Template Policy on Diagnostic Testing for Obstructive Sleep Apnea

AASM Payer Policy Review Committee: Neeraj Kaplish, MD (Chair); Kunwar Praveen Vohra, MD (Vice Chair); R. Robert Auger, MD; Lynn D'Andrea, MD; Eliot Friedman, MD; Karin Johnson, MD; Susheel Patil, MD, PhD; Michael Summers, MD; Peter Gay, MD; Amy Licis, MD; Colleen Lance, MD; Ofer Jacobowitz, MD, PhD

The following working document by the Payer Policy Review Committee of the AASM is a *Template Policy on Diagnostic Testing for Obstructive Sleep Apnea* that meets AASM guidelines. This policy does not address testing or coverage for positive airway pressure therapy, for sleep disorders other than OSA, or for patients < 18 years of age.

Obstructive Sleep Apnea (OSA) is a chronic medical condition, characterized by repetitive upper airway (pharyngeal) collapse during sleep.[1, 2] This collapse leads to nocturnal oxygen desaturation, hypercapnia, and sleep fragmentation. OSA is a prevalent condition, and it is estimated that millions of men and women have OSA.[3] It is estimated that the cost burden of undiagnosed OSA among U.S. adults was more than 100 billion dollars in 2015.[4] This elevated cost is related to the symptoms and co-morbid conditions associated with OSA. OSA is a cause of systemic hypertension and is associated with an increased incidence of stroke, heart failure, atrial fibrillation, and coronary heart disease. OSA is also associated with increased all-cause mortality from cardiovascular disease.[5-7] It is also associated with increased risks of depression, diabetes and worsening work productivity.[4]

Diagnosing and treating OSA is also associated with a significant cost burden. The estimated cost of diagnosing and treating OSA in 2015 was approximately $12.4 billion, with 7% of these costs attributed to physician office visits and diagnostic testing.[4] Thus, it is necessary to keep these costs down while ensuring that the greatest number of OSA patients are properly diagnosed and treated.

The gold standard for diagnosis of OSA is polysomnography (PSG) performed in an attended setting at an accredited sleep laboratory.[2] PSG, the traditional benchmark for validation of other diagnostic testing such as a home sleep apnea test (HSAT), also allows for assessment and arousals as well as other sleep disorders that cannot be fully assessed with HSAT. An HSAT is an acceptable alternative as the initial test in a select group of patients. Either PSG or an HSAT is medically necessary for the diagnosis of OSA and should be interpreted by a board-certified or board-eligible sleep medicine physician.[2]

Testing with either PSG or HSAT should be performed in conjunction with a comprehensive sleep evaluation with adequate follow-up after testing. The patient's medical record must document OSA symptoms and/or signs along with co-morbid conditions to support diagnostic testing for sleep-disordered breathing (See Tables 1 and 2).

Coverage for a Home Sleep Apnea Test (HSAT) for the Diagnosis of Obstructive Sleep Apnea

1. Home (unattended) sleep apnea testing could be used in uncomplicated adult patients who have an ***increased*** risk of moderate-to-severe OSA.[2]

    1.1 An uncomplicated patient is defined by the absence of:
    a. Conditions that place the patient at increased risk of non-obstructive sleep-disordered breathing (e.g., central sleep apnea, hypoventilation and sleep-related hypoxemia). Examples of these conditions include significant cardiopulmonary disease, potential

respiratory muscle weakness due to neuromuscular conditions, history of stroke and chronic opiate medication use.

b. Concern for significant non-respiratory sleep disorder(s) that require evaluation (e.g., disorders of central hypersomnolence, parasomnias, sleep related movement disorders) or conditions that may interfere with accuracy of the HSAT (e.g. severe insomnia).[2]
c. Environmental or personal factors that preclude the adequate acquisition and interpretation of data from the HSAT.[2]

1.2 An ***increased*** risk of moderate-to-severe OSA is indicated by the presence of:
a. Excessive daytime sleepiness and
b. At least two of the following three criteria: habitual loud snoring, witnessed apnea or gasping or choking associated with sleep or diagnosed hypertension.[2]

2. A single HSAT recording is conducted over one night. Repeat home sleep apnea testing on multiple consecutive nights has no proven value and is not recommended.[2]

3. A technically adequate HSAT device incorporates a minimum of the following sensors: nasal pressure, respiratory effort inductance plethysmography, and oximetry; or else peripheral arterial tonometry (PAT) with oximetry and integrated actigraphy.[2] For additional information regarding HSAT sensor requirements, refer to The AASM Manual for the Scoring of Sleep and Associated Events.[8]

4. A technically adequate diagnostic test includes a minimum of 4 hours of technically adequate oximetry and flow data, obtained during a recording attempt that encompasses the habitual sleep period.[2]

5. HSAT may be repeated to establish the diagnosis of OSA if the initial HSAT was technically inadequate due to equipment failure[i].

6. HSAT is not indicated in patients less than 18 y ears of age[2, 9]

<u>Coverage for Polysomnography (PSG)</u>

PSG is considered medically necessary, rather than HSAT, as a covered benefit when:

1. A patient with suspected OSA is assessed and documented to have low probability of having moderate to severe OSA.[2] Patients who do not snore, deny excessive daytime sleepiness, have a BMI less than 30 or do not have enlarged neck circumference are generally considered not at an increased risk of having moderate to severe OSA.

2. A previous HSAT is negative or inconclusive to establish the diagnosis of OSA.[2, 10-12]

3. Patient is < 18 years of age.

[i] Please note that the *Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea* recommends performing a PSG if a single home sleep apnea test is technically inadequate, however, this template policy permits a repeat HSAT if the technical adequacy is specifically due to equipment failure.

4. Patient has known or suspected medical conditions where an HSAT is not appropriate for testing of OSA. These medical conditions include the following:
   a. Significant cardiorespiratory disease (such as, but not limited to, chronic obstructive pulmonary disease, congestive heart failure [CHF], severe asthma, pulmonary fibrosis, cystic fibrosis or certain life-threatening arrhythmias).[13-16]
   b. Neurological or muscular disease [2] likely to affect muscles of respiration resulting in non-obstructive sleep disordered breathing (such as, but not limited to, amyotrophic lateral sclerosis [ALS], Parkinson disease, muscular or myotonic dystrophies, stroke, spinal cord injury or multiple sclerosis).
      c. Obesity hypoventilation syndrome due to severe obesity (BMI > 40 and with elevated serum bicarbonate levels (> 27 mEq/L). [17, 18]
   d. Sleep-related hypoventilation.
   e. Central sleep apnea (such as patients with significant CHF, on chronic opioid medications, brainstem lesions, or other predisposing conditions).

5. Patient is suspected to have a sleep disorder that is not OSA or patient is suspected to have a comorbid sleep disorder that could affect the accuracy of HSAT or where HSAT is going to be inconclusive for diagnosis under consideration such as:
   a. Disorders of central hypersomnolence such as narcolepsy or idiopathic hypersomnia.
   b. Complex motor behaviors in sleep such as REM sleep behavior disorder (RBD), nocturnal epilepsy or other parasomnias refractory to therapy.
   c. Periodic limb movement disorder (PLMD) or refractory restless legs syndrome (RLS).
   d. Severe insomnia.[2]
   e. Patients with cognitive impairment or dexterity/mobility issues, or environmental factors precluding adequate acquisition and interpretation of data from HSAT.

6. Repeat diagnostic testing with HSAT or PSG in a patient previously diagnosed with OSA is medically necessary when there is significant change in weight, following sleep apnea surgery, change in sleep apnea symptoms (that warrant change or discontinuation of prescribed therapy) or to assess the efficacy of oral appliance therapy. PSG is the preferred test to reevaluate if patient does not meet the criteria for an uncomplicated patient or repeat HSAT was inconclusive.

Table 1. Potential OSA signs or symptoms to be evaluated during a comprehensive sleep evaluation .[2, 19]

• Habitual or loud snoring • Witnessed apneas, gasping or choking in sleep • Excessive daytime sleepiness • Unrefreshing sleep or abnormal sleep inertia • Unexplained frequent arousals from sleep • Secondary enuresis or unexplained nocturia	• Sleep related bruxism • Cognitive deficits such as inattention or memory • Unexplained nocturnal reflux • Erectile dysfunction • Apneas or hypoxemia during procedures requiring anesthesia (such as colonoscopy) • Refractory insomnia • Morning headaches

Table 2. Examples of findings and/or comorbidities suggestive of OSA.[2, 19]

• Obesity, defined as BMI > 30 kg/m^2
• Neck Circumference of ≥17 inches in men and ≥ 16 inches in women.
• Craniofacial anatomy such as
  ○ Macroglossia
  ○ Retrognathia or Micrognathia
  ○ Narrow upper airway
  ○ Tonsillar Hypertrophy
  ○ Long or Edematous Uvula
• Type 2 Diabetes
• Polycystic ovarian syndrome
	• Neuromuscular weakness
	• Bulbar muscle weakness
	• Hypertension
	• Metabolic Syndrome
	• Refractory Atrial Fibrillation
	• Pregnancy complicated by Preeclampsia or Gestational Diabetes
	• Transient ischemic attack or stroke
	• Congestive Heart Failure
	• Pulmonary hypertension
	• Nocturnal dysrhythmias

References

1. Jordan AS, McSharry DG, Malhotra A. Adult obstructive sleep apnoea. *Lancet*. 2014;383(9918):736-47.
2. 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.
3. 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):1006-14.
4. Watson NF. Health Care Savings: The Economic Value of Diagnostic and Therapeutic Care for Obstructive Sleep Apnea. *J Clin Sleep Med*. 2016;12(8):1075-7.
5. Javaheri S, Barbe F, Campos-Rodriguez F, et al. Sleep Apnea: Types, Mechanisms, and Clinical Cardiovascular Consequences. *J Am Coll Cardiol*. 2017;69(7):841-58.
6. Punjabi NM, Caffo BS, Goodwin JL, et al. Sleep-disordered breathing and mortality: a prospective cohort study. *PLoS Med*. 2009;6(8):e1000132.
7. Young T, Finn L, Peppard PE, et al. Sleep disordered breathing and mortality: eighteen-year follow-up of the Wisconsin sleep cohort. *Sleep*. 2008;31(8):1071-8.
8. Berry RB, Albertario C, Harding SM, et al. *The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications*. Darien, IL: American Academy of Sleep Medicine; 2018.
9. Kirk V, Baughn J, D'Andrea L, et al. American Academy of Sleep Medicine Position Paper for the Use of a Home Sleep Apnea Test for the Diagnosis of OSA in Children. *J Clin Sleep Med*. 2017;13(10):1199-203.
10. 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):1423-31.
11. 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):1238-44.
12. 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):757-67.
13. Abraham WT, Trupp RJ, Phillilps B, et al. Validation and clinical utility of a simple in-home testing tool for sleep-disordered breathing and arrhythmias in heart failure: results of the Sleep Events, Arrhythmias, and Respiratory Analysis in Congestive Heart Failure (SEARCH) study. *Congest Heart Fail*. 2006;12(5):241-7; quiz 48-9.

14. de Vries GE, van der Wal HH, Kerstjens HA, et al. Validity and Predictive Value of a Portable Two-Channel Sleep-Screening Tool in the Identification of Sleep Apnea in Patients With Heart Failure. *J Card Fail*. 2015;21(10):848-55.
15. Oliveira MG, Nery LE, Santos-Silva R, et al. Is portable monitoring accurate in the diagnosis of obstructive sleep apnea syndrome in chronic pulmonary obstructive disease? *Sleep Med*. 2012;13(8):1033-8.
16. Series F, Kimoff RJ, Morrison D, et al. Prospective evaluation of nocturnal oximetry for detection of sleep-related breathing disturbances in patients with chronic heart failure. *Chest*. 2005;127(5):1507-14.
17. Centers for Disease Control and Prevention. Defining Adult Overweight and Obesity. https://www.cdc.gov/obesity/adult/defining.html. Accessed May 21, 2018.
18. Mokhlesi B, Tulaimat A, Faibussowitsch I, Wang Y, Evans AT. Obesity hypoventilation syndrome: prevalence and predictors in patients with obstructive sleep apnea. *Sleep Breath*. 2007;11(2):117-24.
19. Epstein LJ, Kristo D, Strollo PJ, Jr., et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med*. 2009;5(3):263-76.