Medica Central Utilization Management Policy

Policy Name: **Facility-Based Polysomnography (Sleep Studies) For Obstructive Sleep Apnea, Adults MP9676 (III-DIA.16)**

Effective Date: **January 01, 2025**

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all Medica Plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Medica may use tools developed by third parties, such as MCG Care Guidelines®, to assist in administering health benefits. Medica medical policies and MCG Care Guidelines are not intended to be used without the independent clinical judgment of a qualified health care provider taking into account the individual circumstances of each member's case. Medica medical policies and MCG Care Guidelines do not constitute the practice of medicine or medical advice. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this medical policy see Provider Communications for additional information. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

PURPOSE

To promote consistency between utilization management reviewers by providing the criteria that determines the medical necessity.

BACKGROUND

I. Definitions
   A. **Apnea and hypopnea** are two forms of sleep disorders. Apnea is defined by stops in breathing for ten seconds or more while an individual is asleep. Hypopnea is a partial loss of breath for ten seconds or longer while an individual is asleep.
   B. **Apnea-hypopnea index (AHI)** is measured during a sleep study. The number of times breath ceases per hour is calculated. An AHI indicates the severity of obstructive sleep apnea (OSA). In adults normal sleep is defined as fewer than five AHI events per hour, mild OSA is defined as five to 14 AHI events per hour, moderate OSA is 15 to 29 AHI events per hour, and severe OSA is 30 or more AHIs per hour.

C. **Continuous Positive Airway Pressure (CPAP)** devices supply a constant flow of positive air pressure delivered through a blower and mask to keep airways open. An auto titration CPAP (APAP) machine has an algorithm built into the machine allowing it to differentiate when an individual is breathing normally and when breathing is compromised. The APAP can automatically adjust when needed to assure that an individual's airway remains open during sleep. CPAP and APAP units can be standard models or units that can be equipped with a humidifier, therapy tracking software, and/or off grid power options.

D. **CPAP titration** is performed to calibrate CPAP therapy. When having a split-night attended, facility-based polysomnography, the second half of the PSG includes CPAP titration to establish the amount of positive airway pressure (PAP) required to prevent upper airway collapse during sleep for optimal use of a CPAP device. Standard titration protocol includes the following:
   1. An AHI of at least 40 events per hour of sleep recorded during at least two hours during the diagnostic phase of the sleep study, or and AHI between 20-30 events per hour of sleep during at least two hours of sleep with strong supportive evidence of OSA.
   2. PAP titration performed over at least three hours in order to observe whether or not obstructive events worsen as the study progresses
   3. Documented elimination/near elimination of obstructive events with PAP administration during both rapid eye movement (REM) and non-REM sleep, including REM sleep in the supine position.

E. A **home sleep study**, also referred to as portable monitoring, is an unattended/unsupervised sleep study using a sleep study device that monitors and records multiple sleep-related parameters. However, the number of parameters measured are fewer that those measured in a full-channel PSG. Type II or Type III devices are normally recommended for home sleep studies, although Type IV devices have been suggested.

F. **Mallampati Airway Score** is a four-level scale used to assess the ease of intubation and the risk of OSA. To perform the test, the individual opens their mouth as wide as possible while protruding their tongue as far as possible. A score of 3 or 4 indicates an increased risk of difficult intubation or OSA. The scale is defined as:
   1. Class I: The soft palate and uvula are completely visible.
   2. Class II: The soft palate, hard palate, and upper portion of the uvula are visible.
   3. Class III: The soft palate, hard palate, and base of the uvula are visible.
   4. Class IV: Only the hard palate is visible.

G. **New York Heart Association (NYHA) Classification of Heart Failure** is a system that categorizes heart failure based on an individual's physical activity limitations. The NYHA Classification is used to document functional cardiac status and is considered the most important prognostic marker in routine clinical use for heart failure classification. The classes rang from Class 1 (no limitations or symptoms with ordinary activity) to Class IV (unable to carry out any physical activity without discomfort, with symptoms even at rest or minimal exertion). See Appendix 1 for further details.

H. **Obstructive sleep apnea (OSA)** is a chronic condition characterized by frequent episodes of upper airway collapse during sleep. It is the result of blocked airflow during sleep, such as from narrowed airways, but breathing effort persists. Reduces upper airway space produces episodes of slow and/or shallow breathing (hypopnea) or interruptions in breathing (apnea) that lead to decreased blood oxygen saturation levels, sleep fragmentation, and daytime sleepiness. OSA is confirmed when a sleep study validates the presence of OSA as indicated by an apnea hypopnea index (AHI) or respiratory disturbance index (RDI) that is: (1) greater than or equal to 15 events per hour, or between five and 14 events per hour and is accompanied by documentation of at least one symptom of OSA.

I. **Polysomnography (PSG)** is a facility-based sleep study that is attended/monitored by a sleep technologist. The individual sleeps while connected to various monitoring devices while

the technologist periodically monitors and/or records multiple respiratory-related physiologic variables using a Type I or Type II sleep study device. When having a full-night PSG, the individual is monitored and AHI index and RDI is measured throughout night. PSG is performed to diagnose various sleep disorders and evaluate the response to treatments such as CPAP.

J. **Respiratory-effort related arousals (RERAs)** are arousals from sleep that do not meet the definitions of apneas or hypopneas, but they do disrupt sleep. They are characterized as abrupt transitions from a deeper stage of sleep to a shallower stage. A RERA is characterized by increasing respiratory effort, along with airflow limitations, for ten seconds or more and results in sleep arousal.

K. **Respiratory disturbance index (RDI)**, or respiratory distress index, is a formula used in reporting sleep study results. Like the AHI, RDI reports on respiratory events during sleep, but unlike the AHI, it also includes RERAs. An RDI is the average number of the sum of all episodes of all apnea, hypopnea, and RERAs per hour of sleep.

L. **Sleep study devices** are classified according to the number of sleep parameters measured. There are four types available.

1. **Type I devices** are used for attended facility-based PSGs. This is considered full sleep staging and is comprised of a minimum of eight channels, typically including: (a) electroencephalogram (EEG), (b) electro-oculography (EOG), (c) electrocardiogram (EKG/heart rate), (d) chin electromyelogram (EMG), (e) limb EMG, (f) respiratory effort, (g) air flow, (h) oxygen saturation.
2. **Type II devices** can be used in attended or unattended facility-based PSGs or in unattended home sleep studies. These devices measure a minimum of seven channels, and typically include: (a) EEG, (b) EOG, (c) EKG/heart rate, (d) EMG, (e) airflow, (f) respiratory efforts, and (g) oxygen saturation.
3. **Type III devices** are used for unattended home sleep studies. These devices do not record the signals needed to determine sleep stages or sleep disruption. They use a minimum of four channels, and normally include: (a) two respiratory movement/airflow measurements, (b) EKG/heart rate, and (c) oxygen saturation.
4. **Type IV devices** are also suggested for unattended home sleep studies. These devices use a minimum of three channels, and can allow for direct calculation of AHI or RDI as a result of measuring airflow or thoracoabdominal movement.

II. Comments

A. It is estimated that approximately 30 million or more Americans suffer from OSA, with 80% of cases classified as moderate or severe. OSA prevalence is in the range of three to seven percent, with certain subgroups at higher risk. Factors that increase risk are age, male sex, obesity, family history, menopause, craniofacial abnormalities, and certain health behaviors such as cigarette smoking and alcohol use.

B. OSA is being increasingly recognized as an important cause of medical morbidity and mortality, including systemic hypertension, cardiovascular disease, stroke, and abnormal glucose metabolism. Early recognition of OSA and administration of appropriate therapy can ameliorate consequences, including demonstrating a favorable effect on cardiovascular health.

C. American Academy of Sleep Medicine (AASM) is a United States (US) professional organization for the medical subspecialty of sleep medicine and was established in 1975. The AASM serves to accredit sleep medicine centers in the US, Canada, and US territories. It works to improve sleep health and promote quality patient care through advocacy, education, research, and practice standards/guidelines.

BENEFIT CONSIDERATIONS

1. Prior authorization **is required** for attended facility-based polysomnography (PSG) for diagnosis of sleep apnea in ***individuals at least 18 years of age***. Please see the prior authorization list for product specific prior authorization requirements.
2. Facility-based polysomnography (PSG) for diagnosis of sleep apnea in ***individuals at least 18 years of age*** will be considered if the individual demonstrates inconclusive results following a home sleep study, if a home sleep study is contraindicated, or home sleep study services are not available.
3. Coverage may vary according to the terms of the member's plan document.
4. Prior authorization **is not required** for a polysomnography performed in an overnight sleep facility or healthcare facility for ***individuals less than 18 years of age***.
5. See related coverage policy, *Sleep Studies for Initial Diagnosis of Obstructive Sleep Apnea, for criteria not addressed here*.
6. See related coverage policy, Home Use of Continuous Positive Airway Pressure (CPAP) and Bilevel Positive Airway Pressure (BiPAP) for Sleep Apnea.
7. Facility-based polysomnography (PSG) is covered to evaluate for candidacy of an implantable hypoglossal nerve stimulator (i.e. Inspire).
8. Actigraphy as a stand-alone procedure for diagnosis of OSA is investigative and therefore not covered. See Coverage Policy, *Actigraphy*.
9. All sleep studies done for a diagnosis other than those listed in the Medical Necessity criteria are investigative or not medically necessary and therefore not covered.
10. Continuous positive airway pressure (CPAP) titration is a covered benefit. CPAP titration to establish the amount of PAP required to prevent upper airway collapse during sleep is often done during an attended facility-based PSG based on conclusive evidence of obstructive sleep apnea (OSA) documented by a sleep study.
11. If the Medical Necessity Criteria and Benefit Considerations are met, The Health Plan will authorize benefits within the limits in the member's plan document.
12. If it appears that the Medical Necessity Criteria and Benefit Considerations criteria are not met, the individual's case will be reviewed by the medical director or an external reviewer. Practitioners are reminded of the appeals process in their Provider Administrative Manual.

MEDICAL NECESSITY CRITERIA

I. Indications for Initial Assessment

Polysomnography (PSG) or a split-night study in a facility for ***initial evaluation*** of obstructive sleep apnea is considered medically necessary when documentation in the medical records indicates that **all of the following** criteria are met:

A. The individual is 18 years of age or older.
B. The attending provider has documented a diagnosis of suspected sleep apnea.
C. **One or more of the following** criteria are met:
    1. The individual has demonstrated **one of the following**:
        a. Inconclusive results following a home sleep study.
        b. A home sleep study is contraindicated.
        c. Individual is unable to properly operate or tolerate home study equipment and another individual is not available to assist
        d. Home sleep study services are not available.
    2. History of chronic opioid use.

3. Individual has a body mass index [BMI] of 50 kg/m^2 or higher.
4. Low pretest probability of OSA as demonstrated by **one of the following**:
    a. BMI less than 30 kg/m^2
    b. Normal airway [Mallampati score 1 or 2]
    c. Absence of snoring
    d. Normal neck circumference [i.e., 17 inches in biological males, and less than 16 inches in biological females])
5. Individual is employed and/or participates in a critical function and falling asleep would have a major negative impact on the wellbeing of herself/himself and others (e.g. airline pilots, astronauts, bus drivers, taxi drivers, ride-sharing drivers, truck drivers, train operators, police, security, military personnel assigned to at-risk duties).

D. **One of the following** criteria are met:
1. Individual has documentation of **at least one of the following** risk factors:
    a. Moderate to severe, chronic pulmonary disease.
    b. Congestive heart failure as evidenced by New York Heart Association (NYHA) class III or IV.6. Note: See Appendix 1, below, for NYHA classifications..
    c. History of ventricular fibrillation or sustained ventricular tachycardia in the absence of an implanted defibrillator.
    d. Neurologic or neuromuscular disease (e.g., stroke with significant residual effects, epilepsy, Parkinson's disease, spina bifida, myotonic dystrophy, amyotrophic lateral sclerosis).
    e. Provider has documented a concern for significant non-respiratory sleep disorder(s) that require evaluation. (e.g., narcolepsy, restless leg syndrome, periodic limb movements of sleep (PLMS), obesity hypoventilation, central sleep apnea, insomnia, parasomnias).
    f. Hypoventilation syndrome.
2. Individual has signs or symptoms suggestive of moderate- to high- risk obstructive sleep apnea as evidenced by **at least one of the following:**
    a. Epworth Sleepiness Scale score of 10 or greater.
    b. Daytime sleepiness, fatigue, or awakening with gasping or choking, and **one of the following** criteria are met.
        I. Habitual loud snoring.
        II. Refractory hypertension and medication regimen including **all of the following**:
            a) Three or more antihypertensive drugs at therapeutic dosages, including one diuretic
            b) Office blood pressure remains above goal.
        III. Obesity with a BMI greater than 30 kg/m2
    c. Observed apnea or choking episodes.

II. Indications for In-Facility Repeat Assessment
Documentation in the medical records indicates that **all/one of the following** criteria are met:

Polysomnography (PSG) or a split-night study in a facility for ***repeat assessment*** of obstructive sleep apnea is considered medically necessary when documentation in the medical records indicates that **all of the following** criteria are met:

A. All of the criteria in Section I., above, are met.
B. **At least one of the following** criteria are met:
1. Oral appliance has been adjusted for fit and requires assessment of efficacy.

2. A change of device is needed due to intolerance of current device.
3. Assessment is required to evaluate whether PAP treatment settings need to be changed as indicated by **all of the following**:
    a. Documented continued symptoms despite adherent use
    b. Documentation that the individual is wearing a PAP device at least four hours per night for a minimum of 70% of nights (i.e., 21 nights) over a 30-day period.
4. Individual demonstrates significant weight loss (greater than10% of wight when PAP initiated) while using PAP. NOTE: This is in order to determine if PAP can be discontinued.
5. Individual has demonstrated **one of the following** has had significant weight gain or recurrent symptoms and a repeat study will help inform whether PAP should be reinstituted:
    a. Significant weight gain.
    b. Recurrence of symptoms.
6. Postoperative assessment of efficacy of surgery to treat OSA following an upper airway surgical procedures.
7. Previous remote history of OSA and individual not currently on a PAP device. NOTE: This is needed to re-establish diagnosis and/or re-initiate PAP therapy.
8. Individual has had a previous negative study and new signs or symptoms have developed (e.g., weight gain accompanied by symptoms, new nocturia).
9. Individual demonstrates signs, symptoms and strong clinical suspicion of OSA following a negative study performed at least six months previous to this request.

III. Indications for Facility-Based Titration

Facility-based titration of CPAP/BiPAP for evaluation of OSA is considered medically necessary when documentation in the medical records indicates that **all of the following** criteria are met:

A. The individual is 18 years of age or older.
B. **One of the following** criteria are met:
    1. **All of the following** are met:
        a. All of the criteria in Section I., above, are met.
        b. A home-based study for titration of an automatic positive airway pressure (APAP) device was inconclusive, contraindicated, or home services not available.
    2. **All of the following** criteria are met:
        a. Individual has been diagnosed with OSA.
        b. Documentation of failure of an APAP trial including, but not limited to, downloaded compliance data.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

- For Medicare members, refer to the following, as applicable at: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx

DOCUMENT HISTORY

Original Effective Date	January 1, 2024
Began use of MCG™ Care Guidelines	05/01/2024 (28th edition)
MCG Care Guidelines Edition Updates *(The Health Plan Effective Date)*	07/01/2024
MPC Endorsement Date(s)	12/2024 - MPC endorsed this policy and discontinued use of the MCG Care Guidelines criteria.
Administrative Updates	06/20/2024, 05/15/2024, 02/28/2024, MCG Guideline *A-0338 (AC), CPAP Titration, Sleep Center*, added to the policy. 09/16/2024 – Benefit Considerations updated 02/01/2025 - Benefit Considerations updated and Medical Necessity section clarifications made

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APPENDIX 1

NEW YORK HEART ASSOCIATION (NYHA) CLASSIFICATIONS OF HEART FAILURE

Classification	Characteristics
Class I No symptoms or limitations to physical activity	Patients with cardiac disease but without the resulting limitations in physical activity. Ordinary activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
Class II Slight limitations on physical activity	Patients are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.
Class III Marked limitations on physical activity	Patients are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.
Class IV Severe limitations on physical activity	Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. The symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort increases.

***Source*:** American Heart Association. Classes of Heart Failure. Accessed online at www.heart.org. Accessed 11/22/2024.