Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Sleep Studies		
MNG #: 008	**☒SCO ☒One Care**	**Prior Authorization Needed? ☒Yes ☐No**
Clinical: ☒	**Operational: ☐**	**Informational: ☐**
Medicare Benefit: ☐Yes ☒No	**Approval Date:** 1/11/2019;	**Effective Date:** 4/01/2019;
Last Revised Date: 1/25/2019, 3/26/2020; 5/25/2021; 07/01/2021	**Next Annual Review Date:** 1/11/2020, 3/26/2021;5/25/2022; 07/01/2022	**Retire Date:**

OVERVIEW:

Sleep-related breathing disorders are conditions characterized by abnormal and difficult respirations during sleep. *Obstructive sleep apnea* (OSA) is the most common sleep disorder, affecting approximately 10-30% of the population in North America. It is characterized by repeated episodes of *apnea* or *hypopnea* during sleep due to the narrowing or closure of the upper airway. Other similar conditions include *narcolepsy* and *parasomnias* which can also cause abnormal sleep tendencies, and impair one's vigilance, concentration, and cognitive function. The impacts on the individual and their overall health make early recognition and treatment important.

Sleep-related breathing disorders are diagnosed based on symptoms, physical exam findings, presence of comorbidities, and confirmation from a *sleep test*. Sleep studies are tests that are used to diagnose a variety of sleep-related problems and/or to evaluate a patient's response to therapies. Each of the tests (e.g. *polysomnography, home-based sleep test, maintenance of wakefulness test,* and *multiple sleep latency test*) monitor various physiological parameters (e.g. oxygen saturation, respiratory effort, heart rate, etc.) to objectively measure the degree of respiratory disturbance (via the *apnea-hypopnea index* and *respiratory disturbance index*) while the patient sleeps.

Sleep studies are classified based on:

- Whether they are attended or unattended by a qualified physician and/or technologist,
- Whether they are performed at a hospital, sleep laboratory, or the patient's home, and
- The number of biological sensors applied and physiological parameters recorded

Figure 1: Different Types of Diagnostic Tests for Obstructive Sleep Apnea

Sleep Test	Description	Personnel	Location	Minimum Signals Required
Type 1 (In-lab or facility PSG)	Standard polysomnography (PSG) performed in a sleep lab **Considered the gold standard for diagnosing OSA*	Attended	Hospital or sleep lab	≥ 7 signals including: EEG, EOG, EMG, ECG, airflow, respiratory effort, and oxygen saturation
Type 2 (Home Sleep Test)	Comprehensive portable polysomnography	Unattended	Patient's home	≥ 7 signals including: EEG, EOG, EMG, ECG, airflow, respiratory effort, and oxygen saturation
Type 3 (Home Sleep Test)	Portable testing limited to sleep apnea **Does not provide data on sleep staging*	Attended or unattended	Patient's home	≥ 4 signals including: ECG or heart rate, oxygen saturation, and ≥ 2 channels of respiratory movement and airflow saturation
Type 4 (Home Sleep Test)	Continuous recording of 1 or 2 signals or any test not fitting into the other categories	Unattended	Patient's home	≥ 1 signal **Does not provide data on sleep staging*

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DEFINITIONS:

Actigraphy: Non-invasive method that estimates sleep and wakefulness based on body movements and physical activity detected on a wrist worn movement sensor.

Apnea: Upper airway collapse resulting in cessation of airflow (≥ 90% decrease in airflow compared to baseline) for ≥ 10 seconds. Apnea may be classified as obstructive (apnea despite respiratory effort), central (apnea with no accompanying inspiratory effort) or mixed (apnea with initial absence of respiratory effort followed by resumption of respiratory effort).

Apnea-Hypopnea Index (AHI): The average number apneic and hypopneic episodes per hour based on a minimum of two hours of recording, without the use of a positive airway pressure device.

Continuous Positive Airway Pressure (CPAP): Non-invasive technique for providing single levels of air pressure (via from a flow generator such as a nose mask). The purpose of CPAP is to prevent the collapse of oropharyngeal walls and the obstruction of airflow during sleep.

Home-based Sleep Test (HST): Diagnostic test used as an alternative to overnight, attended, in-laboratory polysomnography for sleep-related breathing disorders or follow-up assessments of OSA therapies (e.g. application of continuous positive airway pressure, oral appliance, or surgery) while the patient sleeps. The HST (type I to IV) may measure breathing rate, airflow, heart rate, and blood oxygen levels in the home setting with or without a technologist.

Hypopnea: Upper airway collapse resulting in partial airway obstruction (> 30% reduction in airflow compared to baseline) for ≥ 10 seconds. Hypopnea is associated with a 3-4% oxygen desaturation or sudden arousal from sleep.

Maintenance of Wakefulness Test (MWT): MWT is a daytime sleep study used to measure an individual's ability to stay awake and alert. This test is typically conducted after a polysomnogram to show whether the patient's ability to stay awake and alert poses a public or personal safety risk, and/or to determine whether the individual is responding to treatment.

Multiple Sleep Latency Test (MSLT): MSLT is a daytime sleep study used to determine whether the individual falls asleep during the test, the types of sleep, and stages of sleep that occur. This test is typically conducted after a polysomnogram.

Narcolepsy: Syndrome that is characterized by abnormal sleep tendencies such as excessive daytime sleepiness, and disturbed nocturnal sleep.

Obstructive Sleep Apnea (OSA): Most common sleep-related breathing disorder that is defined as AHI > 5 events/hour with symptoms or AHI ≥ 15 events/hour. It is characterized by obstructive apneic or hypopneic events, and/or respiratory effort-related arousals due to the collapse of the upper airway during sleep. The typical symptoms of OSA are unrefreshing sleep, daytime sleepiness, fatigue, insomnia, awakening with gasping or choking sensation, loud snoring, and witnessed apneas.

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Parasomnia: Group of conditions that represent undesirable or unpleasant occurrences during sleep that may lead to damage to surroundings, or pose as a safety risk for the individual and/or others. Examples may include sleepwalking, sleep terrors, and rapid eye movement (REM) sleep behaviour disorders.

Polysomnography or Polysomnogram (PSG): Diagnostic test used for sleep-related breathing disorders that records physiological variables (including but not limited to electroencephalogram [EEG], electrooculogram [EOG], electromyogram [EMG], electrocardiogram [ECG], nasal or oral airflow, respiratory effort [via chest wall and abdominal movement], gas exchange [via oximetry or transcutaneous monitoring], body positions] while the patient sleeps. PSG (Type 1) is considered the gold standard that can objectively measure wake and sleep time in a clinic, laboratory, or home setting, with or without a technologist.

Respiratory Disturbance Index (RDI): Average number of apneic, hypopneic, and respiratory effort-related arousals per hour based on a minimum of two hours of recording, without the use of a positive airway pressure device.

Split-Night Studies: Test that incorporates an initial diagnostic polysomnogram to diagnose OSA followed by CPAP titration during polysomnography in the same night. This will allow patients to be diagnosed with OSA and to receive treatment earlier.

DECISION GUIDELINES:

Clinical Coverage Criteria:

Commonwealth Care Alliance may cover **polysomnography (Type I)** when all the following criteria are met:

- Documentation that supports the need for diagnostic testing,
- Documentation that it is used to aid in the diagnosis of
    - OSA,
    - Narcolepsy, OR
        - Related to inappropriate sleep episodes or attacks (e.g. while driving, during the middle of a meal or in the middle of a conversation), amnesic episodes, or continuous disabling drowsiness,
    - Parasomnia
        - After seizure disorders have been ruled out AND cases present with a history of repeated violent or injurious episodes during sleep
- For members who have clinical signs and symptoms indicative of OSA,
- For members who have a contraindication to home sleep studies or whose previous home sleep study result is negative, indeterminate, or technically inadequate,
    - This includes having: moderate or severe chronic obstructive pulmonary disease, congestive heart failure, physical or cognitive impairment, suspected or established diagnosis of another sleep-related breathing disorder (e.g. central sleep apnea, periodic limb movement disorder, narcolepsy, idiopathic hypersomnia, parasomnia, nocturnal seizures), chronic opiate narcotic use, and body mass index > 33
- It is performed in an accredited sleep lab facility or clinic, AND
- It is attended by a trained and certified technologist and/or physician

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Commonwealth Care Alliance may cover **home sleep testing (Type II and III)** when all the following are met:

- Documentation that supports the need for diagnostic testing and its use to aid in the diagnosis of OSA,
- For members who have clinical signs and symptoms indicative of OSA,
- It is performed in conjunction with a comprehensive sleep evaluation,
- It is performed outside of a sleep lab facility, AND
- It is not attended by a trained and certified technologist and/or physician

Commonwealth Care Alliance may cover **home sleep testing (Type IV and Other sleep testing devices)** when all the following are met:

- For Type IV sleep testing devices, it measures three or more channels with one of them being airflow, OR
- For Other sleep testing devices, it measures three or more channels that include actigraphy, oximetry, and peripheral arterial tone, AND
- Documentation that supports the need for diagnostic testing and its use to aid in the diagnosis of OSA,
- For members who have clinical signs and symptoms indicative of OSA,
- It is performed in conjunction with a comprehensive sleep evaluation,
- It is performed outside of a sleep lab facility, AND
- It is not attended by a trained and certified technologist and/or physician

Commonwealth Care Alliance may cover **split-night studies** when all the following criteria are met:

- Documentation that it is used to aid in the diagnosis of OSA,
- Documentation that it is used for CPAP titration, AND
- When the member meets the criteria for polysomnography testing

Commonwealth Care Alliance may cover **multiple sleep latency or maintenance of wakefulness testing** when all the following are met:

- Documentation that supports the need for diagnostic testing, AND
    - To aid in the diagnosis of narcolepsy, OR
    - When clinical response is insufficient or when symptoms continue to persist despite adequate treatment of OSA
- Documentation that the member has already received polysomnography testing prior to initiation of a MSLT or MWT trial

Commonwealth Care Alliance may cover **follow-up polysomnography or a cardio-respiratory sleep test** when all the following are met:

- To evaluate the member's response to treatment,
- To re-evaluate the diagnosis of OSA and to ascertain whether CPAP is still needed at the previously titrated pressure after substantial weight loss has occurred in members, who are on CPAP treatment for sleep-related breathing disorders,
- To ascertain whether pressure adjustments are needed after substantial weight gain has occurred in members, who was previously treated with CPAP successfully, OR
- When clinical response is insufficient or when symptoms return despite a good initial response to treatment with CPAP

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LIMITATIONS/EXCLUSIONS:

Commonwealth Care Alliance will limit the following:

- Polysomnography testing to two per year for the diagnosis or adjustment of treatment for sleep-related breathing disorders, AND
- Home sleep testing to one per year

Commonwealth Care Alliance will not cover **polysomnography** or **multiple sleep latency test**, for the following but not limited to:

- The diagnosis of chronic insomnia or insomnia related to depression,
- Preoperative evaluation of a member undergoing laser assisted uvulopalatopharyngoplasty, without clinical evidence that OSA is suspected
- The diagnosis of chronic lung disease (e.g. nocturnal hypoxemia in members with chronic, obstructive, restrictive, or reactive lung disease)
- Cases where seizure disorders have not been ruled out
- Cases of typical, uncomplicated, and non-injurious parasomnias, when the diagnosis is clearly delineated
- Members with epilepsy who have no specific complaints consistent with a sleep disorder
- Members with symptoms suggestive of periodic limb movement disorder or restless leg syndrome, unless symptoms are suspected to be related to a covered indication,
- The diagnosis of circadian rhythm sleep disorders (e.g. rapid time-zone change, shift-work sleep disorder, delayed sleep phase syndrome, advanced sleep phase syndrome, and non- 24-hour sleep wake disorder), OR
- Use of a non-FDA and/or non-Medicare approved device

Commonwealth Care Alliance will not cover **home sleep test**, for the following but not limited to:

- Persons with comorbidities (e.g. moderate to severe pulmonary disease, neuromuscular disease, or congestive heart failure),
- The diagnosis of other sleep disorders (e.g. central sleep apnea, periodic limb movement disorder, insomnia, parasomnias, circadian rhythm disorders, or narcolepsy),
- Screening asymptomatic persons, OR
- Use of a non-FDA and/or non-Medicare approved device

AUTHORIZATION:

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not signify 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 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 claim payment. This Medical Necessity Guideline is subject to all applicable Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

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HCPCS Code	Description
95782	Polysomnography; Younger than 6 years, Sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95783	Polysomnography; Younger than 6 years, Sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist
95800	Sleep study, unattended, simultaneous recording; Heart rate, oxygen saturation, respiratory analysis (e.g. by airflow or peripheral arterial tone), and Sleep time
95801	Sleep study, unattended, simultaneous recording; Minimum of heart rate, oxygen saturation, respiratory analysis (e.g. by airflow or peripheral arterial tone), and Sleep time
95805	Multiple sleep latency of 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 (e.g. thoracoabdominal movement)
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
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 study 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 study test (HST) with type IV portable monitor, unattended; Minimum of 3 channels

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REGULATORY NOTES:

Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the appropriate field, review of FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions. If at any time a CMS Local or National Coverage Determination (LCD or NCD) is published that conflicts with the criteria set forth herein, the NCD or LCD criteria shall supersede these criteria.

Disclaimer:

This Medical Necessity Guideline is not a rigid rule. As with all of CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

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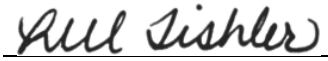
ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION

APPROVALS:

Douglas Hsu, MD, MPH	Vice President, Medical Policy and Utilization Review
CCA Senior Clinical Lead [Print]	**Title [Print]**
	
Signature	1/11/2019 **Date**
Click here to enter text.	
CCA Senior Operational Lead [Print]	**Title [Print]**
Signature	**Date**
Lori Tishler, MD	Senior Vice President, Medical Affairs
CCA CMO or Designee [Print]	**Title [Print]**
	1/11/2019
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