





February 13, 2024

Jennifer T. Lee MD Chief Medical Officer (Acting) Center for Medicaid and CHIP Services (CMCS) Centers for Medicare & Medicaid Services (CMS):

Dr. Lee:

We are writing on behalf of the American Thoracic Society, the American College of Chest Physicians and the American Academy of Sleep Medicine to urge changes in CMS policy to expand access to home sleep apnea testing (HSAT) for Medicaid beneficiaries suspected of having obstructive sleep apnea (OSA). We are requesting a virtual meeting with you and your staff to discuss the possibility of revising the Medicaid national coverage policy for HSAT.

As background, the American Thoracic Society is the world's leading medical society dedicated to improving global respiratory health with over 16,000 members, made up of physicians, scientists, nurses, and other allied healthcare professionals committed to improving the care of patients with respiratory diseases. The AASM represents more than 9,000 sleep clinicians, researchers, and educators and 2,600 accredited sleep facilities, all of whom are dedicated to advancing sleep care and enhancing sleep health to improve lives. The American College of Chest Physicians® (CHEST) is the global leader in the prevention, diagnosis and treatment of chest diseases. Its mission is to champion advanced clinical practice, education, communication and research in chest medicine including sleep-related disorders. Our collective members treat Medicaid beneficiaries, including many Medicaid patients who would benefit from enhanced access to home sleep apnea testing.

OSA is one of the most common respiratory diseases in the US that produces substantial symptom burden and is associated with numerous adverse health consequences including elevated accident risk, cardiovascular disease and stroke. The prevalence of OSA has increased rapidly, reflecting the growing epidemic of its strongest risk factor, obesity. While multiple effective treatments for OSA exist, access to treatment has been limited by difficulties in access to diagnosis. The gold standard diagnostic test for OSA, overnight polysomnography (PSG), requires patients to spend a night at a sleep laboratory wearing wires and monitors placed by a sleep technician. Over the past two decades, newer technologies have been developed to allow home testing that is more accessible, simpler to administer, and preferred by patients. Moreover, HSATs enable an ambulatory approach to diagnosing and treating OSA that incurs lower costs for payors. As such, nearly every private insurer covers HSAT, most preferring home testing because of these advantages. Based on an evidence-based review, CMS approved coverage for HSAT as an alternative to PSG for Medicare beneficiaries over a decade ago. Unfortunately, Medicaid has not followed suit at a national level. State Medicaid coverage for home testing varies widely by state and by policy within each state. This has resulted in avoidable barriers to OSA care for the very

patients who would benefit the most, thereby exacerbating disparities in OSA care, while unnecessarily increasing costs and wasting resources given the substantially higher cost and burden of PSG versus HSAT. We are, therefore, requesting CMCS establish policies at a national level that would allow coverage of HSAT for the diagnosis of OSA. We believe this would lead to net cost savings while simultaneously improving health equity.

Burden of OSA and importance of management

OSA affects approximately 26 million adults in the US,² It occurs due to repetitive upper airway collapse during sleep, resulting in sleep fragmentation and recurrent arousals along with drops in oxygen saturation. Untreated OSA increases the likelihood of errors and performance impairment, worsens inattention and memory deficits,³⁻⁵ and increases the risk of motor vehicle accidents.⁶ Moreover, it is associated with various cardiovascular diseases (CVD),⁷ particularly hypertension (HTN),⁸⁻¹⁰ atrial fibrillation,¹¹ heart failure,¹² and stroke.¹³ Continuous Positive Airway Pressure (CPAP) serves as the cornerstone of OSA treatment, and numerous studies have demonstrated its effectiveness in improving health outcomes such as blood pressure.^{10,14,15} Additionally, numerous randomized trials have established OSA treatment produces significant reductions in daytime sleepiness and improved quality of life.^{16,17}

It's important to note that racial and ethnic minorities have a disproportionately higher burden of OSA along with the health sequelae associated with this condition. Historically marginalized groups exhibit a higher prevalence of OSA compared to white populations, and are more than twice as likely to experience severe OSA, yet paradoxically less likely to receive a diagnosis. Paradoxically less likely to receive a diagnosis. Tructural barriers that adversely impact access to care and in-lab sleep testing may lead to underdiagnosis of OSA. The cost, time burden, and transportation requirements of PSG likely contributes to disparities in OSA diagnosis, especially in the Medicaid population with limited financial resources. Given that CMCS disproportionately serves racial and ethnic minority populations, that a major opportunity to reduce these disparities, by expanding coverage to improve accessibility to OSA diagnosis for adults covered under Medicaid.

Benefits of HSAT

HSATs facilitate an evidence-based and patient-centered approach to OSA diagnosis. Numerous randomized trials have tested HSAT versus PSG. Collectively, these trials support the non-inferiority of HSAT to yield appropriate diagnoses and improve patient-centered outcomes.²⁷⁻³² Specifically, patients randomized to HSAT achieved comparable improvements in sleepiness and sleep-related quality of life and demonstrated similar adherence to subsequent treatment. Accordingly, evidence-based clinical practice guidelines support the use of HSAT for OSA diagnosis.³³ While these guidelines specifically recommend HSAT among populations resembling those included in many of the prior trials (e.g., high risk for OSA, absence of heart failure), HSAT is also non-inferior to PSG in the general population of patients referred for OSA evaluation.³⁴

Beyond a merely non-inferior option, HSATs provide significant advantages and are preferred by most patients.²⁷ PSGs require patients to travel to sleep laboratories and spend at least one night away from their homes, incurring direct travel-related costs (e.g., gasoline, bus fare), child or elder care arrangements and substantial opportunity costs (e.g., missed wages).35 While these patient-incurred costs are often overlooked, they pose a substantial burden among low-income individuals.³⁵ For those who do not own vehicles, public transportation options are typically limited at nighttime when PSG occurs. For rural populations, which include large numbers of American Indian and Alaskan Natives, the nearest sleep center may be 100 miles or more. For single parents and those who serve as caregivers for adult family members, spending a night in the sleep lab for PSG requires identifying someone else to provide childcare/eldercare at home. Given individuals may not get a good night's sleep in the laboratory and need to go home and shower to wash off adhesives applied for testing, patients often need to take a day off from work following PSG. This is a particular barrier for low-income patients who cannot afford to miss a day's work. Contributing to disparities, these cost burdens are disproportionately borne by patients who identify as African American and Hispanic, 35 who are much less likely to have OSA diagnosed. 20,36 Of note, only 38% of African American patients who are referred for PSG complete the testing.³⁷ Beyond costs, PSG poses a barrier due to medical mistrust, as many African American patients report concerns around sleeping in a hospital.³⁸ Reflecting multiple considerations, over 80% of African American patients prefer HSAT over PSG.38,39

By defaulting to PSG, national Medicaid policy is an outlier among payors. Recognizing patient preferences and lower cost per study,⁴⁰ Medicare and the vast majority of commercial insurers have embraced HSAT as the default testing modality. Many state Medicaid plans have followed suit over the past decade and successfully applied for waivers to provide HSAT as a first-line diagnostic test (e.g., Masshealth in Massachusetts, Applehealth in Washington). Moreover, during the COVID-19 pandemic, rules mandating PSG as the only covered diagnostic test for OSA were temporarily lifted for Medicaid programs nationwide. We are unaware of any reports that the widespread use of HSATs at the state and national levels led to unsustainable increases in costs, inappropriate care, or other concerns.

Proposal for CMCS

We believe that updating national Medicaid coverage policies to cover HSAT for evaluating adult patients for OSA will improve patient-centered care by providing a more convenient and rapid evaluation at a lower cost, which has been demonstrated to be preferred by patients. An Agency for Healthcare Research and Quality (AHRQ) technology assessment commissioned by CMS in 2007 demonstrated strong evidence for the accuracy of HSATs. As a result, in 2009, CMS issued a national coverage determination that HSATs would be covered for evaluation of OSA in Medicare beneficiaries. Evidence for their utility in clinical practice has only grown in the subsequent 16 years as numerous private insurers have made HSAT the preferred testing modality for OSA diagnosis. In addition, the use of HSATs will reduce disparities in access to OSA care by making testing more accessible and acceptable to racial minorities as well as rural populations. Prior experience with HSATs in Medicaid populations during the COVID-19 pandemic, as well as in states that were early adopters such as Massachusetts, demonstrate the feasibility, improvement in health equity, and cost savings of such a policy change. Pursuant to Executive Order 13985, it is imperative that CMCS take steps to advance racial equity. Allowing HSAT as an alternative to PSG for diagnosing OSA would advance that goal.

We propose that Medicaid include HSAT as a covered service for the diagnosis of OSA in adult patients presenting with signs and symptoms of OSA. In particular, we would propose enactment of the following policy, in line with current CMS policies for Medicare beneficiaries:

"Type III sleep testing devices, Type IV sleep testing devices with three or more channels one of which is airflow, or sleep testing devices using actigraphy, pulse oximetry, and peripheral arterial tonometry performed in the home are covered when used to aid the diagnosis of OSA in beneficiaries 18 years and older, who have signs and symptoms indicative of OSA."

We look forward to meeting with you and your staff in the near future to discuss in greater detail how Medicaid policies can be revised regarding OSA diagnostic testing so as to improve equity in access to care at a lower cost.

Sincerely,

American Thoracic Society American College of CHEST Physicians American Academy of Sleep Medicine

Cc: Daniel Tsai
Deputy Administrator and Director
Center for Medicaid and CHIP Services (CMCS)
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References

- 1. Kim RD, Kapur VK, Redline-Bruch J, et al. An Economic Evaluation of Home Versus Laboratory-Based Diagnosis of Obstructive Sleep Apnea. *Sleep*. 2015;38(7):1027-1037.
- 2. Peppard PE, Young T, Barnet JH, Palta M, Hagen EW, Hla KM. Increased prevalence of sleep-disordered breathing in adults. *Am J Epidemiol*. 2013;177(9):1006-1014.
- 3. Wallace A, Bucks RS. Memory and obstructive sleep apnea: a meta-analysis. *Sleep.* 2013;36(2):203-220.
- 4. Olaithe M, Bucks RS. Executive dysfunction in OSA before and after treatment: a meta-analysis. *Sleep.* 2013;36(9):1297-1305.
- 5. Leger D, Bayon V, Laaban JP, Philip P. Impact of sleep apnea on economics. Sleep Med Rev. 2012;16(5):455-462.
- 6. George CF. Sleep apnea, alertness, and motor vehicle crashes. *Am J Respir Crit Care Med.* 2007;176(10):954-956.
- 7. Yeghiazarians Y, Jneid H, Tietjens JR, et al. Obstructive Sleep Apnea and Cardiovascular Disease: A Scientific Statement From the American Heart Association. *Circulation*. 2021;144(3):e56-e67.
- 8. Peppard PE, Young T, Palta M, Skatrud J. Prospective study of the association between sleep-disordered breathing and hypertension. *N Engl J Med.* 2000;342(19):1378-1384.
- 9. O'Connor GT, Caffo B, Newman AB, et al. Prospective study of sleep-disordered breathing and hypertension: the Sleep Heart Health Study. *Am J Respir Crit Care Med.* 2009;179(12):1159-1164.
- 10. Marin JM, Agusti A, Villar I, et al. Association between treated and untreated obstructive sleep apnea and risk of hypertension. *JAMA*. 2012;307(20):2169-2176.
- 11. Mehra R, Chung MK, Olshansky B, et al. Sleep-Disordered Breathing and Cardiac Arrhythmias in Adults: Mechanistic Insights and Clinical Implications: A Scientific Statement From the American Heart Association. *Circulation*. 2022;146(9):e119-e136.
- 12. Gottlieb DJ, Yenokyan G, Newman AB, et al. Prospective study of obstructive sleep apnea and incident coronary heart disease and heart failure: the sleep heart health study. *Circulation*. 2010;122(4):352-360.
- 13. Yaggi HK, Concato J, Kernan WN, Lichtman JH, Brass LM, Mohsenin V. Obstructive sleep apnea as a risk factor for stroke and death. *N Engl J Med*. 2005;353(19):2034-2041.
- 14. Navarro-Soriano C, Martinez-Garcia MA, Torres G, et al. Factors associated with the changes from a resistant to a refractory phenotype in hypertensive patients: a Pragmatic Longitudinal Study. *Hypertens Res.* 2019;42(11):1708-1715.
- 15. Javaheri S, Barbe F, Campos-Rodriguez F, et al. Sleep Apnea: Types, Mechanisms, and Clinical Cardiovascular Consequences. *J Am Coll Cardiol*. 2017;69(7):841-858.
- 16. Patil SP, Ayappa IA, Caples SM, Kimoff RJ, Patel SR, Harrod CG. Treatment of Adult Obstructive Sleep Apnea With Positive Airway Pressure: An American Academy of Sleep Medicine Systematic Review, Meta-Analysis, and GRADE Assessment. *J Clin Sleep Med.* 2019;15(2):301-334.
- 17. Ramar K, Dort LC, Katz SG, et al. Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy: An Update for 2015. *J Clin Sleep Med*. 2015;11(7):773-827.
- 18. Johnson DA, Ohanele C, Alcántara C, Jackson CL. The Need for Social and Environmental Determinants of Health Research to Understand and Intervene on Racial/Ethnic Disparities in Obstructive Sleep Apnea. *Clin Chest Med.* 2022;43(2):199-216.
- 19. Alshehri MM, Alqahtani AS, Alenazi AM, et al. Associations between ankle-brachial index, diabetes, and sleep apnea in the Hispanic community health study/study of Latinos (HCHS/SOL) database. *BMC Cardiovasc Disord*. 2020;20(1):118.
- 20. Redline S, Sotres-Alvarez D, Loredo J, et al. Sleep-disordered breathing in Hispanic/Latino individuals of diverse backgrounds. The Hispanic Community Health Study/Study of Latinos. *Am J Respir Crit Care Med*. 2014;189(3):335-344.
- 21. Thornton JD, Dudley KA, Saeed GJ, et al. Differences in Symptoms and Severity of Obstructive Sleep Apnea between Black and White Patients. *Ann Am Thorac Soc.* 2022;19(2):272-278.
- 22. Pranathiageswaran S, Badr MS, Severson R, Rowley JA. The influence of race on the severity of sleep disordered breathing. *J Clin Sleep Med.* 2013;9(4):303-309.
- 23. May AM, Patel SR, Yamauchi M, et al. Moving toward Equitable Care for Sleep Apnea in the United States: Positive Airway Pressure Adherence Thresholds: An Official American Thoracic Society Policy Statement. *Am J Respir Crit Care Med.* 2023;207(3):244-254.
- 24. Billings ME, Cohen RT, Baldwin CM, et al. Disparities in Sleep Health and Potential Intervention Models: A Focused Review. *Chest.* 2021;159(3):1232-1240.

- 25. Race and ethnicity of the national Medicaid and CHIP population in 2020. Center for Medicare and Medicaid Services. https://www.medicaid.gov/sites/default/files/2023-08/2020-race-etncity-data-brf.pdf. Published 2020. Accessed September 1, 2023.
- 26. Proctor K. CMS Releases Data Briefs That Provide Key Medicaid Demographic Data for the First Time. Centers for Medicare and Medicaid Services. <a href="https://www.cms.gov/blog/cms-releases-data-briefs-provide-key-medicaid-demographic-data-first-time#:~:text=Race%20and%20ethnicity%3A%20Medicaid%20and,than%20the%20broader%20U.S.%20population. Published July 25, 2023. Accessed September 7, 2023.
- 27. Skomro RP, Gjevre J, Reid J, et al. Outcomes of home-based diagnosis and treatment of obstructive sleep apnea. *Chest.* 2010;138(2):257-263.
- 28. Rosen CL, Auckley D, Benca R, et al. A multisite randomized trial of portable sleep studies and positive airway pressure autotitration versus laboratory-based polysomnography for the diagnosis and treatment of obstructive sleep apnea: the HomePAP study. *Sleep.* 2012;35(6):757-767.
- 29. Mulgrew AT, Fox N, Ayas NT, Ryan CF. Diagnosis and initial management of obstructive sleep apnea without polysomnography: a randomized validation study. *Ann Intern Med.* 2007;146(3):157-166.
- 30. Kuna ST, Gurubhagavatula I, Maislin G, et al. Noninferiority of functional outcome in ambulatory management of obstructive sleep apnea. *Am J Respir Crit Care Med.* 2011;183(9):1238-1244.
- 31. Hui DS, Ng SS, To KW, et al. A randomized controlled trial of an ambulatory approach versus the hospital-based approach in managing suspected obstructive sleep apnea syndrome. *Sci Rep.* 2017;8:45901.
- 32. Berry RB, Hill G, Thompson L, McLaurin V. Portable monitoring and autotitration versus polysomnography for the diagnosis and treatment of sleep apnea. *Sleep.* 2008;31(10):1423-1431.
- 33. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med*. 2017;13(3):479-504.
- 34. Corral J, Sánchez-Quiroga M, Carmona-Bernal C, et al. Conventional Polysomnography Is Not Necessary for the Management of Most Patients with Suspected Obstructive Sleep Apnea. Noninferiority, Randomized Controlled Trial. *Am J Respir Crit Care Med.* 2017;196(9):1181-1190.
- 35. Montero A KA, Hamel L, Brodie M. Americans' Challenges with Health Care Costs. https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/. Published July 14, 2022. Accessed August 7, 2023.
- 36. Johnson DA, Guo N, Rueschman M, Wang R, Wilson JG, Redline S. Prevalence and correlates of obstructive sleep apnea among African Americans: the Jackson Heart Sleep Study. *Sleep.* 2018;41(10).
- 37. Jean-Louis G, von Gizycki H, Zizi F, Dharawat A, Lazar JM, Brown CD. Evaluation of sleep apnea in a sample of black patients. *J Clin Sleep Med.* 2008;4(5):421-425.
- 38. Shaw R, McKenzie S, Taylor T, et al. Beliefs and attitudes toward obstructive sleep apnea evaluation and treatment among blacks. *J Natl Med Assoc.* 2012;104(11-12):510-519.
- 39. Garg N, Rolle AJ, Lee TA, Prasad B. Home-based diagnosis of obstructive sleep apnea in an urban population. *J Clin Sleep Med.* 2014;10(8):879-885.
- 40. Physician Fee Schedule. Center for Medicare and Medicaid Services. https://www.cms.gov/medicare/physician-fee-schedule/. Published 2023. Accessed August 7, 2023.
- 41. Trikalinos TA, Ip S, Raman G, et al. AHRQ Technology Assessments. In: *Home Diagnosis of Obstructive Sleep Apnea-Hypopnea Syndrome*. Rockville (MD): Agency for Healthcare Research and Quality (US); 2007.
- 42. Sleep Testing for Obstructive Sleep Apnea (OSA). Centers for Medicare And Medicaid Services (CMS).

 <a href="https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=227&keyword=sleep+apnea+diagnosis&keywordType=starts&areald=all&docType=NCA%2cCAL%2cNCD%2cMEDCAC%2cTA%2cMCD%2c6%2c3%2c5%2c1%2cF%2cP&contractOption=all&sortBy=relevance&bc=1. Published March 3, 2009. Accessed September 9, 2023.
- 43. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Federal Register: Executive Office of the President. https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government. Published January 35, 2021. Accessed September 3, 2023.