

# Cigna Medical Coverage Policies – Sleep Disorders Diagnosis & Treatment Guidelines

Effective September 15, 2021



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## Instructions for use

The following coverage policy applies to health benefit plans administered by Cigna. Coverage policies are intended to provide guidance in interpreting certain standard Cigna benefit plans and are used by medical directors and other health care professionals in making medical necessity and other coverage determinations. Please note the terms of a customer's particular benefit plan document may differ significantly from the standard benefit plans upon which these coverage policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a coverage policy.

In the event of a conflict, a customer's benefit plan document always supersedes the information in the coverage policy. In the absence of federal or state coverage mandates, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of:

1. The terms of the applicable benefit plan document in effect on the date of service
2. Any applicable laws and regulations
3. Any relevant collateral source materials including coverage policies
4. The specific facts of the particular situation

Coverage policies relate exclusively to the administration of health benefit plans. Coverage policies are not recommendations for treatment and should never be used as treatment guidelines.

This evidence-based medical coverage policy has been developed by eviCore, Inc. Some information in this coverage policy may not apply to all benefit plans administered by Cigna.

These guidelines include procedures eviCore does not review for Cigna. Please refer to the [Cigna CPT code list](#) for the current list of high-tech imaging procedures that eviCore reviews for Cigna.

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# Sleep Disorders Diagnosis and Treatment Guidelines

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## Abbreviations for Sleep Guidelines

<b>AASM</b>	American Academy of Sleep Medicine
<b>AHI</b>	Apnea-Hypoxia Index: normal AHI < 5 mild OSA: AHI of $\geq 5$ to < 15 moderate OSA: AHI of $\geq 15$ to $\leq 30$ severe OSA: AHI of > 30
<b>AOSATF of AASM</b>	Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine
<b>APAP</b>	Autotitrating positive airway pressure
<b>BMI</b>	Body mass index (body weight divided by the square of the height)
<b>CPAP</b>	Continuous positive airway pressure
<b>DOT</b>	Department of Transportation
<b>EDS</b>	Excessive daytime sleepiness
<b>HCPCS</b>	Healthcare Common Procedural Coding System (Level II alphanumeric codes used to report services not included in CPT®)
<b>HSAT</b>	Home sleep apnea testing
<b>IDTF</b>	Independent Diagnostic Testing Facilities
<b>JCAHO</b>	Joint Commission on Accreditation of Healthcare Organizations
<b>MSLT</b>	Multiple Sleep Latency Test
<b>MWT</b>	Maintenance of Wakefulness Test
<b>OSA</b>	Obstructive sleep apnea
<b>PM</b>	Portable monitoring (in home sleep studies)
<b>PSG</b>	Polysomnography
<b>RDI</b>	Respiratory disturbance index: (respiratory effort related arousals + apneas + hypopneas/total sleep time normal RDI < 5 mild OSA: RDI of $\geq 5$ to < 15 moderate OSA: RDI of $\geq 15$ to $\leq 30$ severe OSA: RDI of > 30
<b>Screening Tools for Sleep Disorders</b>	Epworth Sleepiness Scale, Berlin Questionnaire (for sleep apnea), STOP-BANG questionnaire, Insomnia Severity Index
<b>OA</b>	Oral appliance

## Preface

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## **Preface-1: Guideline Development**

- The cobranded Cigna-eviCore healthcare (eviCore) evidence-based, proprietary clinical guidelines evaluate a range of advanced imaging and procedures, including NM, US, CT, MRI, PET, and Radiation Oncology, Sleep Studies and Cardiac and Spine interventions.
- Cigna and eviCore reserve the right to change and update the guidelines. The guidelines undergo a formal review annually. The Cigna-eviCore guidelines are based upon major national and international association and society guidelines and criteria, peer-reviewed literature, major treatises as well as, input from health plans, practicing academic and community-based physicians.
- These Guidelines are not intended to supersede or replace sound medical judgment, but instead, should facilitate the identification of the most appropriate procedure given the individual's clinical condition. These guidelines are written to cover medical conditions as experienced by the majority of individuals. However, these guidelines may not be applicable in certain clinical circumstances, and physician judgment can override the guidelines.
- Clinical decisions, including treatment decisions, are the responsibility of the individual and his/her provider. Clinicians are expected to use independent medical judgment, which takes into account the clinical circumstances to determine individual management decisions.
- Cigna and eviCore support the Choosing Wisely initiative ([www.choosingwisely.org](http://www.choosingwisely.org)) by the American Board of Internal Medicine (ABIM) Foundation and many national physician organizations, to reduce the overuse of diagnostic tests that are low value, no value, or whose risks are greater than the benefits.
- The terms “male” and “female” used in these guidelines refer to anatomic-specific diseases and disease predispositions associated with individuals' sex assigned at birth rather than their gender identity. It should be noted that gender identity and anatomic-specific diseases as well as disease predispositions are not always linked. As such, these guidelines should be applied to the individual's corresponding known or suspected anatomic-specific disease or disease predisposition. At Cigna and eviCore, we believe that it is important to understand how all individuals, including those who are gender-diverse, choose to identify themselves. To ensure that gender-diverse individuals are treated with respect and that decisions impacting their healthcare are made correctly and with sensitivity, Cigna and eviCore recognize all individuals with the following gender marker options: Male, Female, Transgender male, Transgender female, “X”, and “Not specified”.

## **Preface-2: Benefits, Coverage Policies, and Eligibility Issues**

- Medical benefits, plan coverage, and eligibility issues pertaining may take precedence over Cigna-eviCore's cobranded guidelines.

### **Medicare Coverage Policies**

- For Medicare and Medicare Advantage enrollees, the coverage policies of CMS (Centers for Medicare and Medicaid Services) take precedence over Cigna-eviCore's cobranded guidelines.
- CMS requires coverage for studies requested as part of a CMS approved clinical trial through the CMS CED program. A list of the currently approved studies is available at:  
<http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Index>

### **Experimental, Investigational, or Unproven Studies**

- Certain studies described in these guidelines are considered experimental, investigational, or unproven. Certain procedures may be considered experimental, investigational, or unproven if there is a paucity of supporting evidence; if the evidence has not matured to exhibit improved health parameters or; the procedure lacks a collective opinion of support.

### **Clinical and Research Trials**

- Similar to experimental, investigational, or unproven studies, clinical trial requests will be considered to determine whether they meet coverage.
- Services inconsistent with established clinical standards or requested for data collection and not for use in direct clinical management are not supported.

### ***References***

1. Prospective Payment Systems - General Information. CMS. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PropMedicareFeeSvcPmtGen>.
2. Medicare Coverage with Evidence Development: A Policy-Making Tool in Evolution. *Journal of Oncology Practice*. 2007;3(6):296-301. doi:10.1200/jop.0763501.
3. Coverage of Clinical Trials under the Patient Protection and Affordable Care Act; 42 U.S.C.A. § 300gg-8.

## **SL-1: Obstructive Sleep Apnea and Other Sleep-related Breathing Disorders**

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## **SL-1.0: General Guidelines**

- A current and comprehensive clinical evaluation (within 60 days) by the treating medical provider, either face to face or telehealth, is required before a sleep study can be considered. (Note: The rendering site must be a qualified provider of service per health plan policy). The clinical evaluation may include a relevant history and physical examination, appropriate laboratory studies, and other relevant diagnostic studies (such as a previous sleep study or overnight pulse oximetry). The results of a sleep questionnaire or sleep questionnaire proxy are required. See: **Sleep Questionnaires**.
  - ◆ Documented history may include the following:
    - Persistent symptoms present for greater than 4 weeks in duration and not associated with respiratory infections.
    - House partners/spouses can describe symptoms, including apneic spells, such as gasping and choking.
    - Co-workers, friends, and/or the individual may report that the individual falls asleep during business meetings, conversations, while stopped at traffic lights, or while driving.
    - Daytime tiredness and excessive caffeine or stimulant use.
    - Excessively loud, erratic and variable snoring. (Note: Snoring alone is not always indicative of OSA).
    - Frequent awakening during the night.
    - Increased movements, sleep talking, displaying confused or erratic behavior during sleep.
    - Morning headaches, limited attention, or memory loss.
    - Drowsy driving or history of car crashes or near miss accidents related to sleepiness.
    - Prior diagnosis of OSA and response to therapy.
  - ◆ Documented physical examination should include:
    - Cardiopulmonary evaluation
    - Level of obesity and/or neck circumference
    - Other findings, such as: macroglossia, tonsillar hypertrophy, nasal polyps, septal deviation, turbinate hypertrophy, elongated/enlarged uvula, narrow/high arched hard palate retrognathia (recessed mandible) or micrognathia (small mandible).

### **Note**

HSAT and/or PSG must be ordered by a treating medical provider and interpreted by a board-certified sleep medicine physician or a provider that is overseen by a board-certified sleep medicine physician



## Definitions

- For the purpose of this guideline, criteria for sleep-related breathing disorders are defined as follows:
  - ◆ Obstructive sleep apnea (OSA) as measured by valid testing is defined as:
    - The apnea-hypopnea index (AHI), respiratory disturbance index (RDI), respiratory event index (REI) is  $\geq 15$  events per hour; or
    - The AHI, RDI, or REI is  $\geq 5$  and  $< 15$  events per hour and documentation of:
      - Symptoms of sleepiness, nonrestorative sleep, fatigue, or insomnia
      - Report of awakening with breath holding, gasping, or choking
      - Bed partner or other observer reports habitual snoring, breathing interruptions, or both during sleep
      - Hypertension, a mood disorder, cognitive dysfunction, coronary artery disease, congestive heart failure, atrial fibrillation, type 2 diabetes mellitus, or stroke.
  - ◆ Central sleep apnea (CSA) defined as (both):
    - Central hypopnea/apneas are  $\geq 50\%$  of total
    - Central apnea and/or central hypopnea index  $\geq 5$  per hour
  - ◆ Central sleep apnea (CSA) with Cheyne-Stokes Respiration defined as (all):
    - Central hypopnea/apneas are  $> 50\%$  of total
    - Central apnea and/or central hypopnea index  $\geq 5$  per hour
    - Pattern of breathing meets criteria for Cheyne-Stokes breathing i.e. periodic breathing characterized by the waxing and waning of respiratory effort and airflow (crescendo and decrescendo change in breathing amplitude)
  - ◆ Treatment Emergent Central Sleep Apnea defined as (both):
    - Diagnostic PSG demonstrates 5 or more obstructive respiratory events per hour of sleep
    - PSG during use of positive airway pressure shows improvement of obstructive events and emergence or persistence of central apneas/hypopneas with (both):
      - Central apnea and/or hypopnea index  $\geq 5$  per hour
      - Central hypopnea/apneas are  $\geq 50\%$  of total
  - ◆ Sleep-related hypoventilation defined as when either of the following occur during sleep:
    - Increase in arterial  $PCO_2$ , transcutaneous  $PCO_2$ , or end-tidal  $PCO_2$  to a value  $>55$  mmHg for  $\geq 10$  minutes
    - There is a  $>10$  mmHg increase in arterial  $PCO_2$ , transcutaneous  $PCO_2$ , or end-tidal  $PCO_2$  during sleep (compared to awake supine value) to a value  $> 50$  mmHg for  $> 10$  minutes

**Overutilization of Testing:**

- A review of the testing history, including all of the following, avoids unnecessary repeat testing:
  - ◆ The results of initial studies to narrow the differential diagnosis should be obtained prior to performing further tests
  - ◆ The clinical history should include a potential indication such as a known or suspected sleep disorder. These potential indications are addressed in greater detail within the applicable guidelines.
  - ◆ The results of the requested study should be expected to have an impact on patient management or treatment decisions.
  - ◆ Criteria for repeat studies are addressed in the applicable guideline **SL-2.6: Repeat Sleep Testing - (Home or Attended Sleep Studies)**
  - ◆ Testing when the same or similar studies have already been conducted is not indicated, without clear rationale that fulfills guideline criteria

**Sleep Questionnaires:**

- Four sleep questionnaires (all self-answered by the patient) are commonly used to quantify the level of sleepiness, quality of sleep or probability of having OSA. These validated questionnaires include (but are not be limited to):
  - ◆ Epworth Sleepiness Scale
  - ◆ Berlin Questionnaire
  - ◆ STOP Bang Questionnaire
  - ◆ Insomnia Severity Index
- The results of these questionnaires help formulate an individual's likelihood of having sleep-related disease, so the questionnaires must be appropriate for the specific sleep issue in question (e.g. STOP-BANG and Berlin are most appropriate for OSA evaluation).
  - ◆ To view these questionnaires and their interpretation in their entirety, see **SL-8: Questionnaires.**
- Results of one of these four questionnaires are required, **or** the following condition can serve as a proxy for the sleep questionnaire requirement:
  - ◆ Witnessed apnea by a bed partner
  - ◆ Previous diagnosis of OSA confirmed in record by prior testing
  - ◆ History and physical elements are provided that would permit calculation of the STOP-BANG survey or Berlin Questionnaire

### **SL-1.3: Classifications of sleep-related breathing disorders**

- Sleep apnea is defined as repetitive partial or complete cessations of breathing that occur during sleep. These breathing events can be caused by a physical obstruction of the upper airway, a lack of effort to breathe, or a combination of these two factors. The source of the sleep disordered breathing determines the type or classification of sleep apnea.
  - ◆ Obstructive sleep apnea (OSA):
    - OSA is caused by a physical obstruction in the upper airway.
    - Sleep study recording characterized by:
      - Loud snoring
      - Obstructive apnea events – scored as apneas with apnea index or AI
      - Hypopnea events – scored with hypopnea index or HI
      - Significant oxyhemoglobin desaturations
      - Arousals from sleep
  - ◆ Central sleep apnea (CSA) defined as Central hypopnea/apneas are > 50% of total, and Central apnea and/or central hypopnea index  $\geq 5$  per hour:
    - CSA is caused by a reduction or absence of effort to breathe by the diaphragm or respiratory muscles.
    - Sleep study recording characterized by:
      - Central apnea events, or hypopnea events
      - Occasional snoring
      - Oxyhemoglobin desaturation
      - Occasional arousals from sleep
  - ◆ Central sleep apnea (CSA) with Cheyne-Stokes Respiration defined as Central hypopnea/apneas are > 50% of total, and Central apnea and/or central hypopnea index  $\geq 5$  per hour and the pattern of breathing meets criteria for Cheyne-Stokes breathing:
    - CSR is a form of periodic breathing characterized by the waxing and waning of respiratory effort and airflow
    - CSR generally starts with a gradual waning of breathing effort and airflow which results in a central apnea, or hypopnea, followed by a gradual increase in breathing effort and flow
  - ◆ Sleep-related hypoventilation as defined when either of the below occur during sleep:
    - Increase in arterial PCO<sub>2</sub>, transcutaneous PCO<sub>2</sub>, or end-tidal PCO<sub>2</sub> to a value >55 mmHg for  $\geq 10$  minutes
    - There is a >10 mmHg increase in arterial PCO<sub>2</sub>, transcutaneous PCO<sub>2</sub>, or end-tidal PCO<sub>2</sub> during sleep (compared to awake supine value) to a value > 50 mmHg for > 10 minutes
  - ◆ Treatment emergent central sleep apnea (complex sleep apnea) as measured by valid testing is defined as:
    - Diagnostic PSG demonstrates 5 or more obstructive respiratory events per hour of sleep
    - PSG during use of positive airway pressure shows improvement of obstructive events and emergence or persistence of central apneas/hypopneas with:

- Central apnea and/or hypopnea index  $\geq 5$  per hour and Central hypopnea/apneas are  $\geq 50\%$  of total

## **SL-1.4: Coding**

### **SL-1.4.1: Home Portable Monitoring (PM) (Home Sleep Testing) - Coding**

There are currently 3 levels (HCPCS G0398, G0399 and G0400) of home PM's, with varying number of monitored parameters. Each can be used with or without an attendant but are generally performed unattended in the individual's home.

Home Sleep Studies	HCPCS	Channels
Home sleep study test (HSAT) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation	<b>G0398</b>	At least 7 monitored channels. Can calculate AHI.
Home sleep test (HSAT) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation	<b>G0399</b>	At least 4 monitored channels (airflow/ventilation, heart rate, oxygen saturation, respiratory movement)
Home sleep test (HSAT) with type IV portable monitor, unattended; minimum of 3 channels	<b>G0400</b>	Measures 1 to 3 parameters

PSG PROCEDURE CODES	
Unattended Sleep Studies	CPT®
Sleep study, unattended, measures a minimum of heart rate, oxygen saturation, and respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time.	<b>95800</b>
<ul style="list-style-type: none"> <li>➤ Simultaneous recording; simultaneous recording; heart rate, oxygen saturation, and respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time.</li> <li>➤ For unattended sleep study that measures a minimum of heart rate, oxygen saturation, and respiratory analysis, report 95801</li> </ul>	
Sleep study, unattended, measures a minimum of heart rate, oxygen saturation, and respiratory analysis (e.g., by airflow or peripheral arterial tone)	<b>95801</b>
<ul style="list-style-type: none"> <li>➤ Simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (e.g., by airflow or peripheral arterial tone).</li> <li>➤ For unattended sleep study that measures a minimum of heart rate, oxygen saturation, and sleep time, report 95800</li> </ul>	
Sleep study, unattended, simultaneous recording of heart rate, oxygen saturation, respiratory airflow and respiratory effort (e.g. thoracoabdominal movement)	<b>95806</b>
<ul style="list-style-type: none"> <li>➤ Simultaneous recording; minimum of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation.</li> <li>➤ Do not report CPT® 95806 in conjunction with any of the following codes: CPT® 93041-93229, 93268-93272, or 95800-95801</li> </ul>	

**SL-1.4.2: Polysomnography (Facility-based-PSG) - Coding**

<b>PSG PROCEDURE CODES</b>	
<b>Attended Polysomnography and Sleep Studies</b>	<b>CPT®</b>
Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness or ability to remain awake.	<b>95805</b>
<ul style="list-style-type: none"> <li>➤ Multiple sleep latency testing (MSLT) is performed prior to treatment when the requesting physician suspects narcolepsy.</li> <li>➤ MSLT must be requested with a facility sleep study performed the night before the 95805 (CPT® 95810 or CPT® 95811).</li> <li>➤ See <b>SL-2.3: PSG and Multiple Sleep Latency Testing (excessive sleepiness)</b> - See <b>SL-2.4: Maintenance of Wakefulness Testing (MWT)-Indications and Criteria</b></li> </ul>	
Polysomnography; (any age), sleep staging with 1-3 additional parameters of sleep, attended by a technologist	<b>95808</b>
Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist with PAP titration,	<b>95807</b>
<ul style="list-style-type: none"> <li>➤ May be considered experimental, investigational, or unproven when 95807 or 95807-52 is utilized to request a PAP-NAP.</li> </ul>	
<b>Attended Polysomnography and Sleep Studies</b>	<b>CPT®</b>
Polysomnography; (age 6 years or older), sleep staging with 4 or more additional parameters of sleep, attended by a technologist.	<b>95810</b>
<ul style="list-style-type: none"> <li>➤ CPT® 95810 is used to report full-night studies.</li> <li>➤ One of the more common studies.</li> </ul>	
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 Bi-level ventilation, attended by a technologist	<b>95811</b>
<ul style="list-style-type: none"> <li>➤ One of the more common studies.</li> <li>➤ CPT® 95811 is used either as either a split-night study with both the diagnostic study and the subsequent positive airway pressure or bi-level ventilation are initiated during the same visit, <b>or</b> as PAP titration alone after CPT® 95810 or inability to complete split night sequence or as a retitration of PAP therapy.</li> </ul>	
<b>Attended Polysomnography and Sleep Studies (PEDIATRIC CODES)</b>	<b>CPT®</b>
Polysomnography, (younger than 6 years), sleep staging with 4 or more additional parameters of sleep, attended by a technologist.	<b>95782</b>
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.	<b>95783</b>

<b>SL-2: Indications/Diagnostic Testing</b>	
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### **SL-2.1: Home Sleep Apnea Testing (HSAT) Indications**

- HSAT can be performed when **both of the following** criteria are met:
  - ◆ High pre-test probability of moderate-to-severe OSA as defined by validated questionnaire **or** reported symptoms of excessive daytime sleepiness and **at least two** of the following three criteria (habitual loud snoring, witnessed apnea or gasping or choking, or diagnosed hypertension) **and**
  - ◆ HSAT can physically be performed **and individual** has the mobility, dexterity and cognitive ability to use the available equipment safely at home and the ability to follow instructions
- Individuals who exhibit one of the co-morbid indications for attended sleep studies found in **SL-2.2: In-Laboratory Polysomnography - OSA Indications** can undergo facility testing as outlined in SL 2.2 or home sleep apnea testing (HSAT) if preferred by the treating provider
- HSAT can also be used in follow-up treatment results after any of the following:
  - ◆ Surgical treatment for moderate to severe OSA
  - ◆ OSA Oral appliance trial
  - ◆ Other non-PAP supportive interventions (e.g. positional therapy).

### **SL-2.2: In-Laboratory Polysomnography - OSA Indications**

PSG(CPT® 95810 or 95811) can be considered for the following:

- Sleep survey or proxy symptom(s) lead to **any** pretest probability of OSA and **one** of the following:
  - ◆ HSAT cannot be done due to one of the following reasons:
    - OSA symptoms with low pretest probability of OSA.
    - Individual does not have the mobility, dexterity or cognitive ability to use the available equipment safely at home and the ability to follow instructions.
    - HSAT has been attempted and is negative, inconclusive, or technically inadequate (report submitted for review).
  - ◆ Documentation of at least one of the following suspected or known co-morbid diagnoses:
    - Morbid obesity and one of the following:
      - BMI  $\geq 45$
      - Obesity Hypoventilation Syndrome (OHS) defined as BMI  $\geq 30$  plus arterial blood gas with  $PCO_2 \geq 45$ .
      - If ABG results are not available, serum bicarbonate  $\geq 27$  may be provided as an alternative to determine high risk for OHS).
    - Moderate to severe pulmonary disease (for example: COPD, asthma) as demonstrated by one or more of the following:
      - nocturnal oxygen use
      - documented arterial blood gases showing  $PO_2 < 60$  or  $PCO_2 > 45$
      - documented pulmonary function tests demonstrating moderate to severe obstruction with forced expiratory volume in one second ( $FEV_1$ )  $\leq 69\%$  of predicted

- Documented neuromuscular disease (e.g., Parkinson's, documented stroke or undocumented stroke with residua, active epilepsy, myotonic dystrophy, ALS)
- Moderate to severe congestive heart failure with documented pulmonary congestion or known left ventricular ejection fraction < 45%
- Pulmonary HTN, with documentation of a mean pulmonary artery pressure of  $\geq 25$  mm Hg on right heart cardiac catheterization. Note: If right heart catheterization results are not available, echocardiography results can be provided documenting significant probability of pulmonary HTN based on a peak tricuspid regurgitation velocity of  $\geq 2.9$  m/s
- Other critical illness that would prevent them from using the HSAT equipment.
  - Chronic severe insomnia (by objective measure e.g. sleep diary, validated insomnia questionnaire, such as Insomnia Severity Index  $\geq 22$ )
  - Chronic daily opioid use (typically daily high-potency opioids e.g. Methadone<sup>®</sup>, Suboxone<sup>®</sup>, Dilaudid<sup>®</sup>) with stated concern for presence of central sleep apnea.
  - Bi-level PAP or Adaptive Servo Ventilation PAP are specifically requested (Titration study, CPT<sup>®</sup> 95811, only) and CPAP has already been tried and proven ineffective or not tolerated for an individual with OSA OR the individual has been diagnosed with one of the conditions outlined in **SL-4.2.3: Bilevel Positive Airway Pressure – spontaneous mode, SL-4.2.4: Bilevel Positive Airway Pressure – spontaneous/timed mode, or SL-4.2.6: Adaptive Servo Ventilation (ASV) therapy (E0471)**, meeting criteria for Bilevel Positive Airway Pressure – spontaneous mode, Bilevel Positive Airway Pressure – spontaneous/timed mode, or Adaptive Servo Ventilation (ASV) therapy, respectively
  - Per the ICSD definition of sleep related hypoxemia, sustained oxygen desaturation independent of respiratory events on prior facility-based study or during prior home sleep apnea testing with documentation on the sleep study report of one or more periods of sustained oxygen desaturation less than or equal to 88% lasting a minimum of 5 consecutive minutes in the absence of apneas or hypopneas (Titration study, CPT<sup>®</sup> 95811 only)
  - Documented unsuccessful AutoPAP attempt (Titration study, CPT<sup>®</sup> 95811 only)
    - Initiation of therapy started > 30 days ago and either:
      - ◆ Auto-PAP machine download with AHI > 5/hr with symptoms (of OSA) or > 15/hr with or without return of symptoms
      - ◆ Auto-PAP use > 70% of nights, 4+hrs/night with continued symptoms noted
  - Central sleep apnea in Classifications of Sleep related breathing disorders in **SL-1.0: General guidelines**
  - Treatment – Emergent Central Sleep apnea in Classifications of Sleep related breathing disorders in **SL-1.0: General guidelines**

Note: Please see section **SL-3.1: Proper Uses of Polysomnography in Pediatrics** for criteria for individuals less than 18 years of age.



### **SL-2.2.1: In-Laboratory Polysomnography - Other Indications**

- Suspected narcolepsy or idiopathic hypersomnia (with CPT® 95805): See **SL-2.3: PSG and Multiple Sleep Latency Testing (excessive sleepiness) Indications and Criteria**.
- Complicated parasomnias. (Complicated parasomnias **do NOT** include more common conditions such as typical disorders of arousal, nightmares, enuresis, somniloquy, bruxism).
- Rapid Eye Movement (REM) Behavior Disorder: Characterized by the acting out of dreams that are vivid, intense, and violent. Sleep-related vocalization and complex motor behaviors, which correlate with sleep-related mentation, i.e. dream-enacting behaviors. Dream enacting behaviors may include talking, yelling, punching, kicking, sitting, jumping from bed, arm flailing, and grabbing.
- Periodic limb movement disorder (PLMD), but NOT Restless Leg Syndrome (RLS). Suspected PLMD is defined by periodic episodes of repetitive limb movements during sleep associated with insomnia or hypersomnia not caused by another sleep disorder (such as OSA), while RLS is a subjective uncomfortable sensation experienced while awake. Individuals who are undergoing initial diagnostic testing and have a high pre-test probability of moderate to severe obstructive sleep apnea (as defined in **SL-2.1: Home Sleep Testing (HSAT) Indications**) should be evaluated for obstructive sleep apnea before a diagnosis of PLMD is considered.\* See practice note below.

#### ***Practice note***

Preoperative bariatric surgery testing should also be based on these guidelines criteria.

\* Per the International Classification of Sleep Disorders, PLMD cannot be diagnosed in the context of RLS, narcolepsy, untreated obstructive sleep apnea or REM sleep behavior disorder. The presence of periodic limb movements of sleep (PLMS) on sleep testing does not equate to PLMD. PLMS is common, but PLMD is rare in adults.

Restless Legs Syndrome (Willis-Ekbom Disease) is a clinical diagnosis characterized by uncomfortable sensations in the legs that begin or worsen during rest, occur predominantly in the evening, and are partially or totally relieved by movement.

### **SL-2.3: PSG and Multiple Sleep Latency Testing (excessive sleepiness)**

- Indications and Criteria (all of the following must be met)
  - ◆ CPT® 95810 followed by CPT® 95805 is being performed for suspected narcolepsy or idiopathic hypersomnia as evidenced by:
    - Excessive sleepiness (shown not due to other more common sleep disorders such as obstructive sleep apnea or insufficient sleep syndrome), AND
    - Recurrent daytime naps or lapses into sleep daily for at least 3 months.
    - Additional symptoms may include:
      - Cataplexy- sudden loss of muscle tone occurring in association with intense emotion (laughing or crying), OR
      - Sleep paralysis, hypnagogic hallucinations, hypnopompic hallucinations, automatic behaviors, or disrupted major sleep episode
  - ◆ Multiple Sleep Latency Testing (MSLT) (CPT® 95805) must immediately follow PSG (CPT® 95810). It cannot follow a split night study.
    - Note: When the individual has known OSA which is optimally treated with PAP therapy, and has persistent excessive daytime sleepiness and symptoms concerning for narcolepsy or idiopathic hypersomnia, the preceding night's attended study, prior to the next-day MSLT, should be completed while the individual is using his/her PAP therapy at its optimal setting. Either CPT® 95810 or 95811 can be used to precede MSLT for individuals with known OSA controlled on PAP therapy.
  - ◆ Comprehensive Sleep Evaluation including ESS or Berlin performed,
  - ◆ If OSA is suspected, diagnostic study has been performed, and if OSA is present, therapy is initiated, and has resolved symptoms of increased upper airway resistance (e.g. eliminated snoring).
  - ◆ Is not requested to assess efficacy of PAP therapy for OSA.

### **SL-2.4: Maintenance of Wakefulness Testing (MWT) - Indications and Criteria**

- Maintenance of Wakefulness Testing (MWT)-General information
  - ◆ Maintenance of Wakefulness Testing (MWT) measures the ability to stay awake for a defined period of time. Practice parameters on the clinical use of MWT were published by the American Academy of Sleep Medicine (AASM) in 2005. Unlike MSLT, the performance of overnight polysomnography the night prior to MWT is considered optional. Per the AASM, the MWT 40-minute protocol is recommended. Clinical guidelines specify that MWT may be indicated to assess response to treatment in individuals with sleep disorders associated with excessive daytime sleepiness. MWT may also be useful to assess ability to maintain wakefulness when hypersomnia constitutes a public or personal safety concern.<sup>85</sup> However, the utility of MWT is limited by the lack of large scale studies providing normative data for mean sleep latency on MWT. In addition, assessment of the daily ability to maintain wakefulness is complex and influenced by several variables not assessed during MWT such as long term treatment compliance, sleep duration and quality, circadian factors and shift work

schedules. An updated position paper on the use of multiple sleep latency test (MSLT) and the MWT is expected to be published in Fall/Winter 2019.

- Maintenance of Wakefulness Testing-Indications
  - ◆ Maintenance of Wakefulness Testing (40-minute protocol) can be considered when ALL of the following criteria are met:
    - The individual has a diagnosed sleep disorder associated with excessive daytime sleepiness (e.g.: Obstructive sleep apnea, narcolepsy), AND
    - The individual is actively undergoing treatment for their sleep disorder and is compliant with treatment. If the individual is being treated with positive airway pressure (PAP) for obstructive sleep apnea, objective compliance is provided meeting compliance criteria (Using PAP > 70% of the nights for an average of 4 hours or more per 24-hour period) and therapy has resolved symptoms of increased upper airway resistance (i.e. eliminated snoring)
    - Stated need to objectively document ability to maintain wakefulness as a measure of treatment response due to one of the following
      - Lack of reliable history
      - Personal or public safety concern

*Practice Note:*

**AASM LEVELS OF RECOMMENDATIONS**

*Adapted from Standards of Practice Committee of the American Academy of Sleep Medicine. Practice parameters for clinical use of the multiple sleep latency test and the maintenance of wakefulness test. SLEEP 2005;28(1):113-121.*

- ◆ TERM DEFINITION
  - STANDARD- This is a generally accepted patient-care strategy, which reflects a high degree of clinical certainty. The term standard generally implies the use of Level I Evidence, which directly addresses the clinical issue, or overwhelming Level II Evidence.
  - GUIDELINE- This is a patient-care strategy which reflects a moderate degree of clinical certainty. The term guideline implies the use of Level II Evidence or a consensus of Level III Evidence.
  - OPTION- This is a patient-care strategy, which reflects uncertain clinical use. The term option implies either inconclusive or conflicting evidence or conflicting expert opinion.

General Recommendations	Level of Evidence
♦ The MSLT is a validated objective measure of the ability or tendency to fall asleep	STANDARD
♦ The MWT is a validated objective measure of the ability to stay awake for a defined time	STANDARD
♦ The MWT is used in association with the clinical history to assess the ability to maintain wakefulness	STANDARD
♦ The MWT 40-minute protocol is recommended when the sleep clinician requires objective data to assess an individual's ability to remain awake	OPTION
♦ To provide a valid assessment of sleepiness or wakefulness the MSLT and MWT must be performed under appropriate conditions using proper recording techniques and accepted protocols, with interpretation by a qualified and experienced clinician	STANDARD
Specific indications for the use of multiple sleep latency test (MSLT)	Level of Evidence
♦ The MSLT is indicated as part of the evaluation of patients with suspected narcolepsy to confirm the diagnosis	STANDARD
♦ The MSLT may be indicated as part of the evaluation of patients with suspected idiopathic hypersomnia to help differentiate idiopathic hypersomnia from narcolepsy	OPTION
♦ The MSLT is not routinely indicated in the initial evaluation and diagnosis of obstructive sleep apnea 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	OPTION
♦ Repeat MSLT testing may be indicated in the following situations: <ul style="list-style-type: none"> <li>♦ when the initial test is affected by extraneous circumstances or when appropriate study conditions were not present during initial testing</li> <li>♦ when ambiguous or uninterpretable findings are present</li> <li>♦ when the patient is suspected to have narcolepsy but earlier MSLT evaluation(s) did not provide polygraphic confirmation</li> </ul>	STANDARD
Specific indications for the use of maintenance of wakefulness test (MWT)	Level of Evidence
♦ The MWT 40-minute protocol 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	OPTION
♦ The MWT may be indicated in patients with excessive sleepiness to assess response to treatment.	

Adapted from Standards of Practice Committee of the American Academy of Sleep Medicine. Practice parameters for clinical use of the multiple sleep latency test and the maintenance of wakefulness test. SLEEP 2005;28(1):113-121.

## **SL-2.5: Split Night Study or Two Night Study**

### **Split Night Study**

- Split night study (CPT® 95811) is a single-night PSG + PAP trial, and typically can be completed if both:
  - ◆ Apnea Hypopnea Index (AHI) is greater than or equal to 15/hr during ≥ 2 hours of recording time on the diagnostic PSG
  - ◆ ≥ 3 hours are available for PAP titration
- Split night study (CPT® 95811) can be achieved in the majority of cases in one night. This is the current recommended approach per the American Academy of Sleep Medicine (AASM) if the above criteria are met.

### **Two Night Study**

- In some cases, a split night study cannot be completed because the above criteria is not met and sleep testing must be done in two nights.
  - ◆ The first night's study is performed as (CPT® 95810)
  - ◆ Followed by second night PAP (CPT® 95811)
- When PAP titration (CPT® 95811) is subsequently requested after a completed PSG CPT® 95810 (full-night diagnostic of failed split-study) or HSAT, the following information should be used to consider unattended APAP or attended CPAP titration:
  - ◆ The same indications that were used to consider PSG or HSAT see **SL-2.2: In-Laboratory Polysomnography - OSA Indications**
  - ◆ All new information from the PSG or HSAT
- For more information on the technical and policy requirements of PSG, as well as on PSG scoring, see Practice Notes **SL-7: Practice Notes**

## **SL-2.6: Repeat Sleep Testing - (Home or Attended Sleep Studies)**

### **SL-2.6.1: Repeat Diagnostic Study**

- Either home sleep apnea testing or split night testing (CPT® 95811) based on indications and comorbidities found in **SL-2.1: Home Sleep Testing (HSAT) Indications** and **SL-2.2: In-Laboratory Polysomnography - OSA Indications** can be performed if any of the following criteria is met:
  - ◆ BMI decreases by 10% or falls below 30 and there is a desire to discontinue PAP therapy and/or intolerance to PAP therapy
  - ◆ To reassess for the continued presence of OSA after:
    - Surgical treatment for moderate to severe OSA, or
    - OSA Oral appliance trial, or
    - Other non-PAP supportive interventions (e.g. positional therapy).
  - ◆ Results of previous medically necessary sleep test were inadequate and not diagnostic due to limited sleep time or other specified variables (report of prior sleep testing required).
  - ◆ **NOT** to assess for the continued presence of OSA in the absence of weight loss or one of the clinical interventions listed above
  - ◆ **NOT** to supply new PAP equipment.
- If any of the above criteria is met, please see **SL-2.1: Home Sleep Testing (HSAT) Indications** and **SL-2.2: In-Laboratory Polysomnography - OSA Indications** for determination of appropriateness of home sleep apnea testing versus facility testing.

### **SL-2.6.2: Repeat Titration**

- Repeat Titration study can be performed if any of the following criteria is met:
  - ◆ Reassessment of treatment results (with either CPT® 95811 or unattended APAP based on indications and comorbidities found in **SL-2.2: In-Laboratory Polysomnography - OSA Indications**) for an individual with known OSA currently on CPAP therapy can be performed when any of the following has occurred:
    - Substantial weight gain (10% of body weight) with return of symptoms.
    - BMI decreases by 10% or falls below 30 and there is intolerance of PAP pressure
    - Clinical response is insufficient despite treatment
    - Symptoms return despite a good initial response to CPAP.
    - PAP machine download with AHI > 5/hr with return of symptoms or > 15/hr with or without return of symptoms.
    - Must demonstrate that recurrent or continued symptoms are not due to insufficient compliance (must be using PAP > 70% of nights, 4+hrs/night with continued symptoms).
    - Results of previous medically necessary sleep test were inadequate and not diagnostic due to limited sleep time or other specified variables.
    - **NOT** to assess for the efficacy of PAP therapy in the absence of recurrent or changed symptoms
    - **NOT** to supply new PAP equipment.

- If any of the above criteria is met for an individual on CPAP, please see **SL-2.2** for determination of appropriateness of automatic PAP trial versus facility titration study. Comorbidities in **SL-2.2** are required to perform repeat facility titration study without first undergoing an automatic PAP trial.
- ◆ Re-assessment of treatment results (with CPT® 95811) for an individual with known OSA currently treated with bi-level PAP, APAP, ASV can be performed when any of the following has occurred:
  - Substantial weight gain (10% of body weight) with return of symptoms.
  - BMI falls below 30 and there is intolerance of PAP pressure
  - Clinical response is insufficient despite treatment.
  - Symptoms return despite a good initial response to CPAP.
  - PAP machine download with AHI > 5/hr with return of symptoms or > 15/hr with or without return of symptoms.
  - Must demonstrate that recurrent or continued symptoms are not due to insufficient compliance (must be using PAP > 70% of nights, 4+hrs/night with continued symptoms).
  - Results of previous medically necessary sleep test were inadequate and not diagnostic due to limited sleep time or other specified variables.
  - **NOT** to assess for the efficacy of PAP therapy in the absence of recurrent or changed symptoms
  - **NOT** to supply new PAP equipment.

### **SL-2.6.3: Re-assessment of suspected narcolepsy or idiopathic hypersomnia**

- Reassessment of suspected narcolepsy or idiopathic hypersomnia with a repeat CPT® 95810/CPT® 95805 can be considered if previous testing did not confirm the diagnosis but clinical suspicion is still present despite treatment, or due to a change in symptoms (e.g. development of sleep paralysis, cataplexy, hypnagogic hallucinations or worsening hypersomnolence).
  - ◆ For individuals with OSA on PAP, CPT® 95811 or CPT® 95810 can be used per **SL-2.3 PSG and Multiple Sleep Latency Testing (excessive sleepiness)**.

### **SL-2.7: PAP-NAP (CPT® 95807-52)**

- PAP-NAP, a daytime abbreviated cardiorespiratory sleep study, was developed as a means of improving adherence to positive airway pressure in individuals with sleep disordered breathing and co-morbid insomnia and psychiatric disorders. A pilot study performed in 2008 demonstrated improvement in PAP adherence compared to historical controls in individuals with insomnia and diagnosed and/or symptoms of psychiatric disorders. However, no subsequent controlled studies have been published. Therefore, CPT® **95807 or 95807-52** for the purposes of performing PAP-NAP is experimental, investigational, or unproven.

#### ***Practice Note***

- Result of previous studies should be submitted for review prior to authorization of additional studies

## **SL-2.8: Diagnostic Testing pre- and post- hypoglossal nerve stimulator implantation**

- See Practice note below
- PSG(CPT® 95810 or 95811)
  - ◆ Pre-implantation:
    - **No prior sleep testing:** Individuals with a high pre-test likelihood for moderate to severe obstructive sleep apnea who have not undergone prior sleep testing should undergo home sleep apnea testing, if appropriate per guidelines, and a PAP trial before consideration of facility testing for possible hypoglossal nerve stimulator implantation. Please see sections **SL-2.1: Home Sleep Testing (HSAT) Indication**, prior sections in **SL-2.2: In-Laboratory Polysomnography - OSA Indications**, and **SL-2.2.1: In-Laboratory Polysomnography - Other Indications** for guidelines for individuals who have not undergone prior testing.
    - **Prior diagnosis of OSA based on polysomnography:** Individuals who have recently undergone polysomnography (within 24 months), do not need a repeat study unless there have been changes in weight or symptoms to suggest a clinically significant change in sleep study results. In the setting of recent significant changes in weight or symptoms, repeat polysomnography could be considered if the following criteria are met (BOTH):
      - BMI <35
      - Previous intolerance to CPAP and/or bi-level PAP during a minimum of one-month trial
    - **Prior diagnosis of OSA based on home sleep apnea testing:** In the setting of a known diagnosis of obstructive sleep apnea based on home sleep apnea testing, the following criteria must be met prior to performance of polysomnography (CPT® 98510) for pre-implantation evaluation (ALL):
      - BMI <35
      - AHI or REI less than 65 on home sleep testing
      - Intolerance to CPAP and/or bi-level PAP during a minimum of one-month trial
  - ◆ Post-implantation:
    - As per the clinical trial, polysomnography can be performed at approximately one-month post-implantation for the purpose of titrating device parameters and determining therapeutic stimulation settings.
      - Following the titration study at one month, retesting (either HSAT or PSG CPT® 95810) can be performed if any of the following occurs:
        - Clinical response is insufficient despite regular treatment with hypoglossal nerve stimulator.
        - Substantial weight gain with return of symptoms.
        - Results of previously medically necessary sleep test were inadequate due to limited sleep time or other variables.
    - Following the titration study at one month, the choice of home sleep apnea testing or facility polysomnography for repeat testing will be based on indications and co-morbidities outlined in **SL-2.1: Home Sleep Testing**



**(HSAT) Indication**, prior sections in **SL-2.2: In-Laboratory Polysomnography- OSA Indications**, and **SL-2.2.1: In-Laboratory Polysomnography- Other Indications**.

***Practice note:***

A hypoglossal nerve stimulator is a surgically implanted device that delivers stimulating electrical pulses to the hypoglossal nerve, which controls upper airway musculature. With a sensing lead, the device permits synchronization with ventilatory effort. The Stimulation Treatment for Apnea Reduction (STAR) trial was a prospective, multicenter trial of 126 participants with a body mass index (BMI) less than 32, moderate to severe obstructive sleep apnea (AHI 20-50), and difficulty tolerating/adhering to CPAP. Participants, who served as their own control, experienced a significant reduction in Apnea Hypopnea Index with hypoglossal nerve stimulation (68% decrease) and oxygen desaturation index (70% decrease) at 12 months, as well as a reduction in self-reported outcomes at 12 and 24 months. These improvements were maintained at 3, 4, and 5 years. During the trial, a response to hypoglossal nerve stimulation was defined as a reduction of AHI by at least 50% from baseline and an AHI of less than 20 events per hour at one year. A prospective, single arm study conducted in Germany utilized an inclusion criteria of AHI of 15 to 65 per hour and BMI less than 35 kg/m<sup>2</sup>. Significant reduction in AHI was achieved with median AHI decreasing from 28/h to 8.3/h at 6 months and sustained improvement at one year. In June 2017, the Food and Drug administration revised the criteria to include individuals with AHI between 15 and 65. Retrospectively, no differences have been found for post-operative AHI, oxygen saturation nadir, daytime sleepiness or surgical success with BMI greater than or less than 32.

## **SL-3: Pediatric Sleep Guidelines**

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### **SL-3.1: Proper Uses of Polysomnography in Pediatrics**

Use of home/portable sleep studies for the diagnosis of OSA in children (17 years and younger) is considered experimental, investigational, or unproven at this time. Limited portable studies, or studies in the home, are not sufficient to exclude OSA in a child with suggestive symptoms, nor can they reliably assess the severity of the disorder, which is important in planning treatment. Overnight polysomnography (CPT® 95782 for children less than 6 years of age, CPT® 95810 for children 6 years of age or greater) remains the diagnostic "gold-standard" in children with OSA.

- Overnight polysomnography (PSG) in a sleep lab setting is appropriate for children (17 years of age and younger) for the diagnosis of **any** of the following conditions:
  - ◆ Sleep related breathing disorders, such as obstructive sleep apnea, upper airway resistance syndrome
  - ◆ Narcolepsy or idiopathic hypersomnia (generally would be performed in conjunction with a multiple sleep latency test)
  - ◆ Congenital central alveolar hypoventilation syndrome or sleep related hypoventilation due to neuromuscular disorders or chest wall deformities
    - A pediatric positive airway pressure titration study can be performed without a baseline sleep study for sleep-related hypoventilation under the following circumstances:
      - Documented neuromuscular disease such as Duchenne muscular dystrophy or spinal muscular atrophy
      - Individuals being discharged from the hospital determined to have sleep-related hypoventilation during hospitalization.
  - ◆ Nocturnal seizure activity
  - ◆ REM behavior disorder (rare in childhood)
  - ◆ Repeat PSG following adenotonsillectomy if there are residual symptoms of OSA or to assess for residual OSA
  - ◆ Polysomnography of primary sleep apnea of infancy (when other medical disorders have been ruled out)
  - ◆ Suspected periodic limb movement disorder
- Overnight PSG in a sleep lab is appropriate for children with habitual snoring associated with **any** of the following:
  - ◆ Restless or disturbed sleep
  - ◆ Behavioral disturbance, or learning disorders including deterioration in academic performance, hyperactivity, or attention deficit/hyperactivity disorder
  - ◆ Unexplained enuresis
  - ◆ Frequent awakenings
  - ◆ Failure to thrive or growth impairment
  - ◆ Witnessed apnea
  - ◆ Labored breathing during sleep
  - ◆ Headaches on awakening
  - ◆ Hypertension
  - ◆ Underweight or Overweight
  - ◆ Secondary enuresis during sleep (enuresis after at least 6 months of continence)

- ◆ Excessive daytime somnolence, or altered mental status unexplained by other conditions or etiologies
- ◆ Polycythemia unexplained by other conditions or etiologies
- ◆ Cor pulmonale unexplained by other conditions or etiologies
- ◆ Tonsillar hypertrophy
- ◆ Adenoidal facies
- Polysomnography when there is clinical evidence of a sleep related breathing disorder in infants who have experienced an apparent life-threatening event (ALTE).
- Repeat overnight polysomnography in a sleep lab setting for children is considered medically necessary in **any** of the following circumstances:
  - ◆ Initial polysomnography is inadequate or non-diagnostic and the accompanying caregiver reports that the child's sleep and breathing patterns during the testing were not representative of the child's sleep at home;
  - ◆ For positive airway pressure (PAP) titration (CPT<sup>®</sup> 95783 for children less than 6 years of age, CPT<sup>®</sup> 95811 for children 6 years of age or greater) in children with obstructive sleep apnea syndrome.
  - ◆ A child with previously diagnosed and treated obstructive sleep apnea who continues to exhibit persistent snoring or other symptoms of sleep disordered breathing.
  - ◆ To periodically re-evaluate the appropriateness of continuous positive airway pressure (CPAP) setting based on the child's growth pattern or the presence of recurrent symptoms while on CPAP.
  - ◆ If obesity was a major contributing factor and significant weight loss has been achieved, repeat testing may be indicated to determine the need for continued therapy.
- Repeat polysomnography to assess for residual OSA following adenotonsillectomy is warranted when one of the following is present:
  - ◆ Residual symptoms of OSA are present in children with mild OSA preoperatively OR
  - ◆ One of the following is present:
    - moderate to severe OSA
    - obesity
    - craniofacial abnormalities that obstruct the upper airway
    - neurological disorders such as Down Syndrome, Prader-Willi, and meningocele
- Polysomnographic normal standards differ between children and adults.
  - ◆ Diagnosis of pediatric obstructive sleep apnea is demonstrated by both of the following:
    - The presence of one or more of the following:
      - Snoring
      - Labored, paradoxical or obstructed breathing during the child's sleep
      - Sleepiness, hyperactivity, behavioral problems, or learning problems
    - PSG demonstrates one or more of the following:
      - one or more obstructive apneas, mixed apneas, or hypopneas per hour of sleep **or**

- A pattern of obstructive hypoventilation defined as at least 25% of total sleep time with hypercapnia ( $\text{PaCO}_2 > 50$  mm Hg) in association with one or more of the following: snoring, flattening of the inspiratory nasal pressure waveform, paradoxical thoracoabdominal motion.

### *Practice Note*

- Pediatric definitions for apneas and hypopneas differ compared with adults:
  - ◆ Pediatric apnea: Drop in peak signal excursion by  $\geq 90\%$  of pre-event baseline with an oronasal thermal sensor or alternative apnea sensor (diagnostic) or PAP device flow (titration study) for at least the duration of 2 breaths during the baseline portion of the study (obstructive or mixed events). Note: Duration criteria differ for central events.
  - ◆ Pediatric hypopnea:
    - The peak signal excursion drops by  $> 30\%$  of the pre-event baseline using nasal pressure or alternative hypopnea sensor (diagnostic study) or PAP device flow (titration study) for  $\geq 2$  breaths
    - There is a  $> 3\%$  oxygen desaturation from pre-event baseline or the event is associated with an arousal

### SL-3.2: CPAP in Pediatrics

- CPAP is indicated when **all** of the following criteria are met:
  - ◆ OSA diagnosis has been established by PSG; and
  - ◆ Adenotonsillectomy has been unsuccessful or is determined to be clinically inappropriate, or when definitive surgery is indicated but must await complete dental and facial development

### SL-3.3: Improper Uses of Polysomnography in Pediatrics

- The peer-reviewed medical literature **does not** support the following:
  - ◆ Repeat polysomnography in the follow-up of individuals with obstructive sleep apnea treated with CPAP when symptoms attributable to sleep apnea have resolved
  - ◆ Polysomnography in children for **any** of the following:
    - Sleep walking or night terrors
    - Routine evaluation of adenotonsillar hypertrophy alone without other clinical signs or symptoms suggestive of obstructive sleep disordered breathing
    - Routine follow-up for children with mild OSA whose symptoms have resolved post-adenotonsillectomy

## SL-4: Treatment of Obstructive Sleep Apnea (OSA) and Other Sleep-related Breathing Disorders

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## **SL-4.1: General Requirements**

- Positive diagnosis of a sleep-related breathing disorder, as measured by valid testing demonstrating one or more of the following:
  - ◆ OSA defined as (one of the following):
    - The apnea-hypopnea index (AHI), respiratory disturbance index (RDI), respiratory event index (REI) is  $\geq 15$  events per hour
    - The AHI, RDI, or REI is  $\geq 5$  and  $< 15$  events per hour and documentation of:
      - Symptoms of sleepiness, nonrestorative sleep, fatigue, or insomnia
      - Report of awakening with breath holding, gasping, or choking
      - Bed partner or other observer reports habitual snoring, breathing interruptions, or both during sleep
      - Hypertension, a mood disorder, cognitive dysfunction, coronary artery disease, congestive heart failure, atrial fibrillation, type 2 diabetes mellitus, or stroke.
  - ◆ CSA defined as (both):
    - Central hypopnea/apneas are  $\geq 50\%$  of total
    - Central apnea and/or central hypopnea index  $\geq 5$  per hour
  - ◆ Central sleep apnea (CSA) with Cheyne-Stokes Respiration defined as (all):
    - Central hypopnea/apneas are  $> 50\%$  of total
    - Central apnea and/or central hypopnea index  $\geq 5$  per hour
    - Pattern of breathing meets criteria for Cheyne-Stokes breathing i.e. periodic breathing characterized by the waxing and waning of respiratory effort and airflow (crescendo and decrescendo change in breathing amplitude)
  - ◆ Treatment Emergent Central Sleep Apnea defined as (both):
    - Diagnostic PSG demonstrates 5 or more obstructive respiratory events per hour of sleep
    - PSG during use of positive airway pressure shows improvement of obstructive events and emergence or persistence of central apneas/hypopneas with (both):
      - Central apnea and/or hypopnea index  $\geq 5$  per hour
      - Central hypopnea/apneas are  $\geq 50\%$  of total
  - ◆ Sleep-related hypoventilation defined as (one):
    - Either of the below occur during sleep:
      - Increase in arterial  $\text{PCO}_2$ , transcutaneous  $\text{PCO}_2$ , or end-tidal  $\text{PCO}_2$  to a value  $>55$  mmHg for  $\geq 10$  minutes
      - There is a  $>10$  mmHg increase in arterial  $\text{PCO}_2$ , transcutaneous  $\text{PCO}_2$ , or end-tidal  $\text{PCO}_2$  during sleep (compared to awake supine value) to a value  $> 50$  mmHg for  $> 10$  minutes
- Results from the sleep study are used to determine the type of sleep apnea, the severity of the breathing disorder, and the most appropriate form of treatment. Depending on these factors, a variety of PAP devices, and location of titration of therapy, can be considered.
- Positive airway pressure is the treatment of choice for the various forms of sleep apnea. Positive airway pressure (PAP) is produced by a flow generator and applied to the airway through nasal, oral, or oronasal mask interfaces

**Practice Note:**

Requests for HCPCS E0470 or E0471 for a pulmonary or neurological disorder in the absence of a comorbid sleep-related breathing disorder will be returned to the health plan for medical necessity review.

**SL-4.1.1: Treatment - Coding**

Treatment Description	HCPCS or CPT®
Continuous airway pressure (CPAP/APAP) device	E0601
Respiratory assist device, bi-level pressure (BPAP) capability, WITHOUT backup rate feature, used with noninvasive interface, e.g. nasal or facial mask (intermittent assist device with continuous positive airway pressure device)	E0470
Respiratory assist device, bi-level pressure (BPAP) capability (including ASV), WITH backup rate feature, used with noninvasive interface, e.g. nasal or facial mask (intermittent assist device with continuous positive airway pressure device)	E0471
Respiratory assist device, bi-level pressure (BPAP) capability, WITH backup rate feature, used with invasive interface, e.g. tracheostomy tube (intermittent assist device with continuous positive airway pressure device)	E0472
Humidifier, non-heated, used with positive airway pressure (CPAP/BPAP/APAP) device	E0561
Humidifier, heated, used with positive airway pressure (CPAP/BPAP/APAP) device	E0562
Tubing with heating element	A4604
Combination oral/nasal mask	A7027
Replacement oral cushion combo mask	A7028
Replacement nasal pillow comb mask	A7029
CPAP full face mask	A7030
Replacement facemask interface	A7031
Replacement nasal cushion	A7032
Replacement nasal pillows	A7033
Nasal interface (mask or cannula type) used with PAP device	A7034
Positive airway pressure headgear	A7035
Positive airway pressure chinstrap	A7036
Positive airway pressure tubing	A7037
Positive airway pressure filter	A7038
Filter, non-disposable w/ PAP	A7039
PAP oral interface	A7044
Replace exhalation port	A7045
Replacement, water chamber, PAP device	A7046
Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified (this code relates to Compliance and the data download of an individual's PAP therapy).	A9279
CPAP initiation and management (code is used to report the initiation and instruction when an individual begins therapy)	CPT® 94660



### **SL-4.1.2: Current Practice Recommendations for CSA with CHF**

- CPAP: Standard
- Bi-level PAP (including ST): Option if CPAP ineffective
- ASV:
  - ◆ OPTION if EF > 45% **or** mild central sleep apnea syndrome
  - ◆ **STANDARD AGAINST** if EF ≤ 45% with moderate/severe central sleep apnea syndrome

### **SL-4.1.3: Treatment of Opioid-Induced Sleep Disordered Breathing**

- CSAS associated with drug or substance use: There is currently no evidence to support routine use of facility-based diagnostic sleep testing due to concurrent opioid or other substance use in the absence of clinical history or previous diagnostic testing suggesting or confirming the presence of sleep disordered breathing. Recent studies suggest “medium increased risk” for central apnea in long-term opioid users, but further investigation is recommended. If diagnostic testing is indicated, home sleep testing is not supported for evaluation of chronic opioid users (see **SL-2.2.1: In-Laboratory Polysomnography - Other Indications**). With respect to treatment, current literature is “markedly limited” and further studies are clearly needed to conclusively determine if CPAP is less effective than Bi-level PAP or ASV, although recent studies suggest ASV may be effective in treatment-resistant individuals.

## **SL-4.2: Positive Airway Pressure Devices**

### **SL-4.2.1: Auto-titration of positive airway pressure in unattended setting**

- Initial E0601 APAP Titration can be considered for positive diagnosis of OSA, as defined in **SL-1.0: General Guidelines**
- Repeat E0601 APAP Titration (includes re-titration following initial CPT® 95811 when uncomplicated) can be considered for the following (ALL):
  - ◆ A positive diagnosis of OSA, as measured by HSAT or PSG as defined in **SL-1.0: General Guidelines**
  - ◆ Attempted compliance with preexisting or existing therapy (70% of nights, 4+ hours/night) has not adequately treated signs and symptoms.
  - ◆ Persistent symptoms or unimproved AHI/RDI in individual currently on APAP/CPAP therapy, when the individual and/or their caregiver has received the following from the treating physician or supplier of the PAP device:
    - Instruction in the proper use and care of the equipment
    - Mask re-fitting or adjustment if necessary
    - Education for proper use of PAP accessories

### **SL-4.2.2: Continuous Positive Airway Pressure therapy**

- Initiation of HCPCS E0601 PAP Therapy and establishing compliance (All of the following):
  - ◆ A positive diagnosis of OSA or central sleep apnea, as measured by HSAT or PSG as defined in **SL-1.0** and **SL-4.1: General Requirements**
  - ◆ The individual and/or their caregiver have received instruction from the treating physician and supplier of the CPAP device and accessories in the proper use and care of the equipment
  - ◆ A compliance support plan between the treating physician and DME supplier has been established
- Authorization for equipment purchase:
  - ◆ PAP device must be used  $\geq 4$  hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage.
  - ◆ Individual has regular follow-up to evaluate symptoms
- Extension of establishing compliance with E0601 (All of the following):
  - ◆ Individual history includes **one** of the following:
    - Failure to resolve symptoms or unimproved AHI during initial compliance period, OR
    - Inconsistent usage of device related to improper fit, lack of education, intolerance of PAP therapy, or device malfunction
  - ◆ Individual has received from the ordering physician or supplier of the PAP device in the past 30 days (**all** of the following):
    - Instruction in the proper use and care of the equipment
    - Mask refitting or adjustment if necessary
    - Education for proper use of PAP accessories
- Replacement APAP/CPAP HCPCS E0601 device (**All** of the following):
  - ◆ Continued resolution of symptoms and improved AHI on therapy
  - ◆ Device consistently used  $\geq 4$  hours per night on 70% of nights
  - ◆ Device is not operating
  - ◆ DME supplier has physically evaluated the device and determined that it is unable to be repaired
  - ◆ Device to be replaced is no longer covered under a warranty

### **SL-4.2.3: Bilevel Positive Airway Pressure – spontaneous mode**

- Initiation of HCPCS E0470 PAP Therapy and establishing compliance (ALL):
  - ◆ Diagnosis of sleep disordered breathing as defined in **SL-4.1: General Requirements**
  - ◆ One of the following medical conditions must be documented in the individual's record:
    - Neuromuscular disease or restrictive thoracic disorder:
      - Neuromuscular disease (e.g. amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (e.g. severe kyphoscoliosis, post-thoracoplasty), AND
      - One of the following:
        - An arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the individual's prescribed FiO<sub>2</sub>, is ≥ 45 mm Hg, or
        - Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the individual's prescribed FiO<sub>2</sub>, or
        - Neuromuscular disease only:
          - ◆ Maximal inspiratory pressure is < 60cm H<sub>2</sub>O, or
          - ◆ Forced vital capacity is < 50% predicted, or
          - ◆ Symptomatic respiratory disease impairing activities of daily living
    - Severe COPD:
      - An arterial blood gas PaCO<sub>2</sub> is ≥ 52 mm Hg done while awake and breathing the individual's prescribed FiO<sub>2</sub>, or
      - Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing 2 LPM or the individual's prescribed FiO<sub>2</sub> (whichever is higher), and
      - OSA and treatment with CPAP has been considered and ruled out
    - Central sleep apnea diagnosis
      - Valid testing meeting criteria for central sleep apnea as defined in **SL-4.1: General Requirements**
      - Significant improvement of the central events with the use of HCPCS E0470 device on the settings that will be prescribed for initial use at home.
    - Treatment-Emergent Central Sleep Apnea when:
      - Valid testing meeting criteria for treatment emergent central sleep apnea as defined in **SL-4.1: General Requirements**
      - Significant improvement of the central events with the use of HCPCS E0470 device on the settings that will be prescribed for initial use at home.
    - Obstructive sleep apnea when:
      - Diagnosis of OSA as defined in **SL-1.0: General Guidelines**, and
      - CPAP (HCPCS E0601) has been tried and proven either ineffective or not tolerated, based on a therapeutic trial conducted in either a facility or a home setting
    - Obesity-hypoventilation syndrome during sleep:
      - ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), and

- Occurs in the absence of obstructive events, and
  - Individual has BMI > 30 kg/m<sup>2</sup> plus arterial blood gas with PCO<sub>2</sub> > 45
- Other sleep-related hypoventilation syndrome:
  - As defined in **SL-4.1: General Requirements**
- Continued HCPCS E0470 therapy after initial 3 months:
  - ◆ PAP device must be used ≥4 hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage.
  - ◆ Individual has regular follow-up to evaluate symptoms
- Replacement Bilevel PAP HCPCS E0470 device (All of the following):
  - ◆ Continued resolution of symptoms and improved AHI/RDI on therapy
  - ◆ Device consistently used ≥4 hours per night on 70% of nights
  - ◆ Device is not operating
  - ◆ DME supplier has physically evaluated the device and determined that it is unable to be repaired
  - ◆ Device to be replaced is no longer covered under a warranty

#### **SL-4.2.4: Bilevel Positive Airway Pressure – spontaneous/timed mode**

- Diagnosis of sleep disordered breathing as defined in **SL-4.1: General Requirements**
- Initiation of HCPCS E0471 PAP Therapy and establishing compliance (ALL):
  - ◆ One of the following medical conditions must be documented in the individual's record:
    - Neuromuscular disease or restrictive thoracic disorder:
      - Neuromuscular disease (e.g. amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (e.g. severe kyphoscoliosis, post-thoracoplasty), AND
      - One of the following:
        - An arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the individual's prescribed FiO<sub>2</sub>, is ≥ 45 mm Hg, or
        - Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the individual's prescribed FiO<sub>2</sub>, or
        - Neuromuscular disease only:
          - ◆ Maximal inspiratory pressure is < 60cm H<sub>2</sub>O, or
          - ◆ Forced vital capacity is < 50% predicted, OR
    - Severe COPD:
      - PaCO<sub>2</sub> is ≥ 7mm Hg during sleep compared to the initial blood gas taken while awake and breathing prescribed FiO<sub>2</sub>, and
      - A facility-based PSG demonstrates oxygen saturation of < 88% for ≥5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events (AHI < 5)
        - ◆ See above for coverage of HCPCS E0470 for OSA, OR

- An arterial blood gas PaCO<sub>2</sub> done while awake and breathing the individual's prescribed FiO<sub>2</sub> is ≥ 52 mm Hg, and
    - Sleep oximetry while breathing with the HCPCS E0470 device, demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the individual's prescribed FiO<sub>2</sub> (whichever is higher), OR
  - Central sleep apnea diagnosis (either primary central sleep apnea or central sleep apnea with Cheyne-Stokes Breathing) when:
    - Valid testing meeting criteria for central sleep apnea as defined in **SL-4.1: General Requirements**
    - Significant improvement of the central events with the use of HCPCS E0471 device on the settings that will be prescribed for initial use at home.
    - See **SL-4.2.6** for guidelines specific to adaptive servo ventilation (ASV)
  - Treatment-Emergent Central Sleep Apnea when:
    - Valid testing meeting criteria for treatment-emergent central sleep apnea as defined in **SL-4.1: General Requirements**
    - Significant improvement of the central events with the use of HCPCS E0471 device on the settings that will be prescribed for initial use at home.
  - Other hypoventilation syndrome when:
    - A covered HCPCS E0470 device is being used, and
    - Continued sleep-related hypoventilation is present as defined in **SL-4.1: General Requirements**
- Continued HCPCS E0471 therapy after initial 3 months:
- ◆ PAP device must be used ≥4 hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage Individual has regular follow-up to evaluate symptoms
- Replacement Bilevel PAP HCPCS E0471 device (All of the following):
- ◆ Continued resolution of symptoms and improved AHI/RDI on therapy
  - ◆ Device consistently used ≥4 hours per night on 70% of nights
  - ◆ Device is not operating
  - ◆ DME supplier has physically evaluated the device and determined that it is unable to be repaired
  - ◆ Device to be replaced is no longer covered under a warranty

### **SL-4.2.5: Heated and non-heated humidifier**

- Initial set-up (heated HCPCS E0562 and non-heated HCPCS E0561) **all** of the following:
  - ◆ When requested by treating physician and PAP device (HCPCS E0470/471 or E0601) has been approved
  - ◆ No previous humidifier has been provided
- Replacement heated or non-heated humidifier (HCPCS E0562 or E0561) device (All of the following):
  - ◆ Continued resolution of symptoms and improved AHI on PAP therapy
  - ◆ Device consistently used  $\geq 4$  hours per night on 70% of nights
  - ◆ Humidifier device is not operating
  - ◆ DME supplier has physically evaluated the device and determined that it is unable to be repaired
  - ◆ Device to be replaced is no longer covered under a warranty

### **SL-4.2.6: Adaptive Servo Ventilation (ASV) therapy**

- Initiation of ASV Therapy (HCPCS E0471) and establishing compliance (ALL):
  - ◆ One of the following medical conditions must be documented in the individual's record:
    - Central sleep apnea (including Cheyne-Stokes breathing):
      - Diagnosis of central sleep apnea as defined in **SL-4.1: General Requirements**
      - Mild CSA, or Moderate to Severe CSA with EF > 45%.
- OR
- Treatment Emergent Central Sleep Apnea Documented persistent, treatment-emergent central or mixed apnea with application of CPAP
  - Central hypopnea/apneas are  $\geq 50\%$  of total, and
  - Central apnea index  $\geq 5$  per hour,
- OR
- Central Sleep Apnea Syndrome due to opioid or substance use:
  - CPAP has been shown to be ineffective following a reasonable treatment attempt/trial, **AND**
  - Opioid therapy cannot be reduced or discontinued, **and**
  - Central hypopnea/apneas are  $\geq 50\%$  of total, **and**
  - Central apnea index  $\geq 5$  per hour.
- Continued ASV therapy HCPCS E0471 after initial 3 months:
  - ◆ PAP device must be used  $\geq 4$  hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage Individual has regular follow-up to evaluate symptoms
- Replacement ASV HCPCS E0471 device (All of the following):
  - ◆ Continued resolution of symptoms and improved AHI/RDI on therapy; **and**
  - ◆ Device consistently used  $\geq 4$  hours per night on 70% of nights **and**
  - ◆ Device is not operating, **and**

- ◆ DME supplier has physically evaluated the device and determined that it is unable to be repaired, **and**
- ◆ Device to be replaced is no longer covered under a warranty

#### **SL-4.2.7: Continuous positive airway pressure ventilation (CPAP), initiation, and management**

- Physician face-to-face service addressing PAP usage (CPT® 94660):
  - ◆ Physician application or adjustment of mask or pressure titration or PAP related service; **and**
  - ◆ Service cannot be adequately provided by a certified or registered respiratory therapist, licensed clinician, or sleep technologist when within scope of practice per state regulations; **and**
  - ◆ Another evaluation and management service is not performed.

#### **SL-4.2.8: Continuous PAP, Bilevel PAP, or automatic PAP Loaner Rental**

- CPAP, APAP, or BPAP loaner rental for up to 30 days is considered medically necessary when there is a description of the device malfunction and documentation that equipment has been sent for repair/assessment

### **SL-4.3: Positive Airway Pressure Treatment Supplies**

#### **SL-4.3.1: PAP Masks and parts**

- Combination oral/nasal mask, used with PAP, each (HCPCS A7027):
  - ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
  - ◆ Frequency: 1 per 3 months.
  - ◆ No other PAP mask ordered (i.e., HCPCS A7030, A7034, or A7044).
- Oral cushion used with combination oral/nasal mask, replacement only (HCPCS A7028):
  - ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
  - ◆ Only compatible with HCPCS A7027 mask.
  - ◆ Frequency: 2 per month.
- Nasal pillows used with combination oral/nasal mask, replacement only, pair (HCPCS A7029):
  - ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
  - ◆ Only compatible with HCPCS A7027 mask.
  - ◆ Frequency: 2 per month.
- Full face mask used with PAP, each (HCPCS A7030):

- ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
- ◆ Frequency: 1 per 3 months.
- ◆ No other PAP mask ordered (i.e., HCPCS A7027, A7034, or A7044).
- Full face mask interface replacement, each (HCPCS A7031):
  - ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
  - ◆ Only compatible with HCPCS A7030 mask.
  - ◆ Frequency: 2 per month.
- Nasal interface (mask or cannula type) used with PAP, each (HCPCS A7034):
  - ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
  - ◆ Frequency: 1 per 3 months.
  - ◆ No other PAP mask ordered (i.e., HCPCS A7027, A7030, or A7044).
- Cushion for use on nasal mask interface, replacement only, each (HCPCS A7032):
  - ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
  - ◆ Only compatible with HCPCS A7034 mask.
  - ◆ Frequency: 2 per month.
- Nasal pillow for use on nasal cannula type interface, replacement only, pair (HCPCS A7033):
  - ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
  - ◆ Only compatible with HCPCS A7034 mask.
  - ◆ Frequency: 2 per month.
- Oral interface used with PAP, each (HCPCS A7044):
  - ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
  - ◆ Frequency: 1 per 6 months.
  - ◆ No other PAP mask ordered (i.e., HCPCS A7027, A7030, or A7034).
- Headgear used with PAP, each (HCPCS A7035):
  - ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
  - ◆ Frequency: 1 per 6 months.
- Chinstrap used with PAP, each (HCPCS A7036):



- ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
- ◆ Frequency: 1 per 6 months.

#### **SL-4.3.2: Positive airway pressure tubing**

- Tubing with integrated heating element for use with PAP devices, each (HCPCS A4604):
  - ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
  - ◆ Frequency: 1 per 3 months.
  - ◆ No other PAP tubing ordered (i.e., HCPCS A7037).
- Tubing used with PAP devices, each (HCPCS A7037):
  - ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
  - ◆ Frequency: 1 per 3 months.
  - ◆ No other PAP tubing ordered (i.e., HCPCS A4604).

#### **SL-4.3.3: Positive airway pressure device filters**

- Filter, disposable, used with PAP devices (HCPCS A7038):
  - ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
  - ◆ Frequency: 2 per 1 month.
- Filter, non-disposable, used with PAP devices (HCPCS A7039):
  - ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
  - ◆ Frequency: 1 per 6 months.

**SL-4.3.4: Miscellaneous positive airway pressure supplies**

- Exhalation port with or without swivel used with accessories for positive airway devices, replacement only (HCPCS A7045):
  - ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
  - ◆ Frequency: 1 per 6 months.
- Water chamber for humidifier, used with positive airway pressure device, replacement, each (HCPCS A7046):
  - ◆ Provided data meets compliance criteria (device used  $\geq 4$  hours per night on 70% of nights), with 30 continuous days of compliance data provided from the time period within 6 months prior to the date of request
  - ◆ Frequency: 1 per 6 months.

## **SL-5: Sleep Apnea Treatment Program Exclusions**

<b>SL-5.1: Experimental, Investigational, or Unproven</b>	<b>44</b>
<b>SL-5.2: Durable Medical Equipment Device and Supply Exclusions</b>	<b>44</b>

### **SL-5.1: Experimental, Investigational, or Unproven**

- Certain therapies may be considered experimental, investigational, or unproven if there is any of the following:
  - ◆ A paucity of supporting evidence in the peer reviewed literature
  - ◆ The evidence has not matured to exhibit improved health parameters
  - ◆ The therapy lacks a collective opinion of support
- The effectiveness of the following therapies has not been established in the treatment of OSA; these therapies, as well as other therapies not addressed in these guidelines, may be considered experimental, investigational, or unproven:
  - ◆ Provent Sleep Apnea Therapy
  - ◆ Winx Therapy System/Oral Pressure Therapy
  - ◆ MATRx oral appliance test

### **SL-5.2: Durable Medical Equipment Device and Supply Exclusions**

- CPT® 94799 – Unlisted pulmonary service or procedure
  - ◆ Due to the presence of more specific codes, medical necessity for this code cannot be established
- HCPCS E1399 – Miscellaneous durable medical equipment items, components, and accessories
  - ◆ Due to the presence of more specific codes for PAP equipment, medical necessity for this code cannot be established for PAP equipment
- HCPCS K1001 - Electronic positional obstructive sleep apnea treatment with sensor is considered experimental, investigational or unproven.

## **SL-6: Actigraphy (CPT® 95803)**

### **SL-6.1: Actigraphy-Indications**

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### **SL-6.1: Actigraphy-Indications**

- Actigraph devices, worn on the wrist, record movement and utilize rest activity patterns to estimate sleep parameters.
- Actigraphy performed as a stand-alone study is not a covered service.

## **SL-7: Practice Notes**

<b>SL-7.1: Occupational Health Examinations</b>	<b>48</b>
<b>SL-7.2: Technical and Policy Requirements of PSG</b>	<b>48</b>

### SL-7.1: Occupational Health Examinations

- ◆ The guidelines herein are also applicable to cases involving medical qualifying examinations performed for occupational health purposes.

### SL-7.2: Technical and Policy Requirements of PSG

- The parameters, settings, filters, technical specifications, sleep stage scoring and event scoring should be done in accordance with the AASM Manual for the Scoring of Sleep and Associated Events.
- HSAT should, at a minimum, record airflow, respiratory effort, and blood oxygenation. The type of biosensors used to monitor these parameters for in-laboratory PSG are recommended for use in HSATs and include the following:
  - ◆ Oronasal thermal sensor and nasal pressure transducer for airflow, apnea and hypopnea; **and**
  - ◆ Oximetry with a high sampling rate and fast averaging time for blood oxygenation; **and**
  - ◆ Ideally, a calibrated or uncalibrated respiratory inductance plethysmography for respiratory effort; **or**
  - ◆ Peripheral Arterial Tonometry (PAT) with oximetry and actigraphy
- Apnea-Hypopnea Index (AHI) by HSAT is the number of apneas + hypopneas / total recording time rather than total sleep time. As a result, HSAT's are likely to underestimate the severity of events compared to the Apnea- Hypopnea Index (AHI) by PSG. Due to the known rate of false negative HSAT, in-laboratory PSG should be performed in cases where HSAT is technically inadequate or fails to establish the diagnosis of OSA in individuals with a high pretest probability.
- HSAT can be appropriately performed by Joint Commission (JCAHO) and Medicare IDTF-approved facilities.
- PSG is called Type I monitoring:
  - ◆ Consists of minimum of 6 hours of constant monitoring in a controlled facility environment.
  - ◆ Involves 7 measurement parameters (3 channels of EEG, 2 channel electrooculography, 2 channels of anterior tibialis EMG, ECG or heart rate, oxygen saturation, airflow monitoring, and measures of sub-mental breathing/respiratory effort).
  - ◆ Facilities also typically record body position (with video) and snoring (via microphone).
- Results are reported and calculations of the Apnea-Hypoxia Index (AHI) or Respiratory Disturbance Index (RDI) are performed.
  - ◆ Scoring PSG:
    - OSA is confirmed if > 15 obstructive events per hour or > 5 obstructive events per hour plus clinical symptoms
    - Obstructive events include apneas, hypopneas, or respiratory-effort related arousals for calculation of RDI.



- Obstructive events include apneas and hypopneas for calculation of AHI. RDI cannot accurately be calculated by HSAT.
- Respiratory Event Index (REI) is appropriate for reporting sleep disordered breathing by HSAT.

## SL-8: Questionnaires

<b>SL-8.1: Epworth Sleepiness Scale</b>	<b>51</b>
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### **SL-8.1: Epworth Sleepiness Scale**

The **Epworth Sleepiness Scale** is comprised of eight questions, with a maximum score of 24. A score >10 indicates moderate to high probability of excessive daytime sleepiness.

<b>Epworth Sleepiness Scale</b>	
Use the following scale to choose the most appropriate number for each situation: 0 = would never doze or sleep; 1 = slight chance of dozing or sleeping 2 = moderate chance of dozing or sleeping; 3 = high chance of dozing or sleeping	
<b>Situation</b>	<b>Chance of Dozing or Sleeping</b>
1. Sitting and reading	
2. Watching TV	
3. Sitting inactive in a public place	
4. Being a passenger in a motor vehicle for an hour or more	
5. Lying down in the afternoon	
6. Sitting and talking to someone	
7. Sitting quietly after lunch (no alcohol)	
8. Stopped for a few minutes in traffic while driving	
<b>Total Epworth Score (add up the points)</b>	

### SL-8.2: The Berlin Questionnaire

The **Berlin Questionnaire** is comprised of 3 categories and ten questions. Two or more categories with a positive score indicate high probability of OSA.

Patient BMI - _____	
<b>Category 1</b>	<b>Category 2</b>
1. Do you snore? a. Yes b. No c. Don't know <i>If you snore:.....</i>	6. How often do you feel tired or fatigued after your sleep a. Nearly every day b. 3-4 times a week c. 1-2 times a week d. 1-2 times a month e. Never or nearly never
2. Your snoring is: a. Slightly louder than breathing b. As loud as talking c. Louder than talking d. Very loud-can be heard in adjacent rooms	7. During your waking time, do you feel tired, fatigued, or not up to par? a. Nearly every day b. 3-4 times a week c. 1-2 times a week d. 1-2 times a month e. Never or nearly never
3. How often do you snore? a. Almost every day b. 3-4 times a week c. 1-2 times a week d. 1-2 times a month e. Never or almost never	8. Have you ever nodded off or fallen asleep while driving a vehicle a. Yes b. No <i>If yes:</i>
4. Does your snoring bother other people? a. Yes b. No c. Don't know	9. How often does this occur? a. Nearly every day b. 3-4 times a week c. 1-2 times a week d. 1-2 times a month e. Never or nearly never
5. Has anyone noticed that you quit breathing during your sleep? a. Nearly every day b. 3-4 times a week c. 1-2 times a week d. 1-2 times a month e. Never or nearly never	<b>Category 3</b>
	a. Do you have high blood pressure? b. Yes c. No Don't know

### **Berlin Questionnaire Scoring**

- **Category 1:** Items 1-5
  - ◆ Item 1: if 'Yes', assign **1 point**
  - ◆ Item 2: if 'c' or 'd' is the response, assign **1 point**
  - ◆ Item 3: if 'a' or 'b' is the response, assign **1 point**
  - ◆ Item 4: if 'a' is the response, assign **1 point**
  - ◆ Item 5: if 'a' or 'b' is the response, assign **2 points**
  - ◆ Add Points. Category 1 is positive if the total score is 2 or more points.
- **Category 2:** Items 6, 7, 8 (item 9 should be noted separately)
  - ◆ Item 6: if 'a' or 'b' is the response, assign **1 point**
  - ◆ Item 7: if 'a' or 'b' is the response, assign **1 point**
  - ◆ Item 8: if 'a' is the response, assign **1 point**
  - ◆ Add Points. Category 2 is positive if the total score is 2 or more points
- **Category 3:** is positive if the answer to Item 10 is 'Yes' **OR** if the BMI of the patient is greater than 30kg/m<sup>2</sup>.
- **High Risk:** if there are 2 or more Categories where the score is positive
- **Low Risk:** if there is only 1 or no Categories where the score is positive

### **SL-8.3: STOP Bang**

**STOP Bang** questionnaire has eight yes/no questions. A “yes” answer on three or more questions indicates high probability of OSA.

#### **Snoring**

1. Do you snore loudly (louder than talking or loud enough to be heard through closed doors?)

#### **Tired**

2. Do you often feel tired, fatigued, or sleepy during daytime?

#### **Observed**

3. Has anyone observed you stop breathing during your sleep?

#### **Blood Pressure**

4. Do you have or are you being treated for high blood pressure?

#### **BMI**

5. BMI higher than 35kg/m<sup>2</sup>

#### **Age**

6. Age over 50 years old?

#### **Neck Circumference**

7. Neck circumference greater than 40cm?

#### **Gender**

8. Gender male?
  - Intermediate to High risk of OSA: answering “yes” to three or more items. Please see note below for score of three or greater.
  - Low risk of OSA: answering “yes” to less than three items

#### **Practice Note:**

- **High Risk is determined by either one of the following:**
  - ◆ Answering “yes” to two or more of four STOP questions + any one BANG question except age OR
  - ◆ Answering “yes” to 5 or more questions

## SL-8.4: Insomnia Severity Index

The Insomnia Severity Index has seven questions. The seven answers are added up to get a total score. When you have your total score, look at the 'Guidelines for Scoring/Interpretation' at the bottom of the Insomnia Severity Index page to see where your sleep difficulty fits. Print out a copy of your completed Insomnia Severity Index to take to your health care provider.

**For each question, please *CIRCLE* the number that best describes your answer.** [Click here to print the Insomnia Severity Index.](#)

Please rate the **CURRENT (i.e. LAST 2 WEEKS) SEVERITY** of your insomnia problem(s).

Insomnia problem	None	Mild	Moderate	Severe	Very severe
1. Difficulty falling asleep	0	1	2	3	4
2. Difficulty staying asleep	0	1	2	3	4
3. Problem waking up too early	0	1	2	3	4

4. How **SATISFIED/DISSATISFIED** are you with your **CURRENT** sleep pattern?

Very Satisfied	Satisfied	Moderately Satisfied	Dissatisfied	Very Dissatisfied
0	1	2	3	4

5. How **NOTICEABLE** to others do you think your sleep problem is in terms of impairing the quality of your life?

Not at all Noticeable	A Little	Somewhat	Much	Very Much Noticeable
0	1	2	3	4

6. How **WORRIED/DISTRESSED** are you about your current sleep problem?

Not at all Worried	A Little	Somewhat	Much	Very Much Worried
0	1	2	3	4

7. To what extent do you consider your sleep problem to **INTERFERE** with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) **CURRENTLY**?

Not at all Interfering	A Little	Somewhat	Much	Very Much Interfering
0	1	2	3	4

### **Guidelines for Scoring/Interpretation:**

Add the scores for all seven items (questions 1 + 2 + 3 + 4 + 5 + 6 + 7) = \_\_\_\_\_ your total score.

#### **Total score categories:**

0-7 = No clinically significant insomnia

8-14 = Sub threshold insomnia

15-21 = Clinical insomnia (moderate severity)

22-28 = Clinical insomnia (severe)

## **SL-9: Oral Appliances for the Treatment of Obstructive Sleep Apnea**

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Treatment Description	HCPCS
Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment	E0485
Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment	E0486
Non-covered item or service (Used for oral appliances that do not incorporate all of the criteria as set forth in the Policy Article; tongue-retaining or tongue-positioning devices; and devices that are used only to treat snoring without a diagnosis of obstructive sleep apnea)	A9270

## SL-9.1: Custom-fit Oral Appliances

### SL-9.1.1: General Information

- Continuous positive airway pressure is the gold standard for treatment of obstructive sleep apnea. Oral appliances are an alternative treatment option for individuals who are intolerant to PAP therapy or who prefer an alternative to CPAP. Subjective adherence and side effect profile are improved with oral appliances compared to CPAP. However, CPAP results in a greater reduction in respiratory events (AHI, RDI or REI) and greater improvement in oxygen saturation. Oral appliances significantly reduce apnea hypopnea index regardless of severity of obstructive sleep apnea, although individuals with moderate to severe OSA are more likely to achieve their target AHI with CPAP compared to the oral appliance. Both oral appliances and CPAP improve excessive daytime sleepiness, quality of life, and cognitive performance.
  - ◆ The AASM task force indicates that use of oral appliances in individuals with severe obstructive sleep apnea should be reserved for clinical scenarios where CPAP is not tolerated **or** does not provide benefit.
- The most common oral appliance utilized for the treatment of obstructive sleep apnea is the mandibular advancement device. There was insufficient evidence for the AASM task force to assess the efficacy of tongue retaining devices, which are also less well tolerated. Custom-made mandibular advancement devices appliances are more effective for symptom improvement, compliance and tolerance compared to ready-made appliances.

### SL-9.1.2: Custom-fit Oral Appliances Indications

- Custom-fit oral appliances are indicated when all of the following are met:
  - ◆ A positive diagnosis of obstructive sleep apnea on a covered sleep study as demonstrated by one of the following:
    - AHI, RDI, or REI  $\geq 5 < 15$  events per hour and documentation of:
      - Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia, or
      - Hypertension, ischemic heart disease, or history of stroke; **OR**
    - AHI, RDI, or REI  $\geq 15 \leq 30$  events per hour over the duration of the sleep test;
    - AHI, RDI, or REI AHI  $> 30$  events per hour
  - ◆ Documentation of:
    - Intolerance or lack of benefit after a minimum of a one-month trial of PAP, **or**

- PAP is contraindicated for the individual as documented by the treating physician, **or**
  - Individual prefers alternative treatment to CPAP **AND** AHI, RDI, or REI is less than 30.
  - ◆ The device is ordered by the treating physician following a face to face visit and review of sleep study results.
  - ◆ A qualified licensed dentist (DDS and DMD) provides a custom device and follow-up to assess for dental-related side effects.
- Note: Oral devices to prevent temporomandibular joint (TMJ) disorders are considered experimental, investigational, or unproven (EIU).

### **SL-9.1.3: Replacement custom fit oral appliances**

- Custom fit oral appliances can be replaced when **all** of the following criteria are met:
- ◆ Device is being used consistently with continued resolution of symptoms
  - ◆ The device is ordered by the treating physician following a face to face visit
  - ◆ A qualified licensed dentist (DDS and DMD) provides a custom device and follow-up to assess for dental-related side effects.
  - ◆ One of the following applies:
    - Device has been lost or irreparably damaged due to a specific accident, natural disaster or breakdown of device from regular use
    - Device is greater than 5 years old

### **SL-9.2: Pediatric Oral Appliances**

- Oral appliances may be considered medically necessary in the treatment of children with craniofacial anomalies with signs and symptoms of OSA.
- Oral appliances are considered EIU for the treatment of OSA in children not meeting the above criteria.

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