST

With warmer weather and longer days now upon us, summertime is officially here! While the next few months are traditionally a time to relax and rejuvenate, AAST is ramping up for an eventful summer.

On June 1, we launched the 2022 6/18-month AAST membership campaign. Lapsed members and non-members can join or rejoin AAST for six or 18 months at discounted rates of $100 and $210 respectively. Six-month memberships will be valid through the end of 2022 and 18-month memberships will be valid through December of 2023. I encourage you to invite your fellow sleep-profession colleagues to join our community of over 2,900 sleep professionals. More information on AAST memberships, including member benefit breakdowns, can be found on our website here.

I'm also excited to share that we've recently rolled out not one, but two new education offerings to aid you in your summer studies. The Fundamentals of Virtual Patient Monitoring course is comprised of three online learning modules, including a knowledge assessment and case studies, and is perfect for those looking to learn more about utilizing connected technologies for improved clinical outcomes. Additionally, we launched the Advanced Pediatrics Workbook, which is a 108-page complementary resource to the Advanced Pediatrics Modules course. Those interested in becoming more proficient in pediatric care in the sleep center can purchase physical and digital copies of the workbook here.

Lastly, I'd like to provide an update from the AAST Workforce Summit. Myself and the AAST Board of Directors met with industry leaders in April to review key findings from the 2021Workforce Survey and I'm happy to share that we were able to identify actionable ways to advance the industry.

I wish you all a healthy and relaxing summer ahead.

Instructions for Earning Credit

AAST members who read *A$_2$Zzz* and claim their credits online by the deadline can earn 2.00 AAST Continuing Education Credits (CECs) per issue, for up to 8.00 AAST CECs per year. AAST CECs are accepted by the Board of Registered Polysomnographic Technologists (BRPT) and the American Board of Sleep Medicine (ABSM).

To earn AAST CECs, carefully read the four designated CEC articles listed below and claim your credits online. You must go online to claim your credits by the deadline of **Sept. 30, 2022**. After the successful completion of this educational activity, your certificates will be available in the My CEC Portal acknowledging the credits earned.

COST

The *A$_2$Zzz* continuing education credit offering is an exclusive learning opportunity for AAST members only and is a free benefit of membership.

STATEMENT OF APPROVAL

This activity has been planned and implemented by the AAST Board of Directors to meet the educational needs of sleep technologists. AAST CECs are accepted by the Board of Registered Polysomnographic Technologists (BRPT) and the American Board of Sleep Medicine (ABSM). Individuals should only claim credit for the articles that they actually read and evaluate for this educational activity.

STATEMENT OF EDUCATIONAL PURPOSE & OVERALL EDUCATIONAL OBJECTIVES

A$_2$Zzz provides current sleep-related information that is relevant to sleep technologists. The magazine also informs readers about recent and upcoming activities of AAST. CEC articles should benefit readers in their practice of sleep technology or in their management and administration of a sleep disorders center.

READERS OF *A$_2$ZZZ* SHOULD BE ABLE TO DO THE FOLLOWING:

- Analyze articles for information that improves their understanding of sleep, sleep disorders, sleep studies and treatment options
- Interpret this information to determine how it relates to the practice of sleep technology
- Decide how this information can improve the techniques and procedures that are used to evaluate sleep disorders patients and treatments
- Apply this knowledge in the practice of sleep technology

You must go online to claim your CECs by the deadline of **Sept. 30, 2022**.

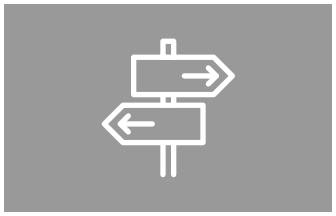
READ AND EVALUATE THE FOLLOWING FOUR ARTICLES TO EARN 2.0 AAST CECS:

A New Sleep Apnea Therapy Alternative

Objective: *Readers will review multiple research studies on airflow and the effects of daytime genioglossus muscle stimulation on OSA.*

The Underperformance of Sleep Screening

Objective: *Readers will evaluate the current state of screening for sleep disorders and understand the importance of working with providers and patients to develop a more effective screening process.*



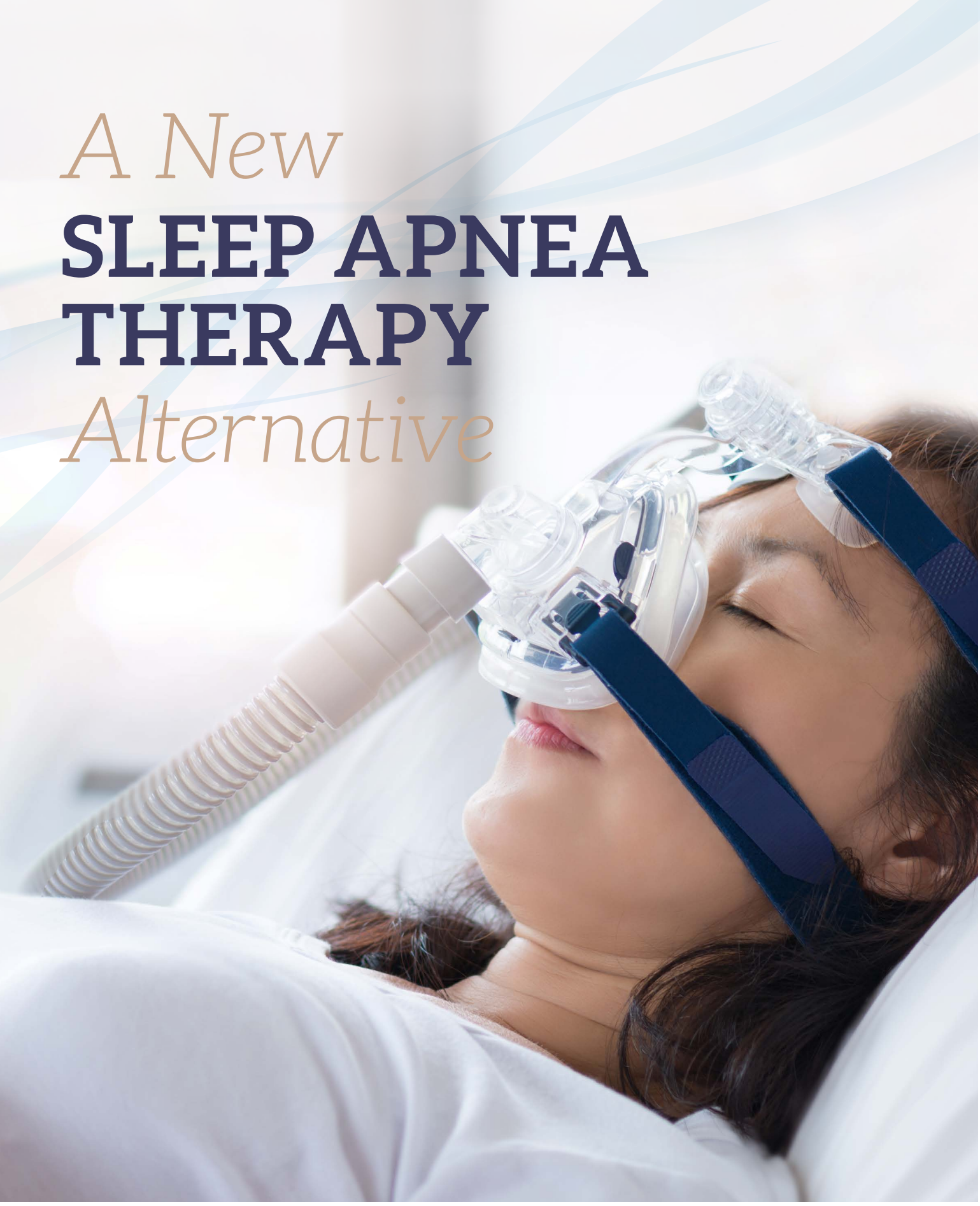
A New Direction for Oral Appliance and CPAP Combination Therapy

Objective: *Readers will review the history of oral appliances and apparatuses and develop a working knowledge of new oral appliance combination therapies.*

Differences in Terminology Can Determine Successes

Objective: *Readers will take a deep dive into the difference between the terms compliance and adherence and gain a better understanding of why the two terms need to be approached separately in treatment plans.*

A New SLEEP APNEA THERAPY *Alternative*



By Regina Patrick, RPSGT, RST

Read more

Continuous positive airway pressure (CPAP) is the gold standard treatment for obstructive sleep apnea (OSA). In OSA, the upper airway muscle tone reduces excessively during sleep, allowing structures supported by these muscles to collapse into and block airflow partially or fully. CPAP treatment involves blowing slightly pressurized air through a mask, which fits over the nose and/or mouth, to push against airway structures so they do not collapse into the airway during sleep. Unfortunately, many patients are not compliant with CPAP treatment because of discomfort from the pressure or mask and adverse effects (e.g., aerophagia [air in the stomach]).

To counteract noncompliance, other treatment methods have been developed to maintain an open airway and prevent apnea episodes during sleep such as surgery (e.g., uvulopalatopharyngoplasty [UPPP], tonsillectomy/adenectomy; mandibular advancement surgery) and oral appliances that pull the tongue forward. In recent years, another approach — strengthening the upper airway dilator muscles, in particular the genioglossus muscle — has been studied with encouraging results.

In 1966, Gastaut and colleagues[1] were the first to propose that the cessation in airflow (i.e., OSA) occurs because the tongue moves backward into the airway during sleep. In a study conducted after this proposal, Remmers and colleagues[2] recorded genioglossus muscle activity during the sleep of individuals with OSA. They found that the highest activity of the muscle occurred the instant a person resumed breathing at the end of an apnea event and declined steadily thereafter as a person took breaths after the apnea. They also demonstrated that site of closure in an apnea episode was the oropharynx. Based on these findings, Remmers concluded that loss of genioglossus muscle activity during sleep was directly linked to upper airway collapsibility in patients with OSA.

The genioglossus muscle is a fan-shaped muscle that emerges from behind the chin bone and inserts on the hyoid bone (i.e., a small horseshoe-shaped bone above the thyroid) and on the bottom portion of the tongue. It forms most of the tongue mass. When it is contracted, it causes the tongue to protrude, thereby widening the oropharynx in the anterior-posterior direction.

In 1989, Miki et al.[3] conducted the first studies on a device that provided external electrical stimulation of the genioglossus muscle during sleep in patients with OSA. The device consisted of a stimulator that was placed on the skin below the submental area and patients were studied overnight with and without the device. The device applied electrical pulses when it detected an apnea episode lasting less than five seconds, and the pulses immediately stopped once breathing resumed or after 10 seconds. The apnea index, apnea time/total sleep time, longest apnea duration and the number of times per hour that oxygen saturation dropped below 85% decreased significantly on the stimulation night compared to the nonstimulation night. Based on these findings, Miki suggested that an apnea demand-type stimulator could be a noninvasive and effective treatment for OSA.

Carrera et al.[4] were the first scientists to report alterations in the proportions of fast-twitch and slow-twitch fibers in the genioglossal muscles of people with OSA. Fast-twitch muscle fibers quickly contract and generate short bursts of strength but fatigue easily (i.e., loss of power when contracting). Slow-twitch fibers have a slower speed of contraction, can maintain contractions for longer and can resist fatigue. The biopsy findings of genioglossus muscles from people with and without OSA revealed the percentage of fast-twitch fibers was significantly higher in people with OSA than in people without OSA. Carrera also found that genioglossus muscle fatigability was greater in patients with OSA than in patients without OSA. After a year of CPAP treatment, the patients with OSA underwent a second biopsy, which revealed that the percentage of fast-twitch to slow-twitch fibers was more like that of people without OSA.

Unfortunately, many patients are not compliant with CPAP treatment because of discomfort from the pressure or mask and adverse effects.

Pae and colleagues[5] similarly demonstrated that short-term external electrical stimulation of the genioglossus muscle resulted in an approximately 13% increase in slow-twitch fibers and a proportional decrease in fast-twitch fibers. Based on this finding, they suggested that exogenous electrical stimulation could be a potential therapy for OSA.

A New Daytime Treatment

An outgrowth of research into external electrical stimulation of the genioglossus muscle to treat OSA is the development of the eXciteOSA device (called "SnooZeal" outside of the United States). The eXciteOSA device consists of a somewhat Y-shaped mouthpiece that has four electrodes: one electrode sits on each side of the top of the tongue and one electrode sits on each side below the tongue, together providing electrical stimulation to the genioglossus muscle.

The components of the eXciteOSA system are the mouthpiece, a USB cable and a control unit. (The mouthpiece and control unit are connected by the USB port.) The mouthpiece is placed inside the mouth to apply the electrical stimulation and the control unit connects to a smartphone app via Bluetooth connection. Stimulation is delivered at predetermined stimulation and rest periods and migrates between three low frequencies (ranging from 0 to 20 Hz). The patient controls the intensity of therapy (to a maximum of 15 mV) to a level that does not cause discomfort. The smartphone app is used to start and stop the

device, which is set to 20 minutes. After use, the control unit is disconnected from the mouthpiece, cleaned, and stored or charged (if necessary), using the USB charging cable. The stimulation is applied in 20-minute sessions once daily while a person is awake for six weeks, followed by once weekly thereafter. The eXciteOSA device (Signifier Medical Technologies, LLC, Needham, MA) was approved for clinical use in February 2021 by the US Food and Drug Administration (FDA)[6] and is currently a prescription-only treatment for adults 18 years of age or older.

Recent eXciteOSA Studies and Research

Wessoleck and colleagues[7] were the first scientists to examine the effects of using the eXciteOSA device on nocturnal snoring. After having participants use the device twice daily for 20 minutes for six weeks, the researchers found that the mean snoring score was reduced by approximately 43% and that the reduction in snoring remained when re-evaluated two weeks after treatment stopped. However, snoring was more greatly reduced in patients with an apnea-hypopnea index (AHI) less than 10 than in patients with an AHI greater than 10, where the treatment had no effect on reducing the AHI. They suggested that the device could be beneficial for snorers and for people with an AHI of less than 10.

The treatment also improved sleep quality, latency, efficiency and daytime dysfunction in the participants and their bedpartners.

Baptista et al.[8] demonstrated similar findings. In their study, individuals who snored only and had mild OSA used the device for 20 minutes once daily for six weeks. The change in the percentage of time spent snoring was measured objectively with a two-night sleep study before and after therapy. Ninety percent of the participants objectively experienced, on average, a 41% reduction in snoring time (based on sleep study findings). The bedpartners subjectively reported that the snoring of the participants had reduced significantly. The treatment also improved sleep quality, latency, efficiency and daytime dysfunction in the participants and their bedpartners.

Daytime oral stimulation of the genioglossus muscle is a novel, effective, noninvasive treatment for people with mild OSA or who snore only. However, this information is based on findings of participants who had used daytime oral stimulation of the genioglossus muscle for six weeks. Therefore, scientists currently do not know whether a longer period would be necessary to induce changes in fast-twitch and slow-twitch fibers of the genioglossus muscle in people with moderate to severe OSA. Future research may clarify this issue and determine whether other types of patients with OSA can benefit from this novel therapy, such as patients who have undergone unsuccessful OSA surgery. Future research may also determine whether combining daytime oral stimulation with CPAP treatment could help reduce the pressure required for CPAP treatment (and potentially increase CPAP treatment compliance). For now, research continues to focus on the efficacy and safety of daytime genioglossus muscle stimulation to treat OSA.

Note: For more information on the eXciteOSA (SnooZeal) device, visit exciteosa.com.

REGINA PATRICK, RPSGT, RST, *has been in the sleep field for more than 20 years and works as a sleep technologist at the Wolverine Sleep Disorders Center in Tecumseh, Michigan.*

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A Technologist's Guide to Performing Sleep Studies

Designed as an introductory resource, the *Technologist's Guide to Performing Sleep Studies* provides step-by-step instructions for collecting sleep study data from patients. It includes sections that cover suggestions for putting the patient at ease, reviewing the patient's symptoms and medications, attaching the sensors, preparing to record, biological calibrations, artifact detection and correction, and documentation.

Purchase *A Technologist's Guide to Performing Sleep Studies* eBook in the AAST Learning Center

AAST

The Underperformance of Sleep Screening

By Geoff Eade, RPSGT, CCSH, Ashley Gould, CRT, and Bretton Lane, BS, RPSGT

Many studies have been done to assess the North American population for the presence of obstructive sleep apnea (OSA). These studies have shown that up to 80% of all patients with moderate to severe sleep apnea have not yet been diagnosed.[1] With the population aging and obesity on the rise, we are not making a dent into this statistic, despite the growing awareness and the advancements in home sleep testing.

The importance of diagnosing and treating sleep apnea cannot be understated. All of us working in the sleep industry witness daily the improvement of patient's sleepiness and quality of life when their OSA is treated. The study of comorbidities and their association with sleep apnea has been prevalent over the past years. These studies have identified that 80% of patients with OSA have multiple comorbidities[2] ranging from cardiovascular, stroke, chronic obstructive pulmonary disease (COPD), diabetes Type 2, asthma, cancer, metabolic diseases, mental health and more.

There are several studies and papers that describe regular positive airway pressure (PAP) usage may exert a protective effect against cardiovascular events.[2] Just recently, the Mayo Clinic published a paper that showed a 32-month population of patients who suffered from cardiovascular disease. In this population, only .28% underwent a diagnostic sleep test.[3] Additionally, the Mayo Clinic reported that Medicare patients with cardiovascular disease (CVD) and OSA who are adherent to PAP treatment reduce annual health care related expenses by 40%.[3]

There has also been a significant number of studies regarding the relationship between OSA and hypertension. It has been documented that OSA, especially in patients who present as resistant to anti-hypertensive medications, is causal for hypertension. Higher nocturnal blood pressure, independent of daytime hypertension, may play a significant role in the development of cardiovascular complications.[4]

Another body of work has shown that patients with sleep apnea have increased glucose levels and increased insulin resistance. It has been estimated that 86% of obese, Type 2 diabetic patients suffer from sleep apnea.[5] With all of this evidence regarding the importance of treating sleep apnea, we continue to ask ourselves, why is screening for

sleep apnea so underperformed and fragmented, when the mere presence of one or more comorbidities should trigger a sleep assessment?

From September to October of 2021, Idorsia Pharmaceuticals U.S. conducted an online survey through The Harris Poll. The subjects consisted of 300 primary care physicians (PCPs), 152 psychiatrists and 1,001 U.S. adults ages 18 and older who have difficulty sleeping or have been diagnosed with insomnia. The survey, Wake Up America: The Night & Day Impact of Insomnia,[6] produced interesting results. Although the study was primarily focused on insomnia, it reviews the disparity of screening for sleep disorders in general.

One of the highlights showed 98% of PCPs and 91% of adults surveyed agreed that sleep is one of the three pillars of health in addition to exercise and diet.[6] Although that is a strong indicator, unfortunately only 66% of PCPs and a mere 27% of adults surveyed reported discussing sleep during their clinic visit.[6] The adults surveyed reported a rate of 29% that struggle at work, 27% that struggle financially and 19% ending an important relationship due to sleep problems.[6] On average, the survey reported adults estimated a loss of eight hours of work per week.[6] This information indicates millions of dollars in lost revenue for organizations, not to mention the potential in lost wages for employees. More studies like this need to be conducted to update the persistent lack of awareness of sleep disorders. We need to close the gap to capture the undiagnosed and suffering population.

In 2015, Miller and Berger published results of a study that focused on the screening and assessment of OSA in primary care.[7] They concluded that the methods of screening and assessing patients for OSA in primary care was "fragmented and ineffective."[7] These methods are still used today with the Epworth Sleepiness Scale, STOP-Bang questionnaire and Berlin questionnaire, which have been tried and tested screening tools, although may sometimes be subjective. They may also be intimidating for providers and health care workers unfamiliar with sleep-specific signs and symptoms. This can result in inaccurate results, which may hinder a patient from being properly screened. It is also additional work for the staff to perform when they are already swamped in the chaos of a medical clinic. Could there be another way to screen patients for sleep disorders?

Many sleep centers have resorted to using known conditions that are empirically correlated with sleep disorders to create new and innovative screening tools. Once the screening tool brochure/card is distributed to primary care clinics, patients view these conditions (e.g. high blood pressure, diabetes, cardiac conditions, breathing problems or obesity) and then notify their PCP or call the sleep center to request a sleep evaluation. Once the patient gets to the sleep center or clinic for a sleep evaluation, more detailed questionnaires may be completed in addition to the evaluation by the sleep provider. At this point, the sleep provider will determine the means of diagnostic testing, diagnosis and treatment of the potential sleep disorder.

Another difficult challenge for sleep screening is informing the PCP of additional ways to detect possible sleep disorders in their patients. Many providers listen for the primary complaints of insomnia and snoring, and maybe even witnessed apnea. Unfortunately, they may not be aware of other symptoms or how they correlate with medical conditions. The wrong approach to a provider could be perceived as an attack on their medical knowledge or that someone is attempting to instruct them on how to assess their patient. This is a very tricky situation for sleep center marketers, and the objective should be to

Although the study was primarily focused on insomnia, it reviews the disparity of screening for sleep disorders in general.

give them more "red flags" to look for during the regular evaluation to trigger a sleep referral. Once trust is established with the provider and positive results of a referred patient are witnessed, the provider may open up to suggestions on other means of assessing sleep disorders. This process may take time but will be rewarding in the end.

On the other hand, PCPs may not be interested in assessing sleep disorders as they may feel this would require them to perform sleep-specific follow-up clinic visits. One option for this situation is to develop a way for patients to be screened and referred to a sleep center before the patient gets to the PCP. Involve the provider in that decision process and assure them the test results and office visit notes will be sent to their office to maintain the continuity of care with their referred patient.

In an interview conducted with Bill Kleiman, vice president of marketing at BetterNight, he spoke about a recent appointment he had with his own cardiologist and the relevance of screening for OSA. This is a prime example of the need to create awareness to PCPs, and the general population alike, to integrate the discussion of sleep as a staple in everyday medical practice. Kleiman himself has been using a PAP device for 20 years and holds 30 years of experience in the sleep industry, so it was a surprise that at the conclusion of his visit, his cardiologist had failed to ask about the nature of his sleep or OSA.

Upon further discussion about the lack of screening done by his cardiologist, it was revealed that Kleiman's doctor "had no idea his staff was not asking patients about their sleep habits." Kleiman further inquired when his doctor screens a patient for OSA, to which his cardiologist said screening usually occurred "when a patient proactively tells him they are feeling fatigued." In-turn, Kleiman shared that "being reliant on the patient telling you

they are feeling this way, when we know people with OSA are walking around with no clue, how can you not test what we are spending one-third of our lives doing every day?" With all the research and the number of patients that are seen every day, it poses a serious disservice to patients. How many unnecessary medical events or deaths occur daily because of the underperformance of sleep screening?

With about 80% of the population being left undiagnosed, it is imperative to improve the awareness and understanding of the importance of screening for sleep disorders. When asked to reflect on how being in the sleep industry has changed him, Kleiman stated, "The biggest charge I get out of this is knowing that I am affecting so many human beings' lives in a positive way at the end of the day, just through increasing the number of physicians who consistently screen their patients for sleep disorders."

With all of the studies and reports that have been conducted and are currently being conducted, we in the sleep industry need to work together to find better ways to communicate with providers. We must also determine better and more effective methods to screen for sleep disorders. Awareness of sleep disorders and the correlation with health conditions is the key to informing providers and patients alike. We face a larger challenge than the other two pillars of health as the general population is already aware of the importance of diet and exercise. By working together, we can develop new and innovative ways to drive awareness to the importance of sleep and sleep disorders.

Let Us Know Your Thoughts!

- What innovative ways does your sleep center screen patients for referrals?
- How do you approach and convince a new potential referral source to screen their patients for sleep disorders?

Send in your answers, questions or comments to AAST Managing Editor Monica Roselli at mroselli@aastweb.org. We appreciate your feedback!

GEOFF EADE, RPSGT, CCSH, *has been in the sleep field for over 13 years. He received his training through the A-STEP pathway and is now the clinical lead technologist of a four-bed sleep center, the current president of the Mississippi Sleep Society, a sleep consultant and volunteer on various AAST committees. He lives in Brandon, Mississippi, and is enrolled at Jackson State University for his bachelor's degree in health care administration.*

ASHLEY GOULD, CRT, *has been a respiratory therapist for 13 years and has spent the last nine in the sleep industry. During school, she attended a clinical rotation at a sleep center through Kaiser, and immediately knew that she found her calling. Over the years, Ashley has worked with a multitude of patients in various clinical settings to help them get a good night's sleep, which is what drives her every day to provide the utmost care.*

BRETTON LANE, BS, RPSGT, *has over 20 years of experience in sleep medicine. She began her career at the National Jewish Medical and Research Sleep Center and the University of Colorado's Children's Hospital Sleep Center in Denver, Colorado, as a sleep technologist. In 2005, she transitioned from the clinical side of sleep medicine to operations. As general manager at Pacific Sleep Medicine, Bretton had direct involvement and oversight responsibilities for the sleep clinics and labs, pharmaceutical and clinical trials, and DME fulfillment. In 2010, she brought her expertise to BetterNight, where she has woven her experiences together to present a virtual sleep care management service focused on improving patient outcomes and providing population management metrics to customers.*

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A New Direction for Oral Appliance and CPAP Combination Therapy

By Chris Kelly, Cert DT, Adv Cert DP, GradCertScMed

Oral appliances and apparatus have been in existence in one way or another since 1923 when a dental surgeon and physician named Pierre Robin found that babies with micrognathia and posteriorly placed tongue (glossoptosis) not only had difficulty with feeding, but also had issues with breathing in general.[1] It was from these observations, and the previous work of Lannelongue and Menard in 1891,[1] that Robin subsequently published the first case of an infant with the complete Pierre Robin Syndrome (PRS) (sequence) in 1926.[2] The idea of posteriorly positioned tongues and lower jaws narrowing the pharyngeal airway in general, outside of PRS, was to be further postulated for the next 30 years and a generation of dental academics.

The 1970's brought with it much research on the association of the tongue and breathing. A dental academic named Eberhart Sauerland reported that genioglossal activity occurred in "bursts" during inspiration. He teamed up with Ron Harper in 1976, who added that the stiffening of the pharyngeal walls and movement of the tongue upon inspirations was shown to be a normal activity in "normal" humans while asleep.[3]

The tongue has been known to be of great importance to the normal function of airway support for many years. Given the known cardiovascular issues that can threaten sufferers of obstructive sleep apnea (OSA), any therapy that is oral appliance based needs to be effective. This is especially important when one considers the known issues with the genioglossal activity in sufferers of OSA. Since at least 1993, Douglas et al.[4] have written about the fact that those with OSA have a dulled response to intraluminal negative pressure upon inspiration during sleep. But is holding the tongue forward enough to solve the problem? This seems to be a somewhat unnatural way to alleviate an issue that is based in the unconscious patient. Is bringing the lower jaw forward with a mandibular advancement splint (MAS) going to control the tongue on its own?

The tongue has been known to be of great importance to the normal function of airway support for many years.

Tongue retaining devices have mixed results. The action of a tongue bulb, a device that the user inserts their tongue into, and with suction that holds the tongue in place, is premised on the theory that this muscular hydrostat that is the tongue is going to be a compliant and still muscle that is held into the tongue bulb at the position of the front teeth (in between them) and therefore out of the throat. Unfortunately, for this theory, the 3D muscle fibre orientation present within this organ means that the tongue will quickly lose its place within the tongue bulb. The other factor that resists the static position of the tongue is the nature of the tongue activity at night. We all normally swallow about 500-700 times a day, and about 20-30 times at night in an average sleep period of eight hours.[5,6]

This frequency is increased in patients who have sleep-disordered breathing due to arousal and increased muscle tone. In fact, Lichter and Muir, circa 1975,[7] found that the pattern of swallowing more was associated with movement arousals from sleep and more frequent tonal activity during these times.

Interestingly, rapid eye movement (REM) sleep contained frequent swallow episodes, which points to the hypothesis that the vagal system is still quite active and influencing dilator and genioglossal muscle activity during REM when more wide-spread atonia is also present.

A more recent option for assistance in control of the tongue has been developed off the back of prior research into tongue retention during sleep, as well as myofunctional training and assistance during the day. In 2010, Wilfried Engelke et al.[8] published a ground-breaking article, "Functional Treatment of Snoring Based on the Tongue-Repositioning Manoeuvre." The article proposed that after 4.6 months, patients with a normal body mass index (BMI) and primary snoring could be assisted in the reduction of snoring via the use of a simple shield worn in the mouth in front of the teeth and behind the lips. This simple addition to the sleeping habits promised to control the tongue and the soft palate more often to create a more stable velo and oral pharyngeal space for nasal breathing to pass through.

Advances in this area in terms of devices has led to the novel intermittent negative air pressure device (iNAP). This device has been shown in small studies to be very effective in the treatment of moderate to severe apnea. Reductions in the apnea hypopnea index (AHI) have been reported to reduce from 32.0 ± 11.3 events/h to 8.7 ± 9.4 events/hour.[9]

In 2017, a pilot study[10] with a very small cohort of participants was conducted in

Japan by Yuji Yamaguchi and Masako Kato at the Sleep Disorders Centre at the Fukuoka Urasoe Clinic in Japan. A small but significant reduction in the AHI was recorded, and more importantly, the wake after sleep onset (WASO) was reduced by approximately 20 minutes on first night use. This is promising because it suggests that the comfort of wear of the device is immediate and should be easy to get used to compared to other modes of therapy. In 2019, a larger cohort[11] was studied by professor Christian Guilleminault which showed an improvement in the AHI and the oxygen desaturation index (ODI) of users, with those with a greater body mass index (BMI) having more success.

Of course, no device is a panacea, and no research is free of appropriate scientific skepticism. The fact remains that oral appliances really need help when it comes to control of the tongue and the soft palate if these devices are going to rise above the reported 30% efficacy rate. This author believes that the combination of oral appliance therapy with an alternative treatment like negative air pressure could be a solution to the issue of residual snoring and positional snoring in all users of oral appliance therapy.

The oral appliance makes room in the mouth for the tongue by increasing occlusal vertical dimension (OVD) and bringing the insertion point of the genioglossus at the genial tubercles forward-mandibular advancement. What the oral appliance can't do is elevate the laryngopharyngeal position to create a larger cross section for inspired air to pass through. The oral appliance can't control the spasmodic and abhorrent position and posture of the velar space, and so the soft palate is "lost in space."

The advantage of intermittent negative air pressure control in oral appliance patients is that the tongue is allowed to behave in its own way during the various stages of sleep. The posture of the tongue is controlled, especially when the patient is in the supine position or when they are in REM sleep, as well as during potential arousal events. All this assistance equates to a most important benefit, a more stable and less disrupted sleep pattern. It is the goal of all who provide therapy to sufferers of OSA to assist the medical providers in assuring a more restful and architecturally correct sleep pattern for the patient.

Given the research that has been performed on tongue position, and the known relationship that tongue encroachment has on OSA, in relation to the pharyngeal space, this author believes it is time to look harder at combination therapies that will work together to achieve better, long-term results for sufferers of OSA who do not wish to use continuous positive airway pressure (CPAP) or cannot tolerate CPAP. Also, CPAP users who struggle with tongue position may not even be aware of this issue, and because of this, they may be giving up on a therapy out of ignorance that can help them to lead more healthy lives. It is this authors hope that this article will inspire readers to investigate combination therapy and thus be able to offer the patient more therapy options for OSA.

CHRIS KELLY, CERT DT, ADV CERT DP, GRADCERTSCMED, *is a dental prosthetist and a sleep scientist with more than 25 years of experience with oral appliances. He completed his advanced certificate in dental prosthetics at the United Dental Hospital Sydney in 1998 and his graduate certificate in science in medicine (sleep medicine) at the University of Sydney in 2020. Kelly is the CEO of Aer Healthcare, a company that delivers type 2 Medicare funded sleep tests across Australia.*

The advantage of intermittent negative air pressure control in oral appliance patients is that the tongue is allowed to behave in its own way during the various stages of sleep.

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Differences in Terminology Can Determine Successes

By Jocelyn Zakri, MPH, RRT, RPSGT, RST, CCSH

Positive airway pressure (PAP) therapy is widely known as the gold standard of care for patients with sleep apnea,[1] and PAP compliance and adherence are common terms in the realm of sleep medicine. PAP compliance reports can help to determine if a set pressure is working, whether or not the range for an auto-PAP is appropriate and a treasure trove of other data that can help paint the picture for how a patient is tolerating, or better yet, succeeding with their PAP therapy.

Thanks to technology advancements such as the switch from SD card manual downloads to cloud-based data storage, up-to-date data reports can be retrieved quickly. Additionally, reports can be customized and altered to show a number of different vantage points to evaluate how a patient is using, or in some cases not using, their PAP machine. Despite these advancements, PAP therapy terminology is becoming more and more misused, particularly when it comes to the terms compliance and adherence. While compliance and adherence are often used synonymously, the terms are slightly different and should be approached accordingly.

In an article by Brown and Bussell,[2] a key point providing the difference between the terms is discussed. "Often the terms adherence and compliance are used interchangeably. However, their connotations are somewhat different; adherence presumes the patient's agreement with recommendations, whereas compliance implies patient passivity." The guidelines from the Centers for Medicare and Medicaid (CMS) reiterate this idea of conformity given the specificity underlined in what is expected for patients. In reading them through PAP use, it appears to be a simplistic, easy-to-follow therapy; certain hours per night for a certain number of nights per month.[1]

However, the linear tone of CMS's PAP usage provides limited space for patients to acclimate in a way that works for them. Such a definition of compliance does not allow for subjective input from patients or for any problems that may occur. Issues, such as pressure sensitivity, mask discomfort or physiological complications like nasal dryness are not taken into consideration despite these issues occurring in the timeframe when the patient is to become "compliant." Since many insurance companies follow these guidelines for reimbursement purposes, some patients are put in a difficult position from the beginning. PAP usage is not like taking a new prescription. It is a change in lifestyle that needs adaptation and fluidity in order to succeed. Passivity therefore does not set the stage for success and compliance merely serves as the means to an end; to get a patient using PAP regularly to meet specific requirements with the hope of being able to help them become adherent for long-term success.

Adherence, unlike compliance, is a more dynamic and engaging process on the part of the patient. The World Health Organization (WHO) defines adherence as "the degree to which the person's behavior corresponds with the agreed recommendations from a health care provider."[3] PAP usage then, in terms of adherence, suggests that not only does the patient follow set recommendations but also internalizes them and makes the necessary lifestyle changes and adaptations as needed. Again, adherence is not a simple task and various factors should be considered when working towards adherence with patients.

WHO considers five factors to be at play in determining ease of helping patients with adherence.[4] Such factors include socioeconomic factors like age, gender, social support and clinical related issues such as a patient's airway structure, severity of OSA or comorbidities, as well as patient-related factors like level of commitment and subjective perception. In addition, there can be health care system issues such as the length of time from a test to receiving equipment and factors related directly to the therapy like nasal dryness, mask discomfort or pressure issues.

Considering the various difficulties patients and providers face in achieving long-term success with PAP therapy, each case should be approached with a personalized plan in mind. For some, initial compliance for insurance purposes may not be an issue, but long-term adherence six to nine months following the start of PAP therapy may be challenging. Likewise, there are patients who may struggle to

Acknowledging that there are differences between the terminology frequently used is an important step.

meet initial compliance but flourish with extended PAP use due to working with their durable medical equipment (DME) provider or sleep technologist for corrective mask fittings, pressure relief options and humidity settings.

Weaver et al. created the Self-Efficacy Measure for Sleep Apnea (SEMSA) as a way for providers to gain insight into which patients may or may not be appropriate candidates for PAP therapy. It asks questions regarding acknowledging the use of PAP in front of a bed partner, financial obligations that may occur and other poignant ideas that help to broaden the scope of what PAP therapy entails before the patient begins the journey from compliance to adherence.[5]

PAP has a long-standing history of low, long-term usage. Acknowledging that there are differences between the terminology frequently used is an important step, not only for patients but also for providers and support staff. For some, compliance comes easily and subsequently adherence follows suit. For many, compliance and adherence are a difficult process. Recognizing, or even foreseeing, some of the various factors involved in their struggle can help them to become more successful. While masks and machines have evolved throughout the years, it's time to take a look at the terminology used in determining patients' success.

JOCELYN ZAKRI, MPH, RRT, RPSGT, RST, CCSH, *has been working in sleep for nearly 15 years. She previously worked as a night technologist, daytime scoring technologist and contract sleep scorer before starting her current role as the clinical sleep health coordinator for a large sleep center in Central New York. She is passionate about educating patients about sleep disorders and working to help those struggling with PAP adherence become successful.*

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PAP or Pill? Pharmaceutical Alternatives to Sleep Apnea

By Brandon Ramirez, BA, RPSGT, CCSH, PSC

Would you rather wear positive airway pressure (PAP) therapy each night or take a pill before bed? For most, it would seem they would love to choose the latter option as PAP machines can be viewed as burdensome.

Wearing a mask to bed has long been an issue for many sleep apnea sufferers who are seeking a better night of sleep. As sleep apnea treatment continues to evolve, there is a growing population of patients interested in taking a pill before bed and not worrying about wearing a mask throughout the night. However, is it worth throwing out the mask and takingthe chance that a pill can be as effective asthe tried-and-true PAP machine?

The current gold standard of treatment for obstructive sleep apnea (OSA) is PAP therapy. The most commonly prescribed PAP device used to treat straightforward OSA, in patients without additional factors like chronic respiratory failure or central sleep apnea (CSA), is continuous positive airway pressure, or CPAP. This approach to OSA treats the underlying mechanisms of sleep apnea by providing an airway shunt with each breath, allowing optimal airflow and eliminating the nocturnal hypoxic effects of airway closure. Compliance with CPAP has been shown to eliminate OSA and hypoxemia caused by nocturnal airway closure, as well as reduce secondary negative effects of chronic hypoxemia on endocrine and cardiopulmonary systems. The downside to using a PAP device is that it must be worn each night — one-time use is not a cure. The average national compliance for PAP use in the clinical setting is only between 30%-60%.[1] Many people dislike wearing a mask to bed, finding it to be uncomfortable and cumbersome in new social scenarios, especially when the patient begins to co-sleep with a partner.

As OSA treatments continue to evolve, a new alternative treatment has arisen — a pharmaceutical approach, which includes a handful of options, such as selective serotonin reuptake inhibitors (SSRIs), tricyclic anti-depressants, acetazolamide, medroxyprogesterone and the more recent dopamine/norepinephrine reuptake inhibitor (DNRI), Solriamfetol.[2] Each of these medications are primarily prescribed by medical providers for a conventional purpose other than treating OSA.[3]

SSRIs are conventionally prescribed as anti-depressant medications that are considered non-stimulating. Protryptyline in particular is a tricyclic anti-depressant drug increasingly thought to have a positive effect on breathing at night. In relation to improvement of OSA as a secondary effect, it is thought the improvement in patients' excessive daytime sleepiness occurs by means of suppressing rapid eye movement (REM) sleep and shortening the time spent in the most severe period of OSA expression with the lowest oxygenation.[4]

There is also the very mild stimulating effect of SSRI's with a serotonin increase that could provide enough upper airway nerve stimulation to maintain airway compliance. The findings being observed in the laboratory setting include an increase in blood flow and volume in association with increased upper airway tone for patients taking SSRIs that also express sleep apnea. The effect is considered incomplete and SSRIs should not be seen as a primary approach for the treatment of OSA at this time.

Acetazolamide, a carbonic anhydrase inhibitor, is typically prescribed to reduce the effects of damage to the heart by increasing ventilation via metabolic acidosis. Increasing metabolic acidosis also increases the ventilatory drive, thereby increasing the patient's respiratory rate. The increased ventilatory drive is thought to be the reason behind the reduction of severity in CSA, otherwise known as the "other type of apnea." In CSA, there is an absence of respiratory effort and a pause in airflow and breathing, which can result in a decrease in minute ventilation. For many reasons, some patients with CSA are observed to have periodic breathing where they are no longer breathing in a stable pattern and the airflow and effort channels show intermittent waxing and waning for multiple rounds of periodicity during an overnight in-lab polysomnography study (PSG). The increased ventilation that occurs when taking acetazolamide however has been shown to change CSA to OSA.[5] The transference of apneas from central to obstructive appears to occur due to an increased respiratory drive however, there is no additional stimulation to maintain upper airway tone to eliminate obstruction.

This approach to improvement in sleep pathology is a positive step that supports the conventional purpose for the prescription of the medication — cardiac improvement via reduction in retaining carbon dioxide.[6] However, the switch from central to obstructive apnea does not resolve pathologic breathing and leaves much room for treatment still needed.

Medroxyprogesterone is an estrogen hormonal replacement therapeutic and has been observed to reduce the effects of obesity hypoventilation syndrome. The increased ventilation has also not been seen as effective on treating obstructive apneas. The best improvement is in the patient population using hormonal therapy that express a combination of hypercapnic hypoxemia and OSA.[7]

Solriamfetol, a DNRI recently found to improve daytime OSA symptoms, is used to decrease daytime fatigue and excessive tiredness in the narcoleptic population. However, it can improve excessive daytime sleepiness in patients with OSA that are also being treated with CPAP. It is important to note that this class of medication is used to increase daytime wakefulness and not to correct the underlying obstruction of the airway when sleeping.[8]

These medications are among a handful of the others in the same pharmaceutical classes that can be used for similar approaches; however, they all have something in common. They affect OSA in a manner only to be considered as a minor improvement and not as a primary approach to the treatment of OSA. The gold standard treatment for OSA is CPAP, which is still the leading line of defense to resolve the core mechanisms of nocturnal airway collapse. These medications are possible new steps to take in the overall treatment plan, especially for those who struggle with CPAP compliance.

BRANDON RAMIREZ, BA, RPSGT, CCSH, PSC, *began his career in sleep by working at a sleep lab on the weekends while studying archaeology at the University of Central Florida and completing prerequisites for medical school. Through this, he found a love of clinical presentation and a strong connection to many frustrations patients expressed preparing for the overnight PSG. He decided to take his experience with sleep issues and apply his passion of biochemistry and appreciation of perspective in broadening the foundation of patient education, thereby working to achieve patient success.*

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Compliance Corner

By Laura A. Linley, CRT, RPSGT, FAAST

Review of Commercial Treatment Medical Policy for Obstructive Sleep Apnea

I recently have been receiving questions on the hypopnea scoring criteria to use for qualification of positive airway pressure (PAP) therapy for obstructive sleep apnea (OSA). The questions seem to be focused on commercial plans available for Medicare replacement plans and Aetna commercial plans; however, I have to stress that there needs to be an understanding of the treatment of OSA criteria for all of our patients' plans. Durable medical equipment (DME) companies are already experiencing delays in fulfilling PAP orders due to the national shortage of PAP machines and are experiencing even greater delays in processing orders if therapy is being ordered based on sleep studies using the 3% scoring rule in identifying hypopnea. Unfortunately, it wouldn't matter what DME you send the order to as they should, and likely will be, rejecting it if the patient's insurance plan follows the 4% rule in identifying hypopneas.

To review, the current American Association of Sleep Medicine (AASM) Scoring Manual Version 2.6 defines the scoring of hypopneas in two rules:[1]

Rule 1A: Score a respiratory event as a hypopnea if all of the following criteria are met:

a. The peak signal excursions drop by ≥30% of pre-event baseline using nasal pressure during a diagnostic study or PAP device flow during a titration study, or an alternative hypopnea sensor
b. The duration of the ≥30% drop in signal excursion is ≥10 seconds
c. There is a ≥3% oxygen desaturation from pre-event baseline or the event is associated with an arousal.

Rule 1B: Score a respiratory event as a hypopnea if all of the following criteria are met:

a. The peak signal excursions drop by ≥30% of pre-event baseline using nasal pressure during a diagnostic study or PAP device flow during a titration study, or an alternative hypopnea sensor
b. The duration of the ≥30% drop in signal excursion is ≥10 seconds
c. There is a ≥4% oxygen desaturation from pe-event baseline.

The criteria used to score a respiratory event as a hypopnea (rule A or B) should be reported on the sleep study report as the patient's payor will look at this to qualify the patient for PAP therapy.

I have pulled policies and will attempt to summarize the rules used to qualify events by insurer definition below.

Here is an example of the guidelines you may see outlined for treatment of OSA:

- Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.[2]
- The apnea-hypopnea index (AHI) is equal to the average number of episodes of apnea and hypopnea per hour of sleep without the use of a PAP device. Sleep time can only be measured in a Type I (facility-based polysomnogram) or Type II sleep study. Thus, the AHI is reported only in Type I or Type II sleep studies.
- The respiratory disturbance index (RDI) is equal to the episodes of apnea and hypopnea per hour of recording without the use of a PAP device. The RDI is reported in Type III, Type IV and other home sleep studies.[3]
- Leg movement, snoring, respiratory effort related arousals (RERAs) and other sleep disturbances that may be included by

Compliance Corner *continued*

By Laura A. Linley, CRT, RPSGT, FAAST

some polysomnographic facilities are not considered to meet the AHI and/or RDI definition in many policies. Although AHI and RDI have been used interchangeably, some facilities use the term RDI to describe a calculation that includes these other sleep disturbances. Requests for PAP devices will be considered not medically necessary if based upon an index that does not score apneas and hypopneas separately from other sleep disturbance events. Only persons with an AHI and/or RDI, as defined in the policy that meet medical necessity criteria may qualify for a PAP device.[4]

- Bilevel positive airway pressure (BiPAP) without a backup rate feature, BiPAP with pressure relief technology (Bi-Flex), DPAP, and variable positive airway pressure (VPAP) are considered medically necessary for members who are intolerant to continuous positive airway pressure (CPAP) or automatic titrating airway pressure (AutoPAP), or for whom CPAP or AutoPAP is ineffective. Ineffective is defined as documented failure to meet therapeutic goals using CPAP or AutoPAP during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings). The records must document that both of the following medical necessity criteria are met:[4]
  - An appropriate interface for the CPAP and AutoPAP has been properly fit, and the member is using it without difficulty; and
  - The current pressure setting of the CPAP or AutoPAP prevents the member from tolerating the therapy and lower pressure settings of the CPAP or AutoPAP were tried but failed to:
    - Adequately control the symptoms of OSA; or
    - Improve sleep quality; or
    - Reduce the AHI/RDI to acceptable levels.
  - These alternatives to CPAP may also be considered medically necessary for OSA members with concomitant breathing disorders, which include restrictive thoracic disorders, chronic obstructive pulmonary disease (COPD) and nocturnal hypoventilation.
  - An oral pressure appliance (OPAP) is considered medically necessary DME only on an exception basis for members who are unable to tolerate a standard nasal/face mask due to facial discomfort, sinus pain or claustrophobia from masks.
- A BiPAP device with a backup rate feature (e.g., adaptive servoventilation, VPAP Adapt SV) is considered experimental and investigational for OSA.[4]
- Replacement of PAP devices is considered medically necessary at the end of their five-year reasonable useful lifetime (RUL). Replacement of these items is considered medically necessary prior to the end of the five-year RUL due to a change in the member's condition. Replacements needed due to misuse or abuse are not covered.[4]

It is important to be mindful of the standard that payers retain the right to review and revise their medical policy guidelines at their sole discretion at any time without prior notice. Your facility compliance officer should regularly check for updates to not only the criteria being used to qualify a patient for a type of diagnostic study but also what needs to be reported to allow patients to be treated.

Below are a few policy links for reference, pulled on May 5, 2022. This list is a representation of the policies in place and not intended to be a complete list.

Insurances Requiring 4% Scoring
All Medicare Advantage Plans
Aetna
Aetna Medicare
Gateway Medicare (Highmark Wholecare)
CareCentrix
Clover
United Healthcare/Dual Medicare
Blue Journey CBC Advantage Plan
FFS Medicare (Traditional Medicare)
Horizon NJ (CCX)
Highmark Advantage Plan

References:

1. American Association of Sleep Medicine Scoring Manual Version 2.6. Retrieved from https://aasm.org/clinical-resources/scoring-manual/
2. Centers for Medicare and Medicaid Services. CPAP for Obstructive Sleep Apnea. Retrieved from https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/CPAP
3. Centers for Medicare and Medicaid Services. Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea. Retrieved from https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33718&ver=20&articleId=52467&NCDId=226&ncdver=3&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7CCAL%7CNCD%7CMEDCAC%7CTA%7CMCD&ArticleType=SAD%7Ced&PolicyType=Both&s=-&AdvSearchName=3%7C9%7C4%7C1%7C7%7C5%7C6%7C2%7C8&KeyWord=positive+airway+pressure&KeyWordLookUp=Title&KeyWordSearchType=Exact&kq=true&bc=IAAAACgAEAAAAAAA&
4. Aetna. Obstructive Sleep Apnea in Adults. Retrieved from http://www.aetna.com/cpb/medical/data/1_99/0004.html