

AMERICAN THORACIC SOCIETY DOCUMENTS

Moving toward Equitable Care for Sleep Apnea in the United States: Positive Airway Pressure Adherence Thresholds An Official American Thoracic Society Policy Statement

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Abstract

Background: Positive airway pressure (PAP) is a highly effective treatment for obstructive sleep apnea (OSA), but adherence limits its efficacy. In addition, coverage of PAP by CMS (Centers for Medicare & Medicaid Services) and other insurers in the United States depends on adherence. This leaves many beneficiaries without PAP, disproportionately impacting non-white and low socioeconomic position patients with OSA and exacerbating sleep health disparities.

Methods: An inter-professional, multidisciplinary, international committee with various stakeholders was formed. Three working groups (the historical policy origins, impact of current policy, and international PAP coverage models) met and performed literature reviews and discussions. Using surveys and an iterative

discussion-based consensus process, the policy statement recommendations were created.

Results: In this position paper, we advocate for policy change to CMS PAP coverage requirements to reduce inequities and align with patient-centered goals. We specifically call for eradicating repeat polysomnography, eliminating the 4-hour rule, and focusing on patient-oriented outcomes such as improved sleepiness and sleep quality.

Conclusions: Modifications to the current policies for PAP insurance coverage could improve health disparities.

Keywords: obstructive sleep apnea; sleep health disparities; continuous positive airway pressure; race; socioeconomic position

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Introduction

Obstructive sleep apnea (OSA) is a highly prevalent disorder associated with cardiovascular disease (e.g., atrial fibrillation, stroke, and heart failure), dementia, and cancer risk (1, 2). OSA causes daytime sleepiness, loss of productivity, and poor sleep quality (3–9). Positive airway pressure (PAP) is efficacious in treating OSA, with extensive literature demonstrating improvements in daytime sleepiness and sleep-related quality of life (4, 7, 8, 10–13). PAP use decreases subjective and objective sleepiness, improves health-related quality of life, improves mood, increases the success of psychiatric therapy (9, 14–20), and reduces motor vehicle accidents related to drowsiness (21–23). In addition, consistent PAP therapy for OSA may improve other cardiovascular outcomes, such as improving hypertension management and decreasing atrial fibrillation recurrence (14, 24–28). Economic analyses from the United States, Great Britain, France, Australia, and Canada have repeatedly shown that PAP is cost-effective (21, 22, 29–35). Despite clear evidence of efficacy and cost-effectiveness, the real-world benefits of CPAP have been hindered by a lack of consistent and adequate use among patients (29, 36).

CMS (the Centers for Medicaid and Medicare Services) requires beneficiaries to meet short-term adherence criteria to qualify for long-term coverage of OSA treatment with PAP. PAP is relatively inexpensive compared with other covered durable medical equipment (e.g., power wheelchairs, hospital beds, continuous blood glucose monitors, and portable oxygen concentrators), for which coverage does not depend on usage (37). To be eligible for long-term coverage, CMS mandates that beneficiaries use PAP 4 or more hours per day for 70% of days over a continuous 30-day period within the first 90 days of receiving the device (37). These rules have been widely adopted by other large insurance carriers across the United States without any validity testing. This 4-hour rule is strict; coverage benefits are withdrawn if beneficiaries do not attain the required usage regardless of patient or treatment factors. However, the origins of this cutoff definition

for adherence were not on the basis of rigorous scientific evidence but rather an expert opinion (38). The consequences of these thresholds are substantial for patients with OSA.

Despite being widely adopted, the 4-hour rule has not undergone empirical testing to demonstrate superiority compared with other less stringent rules, nor is this threshold validated as critical to patient outcomes. Furthermore, the 4-hour rule has the unintended consequence of worsening access to PAP in patients with the fewest resources, often the most vulnerable to the effects of untreated sleep apnea. Specifically, the policy exacerbates disparities by disproportionately affecting beneficiaries with greater barriers and challenges to meeting the CMS adherence requirement because of structural and socioeconomic factors. Differences in care and outcomes because of economic or social disadvantage are called health disparities (39). We advocate for the revision of adherence requirements for PAP coverage to promote health equity and the commitment to eliminate health disparities (39). The coronavirus disease (COVID-19) pandemic has unmasked how social determinants of health lead to severe disparities in outcomes. The current adherence definition does not account for patient-specific factors such as OSA phenotypes, comorbidities, social situations, and PAP benefits (i.e., extrinsic factors that influence tailoring therapy) (40).

Background

How Did We Get Here?

The CMS coverage determination 4-hour rule was instituted in 2008 and quickly became the standard measure of adherence as most commercial payers subsequently adopted it (41). In contrast, the Department of Veterans Affairs, another U.S. government entity, does not use this determination and instead explicitly provides the rationale that even low hourly PAP use may benefit patients (42). In fact, the evidence for the CMS coverage determination remains unclear after an extensive review of the literature. Furthermore, interviews with sleep medicine experts and PAP-use investigators

from this era failed to identify the clinical justification for this threshold. The likely origin of the 4-hour threshold for PAP was a 1993 manuscript on CPAP adherence (38). Kribbs and colleagues described a threshold of “regular PAP use” for 4 hours per day “on the basis of what is known about the need for sleep” and 70% of days monitored (or 5 out of 7 days per week to allow nonuse on weekends) “determined by expert clinical opinion (consensus of the authors).” Thus, this threshold was on the basis of judgment rather than empirical evidence. Interestingly, only 46% of patients (16 out of 35) met the threshold of adherence in this seminal paper. In addition, hours of PAP use were highly correlated ($r = 0.7$) with total nights used. With this high correlation, considering both hours used and days used to measure adherence is unnecessary. A later study suggested that the use of PAP for 4 hours improved subjective sleepiness significantly (43), perhaps furthering this threshold as an “adherence” cutoff.

It should be noted that subjective and objective sleepiness and quality of life improve in a continuous fashion with increasing PAP use (43, 44). Improvements have been noted before the 4-hour threshold and continue after it. Other sleep symptoms and adverse outcomes associated with OSA may improve with variable durations of PAP therapy, including nocturnal awakenings, sleep quality, and daytime energy. In fact, the use of PAP for just 2 hours has been associated with improved symptoms (45). This is echoed in work by Gaisl and colleagues, showing that among those nonadherent by the current CMS definition, therapeutic CPAP compared with sham CPAP decreased sleepiness while providing better systolic and diastolic blood pressure (45). Thus, a shorter minimal use may still result in improved patient outcomes.

Consequences of CMS Policy

The policy may improve care by incentivizing durable medical equipment (DME) providers to deliver more comprehensive PAP services. The policy provides an incentive for DME providers to educate and facilitate PAP use. It also encourages DME providers to reach out to struggling patients to troubleshoot problems

with PAP that may arise in that trial period. Both the patient and DME provider have aligned interests in reaching adherence thresholds for long-term coverage. For people who are no longer interested in using PAP, the policy saves costs by reducing wasteful expenses for all parties.

However, the current threshold model exacerbates inequities because DME providers are incentivized to prioritize people that are most likely to be adherent with minimal effort to maximize their reimbursement. More difficult patients are more likely to require additional resources such as time and supplies and may still fall short of the threshold. Such patients can be seen as a financial hit to the bottom line; investing in these challenging patients is not worthwhile in this market-driven, for-profit system. Modern tracking tools created by the CPAP manufacturers can allow for early intervention and identification of issues, but those without technical skills, English proficiency, and smartphones with Wi-Fi are often left behind. This policy statement focuses on those patients who are interested in using PAP, trying but not able to meet CMS requirements. These patients often take additional time and resources for DME providers, and currently, policy incentives counter the investment in these users, given the lack of reimbursement and potential penalties, thus worsening disparities.

Some may believe that the CMS policy is required as a safeguard against fraud and abuse because of inappropriate billing for unnecessary supplies, which the Federal False Claims Act prosecutes. Indeed, prominent PAP manufacturers have been prosecuted for allegedly offering kickbacks to DME providers and sleep labs for prescribing and providing their devices. Therefore, specific requirements for prescription are generally required for many items in addition to PAP, including oxygen, wheelchairs, and nebulizers (37). However, CMS does not require adherence monitoring for any other therapy. This disparate approach contradicts the principle of justice, a key principle of healthcare ethics, accounting for a fair and equitable distribution of healthcare resources. Furthermore, it is not clear that fraud is substantially reduced by using adherence thresholds. The temporary loosening of requirements secondary to the COVID-19 pandemic poses an opportunity for a natural experiment which could be informative in assessing if the incidence of fraud and abuse cases rose.

Comparison with International PAP Coverage

Models from around the world can be instructive on other approaches to cover PAP therapy for patients with OSA. PAP coverage varies greatly within and across countries, ranging from costs borne entirely by patients to that covered entirely by health systems. Therefore, our multinational writing group surveyed several models. There are many models of CPAP coverage and care, but we did not find any evidence-based models guiding insurance coverage determination. These international models can impart lessons pertinent to value-based care in the United States. We reviewed coverage models in Australia, England, and Canada; none of these systems had any required adherence for coverage, yet each had differences within the country on the basis of local, provincial government funding.

The Japanese system mandates very strict qualification criteria and a high patient burden for face-to-face visits (some accommodations were made because of the COVID-19 pandemic to allow less frequent visits). In Japan, PAP coverage requires diagnosis with in-lab polysomnography followed by visits with a sleep practitioner every 1–3 months for the duration of therapy. Recent work suggests that telemonitoring with reduced visit frequency is just as effective as the current Japanese standard of care (46). Studies from this model highlight the importance of investment in patient engagement early in adherence but a lack of added benefit for increased monitoring in those who demonstrate high PAP therapy adherence. Telemedicine increased adherence comparably to face-to-face visits but led to greater patient satisfaction. This may be a method to reach underserved communities, which are more likely to have difficulty with transportation and work accommodations for medical care (presuming adequate infrastructure for telemedicine in these communities).

Current U.S. Adherence Requirement and Signaling Theory

Signaling theory may be a useful model to understand why there is an incentive to create a high bar before continued financial support of PAP equipment and supplies. Asymmetric information, in which one party knows something the other party does not, may contribute to the current system.

The insurance payer does not know how much the patient desires (or not) to continue therapy. Continued expense when the patient has little motivation to use the therapy is wasteful and to be avoided. Therefore, a credible signal is needed to indicate the presence of an unobservable element to the payer (the patient's interest and seriousness in therapy continuation). An ideal signal is one that is too costly (in terms of time, effort, or money) for people who have no intention of using the therapy to exhibit but inexpensive enough that those who want to use PAP can afford to do so. This signal currently is the CMS 4 hour/night PAP use in 70% of days requirement. However, research suggests social determinants of health may conflate this signal and accentuate health disparities. Thus, those who want and need the therapy but are unable to because of other contextual reasons with this sleep requirement and burdensome signal.

Current U.S. Adherence Requirement and Sleep Disparities

Studies have shown a consistent difference in PAP adherence by race and ethnicity. In the HomePAP trial, a multicenter randomized trial comparing home study versus full polysomnography diagnostic and treatment strategies, large differences were observed by race, with 92 min/d less PAP use among Black participants compared with whites. Equipment and clinical visits were paid for by the trial, not participants, yet disparities remained (47). A more recent single-center Department of Veterans Affairs study showed differences in adherence by race, with lower adherence in Black veterans compared with white (48). Non-white race has been consistently associated with lower PAP adherence across studies in the United States (49). Black race was associated with less CPAP use during the first week of treatment, which predicts long-term use (50). Differences in PAP adherence were also observed in Maori people compared with white people in New Zealand (51). In a sham versus active PAP trial enriched with minorities, the analysis found greater adherence in whites, particularly women (52). Recent data gathered from a large nationwide sample of PAP users in the United States found differences in adherence by the racial composition of residential neighborhoods. Those residing in areas with a high proportion of Black or

Hispanic residents had lower PAP use compared with those residing in areas with a majority of white residents (53). These studies suggest persistent and long-lasting adverse effects on health.

In the United States, neighborhoods with low socioeconomic position (SEP) have higher proportions of Black, Latinx, and indigenous populations in part because of historical discriminatory housing policies and Federal American Indian treaties (54). These communities have higher rates of poverty, unemployment, and low homeownership (55, 56). Many adverse health outcomes more prevalent in non-white communities are linked with chronic economic and social deprivation, related to the consequences of structural and institutional inequity, unjust social policies, and chronic discrimination (57). Studies examining OSA disparities observe differences by race and ethnicity and similar disparities by SEP (58). In addition, there is evidence from large-scale studies that women have lower OSA therapy adherence (59–62). These adherence differences in women have multifactorial causes (e.g., lower SEP, increased insomnia prevalence, etc.) and intersectionality (the combination of multiple overlapping characteristics that may lead to marginalization). An understanding of interactions between different marginalized categories may improve communication and support for these communities.

Socioeconomically disadvantaged populations are also less likely to meet CMS PAP adherence requirements. Specifically, those with lower socioeconomic positions tend to have lower PAP use compared with those with a higher position. In an observational study of veterans, PAP adherence was associated with neighborhood SEP, with only 34% using CPAP for 4 or more hours among those residing in the lowest SEP census block compared with 62% among those living in the highest SEP census blocks. This difference could not be attributed to the financial burdens of treatment as all PAP costs were covered under Veterans Administration benefits (63). In the HomePAP trial, participants residing in the lowest 25% SEP ZIP codes had an average of 50 fewer minutes of PAP use compared with those participants in higher SEP ZIP codes after adjustment for OSA severity and study arm (47). A recent cohort study using geolinked PAP data from a large U.S. national sample showed PAP users

living in ZIP codes with the lowest median household income had significantly lower adherence degrees than those living in the highest at 40% versus 47%, respectively. These studies suggest that disadvantaged PAP users are less likely to meet CMS standards of adherence (64). Moreover, the similarity of these findings over the last two decades suggests that the association between lower SEP and poor PAP adherence persists despite changes in healthcare coverage, including the initiation of the Affordable Care Act. A recent study of similarly insured Medicare beneficiaries found that lower SEP was associated with lower CPAP adherence (65).

There are several possible factors contributing to this disparity in PAP adherence, (see Figure 1) such as differences in insomnia symptoms and sleep duration observed by race and SEP (66). In addition, low SEP populations more often engage in shift work, which further limits sleep opportunity. This leads to fewer hours of sleep to use PAP, often out of alignment with the family sleep schedule. Similarly, with limited resources, a major life event such as hospitalization may have a more profound impact on sleep and the ability to use PAP therapy in those at the margins. People living in disadvantaged and minority-predominant neighborhoods are more likely to report insufficient, delayed onset, and poor sleep quality (67). In addition, those residing in composite low SEP neighborhoods have more insomnia symptoms (68). Shorter sleep duration and reduced sleep continuity, measured objectively by actigraphy, are also associated with neighborhood disadvantage (67). Living in disordered neighborhoods, neighborhoods with greater perceived crime, more blight, and lower SEP have been associated with difficulty falling asleep and more awakenings in the night (68). Fear of crime, violence, lower perceived safety, and lack of cohesion, features more prevalent in low SEP neighborhoods, substantially impact sleep quality and have been associated with insomnia symptoms (69). Insomnia is itself a risk factor for worse PAP adherence (70). Poor sleep and difficulty getting to sleep may make adapting to PAP use more challenging and limit use. Longer sleep duration by objective measurements was observed in neighborhoods perceived to be safer and with greater cohesion (71). When sleep remains disturbed by the neighborhood environment, the benefits of PAP on sleep continuity may be less significant. Thus,

disadvantaged groups may have less benefit from PAP because of continued fragmented and insufficient sleep unrelated to OSA than those living in more affluent neighborhoods and, as a result, find adherence more challenging to sustain.

Other environmental features more prevalent in disadvantaged neighborhoods may also impair PAP adherence. Inopportune light and excess noise, common in dense, poor urban areas, may further delay or disturb sleep and natural circadian rhythm (72, 73). Low SEP neighborhoods are also more likely to have worse air quality and greater urban heat (74, 75), which may impact sleep quality; furthermore, greater pollution has been associated with worse sleep apnea (76). These factors may disrupt and delay sleep and make PAP use more challenging as a result. With less access to air conditioning and more reliance on open windows, outdoor noises and pollution are more likely to disrupt sleep in patients with lower SEP. Pollution may lead to more upper airway inflammation and decrease nasal airflow (77). These factors, together with heat, may lead to more frustration with PAP masks and limit adherence. Finally, those residing in low SEP neighborhoods may experience less stable sleeping space because of housing insecurity, crowding, or homelessness, which has been associated with lower PAP adherence (78). They may have less consistent access to electricity to plug in and use the PAP device, as well as an inability to store equipment safely in the daytime.

Beyond neighborhood, household, and environmental factors, those in lower SEP and minority groups may have other barriers to PAP use, including a greater burden of costs, lack of access, and competing health burdens. With less disposable income, lower SEP groups may be unable to obtain extra supplies (e.g., the ability to try an additional mask) and have reduced healthcare access to follow-up care to enable PAP tolerance. Many in minority populations have a lower health literacy. Complicating communication with DME and clinicians, in addition to low health literacy, are language barriers, lack of technical skills, and limited access to the internet without broadband Wi-Fi. Non-white patients may face additional discrimination and implicit bias from clinicians and DME providers (79). The absence of trust in the healthcare system may be an additional factor limiting adherence. Studies in cardiovascular medication adherence find differences by race and/or

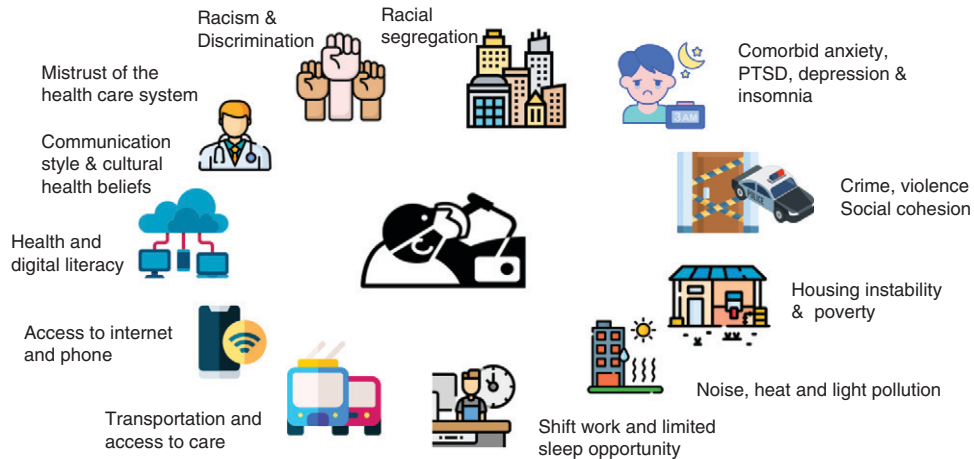


Figure 1. Societal features, structural forces, and socioecological factors that may contribute to sleep health disparities and continuous positive airway pressure (CPAP) use differences. PTSD = posttraumatic stress disorder.

ethnicity concordance. Building a sleep workforce with diversity and inclusivity that fosters cultural competency may reduce these biases and enhance adherence. Low SEP and minority patients with OSA may have greater competing psychosocial demands and more substantial medical and psychiatric comorbidities compared with white, upper SEP patients with OSA (39–42). Each of these additional burdens may hinder PAP use and diminish the ability to achieve adherence in these at-risk populations.

Unfortunately, the current payer policy on the basis of the CMS coverage determination does not fund additional time, staff, supplies, or educational resources to reduce barriers to reaching adherence. Just like using insulin or wearing hearing aids, PAP is a treatment that requires long-term daily use. But little has been done to address social determinants of health as causal factors for nonadherence or the differential impact of the current requirements. Thus, at-risk patients may become disenfranchised from access to effective OSA therapy. A larger proportion of those residing in low socioeconomic status and minority-predominant neighborhoods do not reach CMS requirements (53). Largely because of the lack of reimbursement, insufficient additional supports in marginalized populations lead to health disparities in OSA care.

When DME providers repossess PAP devices per insurance rules, they are removing therapy that can potentially improve health-related quality of life, daytime sleepiness, and healthcare usage and can decrease rates of motor vehicle collisions

and absenteeism. The withdrawal of care also exacerbates mistrust in the healthcare system and adversely impacts subsequent attempts. Thus, the current rules are particularly pernicious for those living at the margins and arguably in greatest need of better quality sleep. Current CMS policy may paradoxically create incentives to invest fewer resources in socially disadvantaged patients with OSA who may require greater time investments for education and support with lower reimbursement rates for supplies.

Methods

An interprofessional, multidisciplinary committee comprised of patients with OSA on PAP therapy, respiratory therapists, insurance representatives, and experts in sleep medicine, health policy, and health disparities developed this policy statement. Working groups were created within the committee to review relevant literature and convene focused discussions to review the findings. Working groups included the review of the historical context informing the formulation of the current CMS PAP policy, the impact of current policy on health disparities, and international models for PAP coverage. The working groups sought topic-specific expertise during the review, discussion, and writing process. The committee then developed this policy through an iterative discussion-based consensus process. On the basis of these discussions, the committee chairs compiled policy considerations. Members rated all potential proposals on a one to five Likert

scale (ranging from strongly disagree to strongly agree). These ratings were collected and summarized by the co-chairs of the committee. Proposals rated most highly were retained as consensus policy considerations. A writing committee consisting of the two policy statement co-chairs drafted the policy statement. The working group used an iterative process to review and revise the policy statement. The statement was reviewed and approved by the American Thoracic Society Board of Directors.

Recommendations

Redefining PAP Adherence

We recommend defining adherence as consistent, long-term use of PAP therapy that yields sustained patient benefit (e.g., less daytime sleepiness, improved quality of life, more daytime energy, greater sleep quality, etc.) over a 6-month period. We favor a patient-centered definition on the basis of goals rather than a specific time-use cutoff to define adherence. However, a reasonable minimal PAP use threshold would be 2 hours per night, averaged after a 6-month trial to continue coverage.

- Personalized, patient-centered targets for use on the basis of benefit:
 - Accounting for individual habitual sleep time and patient-specific life circumstances;
 - Flexibility in the timing of adherence determination to allow sufficient time to develop tailored

approaches to address adherence barriers and challenges.

- Consistent patient intent to use therapy and forward progress toward increasing usage consistency, frequency, or both.
- Progress toward the ultimate goal: consistent PAP use for the entire sleep time, including both the main sleep period and any naps.

Comments: The adherence definition is at the crux of the policy statement. We recommend an adherence definition with enough flexibility to address current health equity disparities. Therefore, the working group took a broader view of adherence: One that is patient-centered and goal-oriented. Such a definition would consider both the time used and qualitative measures of patient-centered outcomes. The outcome(s) most important to the patient, identified via shared discussion between patient and clinician, would be the focus of assessing PAP efficacy. Clinicians would assess these metrics before and after PAP therapy initiation. The patient reported outcomes most relevant on the basis of patient symptoms and goals; prominent examples are improvements in sleep quality, ability to focus, and daytime sleepiness. The patient would determine the desired care goals aligning with their cultural values of health and sleep. Consideration of patient-specific obstacles and effort to achieve consistent use with personalized hourly adherence targets is particularly important. If the patient wishes to continue therapy, adherence should be assessed after the implementation of applicable PAP adherence interventions. As payors may require a threshold, we advocate for the least restrictive threshold that has evidence of improvement in patient-centered outcomes (2 hours of use a night) to demonstrate a credible yet achievable signal of effort to use the therapy (*see* signal theory section for additional information).

Critical policy changes to mitigate worsening health disparities in PAP coverage, as determined by our group, include 1) eliminate the 4 hours, 70% of 30-day metric in favor of qualitative patient experience targets; 2) allow continued CPAP coverage beyond 90 days without requiring repeat in-lab study in those motivated and requesting to continue who have not yet met requirements; 3) require a minimum of

2 hours of use per night on average over 30 days by the end of a 6-month trial coverage period to allow for the implementation of additional support and therapies to enhance adherence (80); and 4) foster early patient participation in adjuvant therapies to enhance adherence, including outreach to vulnerable patients such as those with comorbid psychiatric illness, severe chronic health problems, insomnia, decreased access to care, health literacy, limited English proficiency, and other contextual factors.

Interventions to Eliminate Health Disparities in PAP Adherence

Before therapy initiation. The working group endeavored to balance inclusiveness in health care with practical considerations of cost and time constraints.

1. Set expectations for therapy, identify barriers to adherence, and establish reasonable adherence targets.

Comments: The clinician should educate the patient on all reasonable treatment options before collaboratively deciding on PAP therapy. The clinician and patient should work together to identify potential barriers to adherence, navigate negative perceptions of PAP, and assess dedication to mastering PAP use. Personalized adherence targets should account for patient-specific factors such as comorbidities, contextual factors, social and economic conditions, and unique circumstances.

2. Anticipate potential issues with PAP use and provide early referral and/or additional support before or during PAP initiation.

Comments: Initiation of preemptive adjuvant therapies before PAP therapy may be useful in patients anticipated to have challenges with PAP. Several domains, including psychiatric (e.g., anxiety and posttraumatic stress disorder), comorbid sleep disorders (e.g., insomnia and nightmare disorder), claustrophobia, cognitive dysfunction, and limited dexterity or mobility negatively affect PAP adherence (15, 70, 81–89). Identification of these factors can facilitate targeted therapy referral. Cognitive behavioral therapy for insomnia or

the shorter format (brief behavioral therapy for insomnia) may facilitate PAP adherence in those with comorbid insomnia and allow faster adoption (90). Integrating rehearsal imagery for nightmares and posttraumatic stress disorder, acclimation, motivational interviewing, and other behavioral interventions in addition to a short supportive trial of PAP (PAPNAP) may improve PAP adherence in populations with psychiatric comorbidities (20, 91–96). Addressing comorbid psychiatric disorders before or during PAP therapy initiation can improve adherence. Addressing limitations on time, access to mental health care, and added costs will also be crucial to implementing these referrals. Improving PAP tolerance through gradual acclimation, behavioral change, and desensitization often requires extended time, particularly for underresourced populations (70, 97).

Starting Therapy. Initial PAP therapy impressions are important, and additional time should be spent at therapy initiation to discuss goal setting, troubleshooting, and answering questions.

3. DME providers contracted with CMS must contact the patient early in therapy to answer questions and assess for side effects; identified issues should be promptly addressed by DME provider staff.

Comment: Early adherence is indicative of long-term adherence. Studies suggest that use patterns are set in the first week of therapy. Therefore, early intervention has the best chance of improving long-term adherence. Common early and addressable issues include poor mask fit, nasal/oral dryness, and pressure discomfort. DME provider staff can solve issues with additional mask options and setting adjustments for comfort. Poorly-fitting masks are the most common cause of PAP therapy side effects. Allowing an at-home trial of up to four masks would improve the probability of finding a well-fitting mask at therapy initiation.

4. Timely communication between the DME provider and clinical staff regarding PAP therapy initiation and limited use, specifically in the first week of therapy as well as throughout therapy.

Comment: Communication between the DME provider and clinician for intervention coordination and enhancement enables early problem-solving. DME providers should identify the best mode of communication on the basis of patient preference (automated text, phone call, video call, or face-to-face visit) to facilitate timely care.

- Underserved communities may need closer follow-up, flexibility in access to PAP information, translation of educational material, and support by community members.

Comment: Underserved communities often have less trust in the medical system because of prior traumas and misinformation. Outreach by community leaders, cultural mediators, and/or peer buddies may enhance acceptance and understanding of PAP therapy. These adjuvant outreach services should be funded to enable implementation. The added costs to clinicians and DME providers for additional time should be factored into reimbursements by CMS to incentivize care; CMS should consider models like Racial and Ethnic Approaches to Community Health (REACH) or IMPACT to work with underserved communities (98). Family and community support are important factors for adherence. Partner support has been previously shown to be associated with adherence, and those without partners are more likely to have a lower income and education and may require additional support to reach and maintain PAP adherence (99–101). Using family and other social support structures to improve adherence could help eliminate disparities. Improvements to the physical and social environment that promote better sleep (such as green space and safer neighborhoods) and, thereby, PAP use, may be valuable tools to improve adherence. Targeted public health initiatives and social worker involvement can disseminate such sleep-promoting interventions.

- Allow earlier equipment return and clinician follow-up if the patient reports no interest in continuing PAP therapy.

Comments: Some people become categorically opposed to PAP therapy. These patients have no intention of working toward adherence or ever using PAP. Early return of

devices frees up inventory to treat other patients, reduces waste, and decreases monitoring and follow-up burden on staff. This approach allows patients to switch therapies more quickly with a less total cost to them, the payor, and the system.

Policy and program development.

- CMS should discontinue its mandated medically unnecessary but required polysomnography to restart PAP therapy. Instead, CMS should allow continued coverage if the patient is engaged in one of the multiple paths to improve adherence.

Comment: Patients are not able to reach adherence goals for multiple reasons. If a patient wants to continue therapy but is not meeting adherence goals, to signal their resolve and motivation, they should partake in targeted adherence programs (e.g., PAPNAP, educational sessions, webinars, peer buddies, group and individual behavioral therapies, and/or outreach visits). But in-lab polysomnography does not increase PAP adherence, creates burdens and barriers, and adds wasteful costs and time delays.

- CMS should develop programs to encourage expansion into underserved populations, which will require additional funding for adjuvant outreach and engagement. In turn, DME providers should be required to report equity information.

Comments: The committee enthusiastically supports policy changes at the local and national levels to improve care delivery. Outreach to and engagement with underserved communities, as well as equity reporting, could improve health inequities and reduce barriers to PAP use.

Monitoring and early intervention effort expansion can be challenging for DME providers because of the increased workload. This workload needs to be distributed among a limited number of personnel. Personnel workload for follow-up, coaching, and troubleshooting can be offloaded via care delivery innovation. Despite modern telehealth innovations improving adherence (46, 102), their impact is dampened in disadvantaged groups because these tools require internet access, English fluency, medical literacy, and digital literacy. An all-

of-the-above communication strategy employing multifaceted approaches on the basis of patient preference is likely to increase PAP uptake and adherence in underserved communities. Such innovation would increase marginalized community engagement while limiting personnel capacity expenditure. Payment should be structured to provide incentives to foster additional work and engagement. CMS contracts with DME providers should require a demonstration of efforts to improve outreach and engagement.

CMS should incentivize underserved community outreach and engagement, and such efforts should be monitored and reported for CMS contracts. Additional stipends or grants from CMS for new programs in the community and academic centers may be a pathway to foster innovation and build partnerships.

Discussion

Our goal is to eliminate OSA therapy use disparities, starting with policy changes in coverage determination and a reframing of PAP adherence. A strict, inflexible number defining adherence is counter to PAP efficacy research and exacerbates health inequities. Goals and expectations for PAP therapy need to be calibrated to individual circumstances and patient-centered outcomes, and periodic reevaluation of these goals realigns PAP therapy with the updated patient situation.

The committee is in full agreement that consistent PAP use during sleep is a critical component of PAP efficacy, particularly in marginalized populations. However, adherence is not an immutable characteristic. Additional efforts to improve adherence would focus resources both before therapy and at the start of therapy. Education, goal setting, and evaluation and mitigation of factors that hinder PAP use are critical objectives before the initiation of therapy. Close and early follow-up, combined with intervention, if needed, are key to improving PAP adherence. However, these initiatives are not enough. Policy change is needed to promote health equity. Experimentation with different models of care provision and community outreach can improve PAP uptake in marginalized communities. Measurement is necessary for continued focus on productive change. Assessing PAP disparities can inform

change. Therefore, monitoring DME provider equity in care provision would make equity initiatives a priority. A change to CMS guidelines on therapy reinitialization to avoid unnecessary procedures and address the core causes of previous nonadherence could also improve PAP adherence and decrease care disparities while simultaneously reducing costs.

Knowledge Gaps

To sensibly make a coverage determination, priorities need to be stated clearly. The coverage determination process should be transparent, factoring in improvements in quality of life, daytime sleepiness, and other patient-reported benefits, as well as the risk of motor vehicle accidents without treatment. This may need to be adjusted as additional data refine our understanding of the effects of PAP therapy. A clear understanding of priorities in choosing the coverage policy can inform future modifications as the evidence base grows. Our group firmly believes that coverage determinations should be evidence-based and equity-oriented.

Several analyses have used the Veterans Affairs population (48, 70, 89, 103). These studies aid in understanding predictors of adherence in a setting in which therapy is never discontinued secondary to nonadherence. However, there are notable differences between this population and the general medical population, such as an overrepresentation of older men and white people. In addition,

motivations for OSA diagnosis may differ given the associated financial benefits in the veteran population, which may affect adherence. Although this group is helpful in determining longer PAP-trial benefits, the Veterans Affairs (VA) population is not representative of the population covered by most payers. Therefore, trials of different coverage policies in the general population are needed.

The optimal strategy for PAP coverage balancing costs and benefits, particularly in underserved and marginalized populations, is not clear. A transnational evaluation of different coverage models may aid in determining tradeoffs between adherence, quality of life, symptoms, healthcare usage, equity and risk for future adverse events, and costs. All of the PAP coverage models examined by our group had drawbacks and benefits; none yielded ideal adherence, incentives, or equity. If a different coverage model is chosen, pilot studies to ensure that the model translates to the United States healthcare system with similar effects are recommended before full-scale implementation.

Cost containment is a core issue for any insurance coverage. Therefore, economic investigations into waste, fraud, and abuse should be conducted concurrently with the implementation of any proposed coverage change. Specific evaluation of the change in adherence with different durations of the trial period should help inform evidence-based policy. A retrospective evaluation of the impact of the

COVID-19 pandemic waivers on costs and abuse might provide data to this end.

Additional work on strategies to improve adherence is sorely needed. Several small-scale studies have shown improvements with time- and labor-intensive interventions such as motivational enhancement and peer buddies (95, 96, 104). However, this work has rarely translated to widespread changes in clinical care, especially in vulnerable populations. Demonstrations of effectiveness, cost/benefit evaluation, as well as efficacy are needed to aid cost-conscious adherence efforts. Unfortunately, there is a dearth of implementation science work in this area.

Conclusions

The American Thoracic Society supports improving care provision and eliminating health disparities in marginalized groups. This working group identified several policy change considerations with the goal of improving PAP parity in underserved and marginalized communities. Additional resources may be needed to reduce disparities in PAP, the implementation of which requires further studies. In addition, we advocate for support mechanisms to increase outreach in and engagement of underserved populations, restructuring policy to foster equity efforts. We propose the above as a cogent roadmap for future research, which will help align evidence-based OSA treatment with eliminating health disparities. ■

This official policy statement was prepared by an *ad hoc* subcommittee of the ATS Sleep and Respiratory Neurobiology Assembly.

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