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This document applies to the following Participating Organizations:

Priority Partners

US Family Health Plan

#### Keywords: Site of Service, Sleep Study

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#### I. ACTION

	New Policy	
Х	Revising Policy Number	
	Superseding Policy Number	
	Retiring Policy Number	

#### **II. POLICY DISCLAIMER**

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

#### III. POLICY

For Priority Partners (PPMCO) refer to: Code of Maryland Regulations

- Code of Maryland Regulations (COMAR) 10.67.06.11 <u>Diagnostic and Laboratory Services</u>
- No specific information on sleep studies located in COMAR 10.67.01 10.67.13 (Accessed March 15, 2023).

For USFHP refer to: Tricare Policy Manual

- Tricare Policy Manual 6010.63-M, April 1, 2021, Chapter 7, Section 19.1 Diagnostic Sleep Studies (Effective 10/1/2023) **IV. POLICY CRITERIA** 
  - A. This policy applies to *PPMCO & USFHP* members 18 years of age and older and provides clinical guidance for site of service redirection for in-network providers of planned sleep studies or polysomnographies in the outpatient hospital setting.

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- B. It is the policy of Johns Hopkins Health Plans (JHHP) to apply criteria to determine whether an outpatient hospital sleep laboratory site of service is medically necessary, or if a sleep study may be safely and effectively performed at an alternate place of service, (e.g certified freestanding sleep lab).
- C. The individual needs of the member and the availability of services in the contracted network and their ability to meet the member's needs are considered when applying this policy.
- D. This policy takes into consideration the availability of certified freestanding sleep labs within the geographical access standards required by the member's Plan (*Refer to Definitions section*).
- E. Certain sleep study services may also require a medical necessity review of the service using clinical review criteria specific to the service, regardless of site of service (e.g. Tricare Policy) (*Refer to Plan preauthorization requirements*).
- F. JHHP recognizes that evaluations of sleep disturbances may be performed safely in several settings, including a certified freestanding sleep lab or home. However, these settings may not be the appropriate site of service for all members. The outpatient hospital setting will be considered medically necessary for members with any of the following indications/ conditions/comorbidities including but not limited to:
  - 1. The local freestanding sleep laboratory does not have adequate resources to provide safe and effective or medically necessary timely care as documented in the member's record (e.g. the free-standing sleep lab is unable to accommodate member due to body habitus, limited mobility or age-related restrictions).
  - 2. Significant and unstable comorbid cardiovascular disease conditions including:
    - a. Severe heart failure (New York Heart Association class III or IV or decompensated heart failure);
    - b. Life threatening arrhythmias;

3.

- c. Recent myocardial infarction (MI) within 3 months with persistent symptoms.
- Significant and unstable comorbid chronic pulmonary conditions including:
- a. Severe chronic obstructive pulmonary disease with lung function test results of FEV1 < 50%;
- b. Severe restrictive lung disease (e.g. pulmonary fibrosis) with lung function test results of TLC  $\leq$  60% of predicted;
- c. Uncontrolled severe asthma with active symptoms or FEV1 < 80% despite treatment;
- d. Severe chronic alveolar hypoventilation and hypoxemia (e.g., obesity hypoventilation syndrome, severe kyphoscoliosis). These syndromes are generally associated with an elevated serum bicarbonate level (>27 mEq/L) and/or hypercarbia on an arterial blood gas (PCO2 >45 mmHg).
- 4. Significant and unstable comorbid neurological conditions:
  - a. Recent CVA within 3 months with progressing neurological sequela;
  - b. Severe progressive neuromuscular/neurodegenerative conditions (e.g., amyotrophic lateral sclerosis (ALS), myotonic dystrophy, muscular dystrophy);
  - c. Documented ongoing frequent daily seizures.
- 5. Other medical conditions:
  - a. Other conditions with severe life-threatening symptoms at rest;
  - b. Other significant unstable conditions with an increased risk of requiring advanced life support;
  - c. Documented history of anaphylaxis to latex or other products used in the administration of a sleep study;
  - d. Tracheostomy or home ventilator dependent;
  - e. For members on chronic opiates when central sleep apnea is suspected.
  - f. Documented need for oxygen, anticipated need for oxygen, or adjustments to oxygen;
  - g. Documented need for transcutaneous/end-tidal CO2 monitoring to assess conditions of hypoventilation;
  - h. Documented complex patients needing 1:1 care with a sleep technologist.
- 6. When an initial hospital-based test was approved under this initiative, repeat testing in a hospital-based setting may be covered for the following indications:
  - a. The first study is technically inadequate due to equipment failure;
  - b. The member could not sleep or slept for an insufficient amount of time to allow a clinical diagnosis;

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- c. Initiation of therapy or confirmation of the efficacy of prescribed therapy is needed; or
- d. The results were inconclusive or ambiguous.

## V. DEFINITIONS

<u>Sleep Studies and Polysomnography (PSG)</u>: Studies evaluating sleep through continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep for 6 or more hours with physician review, interpretation and report. The studies are performed to diagnose a variety of sleep disorders and to evaluate a patient's response to therapies such as continuous positive airway pressure (CPAP) (CMS LCD L35050). Sleep studies can be characterized by the type of device used. Unattended studies fall into categories, Type II through Type IV (Kapur, 2017; Collop, 2022).

- <u>Type 1</u>: Used for technician-attended, overnight polysomnography (PSG) done in a sleep laboratory setting, (attended polysomnography). Parameters measured include: electroencephalogram (EEG), electrooculogram (EOG), chin electromyogram (EMG), electrocardiogram (ECG), airflow, respiratory effort, oxygen saturation, and sleep staging.
- Type II: An unattended polysomnography that uses the same monitoring sensors as full PSGs (Type I).
- <u>Type III</u>: Device measures a minimum of four parameters; two respiratory variables (e.g., respiratory movement, airflow), oxygen saturation, and a cardiac variable (e.g., heart rate or ECG).
- <u>Type IV</u>: Device that measures only one or two parameters, typically oxygen saturation and heart rate, or in some cases, just air flow.

<u>PPMCO Access Standards</u>: Geographical access for diagnostic laboratories are as follows:

- In urban areas, within 15 minutes or 10 miles;
- In suburban areas, within 30 minutes or 20 miles; and
- In rural areas, within 40 minutes or 30 miles (COMAR 10.67.05.06)

<u>USFHP Access Standards</u>: Travel time for specialty care shall not exceed one hour under normal circumstances, unless a longer time is necessary because of the absence of providers (including providers not part of the network) in the area. (Tricare Manual Chapter 199.17)

# VI. <u>BACKGROUND</u>

An attended polysomnography (PSG) within a sleep laboratory is used along with a comprehensive sleep evaluation and clinical history to diagnose a variety of sleep disorders, including sleep-disordered breathing disorders as well as narcolepsy, sleep-related movement disorders, and certain parasomnias (Kramer, 2022). Seep-disordered breathing disorders are characterized by abnormal respiration during sleep and encompass a range of disorders, with most falling into the categories of obstructive sleep apnea (OSA), central sleep apnea (CSA) or sleep-related hypoventilation (Kapur, 2017). The most common indications for PSG in adults include diagnostic evaluation of suspected sleep-disordered breathing including obstructive sleep apnea (OSA), titration of positive airway pressure, and assessment of the adequacy of therapy that is already being used (Kramer, 2022).

OSA is the most common sleep-related breathing disorder and is most prevalent among older males, but also affects females and children (Kline, 2022). OSA is characterized by repetitive episodes of apnea or reduced inspiratory airflow, due to upper airway obstruction from intermittent collapse of the upper airway during sleep that are typically associated with oxyhemoglobin desaturation. Disease-specific populations with an increased rate of OSA include, but are not limited to, patients with coronary artery disease, congestive heart failure, arrhythmias, refractory hypertension, type 2 diabetes, and polycystic ovarian disease. Undiagnosed and untreated OSA is a significant burden on the healthcare system, with increased healthcare utilization seen in those with untreated OSA, highlighting the importance of early and accurate diagnosis of this

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common disorder. Individuals with OSA can also have other sleep disorders that may be related to or unrelated to OSA. It is also possible that undiagnosed OSA may be disguising another sleep disorder, such as REM Behavior Disorder. Therefore, when OSA is suspected, a comprehensive sleep evaluation is important to ensure the appropriate diagnostic testing is performed to address OSA, as well as other comorbid sleep complaints (Kapur, 2017).

In select patients with OSA, home sleep apnea testing (HSAT), (also referred to as portable monitoring) can be used as an alternative to overnight, attended, in-laboratory polysomnography for both the diagnosis of OSA and for following the response to therapy (Collop, 2022). Home sleep apnea testing is only useful for the diagnosis of OSA in selected patients; it is not a substitute for PSG when other sleep disorders are suspected (Kramer, 2022). Current guidelines do not recommend the use of portable monitoring for diagnosis of sleep hypoventilation or central sleep apnea (Kimoff, 2022).

The American Academy of Sleep Medicine (AASM) recommendations for the diagnosis of OSA include:

- Polysomnography, or home sleep apnea testing with a technically adequate device, be used for the diagnosis of OSA in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA;
- Polysomnography is recommended over a home sleep apnea test for the diagnosis of OSA in patients with significant comorbid medical conditions that may degrade the accuracy of tests, including patients with significant cardiorespiratory disease, potential respiratory muscle weakness due to neuromuscular condition, awake hypoventilation or suspicion of sleep related hypoventilation, chronic opioid medication use, or history of stroke or severe insomnia;
- Repeated testing with polysomnography is recommended if a single home sleep apnea test is negative, inconclusive, or is technically inadequate to diagnose OSA (Kapur, 2017).

When there is high clinical suspicion for OSA, a split-night polysomnography study may be performed. The diagnosis of OSA is established during the first portion of the study and the amount of positive airway pressure (PAP) that is necessary to prevent upper airway collapse during sleep is determined during the remaining portion. The AASM suggests that a split-night diagnostic protocol, rather than a full-night diagnostic protocol for polysomnography be used for the diagnosis of OSA only when the following criteria are met: a moderate to severe degree of OSA is observed during a minimum of 2 hours of recording time on the diagnostic PSG; and at least 3 hours are available to complete CPAP titration. A full-night diagnostic protocol is recommended, followed by a titration study if these criteria are not met (Kramer, 2022; Kapur, 2017).

Complications of polysomnography (PSG) are rare, the most common being skin irritation caused by the adhesive used to attach electrodes to the patient. More common are complaints of discomfort related to the monitoring equipment and difficulty sleeping in the laboratory setting. (Kramer, 2022).

# VII. CODING DISCLAIMER

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*Note:* The following CPT/HCPCS codes are included below for informational purposes and may not be all inclusive. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member's specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply.

Note: All inpatient admissions require preauthorization.

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Adherence to the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits

Priority Partners (PPMCO): Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria.

US Family Health Plan (USFHP): Regulatory guidance supersedes JHHP Medical Policy. If there are no TRICARE policies, or other regulatory guidelines, apply the Medical Policy criteria.

CPT <sup>®</sup> CODES ARE FOR INFORMATIONAL PURPOSES ONLY			
<b>CPT<sup>®</sup> CODES</b>	DESCRIPTION		
95800	Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (eg, by airflow or peripheral arterial tone), and sleep time		
95801	Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (eg, by airflow or peripheral arterial tone)		
95805	Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness		
95806	Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)		
95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist		
95808	Polysomnography; any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist		
95810	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist		
95811	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist		

# VIII. CODING INFORMATION

	HCPCS CODES ARE FOR INFORMATIONAL PURPOSES ONLY		
HCPCS CODES	CODE DESCRIPTION		
G0398	Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation		
G0399	Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation		
G0400	Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels		

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# IX. <u>REFERENCE STATEMENT</u>

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins Health Plans (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

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### XI. APPROVALS

Historical Effective Dates: 08/01/2022, 08/01/2023