ATTENDED POLYSOMNOGRAPHY
FOR EVALUATION OF SLEEP DISORDERS

Guideline Number: MMG105.P  Effective Date: April 1, 2020

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**COVERAGE RATIONALE**

**Home Sleep Apnea Testing**

Home Sleep Apnea Testing (HSAT), using a portable monitor, is medically necessary for evaluating adults with suspected OSA.

Where HSAT is indicated, an autotitrating Positive Airway Pressure (APAP) device is an option to determine a fixed PAP pressure.

**Attended Full-Channel Nocturnal Polysomnography, Performed in a Healthcare Facility or Laboratory Setting**

Attended full-channel nocturnal polysomnography is medically necessary for evaluating members with suspected OSA when:

- Results of previous HSAT are negative, indeterminate or technically inadequate to make a diagnosis of OSA; or
- The member is a child or adolescent (i.e., less than 18 years of age); or
- The member is known to have one or more of the following comorbid medical conditions that prohibits the use of a HSAT:
  - Significant *Chronic Pulmonary Disease* as defined by a forced expiratory volume (FEV₁) % predicted of <60 (Pellegrino et al, 2005)
  - Progressive neuromuscular disease/neurodegenerative disorder examples include, but are not limited to, Parkinson’s disease, myotonic dystrophy, amyotrophic lateral sclerosis, multiple sclerosis with associated pulmonary disease, history of stroke with persistent neurological sequelae.
  - Moderate to severe heart failure (New York Heart Association class III or IV [NYHA, 1994] or left ventricular ejection fraction ≤40 [Yancy et al., 2013; Yancy et al., 2017])
  - Body mass index (BMI) >50 (DeMaria et al, 2007; Blackstone and Cortés, 2010)
  - *Obesity Hypoventilation Syndrome*
  - Documented ongoing epileptic seizures in the presence of symptoms of sleep disorder

Also, see **Attended Repeat Testing** section below.

Attended full-channel nocturnal polysomnography is medically necessary following an appropriate clinical assessment either because OSA has been excluded, OSA has been adequately treated, or documented symptoms suggest one of the following conditions:

- **Periodic Limb Movement Disorder** (PLMD) (not leg movements associated with another disorder such as sleep disordered breathing)
- **Restless Legs Syndrome (RLS)/Willis-Ekbom Disease** that has not responded to treatment
- **Parasomnia** with documented disruptive, violent or potentially injurious sleep behavior suspicious of rapid eye movement sleep behavior disorder (RBD)
- **Narcolepsy**, once other causes of excessive sleepiness have been ruled out by appropriate clinical assessment (also see MSLT section below)
- **Central Sleep Apnea**

The following studies are not medically necessary due to insufficient evidence of efficacy:
- Attended full-channel nocturnal polysomnography for evaluating ANY of the following conditions:
  - Circadian Rhythm Disorders
  - Depression
  - Insomnia
- Actigraphy for any sleep disorders

**Daytime Sleep Studies**

**Multiple Sleep Latency Testing (MSLT)** is medically necessary when it is indicated by all of the following:
- Suspected narcolepsy; and
- Other causes of Excessive Sleepiness have been excluded by appropriate clinical assessment.

For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 24th edition, 2020, Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT), A-0146 (AC).

Click [here](#) to view the MCG™ Care Guidelines.

**Maintenance of Wakefulness Testing (MWT)** is medically necessary for evaluating the following:
- A member who is unable to stay awake, resulting in a safety issue; or
- Assessing response to treatment in individuals with Narcolepsy or idiopathic Hypersomnia.

For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 24th, 2020, Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT), A-0146 (AC)

Click [here](#) to view the MCG™ Care Guidelines.

The following studies are not medically necessary due to insufficient evidence of efficacy:
- Multiple Sleep Latency Testing (MSLT) for evaluating OSA, Insomnia or circadian rhythm disorders
- Maintenance of Wakefulness Testing (MWT) for evaluating OSA, Insomnia or circadian rhythm disorders
- PAP-Nap

**Attended PAP Titration**

When a member meets the above criteria for an attended full-channel nocturnal polysomnography sleep study, the following are medically necessary:
- A split-night study, performed in a healthcare facility or laboratory setting, for diagnosis and PAP titration
- A full night study for PAP titration, when a split-night sleep study is inadequate or not feasible and the member has a confirmed diagnosis of OSA.

Also see Attended Repeat Testing section below.

**Attended Repeat Testing**

Repeat attended full-channel nocturnal polysomnography, performed in a health care facility or laboratory setting, as well as repeat PAP titration, is medically necessary for certain members who have persistent or new symptoms, despite documented appropriate current treatment or PAP therapy (e.g., equipment failure, improper mask fit, pressure leaks, unsuccessful titration, inadequate pressure and medical problems including nasal congestion have been addressed and appropriately managed).

Repeat testing and repositioning/adjustments for oral sleep appliances can be done in the home unless the member meets criteria for an attended sleep study.

**DOCUMENTATION REQUIREMENTS**

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 documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.
**Required Clinical Information**

**Attended Polysomnography for Evaluation of Sleep Disorders**

Medical notes documenting all of the following:

- Physical exam that includes the member's height, weight and BMI
- Clinical signs and symptoms
- Epworth Sleepiness score
- Co-morbid conditions:
  - Pulmonary: provide spirometry results
  - Cardiac: provide the NYHA heart failure class and/or left ventricular ejection fraction
  - Neurologic health issue impacting sleep that may include seizure disorder
  - Obesity hypoventilation syndrome: provide PaCO2 results
- Previous sleep study reports, if applicable
- Indicate whether the testing is for a Commercial Driving License (CDL)
- If requesting 95811, indicate whether the request is for PAP titration or split night study
- For a member already on PAP therapy, provide most recent print out for compliance
- For Multiple Sleep Latency Testing (MSLT; CPT 95805), provide any evaluation/ documentation showing that other causes of Excessive Daytime Sleepiness have been excluded

**DEFINITIONS**

**Actigraphy:** A measurement of physical activity, typically via a wrist-worn movement sensor, employed to estimate sleep and wakefulness based on relative levels of physical inactivity and activity (ICSD-3, 2014).

**Apnea:** The cessation of airflow (≥90% decrease in airflow compared to baseline) lasting at least 10 seconds. Apneas are classified as obstructive, central or mixed based on the pattern of respiratory effort. An obstructive Apnea is associated with continued or increased inspiratory effort throughout the entire period of absent airflow. A central Apnea is associated with absent inspiratory effort throughout the entire period of absent airflow. Mixed Apneas are associated with absent inspiratory effort in the initial portion of the event, followed by resumption of inspiratory effort in the second portion of the event (AASM Scoring Manual, 2020).

**Apnea Hypopnea Index (AHI):** The number of Apneas plus the number of Hypopneas, times 60, divided by total sleep time (AASM Scoring Manual, 2020).

**Central Disorders of Hypersomnolence:** Sleep disorders in which the primary complaint is daytime sleepiness not caused by disturbed nocturnal sleep or misaligned circadian rhythms (ICSD-3, 2014).

**Central Sleep Apnea (CSA):** A condition in which a person stops breathing during sleep because the brain temporarily stops sending signals to the muscles that control breathing (Eckert et al., 2007).

**Chronic Pulmonary Disease (CPD):** A method of categorizing the severity of lung function impairment based on forced expiratory volume (FEV1) % predicted is provided in the below table. Severity of any spirometric abnormality based on the forced expiratory volume in one second (FEV1).

<table>
<thead>
<tr>
<th>Degree of Severity</th>
<th>FEV1 % pred</th>
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<tbody>
<tr>
<td>Mild</td>
<td>&gt;70</td>
</tr>
<tr>
<td>Moderate</td>
<td>60-69</td>
</tr>
<tr>
<td>Moderately severe</td>
<td>50-59</td>
</tr>
<tr>
<td>Severe</td>
<td>35-49</td>
</tr>
<tr>
<td>Very Severe</td>
<td>&lt;35</td>
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(Pellegrino et al., 2005)

**Circadian Rhythm:** Circadian rhythms are near-24-hour biological rhythms that exist in all living organisms. The internal circadian clock is synchronized to the 24-hour light-dark cycle (ICDS-3, 2014).

**Circadian Rhythm Sleep-Wake Disorders:** Sleep disorders caused by alterations of the circadian time-keeping system, its entrainment mechanisms or a misalignment of the endogenous Circadian Rhythm and the external environment (ICDS-3, 2014).

**Epworth Sleepiness Scale (ESS):** The ESS is an 8 item questionnaire which is used to determine the level of a person's daytime sleepiness. The ESS is based on an individual's assessment of the likelihood of falling asleep in
certain situations commonly encountered in daily life. See the following website for further information:  

**Excessive Sleepiness [Somnolence, Hypersomnia, Excessive Daytime Sleepiness (EDS)]:** Sleepiness that occurs in a situation when an individual would usually be expected to be awake and alert (Littner et al., 2005).

**Home Sleep Apnea Testing:** The use of unattended diagnostic studies to assess for OSA without the determination of sleep stage. The term specifies the condition being assessed (i.e., sleep Apnea) by current technology without implying that “sleep” quality, staging or time are determined. Not all such studies are performed at home; however, that is where the vast majority of individuals undergo these tests (AASM Style Guide, 2015). Also referred to as out-of-center sleep testing or portable monitoring.

**Hypersomnia (Excessive Sleepiness):** A disorder characterized by Excessive Sleepiness (e.g., idiopathic Hypersomnia) (ICSD-3, 2014).

**Hypersomnia:**  Excessive Sleepiness during the normal wake period (ICSD-3, 2014).

**Hypopnea:** An abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in airflow and with at least a 3% decrease in oxygen saturation from pre-event baseline or the event is associated with an arousal (AASM Scoring Manual, 2020).

**Insomnia:** A persistent difficulty with sleep initiation, duration, consolidation or quality that occurs despite adequate opportunity and circumstances for sleep, and results in some form of daytime impairment (ICSD-3, 2014).

**Maintenance of Wakefulness Test (MWT):** A daytime sleep study that measures the ability to stay awake for a defined period of time (Littner et al., 2005).

**Medically Necessary (or Medical Necessity):**

a. A health intervention for the purpose of treating a medical condition;

b. The most appropriate supply or level of service, considering potential benefits and harms to the Member;

c. Known to be effective in improving health outcomes. For existing interventions, effectiveness is determined first by scientific evidence, then by professional standards, then by expert opinion. For new interventions, effectiveness is determined by scientific evidence; and

d. If more than one health intervention meets the requirements of (a) through (c) above, furnished in the most cost-effective manner that may be provided safely and effectively to the Member. “Cost-effective” does not necessarily mean lowest price.

A service or item will be covered under the UnitedHealthcare Health Plan if it is an intervention that is an otherwise covered category of service or item, not specifically excluded, and Medically Necessary. An intervention may be medically indicated yet not be a covered benefit or meet the definition of Medical Necessity.

In applying the above definition of Medical Necessity, the following terms shall have the following meanings:

i. **Treating Physician** means a Physician who has personally evaluated the patient.

ii. A **health intervention** is an item or service delivered or undertaken primarily to treat (that is, prevent, diagnose, detect, treat or palliate) a medical condition or to maintain or restore functional ability. A **medical condition** is a disease, illness, injury, genetic or congenital defect, pregnancy or a biological or psychological condition that lies outside the range of normal, age-appropriate human variation. A health intervention is defined not only by the intervention itself, but also by the medical condition and the patient indications for which it is being applied.

iii. **Effective** means that the intervention can reasonably be expected to produce the intended results and to have expected benefits that outweigh potential harmful effects.

iv. **Health outcomes** are outcomes that affect health status as measured by the length or quality (primarily as perceived by the patient) of a person’s life.

v. **Scientific evidence** consists primarily of controlled clinical trials that either directly or indirectly demonstrate the effect of the intervention on health outcomes. If controlled clinical trials are not available, observational studies that suggest a causal relationship between the intervention and health outcomes can be used. Partially controlled observational studies and uncontrolled clinical series may be suggestive but do not by themselves demonstrate a causal relationship unless the magnitude of the effect observed exceeds anything that could be explained either by the natural history of the medical condition or potential Experimental biases. For existing interventions, the scientific evidence should be considered first and, to the greatest extent possible, should be the basis for determinations of Medical Necessity. If no scientific evidence is available, professional standards of care should be considered. If professional standards of care do not exist, or are outdated or contradictory, decisions about existing interventions should be based on expert opinion. Giving priority to scientific evidence does not mean that coverage of existing interventions should be denied in the absence of conclusive scientific evidence. Existing
interventions can meet the definition of Medical Necessity in the absence of scientific evidence if there is a strong conviction of effectiveness and benefit expressed through up-to-date and consistent professional standards of care or, in the absence of such standards, convincing expert opinion.

vi. A new intervention is one that is not yet in widespread use for the medical condition and patient indications being considered. New interventions for which clinical trials have not been conducted because of epidemiological reasons (i.e., rare or new diseases or orphan populations) shall be evaluated on the basis of professional standards of care. If professional standards of care do not exist, or are outdated or contradictory, decisions about such new interventions should be based on convincing expert opinion.

vii. An intervention is considered cost-effective if the benefits and harms relative to costs represent an economically efficient use of resources for patients with this condition. In the application of this criterion to an individual case, the characteristics of the individual patient shall be determinative.

Monitoring Time: Total recording time minus periods of artifact and time the individual was awake as determined by Actigraphy, body position sensor, respiratory pattern or individual diary (AASM Scoring Manual, 2020).

Multiple Sleep Latency Test (MSLT): A daytime sleep study that measures physiological sleep tendency under standardized conditions in the absence of external alerting factors (Littner et al., 2005).

Narcolepsy: A condition in which a person experiences excessive daytime sleepiness and may fall asleep at unexpected times, such as during work, school or driving. Narcolepsy type 1 is characterized by excessive daytime sleepiness, cataplexy and/or low or absent cerebrospinal fluid hypocretin-1 levels (ICSD-3, 2014). Narcolepsy type 2 is characterized by excessive daytime sleepiness, without cataplexy, with unmeasured or normal cerebrospinal fluid hypocretin-1 levels (ICSD-3, 2014).

New York Heart Association (NYHA) Heart Failure Classification (NYHA, 1994):

- I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.
- II: Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.
- III: Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.
- IV: Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

Obesity Hypoventilation Syndrome (OHS): A breathing disorder characterized by obesity (BMI > 30 kg/m²) and daytime hypercapnia (arterial PaCO2 > 45 mm Hg) that cannot be fully attributed to an underlying cardiopulmonary or neurologic disease. The condition leads to low oxygen levels and too much carbon dioxide in the blood (ICSD-3, 2014).

Obstructive Sleep Apnea (OSA): The American Academy of Sleep Medicine (AASM) defines Obstructive Sleep Apnea as a sleep related breathing disorder that involves a decrease or complete halt in airflow despite an ongoing effort to breathe.

OSA severity is defined as:

- Mild for AHI or RDI ≥ 5 and < 15
- Moderate for AHI or RDI ≥ 15 and ≤ 30
- Severe for AHI or RDI > 30/hr

PAP-Nap: A daytime, abbreviated cardio-respiratory sleep study for individuals who experience anxiety about starting PAP therapy or are having problems tolerating PAP therapy. The test combines psychological and physiological treatments into one procedure and includes mask and pressure desensitization, emotion-focused therapy to overcome aversive emotional reactions, mental imagery to divert attention from mask or pressure sensations and physiological exposure to PAP therapy during a 100-minute nap period (Krakow et al., 2008).

Parasomnia: Parasomnias are undesirable physical events or experiences that occur during entry into sleep, within sleep or during arousal from sleep. They may occur during non-rapid eye movement sleep, rapid eye movement sleep (REM) or during transitions to and from sleep. Parasomnias encompass abnormal sleep related complex movements, behaviors, emotions, perceptions, dreams and autonomic nervous system activity. They are clinical disorders because of the resulting injuries, sleep disruption, adverse health effects and untoward psychosocial effects (ICSD-3, 2014). Also see RBD.

Periodic Limb Movement Arousal Index (PLMAI): The number of PLMS associated with an arousal, times 60, divided by total sleep time (AASM Scoring Manual, 2020).
Periodic Limb Movement Disorder (PLMD): A sleep disorder characterized by periodic episodes of repetitive, highly stereotyped limb movements that occur during sleep, in conjunction with clinical sleep disturbance or fatigue that cannot be accounted for by another primary sleep disorder or other etiology (ICSD-3, 2014).

Periodic Limb Movement Index (PLMI): The number of PLMS, times 60, divided by total sleep time (AASM Scoring Manual, 2020).


Polysomnogram: A laboratory-based sleep study that uses multiple channels to record a wide range of physiological information, including brain activity, eye movements, body movements, breathing and heart rate (American Thoracic Society, 2015).

Positive Airway Pressure (PAP): A PAP device is an air pump (fan-driven or turbine system) that draws in external, filtered air and delivers pressurized airflow to keep an individual’s airway open. PAP devices are divided into four basic types depending on their pressure delivery system:
- Continuous Positive Airway Pressure (CPAP): Delivers a steady, fixed flow of air pressure on inhalation
- Bilevel Positive Airway Pressure (BPAP): Delivers a higher flow of air pressure on inhalation than exhalation
- Autotitrating Positive Airway Pressure (APAP): Automatically changes the flow of air pressure (CPAP or BPAP) based on an individual’s breathing patterns
- Adaptive Servoventilation (ASV): Uses a servocontroller to automatically adjust the flow of air pressure by breath-by-breath analysis to maintain steady minute ventilation (Kushida et al., 2008).

Rapid Eye Movement Sleep Behavior Disorder (RBD): A Parasomnia characterized by abnormal behaviors emerging during REM sleep that may cause injury or sleep disruption (ICSD-3, 2014).

Respiratory Disturbance Index (RDI): The number of Apneas plus the number of Hypopneas plus the number of Respiratory Effort-Related Arousals, times 60, divided by total sleep time (AASM Scoring Manual, 2020).

Respiratory Effort-Related Arousal (RERA): A sequence of breaths characterized by increasing respiratory effort, inspiratory flattening in the nasal pressure or PAP device flow channel or an increase in end-tidal PCO₂ (children) leading to an arousal from sleep. Respiratory Effort-Related Arousals do not meet criteria for Hypopnea and have a minimum duration of at least 10 seconds in adults or the duration of at least two breaths in children (AASM Scoring Manual, 2020).

Respiratory Event Index (REI): Total number of respiratory events scored, times 60, divided by Monitoring Time. The REI is used for HSAT and is a surrogate for AHI (AASM Scoring Manual, 2020).

Restless Leg Syndrome (RLS)/Willis-Ekbom Disease: RLS is a sensorimotor disorder characterized by a complaint of a strong, irresistible urge to move the limbs. This urge to move is often, but not always, accompanied by other uncomfortable sensations felt deep inside the limbs or by a feeling that is difficult or impossible to describe. Although the legs are most prominently affected, these sensations may occur in the arms as well (ICSD-3, 2014).

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not 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 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. Other Policies and Guidelines may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>95782</td>
<td>Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist</td>
</tr>
<tr>
<td>95783</td>
<td>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</td>
</tr>
<tr>
<td>95800</td>
<td>Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time</td>
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The evaluation of sleep disorders can be done at home or in a specialized sleep center that can study sleep patterns during the day or at night. Home Sleep Apnea Testing (HSAT) is used to diagnose OSA and records breathing rate, airflow, heart rate and blood oxygen levels during sleep. These studies are performed at home without a sleep technician present (unattended). Polysomnography (PSG) records breathing, heart rate, blood oxygen levels, body movements, brain activity and eye movements during sleep. PSG is performed in a laboratory setting with a sleep technician present (attended) (American Thoracic Society, 2015).

Once a diagnosis of OSA is made, a PAP trial (titration) is performed to determine the optimal amount of pressure needed to prevent the airway from narrowing or closing. An attended split-night study combines diagnostic polysomnography and PAP titration into a single night (American Thoracic Society, 2015).

Sleep studies conducted during the day include the Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT). MSLT is performed to measure daytime sleepiness and is most often used to diagnose Narcolepsy. MWT is performed to measure how well a person can stay awake. In addition to diagnosing sleep disorders, PSG may also be used to assess and adjust the treatment plan (American Thoracic Society, 2015).

Additional Information
According to the American Academy of Sleep Medicine (AASM) (Epstein et al., 2009) the diagnosis of OSA is confirmed if the number of obstructive events* (Apneas, Hypopneas + respiratory event related arousals) on PSG is greater than 15 events/hour in the absence of associated symptoms or greater than 5/hour in an individual who reports any of the...
following: unintentional sleep episodes during wakefulness; daytime sleepiness; unrefreshing sleep; fatigue; Insomnia; waking up breath holding, gasping or choking; or the bed partner describing loud snoring, breathing interruptions, or both during the individual’s sleep.

The frequency of obstructive events is reported as an AHI or RDI. RDI has at times been used synonymously with AHI, but at other times has included the total of Apneas, Hypopneas, and Respiratory Effort Related Arousals (RERAs) per hour of sleep. When a portable monitor is used that does not measure sleep, the RDI refers to the number of Apneas plus Hypopneas per hour of recording.

OSA severity is defined as:
- Mild for AHI or RDI ≥ 5 and < 15
- Moderate for AHI or RDI ≥ 15 and ≤ 30
- Severe for AHI or RDI > 30/hr

The AASM classifies sleep study devices (sometimes referred to as Type or Level) as follows (Collop et al., 2007):
- Type 1: full attended PSG (≥ 7 channels) in a laboratory setting
- Type 2: full unattended PSG (≥ 7 channels)
- Type 3: limited channel devices (usually using 4-7 channels)
- Type 4: 1 or 2 channels usually using oximetry as 1 of the parameters

This classification system was introduced in 1994 and closely mirrored available Current Procedural Terminology (CPT) codes. However, since that time, devices have been developed which do not fit well within that classification scheme. In 2011, Collop et al. presented a new classification system for out-of-center (OOC) testing devices that details the type of signals measured by these devices. This proposed system categorizes OOC devices based on measurements of Sleep, Cardiovascular, Oximetry, Position, Effort, and Respiratory (SCOPER) parameters. Additional information can be found at http://www.aasmnet.org/Resources/PracticeParameters/Outofcenter.pdf. (Accessed January 22, 2020)

**Multiple-Night Home Sleep Apnea Testing Versus One-Night Home Sleep Apnea Testing**

Results of clinical studies demonstrate that night-to-night variability in HSAT is comparable to laboratory-based PSG. The reported RDI variability is small and a single night testing can correctly diagnose OSA in the majority of individuals with a high pretest-probability of OSA. Reported data loss for unattended portable monitoring ranges from 3%-33%. For a new device with an audible alarm only 2% of sleep testing resulted in insufficient data. In instances where a technical failure occurs, a second night home sleep test may be warranted. If HSAT in the high-risk individual is normal or technically inadequate the AASM recommends in-laboratory PSG (Collop et al., 2007).

**CLINICAL EVIDENCE**

In 2011, Collop et al. reported the results of a technology evaluation of sleep testing devices used in the OOC setting performed by an AASM task force. Only peer-reviewed English literature and devices measuring 2 or more bioparameters were included in the analysis. Studies evaluating 20 different devices or models (e.g., ARES, ApneaLink, Embletta, Novasom QSG/Bedbugg/Silent Night, SNAP, Stardust II, Watch-PAT) were reviewed. Devices were judged on whether or not they can produce a positive likelihood ratio (LR+) of at least 5 and a sensitivity of at least 0.825 at an in-lab AHI of at least 5. The authors concluded that:
- The literature is currently inadequate to state with confidence that a thermistor alone without any effort sensor is adequate to diagnose OSA;
- If a thermal sensing device is used as the only measure of respiration, 2 effort belts are required as part of the montage and piezoelectric belts are acceptable in this context;
- Nasal pressure can be an adequate measurement of respiration with no effort measure with the caveat that this may be device specific;
- Nasal pressure may be used in combination with either 2 piezoelectric or respiratory inductance plethysmographic (RIP) belts (but not 1 piezoelectric belt);
- There is insufficient evidence to state that both nasal pressure and thermistor are required to adequately diagnose OSA;
- With respect to alternative devices for diagnosing OSA, the data indicate that:
  - Peripheral arterial tonometry (PAT) devices are adequate for the proposed use;
  - The device based on cardiac signals shows promise, but more study is required as it has not been tested in the home setting;
  - For the device based on end-tidal CO2 (ETCO2), it appears to be adequate for a hospital population; and for devices utilizing acoustic signals;
  - The data are insufficient to determine whether the use of acoustic signals with other signals as a substitute for airflow is adequate to diagnose OSA.
Single-Night versus Multiple-Night Home Sleep Apnea Testing

A single-night PSG is usually considered adequate to determine if OSA is present and the degree of the disorder. Since the PSG is considered the reference standard, the reliability and technical accuracy of PSG is generally accepted without question. However, PSG, even when accurately measured, recorded and analyzed, may misclassify patients based upon night-to-night variability in measured parameters. For example, estimates of the sensitivity of one night of PSG to detect an AHI > 5 in patients with OSA range between 75 to 88% (Kushida et al, 2005).

Levendowski et al. (2009) published the first study that investigated the variability of AHI obtained by PSG and by in-home portable recording in 37 untreated mild to moderate OSA patients at a four- to six-month interval. The in-home studies were performed with Apnea Risk Evaluation System (ARES™) Unicorder. When comparing the test-retest AHI and apnea index (AI), the in-home results were more highly correlated (r = 0.65 and 0.68) than the comparable PSG results (r = 0.56 and 0.58). The in-home results provided approximately 50% less test-retest variability than the comparable PSG AHI and AI values. Both the overall PSG AHI and AI showed a substantial bias toward increased severity upon retest (8 and 6 events/hr respectively) while the in-home bias was essentially zero. The in-home percentage of time supine showed a better correlation compared to PSG (r = 0.72 vs. 0.43). Patients biased toward more time supine during the initial PSG. No trends in time supine for in-home studies were noted.

Night-to-night variability in HSAT was previously assessed in a number of clinical studies. Most of these studies involved a small number of patients. Redline et al. (1991), Quan et al. (2002; erratum 2009) and Davidson et al. (2003) found no evidence of a statistically significant difference in RDI between nights 1 and 2, suggesting that there was no significant respiratory first-night effect.

Fietze et al. (2004) investigated the night-to-night variability and diagnostic accuracy of the oxygen desaturation index (ODI) in 35 patients using the portable recording device MESAM-IV at home during 7 consecutive nights. The authors found that although the reliability of the ODI was adequate, the probability of placing the patient in the wrong severity category (ODI < or =15 or ODI >15) when only one single recording was taken is 14.4%. The authors concluded that in most OSA patients, oxygen desaturation index variability is rather small, and screening could be reliably based on single 1-night recordings.

The largest study by Stepnowsky et al. (2004) examined the nightly variability of AHI in a retrospective comparison of 3 sequential nights of testing performed in the home in 1091 patients who were referred for diagnostic testing of sleep-disordered breathing (SDB). Based on night 1, approximately 90% of patients were classified consistently with "AHI-high" (the highest AHI measured across the 3 nights) using an AHI threshold of 5. However, 10% were misclassified on night 1 relative to the highest AHI level. The authors concluded that there is little, if any, significant nightly change in SDB in the home environment.

The results of these clinical studies demonstrate, that night-to-night variability in HSAT is comparable to laboratory-based PSG and that a single night testing can correctly diagnose OSA in the majority of patients with a high pretest-probability of OSA.

Home-Based Versus In-Laboratory Diagnostic and Therapeutic Pathway

Recent comparative effectiveness research studies have shown that clinical outcomes of patients with a high pretest probability for OSA who receive ambulatory management using portable-monitor testing have similar functional outcomes and adherence to CPAP treatment, compared to patients managed with in-laboratory PSG (Kuna, 2010).

Mulgrew et al. (2007) randomly assigned 68 high-risk patients identified by a diagnostic algorithm to PSG or ambulatory titration by using a combination of auto-CPAP and overnight oximetry. After 3 months, there were no differences in AHI on CPAP between the PSG and ambulatory groups, or in the ESS score, or quality of life. Adherence to CPAP therapy was better in the ambulatory group than in the PSG group. Results of another randomized controlled multicenter non inferiority study by Antic et al. (2009) that compared nurse-led home diagnosis and CPAP therapy with physician-led current best practice in OSA management in 195 patients complement and extend the findings of Mulgrew et al. There were no differences between both groups in ESS score and CPAP adherence at 3 months. Within-trial costs were significantly less in the simplified home model. Cost-effectiveness of home APAP titration compared to manual laboratory titration was also confirmed by McArdle et al. (2010). In this randomized controlled study involving 249 patients with moderate to severe OSA without serious co-morbidities, outcomes at one month indicated that average nightly CPAP use, subjective sleepiness, quality of life, cognitive function and polysomnographic outcomes were similar among the per-protocol groups.

Berry et al. (2008) compared a clinical pathway using portable monitoring (PM) for diagnosis and unattended APAP for selecting an effective CPAP with another pathway using PSG for diagnosis and treatment of OSA in a randomized study involving 400 patients.
parallel group study involving 106 patients with a high likelihood of having OSA. After 6 weeks of treatment 40 patients in the PM-APAP group and 39 in the PSG arm were using CPAP treatment. The mean nightly adherence, decrease in ESS score, improvement in functional score and CPAP satisfaction did not differ between the groups. In a randomized controlled study involving 102 patients with suspected OSA, Skomro et al. (2010) compared a home-based diagnostic and therapeutic strategy for OSA with in-laboratory PSG and CPAP titration (using mostly split-night protocol). Subjects in the home monitoring arm underwent 1 night of level three testing (Embletta) followed by 1 week of auto-CPAP therapy (Auto-Set) and 3 weeks of fixed-pressure CPAP based on the 95% pressure derived from the auto-CPAP device. After 4 weeks of CPAP therapy, there were no significant differences in daytime sleepiness (ESS), sleep quality, quality of life, blood pressure and CPAP adherence.

In another randomized controlled non-inferiority study Kuna et al. (2011) compared functional outcome and treatment adherence in veterans with suspected OSA who received ambulatory versus in-laboratory testing for OSA. Home testing consisted of a type 3 portable monitor recording (Embletta) followed by at least three nights using an APAP device (RemStar Auto). In-laboratory testing was performed as a split-night PSG if clinically indicated. Of the 296 subjects enrolled, 260 (88%) were diagnosed with OSA, and 213 (75%) were initiated on CPAP. At 3 months of CPAP treatment the functional outcome score improved 1.74±2.81 in the home group and 1.85±2.46 in the in-laboratory group. CPAP adherence was 3.5±2.5 hours/day in the home group and 2.9±2.3 hours/day in the in-laboratory group (P=0.08).

Lettieri et al. (2011) conducted an observational cohort study including 210 patients with OSA that were grouped into one of three pathways based on the type and location of their diagnostic and titration. Group 1 underwent unattended, type III home diagnostic (Stardust II) and unattended home APAP titrations (Respironics System One); group 2 underwent in-laboratory, type I diagnostic and CPAP titration studies; group 3 underwent type I diagnostic and APAP titration studies. Group 1 was primarily managed and educated in a primary care clinic, whereas groups 2 and 3 received extensive education in an academic sleep medicine center. The authors found that type of study and location of care did not affect PAP adherence. Patients in all three pathways demonstrated equivalent use of PAP despite differences in polysomnographic procedures, clinical education and follow-up.

A single-blind randomized controlled trial with 200 CPAP-naive patients found home-based APAP to be as effective as automatic in-laboratory titrations in initiating treatment for OSA at 3-month follow-up with no significant difference in CPAP use, ESS score, OSLER, Functional Outcomes of Sleep Questionnaire or SF-36 between the groups (Cross et al., 2006).

In a randomized, single-blinded crossover trial Bakker et al. (2011) compared the effectiveness of CPAP and APAP (S8 Autoset II®, ResMed) over a period of six nights at home, separated by a four-night washout in 12 morbidly obese OSA patients requiring high therapeutic pressure (AHI 75.8±32.7, body mass index 49.9±5.2 kg m⁻², mean pressure 16.4 cm H₂O) without significant co-morbid disease. Both therapies substantially reduced the AHI (APAP 9.8±9.5 and CPAP 7.3±6.6 events h⁻¹; P=0.35), but residual PSG measures of disease (AHI >5) were common. APAP delivered a significantly lower 95th percentile pressure averaged over the home-use arm than CPAP (14.2±2.7 and 16.1±1.8 cm H₂O, respectively, P=0.02). The authors concluded that this study supports the use of either APAP or manually titrated CPAP in this specific population. Since the APAP-scored AHI significantly overestimated the level of residual disease compared with the laboratory-scored AHI the authors recommend objective assessment by sleep study if the APAP indicates a high level of residual disease.

McArble et al. (2000) compared long-term outcomes in all 49 (46 accepting CPAP) patients prescribed split-night studies with those in full-night patients, matched 1:2 using an AHI of +/-15% and Epworth score of +/-3 units. There were no differences between the groups in long-term CPAP use, median nightly CPAP use, post-treatment Epworth scores and frequency of nursing interventions/clinic visits required. The median time from referral to treatment was less for the split-night patients than for full-night patients.

Khawaja et al. (2010) reviewed 114 consecutive full-night PSGs (FN-PSG) on subjects with OSA and compared the AHI from the first 2 hours (2 hr-AHI) and 3 hours (3 hr-AHI) of sleep with the "gold standard" AHI from FN-PSG (FN-AHI), considering OSA present if FN-AHI > or = 5. The authors found that the AHI derived from the first 2 or 3 hours of sleep is of sufficient diagnostic accuracy to rule-in OSA at an AHI threshold of 5 in patients suspected of having OSA. This study suggests that the current recommended threshold for split-night studies (AHI > or = 20 to 40) may be revised to a lower number, allowing for more efficient use of resources.

Collen et al. (2010) evaluated 400 consecutive patients presenting for follow-up 4-6 weeks after initiating CPAP therapy. Among the patients, 267 and 133 underwent split- and dual-night studies, respectively. The mean number of days between diagnosis and titration in the dual-night group was 80.5 days. There was no difference in therapeutic adherence between groups as measured by percentage of nights used (78.7% vs 77.5%; p = 0.42), hours per night used (3.9 vs 3.9; p = 0.95), or percentage of patients using CPAP for >4 hours per night for >70% of nights (52.9%
vs 51.8%; p = 0.81). There was no difference in use after adjusting for severity of disease. The authors concluded that split-night PSG does not adversely affect short-term CPAP adherence in patients with OSA.

Gao et al. (2012) conducted a systematic review to evaluate the effect of automatic titration compared to manual titration prior to CPAP treatment in OSA patients. The authors evaluated APAP in identifying an effective pressure and the improvement of AHI and somnolence, change in sleep quality and the acceptance and compliance of CPAP treatment compared to manual titration. Ten randomized controlled trials (849 patients) met the inclusion criteria. Studies were pooled to yield odds ratios (OR) or mean differences (MD) with 95% confidence intervals (CI). Automatic titration improved the AHI (MD=0.03/h, 95% CI=4.48–4.53) and ESS (SMD=0.02, 95% CI=0.34–0.31) as effectively as manual titration. There was no difference in sleep architecture between auto titration and manual titration. There was also no difference in acceptance of CPAP treatment or compliance with treatment. The authors concluded that automatic titration is as effective as standard manual titration in terms of improvement in AHI, somnolence and sleep quality, as well as acceptance and adherence to CPAP.

**Actigraphy**

Current evidence evaluating actigraphy for the diagnosis of sleep disorders is very limited and does not establish the effectiveness of actigraphy as a stand-alone diagnostic tool. Plante (2014) conducted a systematic review and meta-analysis on the use of leg actigraphy for diagnosing periodic limb movements of sleep (PLMS). Findings demonstrated significant heterogeneity among a limited number of studies in terms of type of actigraph utilized, position of the device on the lower extremity and methods employed to count PLMS. In general, common accelerometers vary in their sensitivity and specificity to detect PLMS, which is likely related to the technical specifications of a given device. A current limitation in the ability to combine data from actigraphs placed on both legs is also a significant barrier to their use in clinical settings. Further research is required to determine the optimal methods to quantify PLMS using leg actigraphy, as well as specific clinical situations in which these devices may prove most useful.

**PAP-Nap Test**

Further results from large, prospective studies are needed to assess the clinical value of this test.

Ulibarri et al. (2020) performed a retrospective chart review on 139 patients diagnosed with OSA (n=116) or upper airway resistance syndrome (n=23). All participants refused to proceed with either a full-night attended titration or an in-home trial of PAP but completed a PAP-NAP instead. The most common risk factors for PAP rejection were depression, insomnia and claustrophobia, while the most common indications for PAP-NAP were general reluctance, anxiety and claustrophobia. Although results showed that improvements in emotional aversion and motivation were associated with increased PAP use, the authors noted that randomized control trials are needed to assess the experiential component at the core of the PAP-NAP procedure and its efficacy in reversing early PAP rejecters.

In a pilot study, Krakow et al. (2008) assessed the impact of the PAP-Nap sleep study on adherence to PAP therapy among insomnia patients with sleep disordered breathing (SDB). The PAP-Nap test combines psychological and physiological treatments into one procedure and includes mask and pressure desensitization, emotion-focused therapy to overcome aversive emotional reactions, mental imagery to divert patient attention from mask or pressure sensations and physiological exposure to PAP therapy during a 100-minute nap period. Patients treated with the PAP-Nap test (n=39) were compared to a historical control group (n = 60) of insomnia patients with SDB who did not receive the test. All 99 insomnia patients were diagnosed with SDB (mean AHI 26.5 +/- 26.3, mean RDI 49.0 +/- 24.9), and all reported a history of psychiatric disorders or symptoms as well as resistance to PAP therapy. Among 39 patients completing the PAP-Nap, 90% completed overnight titrations, compared with 63% in the historical control group. Eight-five percent of the nap-tested group filled PAP therapy prescriptions for home use compared with 35% of controls. Sixty-seven percent of the nap-tested group maintained regular use of PAP therapy compared with 23% of the control group. Using standards from the field of sleep medicine, the nap-tested group demonstrated objective adherence of 49% to 56% compared to 12% to 17% among controls. Further results from large, prospective studies are needed to assess the clinical value of this test.

**Professional Societies**

**American Academy of Sleep Medicine (AASM)**

AASM clinical practice guidelines (Kapur et al., 2017) describe the circumstances under which attended PSG in an accredited sleep center or HSAT should be performed for suspected OSA in adults. In these guidelines, which consisted of a systematic review of the evidence, AASM made the following recommendations:

- **Good Practice Statements:**
  - Diagnostic testing for OSA should be performed in conjunction with a comprehensive sleep evaluation and adequate follow-up.
  - PSG is the standard diagnostic test for the diagnosis of OSA in adult patients in whom there is a concern for OSA based on a comprehensive sleep evaluation.
• Recommendations:
  o AASM recommends that clinical tools, questionnaires and prediction algorithms not be used to diagnose OSA in adults, in the absence of PSG or HSAT. (STRONG)
  o AASM recommends that PSG, or HSAT 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. (STRONG)
  o AASM recommends that if a single HSAT is negative, inconclusive, or technically inadequate, PSG be performed for the diagnosis of OSA. (STRONG)
  o AASM recommends that PSG, rather than HSAT, be used for the diagnosis of OSA in 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, history of stroke or severe insomnia. (STRONG)
  o AASM suggests that, if clinically appropriate, a split-night diagnostic protocol, rather than a full-night diagnostic protocol for PSG be used for the diagnosis of OSA. (WEAK)
  o AASM suggests that when the initial PSG is negative and clinical suspicion for OSA remains, a second PSG be considered for the diagnosis of OSA. (WEAK)

Per AASM, a strong recommendation is one that clinicians should follow under most circumstances. A weak recommendation reflects a lower degree of certainty regarding the outcome and appropriateness of the patient-care strategy for all patients. The ultimate judgment regarding propriety of any specific care must be made by the clinician in light of the individual circumstances presented by the patient, available diagnostic tools, accessible treatment options and resources.

AASM clinical practice guidelines (Smith et al., 2018) present recommendations for the use of actigraphy in patients with suspected or diagnosed sleep disorders or circadian rhythm sleep-wake disorders. In these guidelines, which consisted of a systematic review of the evidence, AASM made the following recommendations:

- Conditional comments indicate a lower degree of certainty regarding the outcome and appropriateness of the patient-care strategy for all patients. The ultimate judgment regarding propriety of any specific care must be made by the clinician in light of the individual circumstances presented by the patient, available diagnostic tools, accessible treatment options and resources.

AASM clinical practice guidelines (Smith et al., 2018) present recommendations for the use of actigraphy in patients with suspected or diagnosed sleep disorders or circadian rhythm sleep-wake disorders. In these guidelines, which consisted of a systematic review of the evidence, AASM made the following recommendations:

- AASM suggests that clinicians use actigraphy to estimate sleep parameters in adult patients with insomnia disorder. (Conditional)
- AASM suggests that clinicians use actigraphy in the assessment of pediatric patients with insomnia disorder. (Conditional)
- AASM suggests that clinicians use actigraphy in the assessment of adult patients with circadian rhythm sleep-wake disorder. (Conditional)
- AASM suggests that clinicians use actigraphy in the assessment of pediatric patients with circadian rhythm sleep-wake disorder. (Conditional)
- AASM suggests that clinicians use actigraphy to estimate total sleep time in adult patients suspected of sleep-disordered breathing. (Conditional)
- AASM suggests that clinicians use actigraphy to monitor total sleep time prior to testing with the Multiple Sleep Latency Test in adult and pediatric patients with suspected central disorders of hypersomnolence. (Conditional)
- AASM suggests that clinicians use actigraphy to estimate total sleep time in adult patients with suspected insufficient sleep syndrome. (Conditional)
- AASM recommends that clinicians not use actigraphy in place of electromyography for the diagnosis of periodic limb movement disorder in adult and pediatric patients. (Strong)

Conditional recommendations reflect a lower degree of certainty regarding the outcome and appropriateness of the patient-care strategy for all patients. A strong recommendation is one that clinicians should follow under most circumstances.

An AASM clinical guideline for the evaluation, management and long-term care of OSA in adults states that MSLT is not routinely indicated in the initial evaluation and diagnosis of OSA or in an assessment of change following treatment with nasal CPAP. However, if excessive sleepiness continues despite optimal treatment, the patient may require an evaluation for possible narcolepsy, including MSLT (Epstein et al., 2009).

An AASM practice parameter by Littner et al. (2005), regarding the clinical use of the MSLT and the MWT concluded the following:

- The MSLT is indicated as part of the evaluation of patients with suspected narcolepsy to confirm the diagnosis.
- The MSLT may be indicated as part of the evaluation of patients with suspected idiopathic hypersomnia to help differentiate idiopathic hypersomnia from narcolepsy.
- The MSLT is not routinely indicated in the initial evaluation and diagnosis of OSA syndrome or in assessment of change following treatment with nasal CPAP.
- The MSLT is not routinely indicated for evaluation of sleepiness in medical and neurological disorders (other than narcolepsy), insomnia or circadian rhythm disorders.
• Repeat MSLT testing may be indicated in the following situations:
  o When the initial test is affected by extraneous circumstances or when appropriate study conditions were not present during initial testing
  o When ambiguous or uninterpretable findings are present
  o When the patient is suspected to have narcolepsy but earlier MSLT evaluation(s) did not provide polygraphic confirmation
• The MWT may be indicated in patients with excessive sleepiness to assess response to treatment.
• The MWT may be used to assess an individual’s ability to remain awake when his or her inability to remain awake constitutes a public or personal safety issue.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Systems to record and analyze PSG information are regulated by the FDA as Class II Devices under the 510(k) premarking notification process. See the following website for more information (use product code GWQ): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 22, 2020)

The FDA has approved several HSAT devices as ventilatory effort recorders under the 510(k) premarking notification process. See the following website for more information (use product code MNR): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 22, 2020)

Actigraphy devices are classified as electroencephalograph devices (product code GWQ) or ventilator effort recorders (product code MNR). See the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 22, 2020)

REFERENCES


Ulibarri VA, Krakow B, McIver ND. The PAP-NAP one decade later: patient risk factors, indications, and clinically relevant emotional and motivational influences on PAP use. Sleep Breath. 2020 Jan 2. [Epub ahead of print]


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**GUIDELINE HISTORY/REVISION INFORMATION**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tbody>
<tr>
<td>04/01/2020</td>
<td><strong>Coverage Rationale</strong>&lt;br&gt;<strong>Attended Full-Channel Nocturnal Polysomnography, Performed in a Healthcare Facility or Laboratory Setting</strong>&lt;br&gt;Revised list of indicators of moderate to severe heart failure; added “left ventricular ejection fraction ≤ 40”&lt;br&gt;Updated language pertaining to sleep disorders other than OSA to clarify attended full-channel nocturnal polysomnography is medically necessary following an appropriate clinical assessment either because OSA has been excluded, OSA has been adequately treated, or documented symptoms suggest one of the [listed] conditions</td>
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<td><strong>Attended Repeat Testing</strong>&lt;br&gt;Updated list of examples of complications with current treatment or PAP therapy that have been addressed and appropriately managed; added “unsuccesful titration”</td>
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<td><strong>Documentation Requirements</strong>&lt;br&gt;Updated required clinical information for attended polysomnography for evaluation of sleep disorders</td>
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<td><strong>Definitions</strong>&lt;br&gt;Added definition of “New York Heart Association (NYHA) Heart Failure Classification”</td>
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<td><strong>Applicable Codes</strong>&lt;br&gt;Revised description for CPT code 95811</td>
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INSTRUCTIONS FOR USE

This Medical Management Guideline provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard benefit plan. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Management Guideline is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare West Medical Management Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Member benefit coverage and limitations may vary based on the member’s benefit plan Health Plan coverage provided by or through UnitedHealthcare of California, UnitedHealthcare Benefits Plan of California, UnitedHealthcare of Oklahoma, Inc., UnitedHealthcare of Oregon, Inc., UnitedHealthcare Benefits of Texas, Inc., or UnitedHealthcare of Washington, Inc.