# Cigna Medical Coverage Policies Sleep Disordered Breathing Diagnosis and Treatment Guidelines

Effective June 15, 2024

**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 cardiac device procedures that eviCore reviews for Cigna.

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# General Information

# Abbreviations for Sleep Guidelines

SL.GG.104.A
**v1.0.2024**

| Abbreviation | Full name |
|---|---|
| AASM | American Academy of Sleep Medicine |
| ABG | Arterial Blood Gas |
| AHI | Apnea-Hypopnea Index |
| AOSATF of AASM | Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine |
| APAP | Auto-titrating positive airway pressure |
| BMI | Body mass index (body weight divided by the square of the height) |
| CPAP | Continuous positive airway pressure |
| EDS | Excessive daytime sleepiness |
| $EtPCO_2$ | End-tidal $PCO_2$ |
| HCPCS | Healthcare Common Procedural Coding System<br>• (Level II alphanumeric codes used to report services not included in CPT®) |
| HSAT | Home sleep apnea testing |
| IDTF | Independent Diagnostic Testing Facilities |
| JCAHO | Joint Commission on Accreditation of Healthcare Organizations |
| MSLT | Multiple Sleep Latency Test |
| MWT | Maintenance of Wakefulness Test |
| OA | Oral appliance |
| OHS | Obesity Hypoventilation Syndrome |
| OSA | Obstructive sleep apnea |
| PM | Portable monitoring (in home sleep studies) |
| PSG | Polysomnography |
| RDI | Respiratory disturbance index: (respiratory effort related arousals + apneas + hypopneas/total sleep time) |
| RERAs | Respiratory effort related arousals |
| Screening Tools for Sleep Disorders | Epworth Sleepiness Scale, Berlin Questionnaire (for sleep apnea), STOP-BANG questionnaire, Insomnia Severity Index |
| $TcPCO_2$ | Transcutaneous $PCO_2$ |



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| Abbreviation | Full name |
|---|---|
| VBG | Venous Blood Gas |



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# Preface to the Sleep Guidelines

**SL.GG.100.C**
**v1.0.2024**

**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 **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



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# General Guidelines (SL-1.0)

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### Clinical evaluation

A current and comprehensive clinical evaluation (within 60 days) by the treating medical provider (either face to face or telehealth), including documentation of sleep symptoms and physical examination elements relevant to the requested service, 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 should include all of the following:

- Comprehensive sleep history including treatment history (if applicable) and one of the following:
  - Sleep symptoms relevant to the suspected diagnosis. (see sleep related signs and symptoms below)
  - Sufficient history as to allow completion of a Sleep Questionnaire as below, OR
  - Results of a sleep questionnaire or sleep questionnaire proxy (see Sleep Questionnaires below)
- Physical examination (see Documented physical examination below)
- Relevant diagnostic studies done at any time in the past (such as previous sleep studies, overnight pulse oximetry, and cardiac and pulmonary testing)
  - The provider (or medical office staff on behalf of the provider) must document a reasonable attempt to obtain results of prior sleep testing prior to requesting repeat testing.
  - If a copy of the prior sleep testing report is not available from the member, a reasonable attempt includes, but is not limited to, contacting the location and/or provider where the prior study was completed, or obtaining a prior result from the individual's previous or current DME company or equipment provider
  - Relevant lab results (ABG or serum bicarbonate performed within one year)

#### Sleep-related signs and symptoms

Sleep testing is not indicated for evaluation of insomnia in the **absence** of symptoms or provider concern for another sleep fragmenting disorder such as obstructive sleep apnea or periodic limb movement disorder.

A description of sleep-related signs and symptoms that are relevant to the suspected diagnosis are required before sleep testing can be considered. For example, if sleep-related breathing disorders are suspected, one or more of the following should be described:

- Daytime Sleepiness or fatigue
- Nocturnal snoring, snorting or gasping

- Nocturnal witnessed apneas or the subjective sensation of awakening short of breath, coughing or choking
- Frequent awakenings during the night
- Prior diagnosis of OSA with a description of response to therapy
- Morning headaches
- Uncontrolled hypertension
- Observed oxygen desaturations during sleep or during drug-induced sedation in a medical setting
- Presence of atrial fibrillation
- Presence of systolic congestive heart failure
- New/recent stroke
- Sleep testing is not indicated for evaluation of insomnia in the absence of symptoms or provider concern for another sleep fragmenting disorder such as obstructive sleep apnea or periodic limb movement disorder

Other sleep-related symptoms that are suggestive of a sleep disorder and may be included are:

- Increased sleep-related movements, sleep talking, displaying confused or erratic behavior during sleep.
- Dream enactment behavior
- Difficulty initiating sleep
- Non-restorative sleep
- Limited attention, or memory loss

**Documented physical examination**

Documented physical examination should include:

- Cardiopulmonary evaluation if visit is conducted in person
- Level of obesity
- Neck circumference
- Oropharyngeal examination including Friedman score or Mallampati classification
- Findings may include 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.

### Relevant diagnostic studies done in the past

When a member is new to a practice, and a record of the previous diagnosis of sleep apnea is needed in order to supply new equipment, the new practice must make an effort to obtain the prior study results from the prior sleep medicine practice or the DME supplier, and this should be documented.

The provider (or medical office staff on behalf of the provider) must document a reasonable attempt to obtain results of prior sleep testing prior to requesting repeat testing.

A reasonable attempt includes but is not limited to, contacting the location and/or provider where the prior study was completed, or obtaining a prior result from the individual's previous or current DME company or equipment provider; and if the prior options do not produce results, asking the member for a copy of prior test results.

### Sleep Questionnaires

Three sleep questionnaires are commonly used to quantify the level of sleepiness or probability of having OSA. These validated questionnaires include (but are not be limited to):

- Epworth Sleepiness Scale
- Berlin Questionnaire
- STOP BANG Questionnaire

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 **Questionnaires (SL-8).**

Results of a questionnaire appropriate for the specific sleep issue in question are required, or any **one** of the following conditions can serve as a proxy for the sleep questionnaire requirement:

- Witnessed apnea, gasping, or choking
- Documented repeated desaturations during sleep by pulse oximetry (performed medically)
- 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

## Definitions: Sleep-related breathing disorders

For the purpose of this guideline, sleep-related breathing disorders are defined by the following criteria.

- Valid sleep testing demonstrates a positive diagnosis of one or more of the following sleep-related breathing disorders:

  **Obstructive sleep apnea (OSA) as measured by valid testing is defined as:**

  - Predominantly obstructive events (obstructive and mixed apneas, hypopneas, or respiratory effort related arousals).
  - The apnea-hypopnea index (AHI), or respiratory disturbance index (RDI) on a PSG, or the AHI or Respiratory Event Index (REI) on a HSAT is ≥15 events per hour; or
  - The AHI or RDI on a PSG, or the AHI or REI on a HSAT is ≥5 and <15 events per hour and documentation of:
    - Symptoms of sleepiness, fatigue, insomnia, or other symptoms leading to impaired sleep-related quality of life
    - 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 (all):**

  - Presence of one or more of the following:
    - Sleepiness
    - Difficulty initiating or maintaining sleep, frequent awakenings or non-restorative sleep
    - Awakening short of breath
    - Witnessed apneas
  - Central apnea and/or central hypopnea index ≥5 per hour
  - Central hypopnea/apneas are >50% of the total number of apneas and hypopneas

  **Central sleep apnea (CSA) with Cheyne-Stokes Respiration defined as (all):**

  - Presence of one or more of the following:
    - Sleepiness
    - Difficulty initiating or maintaining sleep, frequent awakenings or non-restorative sleep
    - Awakening short of breath
    - Witnessed apneas
    - Known atrial fibrillation/flutter, congestive heart failure, or a neurological disorder
  - PSG must show all of the following:
    - Central apnea and/or central hypopnea index ≥5 per hour

- Central hypopnea/apneas are >50% of the total number of apneas and hypopneas
- Pattern of breathing meets criteria for Cheyne-Stokes breathing (episodes of ≥3 consecutive central apneas and/or central hypopneas separated by a crescendo and decrescendo change in breathing amplitude with a cycle length of ≥40 seconds).

**Treatment Emergent Central Sleep Apnea defined as (all):**

- Presence of one or more of the following thought to be attributable to the central events:
  - Sleepiness
  - Difficulty initiating or maintaining sleep, frequent awakenings or nonrestorative sleep
  - Awakening short of breath
  - Witnessed apneas
- Diagnostic PSG demonstrates ≥5 predominantly obstructive respiratory events per hour of sleep (obstructive or mixed apneas, hypopneas, respiratory effort related arousals [RERAs]).
- PSG during use of positive airway pressure without a backup rate shows improvement of obstructive events and emergence or persistence of central apneas/hypopneas with (both):
  - Central apnea and/or hypopnea index ≥5 per hour
  - Central hypopnea/apneas are ≥50% of the total number of apneas and hypopneas

**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 ≥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

## Site of care for sleep testing requests

### Home versus facility

The guidelines herein provide evidence-based guidance for appropriate site of care for diagnostic sleep testing requests (facility sleep testing versus home sleep apnea testing) and positive airway pressure titration requests (facility titration study versus home automatic positive airway pressure use) based on co-morbid conditions and clinical characteristics. These are also provided in **In-lab PSG indications**.

Facility testing can be considered due to one of the following reasons:

- Suspected obstructive sleep apnea with low pretest probability of moderate-to-severe OSA defined by either of the following:
  - Lack of reported symptoms of excessive daytime sleepiness with **at least two** of the following three criteria (habitual loud snoring, witnessed apnea or gasping or choking, or diagnosed hypertension)
  - Validated questionnaire (STOP BANG or Berlin) indicating low risk. See **Questionnaires (SL-8)**
- Individual does not have the mobility, dexterity or cognitive ability to use home sleep apnea testing equipment safely at home and the ability to follow instructions.
- HSAT has been attempted and is negative, or technically inadequate (report submitted for review). Technically inadequate HSAT recordings lack a minimum of 4 hours of oximetry and flow data.
- At least **one** of the following suspected or known co-morbid diagnoses or clinical scenarios is documented:
  - **Obesity and one of the following**:
    - BMI ≥45
    - Obesity hypoventilation syndrome (OHS) defined as:
      - BMI ≥30 kg/$m_2$ plus awake arterial blood gas (ABG), end-tidal $PCO_2$ ($EtPCO_2$), or transcutaneous $PCO_2$ ($TcPCO_2$) with $PCO_2$ ≥45 OR venous blood gas (VBG) showing a $PCO_2$ ≥50 mmHg
      - If ABG, VBG, $EtPCO_2$ or $TcPCO_2$ results are not available, serum bicarbonate ≥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 (FEV1) ≤69% of predicted
  - **Documented neurological disease**
    - Any of the following:
      - The neurological disease precludes the individual's ability to perform home sleep apnea testing due to physical limitation (e.g. documented stroke with residual weakness/lack of coordination that would prevent performance of home sleep apnea testing) **OR**
      - There is stated concern for central sleep apnea or hypoventilation (e.g., neuromuscular disease such as myotonic dystrophy or 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 greater than 20 mmHg on right heart 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 greater than or equal to 2.9 m/s OR documented echocardiographic signs of pulmonary hypertension (Examples may include right atrial or right ventricle enlargement, interventricular septal flattening, enlarged pulmonary artery, dilated IVC, right ventricle outflow Doppler acceleration time >105 msec and/or midsystolic notching, pulmonary regurgitation velocity > 2.2 m/sec)

- **Other critical illness that would prevent the individual from using the HSAT equipment**
  - As documented in the patient record
- **Chronic severe insomnia**
  - Documented by validated questionnaire such as Insomnia Severity Index (ISI) ≥22. See **Questionnaires (SL 8)** for details regarding ISI.
- **Chronic daily opioid use** with stated concern for presence of central sleep apnea (typically daily high-potency opioids e.g. Methadone ®, Suboxone ®, Dilaudid ®)
- **Titration study (CPT® 95811 only)** where bi-level positive airway pressure (HCPCS E0470 or E0471) is specifically requested for **either** of the following:
  - 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 the following:
    - Central sleep apnea
    - Treatment-emergent central sleep apnea
    - Neuromuscular or restrictive thoracic disease
    - Severe COPD (arterial blood gas PaCO2 is ≥52 mmHg done while awake and breathing the individual's prescribed $FiO_2$)
    - Obesity hypoventilation syndrome (OHS) defined as BMI ≥30 $kg/m_2$ plus awake arterial blood gas (ABG), end-tidal $PCO_2$ ($EtPCO_2$), or transcutaneous $PCO_2$ ($TcPCO_2$) with $PCO_2$ ≥45 OR venous blood gas (VBG) showing a $PCO_2$ ≥50 mmHg
    - Other Hypoventilation (defined awake arterial blood gas, end-tidal $PCO_2$ (ET $PCO_2$), or transcutaneous $PCO_2$ with $PCO_2$ ≥45 OR venous blood gas showing a $PCO_2$ ≥50 mmHg)
    - Sleep-related hypoventilation as defined in **General Guidelines (SL-1.0)**.
- **Sleep related hypoxemia (Titration study, CPT ® 95811 only)**
  - 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 saturation less than or equal to 88% lasting a minimum of 5 total minutes without significant apneas or hypopneas.

- **Documented OSA with unsuccessful AutoPAP attempt (Titration study, CPT ® 95811 only)**
  - Therapy trial of at least 30 days duration and **either** :
    - Auto-PAP machine download with AHI ≥5/hr with ongoing symptoms of OSA
    - Auto-PAP use (≥4 hours per night on 70% of nights) with continued symptoms
- **Titration study (CPT ® 95811) is indicated with previously documented Central sleep apnea (CSA) defined as (all)** :
  - Presence of one or more of the following:
    - Sleepiness
    - Difficulty initiating or maintaining sleep, frequent awakenings or non-restorative sleep
    - Awakening short of breath
    - Witnessed apneas
  - Central apnea and/or central hypopnea index ≥5 per hour
  - Central hypopnea/apneas are >50% of the total number of apneas and hypopneas
- **Titration study (CPT ® 95811) is indicated with previously documented Treatment Emergent Central Sleep Apnea defined as (both)** :
  - Diagnostic PSG demonstrates ≥5 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 ≥5 per hour
    - Central hypopnea/apneas are ≥50% of the total number of apneas and hypopneas

# Practice Notes (SL-1.1)

**SL.GG.101.A**
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### Occupational Health Examinations

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

Specific government or regulatory body occupational health requirements can be considered when the regulatory rules are provided.

### 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.
- Home Sleep Apnea Testing Equipment should at a minimum include the following features:
  - FDA approval or clearance for the diagnosis of sleep disordered breathing
  - Unique identifier for each unit
  - Must meet minimum definition for CPT® 95800, 95801, or 95806
  - Ability to record oximetry
  - Ability to record a measure of heart rate
  - Ability to display raw data for review, manual scoring or editing of automated scoring
  - Ability to calculate a respiratory event index (REI) based on monitoring time (as a surrogate for AHI) **OR** based on estimated sleep time derived from actigraphy in the case of a peripheral arterial tonometry (PAT) device
- HSAT can be appropriately performed by Joint Commission (JCAHO) and Medicare IDTF-approved facilities.
- **PSG** is called Type I monitoring:
  - Involves at a minimum, measurement of the following parameters:
    - Electroencephalogram (EEG)
    - Electrooculogram (EOG)
    - Chin electromyogram (EMG)
    - Leg EMG
    - Airflow signals
    - Respiratory effort signals
    - Oxygen saturation
    - Body position
    - Electrocardiogram (EKG)
    - Synchronized PSG video



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  - Facilities also typically record body position (with video) and snoring (via microphone).
- Calculations of the Apnea Hypopnea Index (AHI) , Respiratory Disturbance Index (RDI), and Respiratory Event Index (REI) are performed.
  - Scoring PSG:
    - AHI is the number of apneas and hypopneas per hour of sleep
    - RDI is the number of apneas, hypopneas, and respiratory effort related arousals (RERAs) per hour of sleep
  - Scoring HSAT:
    - AHI (also called the REI) is the number of apneas and hypopneas per hour of estimated sleep
    - The RDI cannot be used since RERAs cannot be scored on HSAT

# Sleep Diagnostics

# Sleep Diagnostics-Coding (SL-1)

**SL.ST.100.A**
**v1.0.2024**

### Home portable monitoring (PM) (home sleep testing)-coding (SL-1.4.1)

There are currently 3 levels (HCPCS G0398, G0399 and G0400) of home PMs, 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.

**Procedure codes for home sleep apnea testing (HSAT)**

| 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 | G0398 | At least 7 monitored channels. |
| 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 | G0399 | 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 | G0400 | Measures 1 to 3 parameters |

**PSG procedure codes for unattended sleep studies**

| Unattended sleep studies | CPT® |
|---|---|
| Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time.<br>• For unattended sleep study that measures a minimum of heart rate, oxygen saturation, and respiratory analysis, report CPT® 95801 | 95800 |
| Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (e.g., by airflow or peripheral arterial tone)<br>• For unattended sleep study that measures a minimum of heart rate, oxygen saturation, and sleep time, report CPT® 95800 | 95801 |

| Unattended sleep studies | CPT® |
|---|---|
| Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement)<br>• Simultaneous recording; minimum of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation.<br>• Do not report CPT® 95806 in conjunction with any of the following codes: CPT® 93041-93229, 93268-93272, or 95800-95801 | 95806 |

**Polysomnography (facility-based-PSG) - coding (SL-1.4.2)**
**PSG procedure codes for attended polysomnography and sleep studies**

| Attended polysomnography and sleep studies | CPT® |
|---|---|
| Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness.<br>• Multiple sleep latency testing (MSLT) is performed prior to treatment when the requesting physician suspects narcolepsy.<br>• MSLT must be requested with a facility sleep study performed the night before the CPT® 95805 (CPT® 95810 or CPT® 95811).<br>• See **Multiple sleep latency testing (MSLT) (SL-2.3)** - See **Maintenance of Wakefulness Testing (MWT)-Indications and Criteria (SL-2.4)** | 95805 |
| Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist with PAP titration<br>• May be considered experimental, investigational, or unproven when 95807 or 95807-52 is utilized to request a PAP-NAP. | 95807 |
| Polysomnography; (any age), sleep staging with 1-3 additional parameters of sleep, attended by a technologist | 95808 |
| Polysomnography; (age 6 years or older), sleep staging with 4 or more additional parameters of sleep, attended by a technologist.<br>• CPT® 95810 is used to report full-night diagnostic sleep study | 95810 |

| Attended polysomnography and sleep studies | CPT® |
|---|---|
| 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<br>• CPT® 95811 is used as either a split-night study when both the diagnostic study and the subsequent positive airway pressure or bi-level ventilation are initiated during the same visit, **or** as PAP titration alone after CPT® 95810 or inability to complete split night sequence or as a re-titration of PAP therapy. | 95811 |

The following are **pediatric codes** .

**Attended polysomnography and sleep studies (pediatric codes)**

| Attended polysomnography and sleep studies | CPT |
|---|---|
| Polysomnography, (younger than 6 years), sleep staging with 4 or more additional parameters of sleep, attended by a technologist. | 95782 |
| 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. | 95783 |

# Initial Sleep Diagnostic and Treatment Testing (SL-2.1)

**SL.ST.101.A**
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**Home sleep apnea testing (HSAT)**

- HSAT can be performed when **both of the following** criteria are met:
  - Increased risk of moderate-to-severe OSA as determined by **one** of the following:
    - 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)
    - Validated questionnaire (STOP BANG or Berlin). See **Questionnaires (SL-8).**
  - 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 **General Guidelines (SL-1.0)** and **In-Laboratory Polysomnography - OSA Indications** can undergo facility testing as outlined in Laboratory Polysomnography - OSA Indications 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).

**In-laboratory polysomnography- sleep disordered breathing**

PSG (CPT® 95810 or 95811) can be considered when sleep survey or proxy symptom(s) lead to concern for OSA and **one** of the following:

- Facility testing can be considered rather than HSAT due to **one** of the following reasons:
  - Suspected obstructive sleep apnea with low pretest probability of moderate-to-severe OSA defined by either of the following:
    - Lack of reported symptoms of excessive daytime sleepiness with **at least two** of the following three criteria (habitual loud snoring, witnessed apnea or gasping or choking, or diagnosed hypertension).
    - Validated questionnaire (STOP BANG or Berlin) indicating low risk. See **Questionnaires (SL-8).**

- Individual does not have the mobility, dexterity or cognitive ability to use home sleep apnea testing equipment safely at home and the ability to follow instructions.
- HSAT has been attempted and is negative, or technically inadequate (report submitted for review). Technically inadequate HSAT recordings lack a minimum of 4 hours of oximetry and flow data.

- At least **one** of the following suspected or known co-morbid diagnoses or clinical scenarios is documented:

  **Obesity and one of the following:**

  - BMI ≥45
  - Obesity hypoventilation syndrome (OHS) defined as:
    - BMI ≥30 $kg/m^2$ plus awake arterial blood gas (ABG), end-tidal $PCO_2$ ($EtPCO_2$), or transcutaneous $PCO_2$ ($TcPCO_2$) with $PCO_2$ ≥45 OR venous blood gas (VBG) showing a $PCO_2$ ≥50 mmHg
    - If ABG, VBG, $EtPCO_2$ or $TcPCO_2$ results are not available, serum bicarbonate ≥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 (FEV1) ≤69% of predicted

  **Documented neurological disease**

  **Any** of the following:

  - The neurological disease precludes the individual's ability to perform home sleep apnea testing due to physical limitation (e.g. documented stroke with residual weakness/lack of coordination that would prevent performance of home sleep apnea testing) OR
  - There is stated concern for central sleep apnea or hypoventilation (e.g. neuromuscular disease such as myotonic dystrophy or 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 >20 mmHg on right heart 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 ≥2.9 m/s OR documented echocardiographic signs of pulmonary hypertension (Examples may include right atrial or right ventricle enlargement, interventricular septal flattening, enlarged pulmonary artery, dilated IVC, right ventricle outflow Doppler acceleration time >105 msec and/or midsystolic notching, pulmonary regurgitation velocity >2.2 m/sec)

**Other critical illness that would prevent the individual from using the HSAT equipment**

As documented in the patient record

**Chronic severe insomnia**

Documented by validated questionnaire (Insomnia Severity Index ≥22). See **Questionnaires (SL 8)** for details regarding ISI.

**Chronic daily opioid use with stated concern for presence of central sleep apnea**

(typically daily high-potency opioids e.g. Methadone®, Suboxone®, Dilaudid®)

**Titration study**

Titration study (CPT® 95811, only) where bilevel positive airway pressure (HCPCS E0470 or E0471) are specifically requested for **either** of the following:

- 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 following:
  - Central sleep apnea
  - Treatment-emergent central sleep apnea
  - Neuromuscular or restrictive thoracic disease
  - Severe COPD (arterial blood gas $PaCO_2$ is ≥52 mmHg done while awake and breathing the individual's prescribed $FiO_2$)
  - Obesity hypoventilation syndrome (OHS) defined as BMI ≥30 $kg/m_2$ plus awake arterial blood gas (ABG), end-tidal $PCO_2$ ($EtPCO_2$), or transcutaneous $PCO_2$ ($TcPCO_2$) with $PCO_2$ ≥45 OR venous blood gas (VBG) showing a $PCO_2$ ≥50 mmHg

- Other hypoventilation (defined awake arterial blood gas, end-tidal $PCO_2$ (ET $PCO_2$), or transcutaneous $PCO_2$ with $PCO_2$ ≥45 OR venous blood gas showing a $PCO_2$ ≥50 mmHg)
- Sleep-related hypoventilation as defined in **General Guidelines (SL-1.0)**.

**Sleep related hypoxemia (Titration study, CPT ® 95811 only)**

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 ≤88% lasting a minimum of 5 total minutes **in the absence of apneas or hypopneas** .

**Documented OSA with unsuccessful AutoPAP attempt (Titration study, CPT® 95811 only)**

Therapy trial of at least 30 days duration and **either**:

- Auto-PAP machine download with AHI ≥5/hr with ongoing symptoms (of OSA)
- Auto-PAP use (≥4 hours per night on 70% of nights) with continued symptoms

**Titration study (CPT ® 95811) is indicated with previously documented Central sleep apnea (CSA) defined as (all):**

- Presence of **one or more** of the following:
  - Sleepiness
  - Difficulty initiating or maintaining sleep, frequent awakenings or non-restorative sleep
  - Awakening short of breath
  - Witnessed apneas
- Central apnea and/or central hypopnea index ≥5 per hour
- Central hypopnea/apneas are >50% of the total number of apneas and hypopneas

**Titration study (CPT ® 95811) is indicated with previously documented Treatment Emergent Central Sleep Apnea defined as (both):**

- Diagnostic PSG demonstrates ≥5 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 ≥5 per hour
  - Central hypopnea/apneas are ≥50% of the total number of apneas and hypopneas

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

**In-laboratory polysomnography - other suspected sleep disorders**

**CPT® 95810 or 95811 for any of the following:**

- Complicated parasomnias (potentially injurious or when there is stated concern for nocturnal seizure activity).A complete description, assessment, and discussion of signs and symptomatology must be included. A simple survey of signs and symptom is not sufficient. Polysomnography is not indicated for uncomplicated typical disorders of arousal (eg: sleep terrors, confusional arousals, sleep walking), nightmares, sleep talking, or bruxism in the absence of concern for safety, sleep disordered breathing, or nocturnal seizures. However, there may be overlap between complicated parasomnia and uncomplicated disorders of arousal, and therefore requests for in-lab studies may be approved on an individual case basis
- Rapid Eye Movement (REM) Behavior Disorder (RBD): Characterized by the acting out of dreams that are vivid, intense, and violent. Consideration of this diagnosis requires a clear description of dream-enacting behaviors, which consist of sleep-related vocalization in addition to complex motor behaviors (such as punching or jumping from bed) correlating with sleep-related mentation.
- 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). RLS is a subjective uncomfortable sensation experienced while awake in the evening that results in an urge to move the legs; it worsens during rest and improves during movement. RLS does not require a sleep study for diagnosis. In the absence of comorbidities indicated in **General Guidelines (SL 1.0)** (site of care), individuals who are undergoing initial diagnostic testing and have a high pre-test probability of moderate to severe obstructive sleep apnea should be evaluated for obstructive sleep apnea before a diagnosis of PLMD is considered.* See Background and Supporting Information. As indicated in **Home sleep apnea testing (HSAT) indications** , increased risk of moderate-to-severe OSA is based on the presence of **one** of the following:
    - 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)
    - Validated questionnaire demonstrating high risk (STOP BANG or Berlin). See **Questionnaires (SL-8)**.
- Sleep testing is not indicated for evaluation of insomnia in the absence of symptoms or provider concern for another sleep fragmenting disorder such as obstructive sleep apnea or periodic limb movement disorder
- Suspected narcolepsy or idiopathic hypersomnia (with CPT® 95805): **See PSG and Multiple Sleep Latency Testing (excessive sleepiness) Indications and Criteria (SL-2.3)**
- Sleep testing of asymptomatic individuals prior to bariatric surgery is not supported

**Background and supporting information**

* 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.

Preoperative sleep testing prior to bariatric surgery testing is based on these guidelines.

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

**MSLT - 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
- Comprehensive sleep evaluation including performance of a relevant sleep questionnaire (ESS or Berlin) and consideration of alternative causes of sleepiness (eg. medication side effects, depression, medical disorder) or comorbid sleep conditions (e.g. circadian rhythm disorders, insufficient sleep syndrome, OSA)
- If there are symptoms or suspicion of OSA (or other types of sleep disordered breathing), diagnostic testing for these conditions must be performed first. See **General Guidelines (SL-1.0)** including section on **Site of care for sleep testing requests (home versus facility)**.
- If OSA (or other types of sleep disordered breathing) is present on diagnostic testing, therapy must be initiated prior to consideration of MSLT. If the individual is being treated with positive airway pressure (PAP) for obstructive sleep apnea, optimal efficacy and adherence has been achieved by demonstration of the following (all):
  - PAP download shows: AHI <5 on download (if available)
  - Currently using PAP ≥70% of the nights for an average of 4 hours or more per 24-hour period based on a 30 contiguous day compliance download during the preceding 6 months.

  - Therapy has resolved symptoms of increased upper airway resistance (i.e. eliminated snoring).
- If the individual is being treated with non-PAP therapy for obstructive sleep apnea, optimal efficacy and adherence has been achieved by demonstration of the following (all):
  - Self-reported adequate use
  - Efficacy confirmed on sleep testing where AHI <5/hour
  - Therapy has resolved symptoms of increased upper airway resistance (i.e., eliminated snoring)
- Is not requested to assess efficacy of PAP therapy for OSA (or other types of sleep disordered breathing).
- Multiple Sleep Latency Testing (MSLT) (CPT® 95805) must immediately follow PSG (CPT® 95810). It cannot follow a split night study or a PAP titration study in individuals for whom OSA (or other types of sleep disordered breathing) is not optimally treated based on ongoing symptoms (such as snoring and witnessed apneas despite compliant use of PAP) or lack of optimal efficacy and adherence (defined as AHI <5 on PAP download [if available] and using PAP ≥70% of the nights for an average of 4 hours or more per 24-hour period) based on downloaded data from the individual's PAP machine.

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**Note** When the individual has known OSA (or other types of sleep disordered breathing) 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.

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- Reassessment of suspected narcolepsy or idiopathic hypersomnia with a repeat CPT 95810/CPT® 95805 is indicated if (**either**):
  - Previous testing did not confirm the diagnosis but clinical suspicion is still present despite consideration of alternative causes of sleepiness (e.g. medication side effects, depression, medical disorder) with adequate treatment of comorbid sleep conditions (e.g., circadian rhythm disorders, insufficient sleep syndrome, OSA as described above)
  - Due to a change in symptoms that might alter a previous diagnosis of Narcolepsy or Idiopathic Hypersomnia

**Background and Supporting information**

The purpose of the PSG followed by MSLT is to measure a patient's physiological tendency to fall asleep in the absence of external alerting factors. It can be utilized to diagnose narcolepsy types 1 and 2 as well as idiopathic hypersomnia.

Per Recommended protocols for the Multiple Sleep Latency Test and Maintenance of Wakefulness Test in adults: guidance from the American Academy of Sleep Medicine. *Journal of Clinical Sleep Medicine 2021*. https://doi.org/10.5664/jcsm.9620:

- The MSLT should be performed following an attended PSG which allows a minimum 7 hours of time in bed with at least 6 hours of sleep, with timing that corresponds with the individual's major sleep period. The test should not be performed after a night during which PAP pressures were adjusted (split-night or PAP titration study).
- "Patients on PAP/non-PAP therapies for sleep-disordered breathing should use them during the PSG and MSLT. The PAP settings and mask interface should match those used at home."
- "For patients with sleep-disordered breathing treated with PAP therapy, the clinician should ensure efficacy and adherence based on a review of downloaded data. If the patient is using non-PAP therapy for sleep-disordered breathing, self-report of adequate use and efficacy of therapy should be confirmed prior to the MSLT."
- "The clinician should develop a plan regarding use of prescription medication, over the counter (OTC) agents, herbal remedies, and other substances. In general, medications with alerting, sedating, and/or REM-modulating properties should be stopped at least two weeks before the MSLT."

**Maintenance of wakefulness testing (MWT)-indications and criteria (SL-2.4)**

**Maintenance of Wakefulness Testing-Indications**

- Maintenance of Wakefulness Testing (CPT® 95805) using a 40-minute protocol is indicated 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 (or other types of sleep disordered breathing), optimal efficacy and adherence has been achieved by demonstration of the following (**both**):
    - PAP download shows: AHI <5 on download (if available) and currently using PAP ≥70% of the nights for an average of 4 hours or more per 24-hour period based on a 30 contiguous day compliance download during the preceding 6 months.
    - 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

**Background and supporting information**

**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 and in 2021. The MWT should be performed following the patient's major sleep period. The MWT should be conducted when a patient is clinically stable and when treatments of any known sleep disorders are well-established and effective. Unlike MSLT, the performance of overnight polysomnography the night prior to MWT is at the discretion of the sleep clinician. 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. 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.

The 2021 AASM practice parameters indicate that:

- "Patients on PAP/non-PAP therapies for sleep-disordered breathing should use them the night before (but not during) the MWT. If a PSG is performed, PAP settings and mask interface should match those used at home."
- "In patients with sleep-disordered breathing who are being evaluated for the effectiveness of therapy, the clinician should ensure the effectiveness (efficacy and adherence) based on review of downloaded data or self-reported use for non-PAP prior to testing."
- "The clinician should develop a plan regarding use of prescription medications, over the counter (OTC) agents, herbal remedies, and other substances. If the patient is chronically taking medications with alerting or sedating properties, they should be continued at a stable dose. Changes in medications should be avoided for two weeks prior to testing. The patient should be instructed to consult with the clinician before starting a prescription or OTC medication prior to the test."

**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 ≥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 study was performed as a diagnostic study (CPT® 95810)
  - Followed by second night PAP titration (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 meeting criteria for the diagnosis of obstructive sleep apnea (OSA) as defined in **General Guidelines (SL 1.0): Definitions,** the following information should be used to consider unattended APAP or attended CPAP titration:
  - Facility titration study CPT® 95811 can be used when there is documentation of at least one of the suspected or known co-morbid diagnoses or clinical scenarios found in **General Guidelines (SL-1.0): Site of care** for sleep testing requests (home versus facility).
  - Immediate treatment with E0601 APAP, or if necessary, an E0601 APAP titration can be considered when there are no co-morbid diagnoses or clinical scenarios found in **General Guidelines (SL-1.0): Site of care** for sleep testing requests (home versus facility)
  - All new information from the PSG or HSAT including but not limited to frequency of central apneas, evidence of nocturnal hypoventilation independent of apnea/ hypopnea, or abnormal sleep related behavior
  - Facility titration studies (CPT® 95811) can also be utilized in the following clinical scenarios:
    - Titrate non-invasive positive pressure ventilation (NIPPV) devices in individuals with diurnal chronic alveolar hypoventilation (defined as hypercapnia, with awake arterial blood gas, end-tidal $PCO_2$ [ET $PCO_2$], or transcutaneous $PCO_2$ with $PCO_2$ >45 **OR** venous blood gas showing a $PCO_2$ ≥50 mmHg)
    - Titrate positive airway pressure or NIPPV for sleep-related hypoventilation (as defined in **General Guidelines (SL 1.0)** )
- For more information on the technical and policy requirements of PSG, as well as on PSG scoring, see **Practice Notes (SL-1.1)**

**Repeat sleep testing - home or attended sleep studies (SL-2.6)**

Most risk factors for obstructive sleep apnea generally do not improve with the passage of time; therefore, follow-up HSAT or PSG is not routinely indicated for asymptomatic individuals on PAP therapy. However, individuals with persistent or recurrent symptoms despite adherence with PAP may require repeat testing.

**Repeat Diagnostic Study (SL-2.6.1)**

- Repeat diagnostic testing is **not** indicated to supply new PAP equipment.
- Either home sleep apnea testing or in-lab testing (CPT® 95810) can be performed based on indications and comorbidities found in **General Guidelines (SL-1.0): Site of care for sleep testing requests (home versus facility)** when there is documentation of **both:**
  - Any one of the following criteria is met:

- BMI decreases by 10% and there is a desire to discontinue PAP therapy and/or intolerance to PAP therapy and/or other planned change in management
- BMI increases by 10% when test results would lead to a significant change in management
- To reassess for the continued presence of OSA after (**any**):
  - Upper airway surgery for OSA both post-operatively after an appropriate period of healing (weeks to months) and repeat testing if there is concern for relapse after an initially successful surgery
  - At least 3 months after bariatric surgery when there is >10% weight loss
  - Individuals with a tracheostomy for OSA who are under consideration for decannulation (PSG or HSAT with trach capped)
  - OSA Oral appliance trial
  - Positional therapy (not necessary if was proven effective on the diagnostic study)
  - Other non-PAP supportive interventions (e.g. nasal expiratory positive airway pressure, oral pressure therapy, eXciteOSA)
- 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). Technically inadequate HSAT recordings lack a minimum of 4 hours of oximetry and flow data
- Results of previous medically necessary sleep test are unavailable and there is a documented effort by the requesting provider to obtain a copy of that test result. See **General guidelines (SL-1.0)**

- Criteria for determination of appropriateness of home sleep apnea testing versus facility testing has been met based on the **General Guidelines (SL-1.0): Site of care for sleep testing requests (home versus facility)**

**Repeat titration (SL-2.6.2)**

- A repeat titration study is **not** indicated to supply new PAP equipment.
- A repeat titration study is **not** indicated to assess for the efficacy of PAP therapy in absence of recurrent or changed symptoms.
- Must demonstrate that recurrent or continued symptoms are not due to insufficient compliance (must be using PAP ≥4 hours per night on 70% of nights with continued symptoms).
- A repeat titration study can be performed if **any** of the following criteria is met:

**OSA currently on CPAP**

If any of the below criteria is met for an individual on CPAP, please see **In-Laboratory Polysomnography- OSA Indications** for determination of appropriateness of automatic PAP trial versus facility titration study. Comorbidities in **General Guidelines (SL-1.0): Site of care for sleep testing requests (home versus facility)** are required to perform repeat facility titration study without first undergoing an automatic PAP trial.

- Re-assessment of treatment results (with either CPT® 95811 or unattended APAP based on indications and comorbidities found in **General Guidelines (SL-1.0)** and **In-Laboratory Polysomnography- OSA Indications** for an individual with known OSA currently using CPAP ≥4 hours on 70% of nights during a consecutive 30 day period anytime during the past 1 year 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% and there is intolerance of PAP pressure (compliant download not required)
  - Clinical response is insufficient due to ongoing symptoms
  - Symptoms return despite a good initial response to CPAP
  - Development of hypertension or worsening of hypertension despite a minimum of three months of adherent PAP usage as defined above
  - New onset decompensated heart failure or new stroke or TIA in an individual treated with PAP therapy
  - Newly discovered arrhythmia (such as atrial fibrillation) or bradycardia (such as atrioventricular block), particularly if the arrhythmia occurs during sleep, in an individual treated with PAP therapy
  - PAP machine download demonstrates elevated AHI with return of symptoms
  - Results of previous PAP titration sleep test were inadequate and not diagnostic due to limited sleep time or other specified variables (report of prior sleep testing required)
  - Results of previous medically necessary sleep test are unavailable and there is a documented effort by the requesting provider to obtain a copy of that test result. See **General guidelines (SL-1.0)**
  - CPAP/APAP is ineffective (as defined in the bullet points above) or is not tolerated and bi-level PAP titration utilizing HCPCS E0470 or E0471 is requested.

**OSA currently treated with bi-level PAP, APAP, ASV**

Re-assessment of treatment results (with CPT® 95811) for a patient with known OSA currently using bilevel PAP, APAP, ASV ≥4 hours on 70% of nights during a consecutive 30 day period anytime during the past 1 year 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% and there is intolerance of PAP pressure (compliant download not required)
- Clinical response is insufficient due to ongoing symptoms
- Symptoms return despite a good initial response to CPAP
- Development of hypertension or worsening of hypertension despite a minimum of three months of adherent PAP usage (as defined above).
- New onset decompensated heart failure or new stroke or TIA in an individual treated with PAP therapy

- Newly discovered arrhythmia (such as atrial fibrillation) or bradycardia (such as atrioventricular block), particularly if the arrhythmia occurs during sleep, in an individual treated with PAP therapy
- PAP machine download demonstrates elevated AHI with return of symptoms.
- Results of previous PAP titration sleep test were inadequate and not diagnostic due to limited sleep time or other specified variables (report of prior sleep testing required)
- Results of previous medically necessary sleep test are unavailable and there is a documented effort by the requesting provider to obtain a copy of that test result. See **General guidelines (SL-1.0)**

**Diagnostic Testing pre- and post- hypoglossal nerve stimulator implantation (SL-2.8)**

**Indications**

PSG (CPT® 95810) is indicated for the following:

**Pre-implantation**

See also **Background and Supporting Information** below

**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 **General Guidelines (SL-1.0): Site of care for sleep testing requests (home versus facility)**,

**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 (CPT® 95810) is indicated if the following criteria are met (**both** ):
  - BMI <35
  - PAP intolerance (inability to use PAP >5 nights per week for >4 hours per night OR unwillingness to use PAP after attempting to use it during minimum 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 <65 on home sleep testing
- PAP intolerance (inability to use PAP > 5 nights per week for > 4 hours per night OR unwillingness to use PAP after attempting to use it during minimum one month trial)

- For individuals age 13-18 years old with Down Syndrome, the following criteria must be met prior to performance of diagnostic polysomnography (CPT® 95810) for pre-implantation evaluation (all):
  - AHI <50 on home sleep apnea testing if done
  - Adenotonsillectomy is contraindicated or ineffective
  - PAP intolerance (inability to use PAP >5 nights per week for > 4 hours per night OR unwillingness to use PAP after attempting to use it during a minimum of one month trial)

**Post-implantation:**

- As per the clinical trial, polysomnography (CPT® 95810) can be performed post-implantation (at approximately 2-3 months post-implantation) for the purpose of titrating device parameters and determining therapeutic stimulation settings.
- Following the initial post-implantation study, 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 initial post-implantation study, the choice of home sleep apnea testing or facility polysomnography for repeat testing will be based on indications and co-morbidities outlined in **General Guidelines (SL-1.0) .**

**Background and supporting information**

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/m2. 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.

In 2023 the FDA expanded the label indications for HGNS therapy to include:

- Expansion of the upper limit baseline apnea-hypopnea index (AHI) to 100
- Expansion of the upper limit body mass index (BMI) to 40 kg/ m2
- Patients with Down syndrome between the ages of 13 to 18 years old with AHI greater than 10 and less than 50 who qualify for the use of HGNS by the other standard indications established from the STAR trial such as PAP therapy failure/ intolerance, and absence of complete concentric upper airway collapsibility, as defined by a drug-induced sleep endoscopy (DISE) procedure. In addition, adenotonsillectomy must be contraindicated or not effective.[99]

A 2020 study investigating outcomes for 18 patients who underwent HGNS implantation outside of US FDA guidelines (AHI, BMI, and CAI cutoffs) exceeded the 1 year STAR trial results with an 83.3% response rate by Sher criteria as compared to the 66% response rate in the STAR trial. However, the number of subjects who qualified was low, and the conclusions are therefore guarded.[100]

Some non-congruent data exist regarding the optimal BMI cutoff for HGNS therapy. A retrospective case-control study of 153 patients comparing the clinical outcome between cohorts with BMI > 32 kg/ $m^2$, and less than 32 kg/m2 showed comparable results. However, data from the ADHERE registry trial, a large, multicenter, prospective, observational study, noted a 8.5% reduced odds of treatment success for each unit increase in BMI.[101] More than half of patient with BMI > 32 kg/$m^2$ demonstrate AP collapse on pattern on DISE. The correlation between higher AHI and BMI with an unfavorable pattern of airway collapse on the DISE procedure is modest at best 102. Therefore, there are patients with AHI > 65 and BMI > 32 who may benefit from HGNS after a DISE showing AP collapse. Nonetheless, the more robust ADHERE trial suggests that the BMI cutoff of 32 defined by the STAR trial remains a useful predictor of surgical success.[102, 103]

Similarly, a large 2022 retrospective study using ADHERE registry data analyzed the outcomes of 1963 subjects stratified into 5 different baseline AHI subgroups. There was no significant difference in treatment success (defined by Sher criteria between the subgroups. However, the conclusions are limited by small numbers, with only 33 subjects in the subgroup with AHI > 65 events/ hr.[104]

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

**SL.ST.203.A**
**v1.0.2024**

**MSLT - 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
- Comprehensive sleep evaluation including performance of a relevant sleep questionnaire (ESS or Berlin) and consideration of alternative causes of sleepiness (eg. medication side effects, depression, medical disorder) or comorbid sleep conditions (e.g. circadian rhythm disorders, insufficient sleep syndrome, OSA)
- If there are symptoms or suspicion of OSA (or other types of sleep disordered breathing), diagnostic testing for these conditions must be performed first. See **General Guidelines (SL-1.0)** including section on **Site of care for sleep testing requests (home versus facility)**.
- If OSA (or other types of sleep disordered breathing) is present on diagnostic testing, therapy must be initiated prior to consideration of MSLT. If the individual is being treated with positive airway pressure (PAP) for obstructive sleep apnea, optimal efficacy and adherence has been achieved by demonstration of the following (all):
  - PAP download shows: AHI <5 on download (if available)
  - Currently using PAP ≥70% of the nights for an average of 4 hours or more per 24-hour period based on a 30 contiguous day compliance download during the preceding 6 months.
  - Therapy has resolved symptoms of increased upper airway resistance (i.e. eliminated snoring).
- If the individual is being treated with non-PAP therapy for obstructive sleep apnea, optimal efficacy and adherence has been achieved by demonstration of the following (all):
  - Self-reported adequate use
  - Efficacy confirmed on sleep testing where AHI <5/hour

  - Therapy has resolved symptoms of increased upper airway resistance (i.e., eliminated snoring)
- Is not requested to assess efficacy of PAP therapy for OSA (or other types of sleep disordered breathing).
- Multiple Sleep Latency Testing (MSLT) (CPT® 95805) must immediately follow PSG (CPT® 95810). It cannot follow a split night study or a PAP titration study in individuals for whom OSA (or other types of sleep disordered breathing) is not optimally treated based on ongoing symptoms (such as snoring and witnessed apneas despite compliant use of PAP) or lack of optimal efficacy and adherence (defined as AHI <5 on PAP download [if available] and using PAP ≥70% of the nights for an average of 4 hours or more per 24-hour period) based on downloaded data from the individual's PAP machine.

**Note** When the individual has known OSA (or other types of sleep disordered breathing) 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.

- Reassessment of suspected narcolepsy or idiopathic hypersomnia with a repeat CPT 95810/CPT® 95805 is indicated if (**either**):
  - Previous testing did not confirm the diagnosis but clinical suspicion is still present despite consideration of alternative causes of sleepiness (e.g. medication side effects, depression, medical disorder) with adequate treatment of comorbid sleep conditions (e.g., circadian rhythm disorders, insufficient sleep syndrome, OSA as described above)
  - Due to a change in symptoms that might alter a previous diagnosis of Narcolepsy or Idiopathic Hypersomnia

**Background and Supporting information**

The purpose of the PSG followed by MSLT is to measure a patient's physiological tendency to fall asleep in the absence of external alerting factors. It can be utilized to diagnose narcolepsy types 1 and 2 as well as idiopathic hypersomnia.

Per Recommended protocols for the Multiple Sleep Latency Test and Maintenance of Wakefulness Test in adults: guidance from the American Academy of Sleep Medicine. *Journal of Clinical Sleep Medicine 2021*. https://doi.org/10.5664/jcsm.9620:

- The MSLT should be performed following an attended PSG which allows a minimum 7 hours of time in bed with at least 6 hours of sleep, with timing that corresponds with the individual's major sleep period. The test should not be performed after a night during which PAP pressures were adjusted (split-night or PAP titration study).
- "Patients on PAP/non-PAP therapies for sleep-disordered breathing should use them during the PSG and MSLT. The PAP settings and mask interface should match those used at home."

- "For patients with sleep-disordered breathing treated with PAP therapy, the clinician should ensure efficacy and adherence based on a review of downloaded data. If the patient is using non-PAP therapy for sleep-disordered breathing, self-report of adequate use and efficacy of therapy should be confirmed prior to the MSLT."
- "The clinician should develop a plan regarding use of prescription medication, over the counter (OTC) agents, herbal remedies, and other substances. In general, medications with alerting, sedating, and/or REM-modulating properties should be stopped at least two weeks before the MSLT."

# Maintenance of wakefulness testing (MWT)-indications and criteria (SL-2.4)

**SL.ST.101.A**
**v1.0.2024**

### Maintenance of Wakefulness Testing-Indications

- Maintenance of Wakefulness Testing (CPT® 95805) using a 40-minute protocol is indicated 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 (or other types of sleep disordered breathing), optimal efficacy and adherence has been achieved by demonstration of the following (**both**):
    - PAP download shows: AHI <5 on download (if available) and currently using PAP ≥70% of the nights for an average of 4 hours or more per 24-hour period based on a 30 contiguous day compliance download during the preceding 6 months.
    - 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

### Background and supporting information

### 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 and in 2021. The MWT should be performed following the patient's major sleep period. The MWT should be conducted when a patient is clinically stable and when treatments of any known sleep disorders are well-established and effective. Unlike MSLT, the performance of overnight polysomnography the night prior to MWT is at the discretion of the sleep clinician. 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. 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.

The 2021 AASM practice parameters indicate that:

- "Patients on PAP/non-PAP therapies for sleep-disordered breathing should use them the night before (but not during) the MWT. If a PSG is performed, PAP settings and mask interface should match those used at home."
- "In patients with sleep-disordered breathing who are being evaluated for the effectiveness of therapy, the clinician should ensure the effectiveness (efficacy and adherence) based on review of downloaded data or self-reported use for non-PAP prior to testing."
- "The clinician should develop a plan regarding use of prescription medications, over the counter (OTC) agents, herbal remedies, and other substances. If the patient is chronically taking medications with alerting or sedating properties, they should be continued at a stable dose. Changes in medications should be avoided for two weeks prior to testing. The patient should be instructed to consult with the clinician before starting a prescription or OTC medication prior to the test."

# Repeat sleep testing - home or attended sleep studies (SL-2.6)

**SL.ST.101.A**
**v1.0.2024**

Most risk factors for obstructive sleep apnea generally do not improve with the passage of time; therefore, follow-up HSAT or PSG is not routinely indicated for asymptomatic individuals on PAP therapy. However, individuals with persistent or recurrent symptoms despite adherence with PAP may require repeat testing.

**Repeat Diagnostic Study (SL-2.6.1)**

- Repeat diagnostic testing is **not** indicated to supply new PAP equipment.
- Either home sleep apnea testing or in-lab testing (CPT® 95810) can be performed based on indications and comorbidities found in **General Guidelines (SL-1.0): Site of care for sleep testing requests (home versus facility)** when there is documentation of **both:**
  - Any one of the following criteria is met:
    - BMI decreases by 10% and there is a desire to discontinue PAP therapy and/or intolerance to PAP therapy and/or other planned change in management
    - BMI increases by 10% when test results would lead to a significant change in management
    - To reassess for the continued presence of OSA after (**any**):
      - Upper airway surgery for OSA both post-operatively after an appropriate period of healing (weeks to months) and repeat testing if there is concern for relapse after an initially successful surgery
      - At least 3 months after bariatric surgery when there is >10% weight loss
      - Individuals with a tracheostomy for OSA who are under consideration for decannulation (PSG or HSAT with trach capped)
      - OSA Oral appliance trial
      - Positional therapy (not necessary if was proven effective on the diagnostic study)
      - Other non-PAP supportive interventions (e.g. nasal expiratory positive airway pressure, oral pressure therapy, eXciteOSA)
    - 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). Technically inadequate HSAT recordings lack a minimum of 4 hours of oximetry and flow data
    - Results of previous medically necessary sleep test are unavailable and there is a documented effort by the requesting provider to obtain a copy of that test result. See **General guidelines (SL-1.0)**

- Criteria for determination of appropriateness of home sleep apnea testing versus facility testing has been met based on the **General Guidelines (SL-1.0): Site of care for sleep testing requests (home versus facility)**

**Repeat titration (SL-2.6.2)**

- A repeat titration study is **not** indicated to supply new PAP equipment.
- A repeat titration study is **not** indicated to assess for the efficacy of PAP therapy in absence of recurrent or changed symptoms.
- Must demonstrate that recurrent or continued symptoms are not due to insufficient compliance (must be using PAP ≥4 hours per night on 70% of nights with continued symptoms).
- A repeat titration study can be performed if **any** of the following criteria is met:

**OSA currently on CPAP**

If any of the below criteria is met for an individual on CPAP, please see **In-Laboratory Polysomnography- OSA Indications** for determination of appropriateness of automatic PAP trial versus facility titration study. Comorbidities in **General Guidelines (SL-1.0): Site of care for sleep testing requests (home versus facility)** are required to perform repeat facility titration study without first undergoing an automatic PAP trial.

- Re-assessment of treatment results (with either CPT® 95811 or unattended APAP based on indications and comorbidities found in **General Guidelines (SL-1.0)** and **In-Laboratory Polysomnography- OSA Indications** for an individual with known OSA currently using CPAP ≥4 hours on 70% of nights during a consecutive 30 day period anytime during the past 1 year 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% and there is intolerance of PAP pressure (compliant download not required)
  - Clinical response is insufficient due to ongoing symptoms
  - Symptoms return despite a good initial response to CPAP
  - Development of hypertension or worsening of hypertension despite a minimum of three months of adherent PAP usage as defined above
  - New onset decompensated heart failure or new stroke or TIA in an individual treated with PAP therapy
  - Newly discovered arrhythmia (such as atrial fibrillation) or bradycardia (such as atrioventricular block), particularly if the arrhythmia occurs during sleep, in an individual treated with PAP therapy
  - PAP machine download demonstrates elevated AHI with return of symptoms
  - Results of previous PAP titration sleep test were inadequate and not diagnostic due to limited sleep time or other specified variables (report of prior sleep testing required)

- Results of previous medically necessary sleep test are unavailable and there is a documented effort by the requesting provider to obtain a copy of that test result. See **General guidelines (SL-1.0)**
- CPAP/APAP is ineffective (as defined in the bullet points above) or is not tolerated and bi-level PAP titration utilizing HCPCS E0470 or E0471 is requested.

**OSA currently treated with bi-level PAP, APAP, ASV**

Re-assessment of treatment results (with CPT® 95811) for a patient with known OSA currently using bilevel PAP, APAP, ASV ≥4 hours on 70% of nights during a consecutive 30 day period anytime during the past 1 year 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% and there is intolerance of PAP pressure (compliant download not required)
- Clinical response is insufficient due to ongoing symptoms
- Symptoms return despite a good initial response to CPAP
- Development of hypertension or worsening of hypertension despite a minimum of three months of adherent PAP usage (as defined above).
- New onset decompensated heart failure or new stroke or TIA in an individual treated with PAP therapy
- Newly discovered arrhythmia (such as atrial fibrillation) or bradycardia (such as atrioventricular block), particularly if the arrhythmia occurs during sleep, in an individual treated with PAP therapy
- PAP machine download demonstrates elevated AHI with return of symptoms.
- Results of previous PAP titration sleep test were inadequate and not diagnostic due to limited sleep time or other specified variables (report of prior sleep testing required)
- Results of previous medically necessary sleep test are unavailable and there is a documented effort by the requesting provider to obtain a copy of that test result. See **General guidelines (SL-1.0)**

# Diagnostic Testing pre- and post-hypoglossal nerve stimulator implantation (SL-2.8)

**SL.ST.208.A**
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**Indications**

PSG (CPT® 95810) is indicated for the following:

**Pre-implantation**

See also **Background and Supporting Information** below

**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 **General Guidelines (SL-1.0): Site of care for sleep testing requests (home versus facility)**,

**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 (CPT® 95810) is indicated if the following criteria are met (**both** ):
  - BMI <35
  - PAP intolerance (inability to use PAP >5 nights per week for >4 hours per night OR unwillingness to use PAP after attempting to use it during minimum 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 <65 on home sleep testing
  - PAP intolerance (inability to use PAP > 5 nights per week for > 4 hours per night OR unwillingness to use PAP after attempting to use it during minimum one month trial)

- For individuals age 13-18 years old with Down Syndrome, the following criteria must be met prior to performance of diagnostic polysomnography (CPT® 95810) for pre-implantation evaluation (all):
  - AHI <50 on home sleep apnea testing if done
  - Adenotonsillectomy is contraindicated or ineffective
  - PAP intolerance (inability to use PAP >5 nights per week for > 4 hours per night OR unwillingness to use PAP after attempting to use it during a minimum of one month trial)

**Post-implantation:**

- As per the clinical trial, polysomnography (CPT® 95810) can be performed post-implantation (at approximately 2-3 months post-implantation) for the purpose of titrating device parameters and determining therapeutic stimulation settings.
- Following the initial post-implantation study, 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 initial post-implantation study, the choice of home sleep apnea testing or facility polysomnography for repeat testing will be based on indications and co-morbidities outlined in **General Guidelines (SL-1.0) .**

**Background and supporting information**

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/m2. 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.

In 2023 the FDA expanded the label indications for HGNS therapy to include:

- Expansion of the upper limit baseline apnea-hypopnea index (AHI) to 100

- Expansion of the upper limit body mass index (BMI) to 40 kg/ m2
- Patients with Down syndrome between the ages of 13 to 18 years old with AHI greater than 10 and less than 50 who qualify for the use of HGNS by the other standard indications established from the STAR trial such as PAP therapy failure/ intolerance, and absence of complete concentric upper airway collapsibility, as defined by a drug-induced sleep endoscopy (DISE) procedure. In addition, adenotonsillectomy must be contraindicated or not effective.[99]

A 2020 study investigating outcomes for 18 patients who underwent HGNS implantation outside of US FDA guidelines (AHI, BMI, and CAI cutoffs) exceeded the 1 year STAR trial results with an 83.3% response rate by Sher criteria as compared to the 66% response rate in the STAR trial. However, the number of subjects who qualified was low, and the conclusions are therefore guarded.[100]

Some non-congruent data exist regarding the optimal BMI cutoff for HGNS therapy. A retrospective case-control study of 153 patients comparing the clinical outcome between cohorts with BMI > 32 kg/ $m^2$, and less than 32 kg/m2 showed comparable results. However, data from the ADHERE registry trial, a large, multicenter, prospective, observational study, noted a 8.5% reduced odds of treatment success for each unit increase in BMI.[101] More than half of patient with BMI > 32 kg/$m^2$ demonstrate AP collapse on pattern on DISE. The correlation between higher AHI and BMI with an unfavorable pattern of airway collapse on the DISE procedure is modest at best 102. Therefore, there are patients with AHI > 65 and BMI > 32 who may benefit from HGNS after a DISE showing AP collapse. Nonetheless, the more robust ADHERE trial suggests that the BMI cutoff of 32 defined by the STAR trial remains a useful predictor of surgical success.[102, 103]

Similarly, a large 2022 retrospective study using ADHERE registry data analyzed the outcomes of 1963 subjects stratified into 5 different baseline AHI subgroups. There was no significant difference in treatment success (defined by Sher criteria between the subgroups. However, the conclusions are limited by small numbers, with only 33 subjects in the subgroup with AHI > 65 events/ hr.[104]

# Treatment of Sleep-Related Breathing Disorders

# Treatment - General information

**SL.TX.101.A**
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### Treatment coding (SL-4.1.1)

The codes for treatment of obstructive sleep apnea include HCPCS and CPT®.

**Treatment codes**

| Treatment codes | HCPCS and CPT® |
|---|---|
| Continuous airway pressure (CPAP/APAP) device | E0601 |
| Respiratory assist device, bi-level pressure (BiPAP) 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 (BiPAP) 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 (BiPAP) 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/BiPAP/APAP) device | E0561 |
| Humidifier, heated, used with positive airway pressure (CPAP/BiPAP/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 |

| Treatment codes | HCPCS and CPT® |
|---|---|
| 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 a patient's PAP therapy). | A9279 |
| CPAP initiation and management<br>(code is used to report the initiation and instruction when a patient begins therapy) | CPT 94660 |

**PAP - General requirements (SL-4.1)**

- Valid sleep testing demonstrates a positive diagnosis of one or more of the following sleep-related breathing disorders:

  **Obstructive sleep apnea (OSA) as measured by valid testing is defined as:**

  - Predominantly obstructive events (obstructive and mixed apneas, hypopneas, or respiratory effort related arousals).
  - The apnea-hypopnea index (AHI), or respiratory disturbance index (RDI) on a PSG, or the AHI or Respiratory Event Index (REI) on a HSAT is ≥15 events per hour; or
  - The AHI or RDI on a PSG, or the AHI or REI on a HSAT is ≥5 and <15 events per hour and documentation of:
    - Symptoms of sleepiness, fatigue, insomnia, or other symptoms leading to impaired sleep-related quality of life
    - 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 (all):**

  - Presence of one or more of the following:

    - Sleepiness
    - Difficulty initiating or maintaining sleep, frequent awakenings or non-restorative sleep
    - Awakening short of breath
    - Witnessed apneas
  - Central apnea and/or central hypopnea index ≥5 per hour
  - Central hypopnea/apneas are >50% of the total number of apneas and hypopneas

**Central sleep apnea (CSA) with Cheyne-Stokes Respiration defined as (all):**

  - Presence of one or more of the following:
    - Sleepiness
    - Difficulty initiating or maintaining sleep, frequent awakenings or non-restorative sleep
    - Awakening short of breath
    - Witnessed apneas
    - Known atrial fibrillation/flutter, congestive heart failure, or a neurological disorder
  - PSG must show all of the following:
    - Central apnea and/or central hypopnea index ≥5 per hour
    - Central hypopnea/apneas are >50% of the total number of apneas and hypopneas
    - Pattern of breathing meets criteria for Cheyne-Stokes breathing (episodes of ≥3 consecutive central apneas and/or central hypopneas separated by a crescendo and decrescendo change in breathing amplitude with a cycle length of ≥40 seconds).

**Treatment Emergent Central Sleep Apnea defined as (all):**

  - Presence of one or more of the following thought to be attributable to the central events:
    - Sleepiness
    - Difficulty initiating or maintaining sleep, frequent awakenings or nonrestorative sleep
    - Awakening short of breath
    - Witnessed apneas
  - Diagnostic PSG demonstrates ≥5 predominantly obstructive respiratory events per hour of sleep (obstructive or mixed apneas, hypopneas, respiratory effort related arousals [RERAs]).
  - PSG during use of positive airway pressure without a backup rate shows improvement of obstructive events and emergence or persistence of central apneas/hypopneas with (both):
    - Central apnea and/or hypopnea index ≥5 per hour

- Central hypopnea/apneas are ≥50% of the total number of apneas and hypopneas

**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 ≥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

Results from a 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

**Current practice recommendations for CSA with CHF (SL-4.1.2)**

- 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

# Positive airway pressure devices (SL-4.2)

**SL.TX.102.A**
**v1.0.2024**

### Auto-titration of positive airway pressure (APAP) in unattended setting (SL-4.2.1)

**Initial Assessment of PAP pressure with APAP**

Please see sections referring to Initiation of E0601 and Authorization of purchase for E0601 in **Continuous Positive Airway Pressure (CPAP) or Automatic Positive Airway Pressure (APAP) Therapy (SL 4.2.2)**

**Repeat Assessment of PAP pressure with APAP**

E0601 APAP Treatment (for the purpose of determining appropriate PAP pressure for individuals currently on fixed pressure treatment with CPAP) can be considered for the following (ALL):

- A positive diagnosis of OSA, as measured by HSAT or PSG as defined in **General Guidelines (SL-1.0)**
- Attempted compliance with fixed CPAP (≥4 hours per night on 70% of nights) has not adequately treated signs and symptoms of OSA.
- Persistent symptoms or unimproved AHI/RDI in individual currently on fixed 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

### Continuous positive airway pressure (CPAP) or Automatic Positive Airway Pressure (APAP) therapy (SL-4.2.2)

**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 **General Guidelines (SL-1.0)** **Auto-titration of positive airway pressure (APAP) in unattended setting (SL-4.2.1)**
- 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 ≥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 had been 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

**Bi-level positive airway pressure- spontaneous mode (SL-4.2.3)**

**Initiation of HCPCS E0470 PAP Therapy and establishing compliance (ALL):**

- One of the following medical conditions must be documented in the individual's record:
  - Obstructive sleep apnea when (**both):**
    - Diagnosis of OSA as defined in **General Guidelines (SL-1.0)**
    - 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
  - Central sleep apnea diagnosis when (**both):**
    - Valid testing meeting criteria for central sleep apnea as defined in **General Guidelines (SL-1.0)**
    - 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 (**both):**
    - Valid testing meeting criteria for treatment emergent central sleep apnea as defined in **General Guidelines (SL-1.0)**

        - 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.
    - Neuromuscular disease or restrictive thoracic disorder when (**both):**
        - Neuromuscular disease (e.g. amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (e.g. severe kyphoscoliosis, post-thoracoplasty), AND
        - One of the following:
            - Symptoms (orthopnea, dyspnea, morning headache, daytime sleepiness, unrefreshing sleep) with vital capacity <80%
            - An arterial blood gas $PaCO_2$, done while awake and breathing the individual's prescribed $FiO_2$, is ≥45 mmHg
            - End-tidal $CO_2$,transcutaneous $CO_2$, or venous blood gas ≥50 mmHg
            - Sleep oximetry, or sleep testing, demonstrates oxygen saturation ≤88% for ≥5 minutes of nocturnal recording time or ≤90% for ≥5% of the night
            - Vital Capacity (Forced Vital Capacity or Slow Vital Capacity) ≤50% of predicted
            - Maximal inspiratory pressure ≤60 cm of $H_2O$
            - Sniff nasal inspiratory pressure ≤40 cm of water
    - Severe COPD when (**both):**
        - An arterial blood gas $PaCO_2$ is ≥52 mm Hg done while awake and breathing the individual's prescribed $FiO_2$
        - OSA and CPAP treatment have been considered and ruled out (formal sleep testing not required)
    - Obesity hypoventilation syndrome (OHS) defined as:
        - BMI ≥30 $kg/m_2$ plus awake arterial blood gas (ABG), end-tidal $PCO_2$ ($EtPCO_2$), or transcutaneous $PCO_2$ ($TcPCO_2$) with $PCO_2$ ≥45 OR venous blood gas (VBG) showing a $PCO_2$ ≥50 mmHg
        - If ABG, VBG, $EtPCO_2$, or $TcPCO_2$ results are not available, serum bicarbonate ≥27 may be provided as an alternative to determine high risk for OHS
- Other hypoventilation syndrome (defined awake arterial blood gas, end-tidal $PCO_2$ (ET $PCO_2$), or transcutaneous $PCO_2$ with $PCO_2$ ≥45 OR venous blood gas showing a PCO2 ≥50 mmHg) when it is due to **one** of the following:
    - Hypoventilation due to central respiratory drive depression (associated with medication, substance use, or other medical conditions).
    - Hypoventilation due to respiratory system failure other than COPD or neuromuscular disease/thoracic cage abnormalities (for example end–stage interstitial lung disease)
- Sleep Related hypoventilation as defined in **General Guidelines (SL-1.0)**

**Continued HCPCS E0470 therapy after initial 3 months:**

If indication is sleep disordered breathing categorized as OSA, central sleep apnea or treatment emergent central sleep apnea:

- 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

For ALL other indications:

- Individual has been re-evaluated by treating practitioner
- Documentation of continued use, benefit, and medical need

**Replacement Bilevel PAP HCPCS E0470 device**

If indication is sleep disordered breathing categorized as OSA, central sleep apnea or treatment emergent central sleep apnea (all of the following):

- Continued resolution of symptoms and improved AHI/RDI on therapy
- Device had been 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

For ALL other indications:

- Continued resolution of symptoms
- 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

**Bi-level positive airway pressure: spontaneous/timed mode (SL-4.2.4)**

**Initiation of HCPCS E0471 PAP Therapy and establishing compliance (All):**

- One of the following medical conditions must be documented in the individual's record:
  - 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 **PAP - General requirements (SL-4.1)** **General Guidelines (SL-1.0)**
    - 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 **Adaptive Servo Ventilation (ASV) Therapy (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 **General Guidelines (SL-1.0)**
    - 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
  - 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:
  - Symptoms (orthopnea, dyspnea, morning headache, daytime sleepiness, unrefreshing sleep) with vital capacity <80%
  - An arterial blood gas $PaCO_2$, done while awake and breathing the individual's prescribed $FiO_2$, is ≥45 mm Hg
  - End-tidal $CO_2$,transcutaneous $CO_2$, or venous blood gas ≥50
  - Sleep oximetry or sleep testing demonstrates oxygen saturation ≤88% for ≥5 minutes of nocturnal recording time or ≤90% for ≥5% of the night
  - Vital Capacity (Forced Vital Capacity or Slow Vital Capacity) ≤50% of predicted
  - Maximal inspiratory pressure ≤60 cm of $H_2O$
  - Sniff nasal inspiratory pressure ≤40 cm of water

- Severe COPD:
  - An arterial blood gas $PaCO_2$ is ≥52 mm Hg done while awake and breathing the individual's prescribed $FiO_2$
  - OSA and CPAP treatment have been considered and ruled out (formal sleep testing not required)
- Obesity hypoventilation syndrome as defined in **General Guidelines: Site of care for sleep testing requests** when any:
  - Individual was recently hospitalized with acute-on-chronic respiratory failure with persistent awake hypoventilation at the time of discharge
  - Individual has been diagnosed with OSA that is not severe (AHI or RDI <30)
  - Individual has been diagnosed with severe OSA (AHI, RDI ≥30) and has ongoing hypoventilation despite 3 months of compliant CPAP or bilevel HCPCS E0470 use
- Other hypoventilation syndrome (defined awake arterial blood gas, end-tidal $PCO_2$ (ET $PCO_2$), or transcutaneous $PCO_2$ with $PCO_2$ ≥45 OR venous blood gas showing a $PCO_2$ ≥50 mmHg) when it is due to one of the following:
  - Hypoventilation due to central respiratory drive depression (associated with medication, substance use, or other medical conditions)
  - Hypoventilation due to respiratory system failure other than COPD or neuromuscular disease/thoracic cage abnormalities (for example end–stage interstitial lung disease).
- Sleep-related hypoventilation as defined in **General Guidelines (SL-1.0)**

**Continued HCPCS E0471 therapy after initial 3 months:**

If the indication is sleep disordered breathing categorized as OSA, central sleep apnea or treatment emergent central sleep apnea:

- 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

For ALL other indications:

- Individual has been re-evaluated by treating practitioner
- Documentation of continued use, benefit, and medical need

**Replacement HCPCS E0471 device**

If indication is sleep disordered breathing categorized as OSA, central sleep apnea or treatment emergent central sleep apnea (All of the following):

- Continued resolution of symptoms and improved AHI on therapy
- Device had been 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

For all other indications:

- Continued resolution of symptoms
- 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

**Heated and non-heated humidifier (SL-4.2.5)**

**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 therapy
- Device had been 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

**Adaptive servo ventilation (ASV) therapy (SL-4.2.6)**

**Initiation of ASV Therapy (HCPCS E0471) and establishing compliance**

- 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 **PAP - General requirements (SL-4.1) General Guidelines (SL-1.0)**
    - Mild CSA, **or** Moderate to Severe CSA with EF >45%. OR
  - Treatment Emergent Central Sleep Apnea
    - Diagnosis of treatment emergent central sleep apnea as defined in **General Guidelines (SL-1.0)**
  - 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 of discontinued, and
    - Central hypopnea/apneas are >50% of total, and
    - Central apnea index ≥5 per hour.

**Continued ASV therapy HCPCS E0471 after initial 3 months:**

All of the following:

- 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 ASV HCPCS E0471 device**

All of the following:

- Continued resolution of symptoms and improved AHI on therapy
- Device had been 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

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

- 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.

**Continuous PAP, Bilevel PAP, or automatic PAP Loaner Rental (SL-4.2.8)**

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

## Positive airway pressure – accessories and supplies (SL-4.3)

### PAP masks and parts

Combination oral/nasal mask, used with PAP, each (HCPCS A7027):

- Frequency: 1 per 3 months.
- No other PAP mask ordered (i.e., HCPCS A7030, A7034, or A7044)
- Provided data meets compliance criteria (device used ≥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

Oral cushion used with combination oral/nasal mask, replacement only (HCPCS A7028):

- Only compatible with HCPCS A7027 mask.
- Frequency: 2 per month.
- Provided data meets compliance criteria (device used ≥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

Nasal pillows used with combination oral/nasal mask, replacement only, pair (HCPCS A7029):

- Only compatible with HCPCS A7027 mask.
- Frequency: 2 per month.
- Provided data meets compliance criteria (device used ≥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

Full face mask used with PAP, each (HCPCS A7030):

- Frequency: 1 per 3 months.
- No other PAP mask ordered (i.e., HCPCS A7027, A7034, or A7044).
- Provided data meets compliance criteria (device used ≥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

Full face mask interface replacement, each (HCPCS A7031):

- Only compatible with HCPCS A7030 mask.
- Frequency: 2 per month.
- Provided data meets compliance criteria (device used ≥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

Nasal interface (mask or cannula type) used with PAP, each (HCPCS A7034):

- Frequency: 1 per 3 months.
- No other PAP mask ordered (i.e., HCPCS A7027, A7030, or A7044)
- Provided data meets compliance criteria (device used ≥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

Cushion for use on nasal mask interface, replacement only, each (HCPCS A7032):

- Only compatible with HCPCS A7034 mask.
- Frequency: 2 per month.
- Provided data meets compliance criteria (device used ≥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

Nasal pillow for use on nasal cannula type interface, replacement only, pair (HCPCS A7033):

- Only compatible with HCPCS A7034 mask.
- Frequency: 2 per month.
- Provided data meets compliance criteria (device used ≥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

Oral interface used with PAP, each (HCPCS A7044):

- Frequency: 1 per 6 months.
- No other PAP mask ordered (i.e., HCPCS A7027, A7030, or A7034).
- Provided data meets compliance criteria (device used ≥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

Headgear used with PAP, each (HCPCS A7035):

- Frequency: 1 per 6 months.
- Provided data meets compliance criteria (device used ≥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

Chinstrap used with PAP, each (HCPCS A7036):

- Frequency: 1 per 6 months.
- Provided data meets compliance criteria (device used ≥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

**Positive airway pressure tubing**

Tubing with integrated heating element for use with PAP devices, each (HCPCS A4604):

- Frequency: 1 per 3 months.
- No other PAP tubing ordered (i.e., HCPCS A7037).
- Provided data meets compliance criteria (device used ≥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

Tubing used with PAP devices, each (HCPCS A7037):

- Frequency: 1 per 3 months.

- No other PAP tubing ordered (i.e., HCPCS A4604).
- Provided data meets compliance criteria (device used ≥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

**Positive airway pressure device filters**

Filter, disposable, used with PAP devices (HCPCS A7038):

- Frequency: 2 per 1 month.
- Provided data meets compliance criteria (device used ≥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

Filter, non-disposable, used with PAP devices (HCPCS A7039):

- Frequency: 1 per 6 months.
- Provided data meets compliance criteria (device used ≥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

**Miscellaneous positive airway pressure supplies**

Exhalation port with or without swivel used with accessories for positive airway devices, replacement only (HCPCS A7045):

- Frequency: 1 per 6 months.
- Provided data meets compliance criteria (device used ≥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

Water chamber for humidifier, used with positive airway pressure device, replacement, each (HCPCS A7046):

- Frequency: 1 per 6 months.
- Provided data meets compliance criteria (device used ≥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

# Oral Appliances for the Treatment of Obstructive Sleep Apnea (SL-9)

**SL.TX.108.A**
**v1.0.2024**

Coding

**Treatment codes for oral appliances**

| 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 |
| Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment | K1027 |

### Custom-fit oral appliances (SL-9.1)

### Custom-fit oral appliances - indications (SL-9.1.2)

Custom fit oral appliances are indicated when **all** of the following criteria 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 ≥5 and <15 events per hour over the duration of the sleep test 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 ≥15 per hour over the duration of the sleep test
- 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 (after a discussion of treatment options with the treating physician) AND AHI, RDI, or REI is <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).

**Replacement custom fit oral appliances (SL-9.1.3)**

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

## Background and supporting information

### 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 are more

effective for symptom improvement, compliance and tolerance compared to ready-made appliances.

**Pediatric Oral Appliances (SL-9.2)**

- 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

# Pediatric Guidelines

# Pediatric Sleep Guidelines (SL-3)

**SL.ST.103.A**
**v1.0.2024**

## Polysomnography in pediatrics (SL-3.1)

### General information

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 due to lack of $CO_2$ monitoring and arousal monitoring among other factors.

### Pediatric definitions

Pediatric definitions for apneas and hypopneas differ compared with adults

- **Pediatric apnea** — Drop in peak signal excursion by ≥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 ≥2 breaths.

  There is a >3% oxygen desaturation from pre-event baseline or the event is associated with an arousal.

### 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:
    - Uncomplicated typical disorders of arousal (eg: sleep terrors, sleep walking), nightmares, sleeptalking, or bruxism in the absence of concern for safety, sleep disordered breathing, or nocturnal seizures.
    - 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.

## Proper uses of polysomnography in pediatrics

### Initial polysomnography for diagnosis

Overnight polysomnography (CPT® 95782 for children less than 6 years of age, CPT® 95810 for children 6 years of age or greater

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 or concern for sleep disordered breathing as evidenced by symptoms which may include:
  - Restless or disturbed sleep
  - Behavioral disturbance, or learning disorders including deterioration in academic performance, hyperactivity, or attention deficit disorder
  - Unexplained enuresis
  - Frequent awakenings
  - Witnessed apnea
  - Labored breathing during sleep
  - Headaches on awakening
  - Hypertension
  - Sleep enuresis in children older than 5 years old
  - 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
  - Documentation of one of the following, with provider concern that finding is related to obstructive sleep apnea:
    - Failure to thrive or growth impairment
    - Underweight or Overweight
    - Tonsillar hypertrophy with symptoms of OSA (any of the symptoms listed above)
    - Adenoidal facies with symptoms of OSA (any of the symptoms listed above)
- While limited data exists on the performance of split night testing (CPT® 95783 for children less than 6 years of age, CPT® 95811 for children 6 years of age or greater) in the pediatric population, recent data has demonstrated the feasibility of split night testing in children. Split night testing may be appropriate in the pediatric population at the discretion of the treating provider.

### Initial polysomnography for positive airway pressure (PAP) titration

Overnight polysomnography for positive airway pressure (PAP) titration (CPT® 95783 for children less than 6 years of age, CPT® 95811 for children 6 years of age

or greater) in children with obstructive sleep apnea syndrome in a sleep lab setting for children is considered medically necessary in any of the following circumstances

- Diagnosis of obstructive sleep apnea
  - 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
      - A pattern of obstructive hypoventilation defined as at least 25% of total sleep time with hypercapnia (PaCO2 > 50 mm Hg) in association with one or more of the following: snoring, flattening of the inspiratory nasal pressure waveform, paradoxical thoracoabdominal motion

**Repeat polysomnography for diagnosis**

- Repeat polysomnography to assess for OSA (CPT® 95782 or 95810) is indicated when one of the following is present:
  - 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
  - A child with previously diagnosed obstructive sleep apnea treated with non PAP therapy (eg medication management, watchful waiting, oral appliance, rapid maxillary expansion) who has ongoing symptoms (such as snoring) despite treatment
  - 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
  - Residual obstructive sleep apnea post-adenotonsillectomy when all of the following criteria are met
    - Residual symptoms of OSA are present in children with mild OSA preoperatively
    - 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

### Special scenarios

Overnight diagnostic and/or split/ titration polysomnography (CPT® 95782/ 95783 for children less than 6 years of age, CPT® 95810/ 95811 for children 6 years of age or greater):

- A pediatric diagnostic sleep study can be performed as a screening for OSA in children with Down syndrome even without symptoms of obstructive sleep apnea
- Congenital central alveolar hypoventilation syndrome or sleep related hypoventilation due to neuromuscular disorders or chest wall deformities
- Atypical, frequent, or potentially injurious parasomnias
- Differentiate a parasomnia from sleep-related epilepsy when the initial clinical evaluation and standard EEG are inconclusive
- 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
- Polysomnography when there is clinical evidence of a sleep related breathing disorder in infants who have experienced an Apparent Life-Threatening Event (ALTE) or a Brief Resolved Unexplained Event (BRUE)
- Primary central sleep apnea of infancy (when not explained by another sleep disorder, medical disorder, or medications)
- PSG as part of the evaluation prior to decannulation for children treated with tracheostomy for sleep related breathing disorders
- Periodic evaluation with polysomnography to adjust ventilator settings
- Suspected nocturnal seizure activity
- Suspected periodic limb movement disorder (when other medical disorders have been ruled out)

### Repeat polysomnography for positive airway pressure (PAP) titration

Repeat PAP titration (CPT® 95783 or 95811) is indicated 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 PAP

**Note** Narcolepsy or idiopathic hypersomnia CPT® 95810 and 95805 should be performed in conjunction with a multiple sleep latency test) See **PSG and Multiple Sleep Latency testing (excessive sleepiness)(SL-2.3)**

## CPAP in pediatrics (SL-3.2)

- 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

# Program Exclusions

# Sleep Apnea Treatment Program Exclusions (SL-5)

**SL.TXS.105.A**
**v1.0.2024**

**Experimental, investigational, or unproven (SL-5.1)**

- 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

**Note** The list below is not comprehensive

- 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:
  - Bongo Rx
  - ULTepap
  - iNAP
  - eXciteOSA (HCPCS E0492 and E0493)
  - Somnera
  - MATRx oral appliance test
  - Electronic positional obstructive sleep apnea treatment with sensor (HCPCS E0530)
- SleepTesting exclusions:
  - Actigraphy (CPT® 95803)
    - Actigraph devices, worn on the wrist, record movement and utilize rest activity patterns to estimate sleep parameters.
    - While actigraphy is performed as part of certain home sleep apnea testing devices, actigraphy performed as a stand-alone study is considered not medically necessary.

**Durable medical equipment device and supply exclusions (SL-5.2)**

- 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



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- Due to the presence of more specific codes for PAP equipment, and supplies needing scheduled replacement, E1399 cannot be approved for routinely replaced PAP machine and parts. E1399 may be approved for parts required in CPAP repair when the DME supplier specifies what needs to be repaired and what replacement parts (ie, blower motor) are needed. Note that K0739 and K0740 which refer to labor costs and rental costs during the repair period do not require approval

**PAP-NAP (SL-2.7)**

**CPT® 95807-52**

PAP-NAP, a daytime abbreviated cardiorespiratory sleep study, was developed as a means of improving adherence to positive airway pressure in patients 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 patients 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 not covered procedure

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

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# General References

**SL**
**v1.0.2024**


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# Questionnaires (SL-8)

**SL.AD.102.A**
**v1.0.2024**

### Epworth Sleepiness Scale (SL-8.1)

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. 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.

| Situation | Chance of dozing or sleeping |
|---|---|
| Sitting and reading | |
| Watching TV | |
| Sitting inactive in a public place | |
| Being a passenger in a motor vehicle for an hour or more | |
| Lying down in the afternoon | |
| Sitting and talking to someone | |
| Sitting quietly after lunch (no alcohol) | |
| Stopped for a few minutes in traffic while driving | |
| **Total Epworth Score (add up the points)** | |



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### The Berlin Questionnaire (SL-8.2)

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

### Berlin Questionnaire scoring

#### Category 1: Items 1-5

- Item 1: if **Yes**, assign 1 point
- Item 2: if **c** or **d**, assign 1 point

- Item 3: if **a** or **b**, assign 1 point
- Item 4: if **a**, assign 1 point
- Item 5: if **a** or **b**, 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**, assign 1 point
- Item 7: if **a** or **b**, assign 1 point
- Item 8: if **a**, assign 1 point
- Add points. Category 2 is positive if the total score is 2 or more points.

**Category 3**

Category 3 is positive if the answer to Item 10 is Yes **OR** if the BMI of the patient is greater than 30 kg/m$^2$.

**High risk**

2 or more categories where the score is positive.

**Low risk**

1 or no categories where the score is positive.

**STOP BANG Questionnaire (SL-8.3)**

**The 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 the 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 35 kg/m$^2$

**Age**

6. Age over 50 years old?

**Neck circumference**

7. Neck circumference 16 inches/40 cm or greater?

**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.

**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
- Answering “yes” to 5 or more questions

**Insomnia Severity Index (SL-8.4)**

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.

For each question, please **circle** the number that best describes your answer.

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 and interpretation**

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

**Total score categories**

The score categories are as follows:

- **0-7** — No clinically significant insomnia
- **8-14** — Sub threshold insomnia
- **15-21** — Clinical insomnia (moderate severity)
- **22-28** — Clinical insomnia (severe)



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