

CIGNA MEDICAL COVERAGE POLICIES

Sleep Disordered Breathing Diagnosis and Treatment Guidelines

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EviCore
By EVERNORTH®

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.

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

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General Information

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Abbreviations for Sleep Guidelines

SL.GG.104.A

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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-adjusting positive airway pressure
ASV	Adaptive servo-ventilation
BMI	Body mass index (body weight divided by the square of the height)
BPAP	Bi-level positive airway pressure
CPAP	Continuous positive airway pressure
CSA	Central Sleep Apnea
EDS	Excessive daytime sleepiness
EtPCO ₂	End-tidal PCO ₂
HCPCS	Healthcare Common Procedural Coding System (Level II alphanumeric codes used to report services not included in CPT®)
HGNS	Hypoglossal Nerve Stimulation
HSAT	Home sleep apnea testing
IDTF	Independent Diagnostic Testing Facilities
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
MSLT	Multiple Sleep Latency Test

Abbreviation	Full name
MWT	Maintenance of Wakefulness Test
OA	Oral appliance
OHS	Obesity Hypoventilation Syndrome
OSA	Obstructive sleep apnea
PAP	Positive airway pressure
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
VBG	Venous Blood Gas

General Guidelines (SL-1.0)

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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 individual 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 medically necessary, without clear rationale that fulfills guideline criteria.

Clinical Evaluation

A current and comprehensive clinical evaluation by the treating medical provider (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 medically necessary.

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 **OR**
 - Sufficient history as to allow completion of a sleep questionnaire **OR**
 - Results of a sleep questionnaire or sleep questionnaire proxy
- Physical examination
- Relevant diagnostic studies done at any time in the past (such as previous sleep studies, overnight pulse oximetry, and cardiac and pulmonary testing)
- Relevant lab results (ABG or serum bicarbonate performed within one year)

Sleep-Related Signs and Symptoms

- Sleep testing is not medically necessary for the evaluation of insomnia in the absence of additional symptoms of another sleep fragmenting disorder such as obstructive sleep apnea or periodic limb movement disorder.
- Sleep testing of asymptomatic individuals prior to bariatric surgery is not medically necessary.
- A description of sleep-related signs and symptoms that are relevant to the suspected diagnosis is required before sleep testing can be considered medically necessary.

If sleep-related breathing disorders are suspected, **ONE or MORE** of the following should be described:

- Unexplained excessive daytime sleepiness or fatigue leading to impaired sleep-related quality of life
- Sleep-related snoring, snorting, choking, or gasping
- Sleep-related witnessed apneas
- The subjective sensation of awakening with breath-holding, shortness of breath, gasping, coughing or choking
- Prior diagnosis of OSA with a description of response to therapy
- Resistant hypertension defined as uncontrolled blood pressure despite the use of ≥ 3 antihypertensive agents of different classes
- Refractory hypertension defined as uncontrolled blood pressure despite use of ≥ 5 antihypertensive agents of different classes
- 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 or transient ischemic attack in the last 6 months
- Additional symptoms of sleep disordered breathing may include:
 - Nonrestorative sleep
 - Morning headaches
 - Insomnia
 - Nocturia
 - Impaired daytime concentration
 - Impaired memory
 - Impaired driving
 - Impaired social functioning
 - Impaired work-related productivity

Sleep Questionnaires

Sleep questionnaires are commonly used to help formulate an individual's likelihood of having sleep-related disease. These validated questionnaires or tools include (but are not limited to):

- STOP BANG Questionnaire
- Epworth Sleepiness Scale
- Berlin Questionnaire
- Insomnia Severity Index
- Sleep log (e.g. sleep diary, personal wearable technology)
- Actigraphy

Note: 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:

- History and physical elements are provided that would permit calculation of a validated questionnaire or tool
- Previous diagnosis of OSA confirmed in record by prior testing

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)

Relevant Diagnostic Studies Done in the Past (Prior Sleep Studies)

- 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 individual for a copy of prior test results.

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. A treating medical provider is defined as a licensed MD, DO, nurse practitioner, clinical nurse specialist, or physician assistant.

Health Equity Consideration

Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which individuals are born, grow, live, work, and age. Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Definitions: Sleep-Related Breathing Disorders

Note: For pediatric definitions, see **Polysomnography in pediatrics (SL-3.1)**.

For the purpose of this guideline, sleep-related breathing disorders are defined by a positive diagnosis by valid sleep testing with **ONE OR MORE** of the following sleep-related breathing disorders:

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

- The predominantly obstructive apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) on a PSG, or the apnea-hypopnea index (AHI) or respiratory event index (REI) on a HSAT is ≥ 15 events per hour; **OR**
- The predominantly obstructive apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) on a PSG, or the apnea-hypopnea index (AHI) or respiratory event index (REI) on a HSAT is ≥ 5 and < 15 events per hour with documentation of **ANY** of the following:
 - 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) is defined as ALL of the following:

- 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 apneas plus central hypopneas are $>50\%$ of the total number of apneas and hypopneas

Central sleep apnea (CSA) with Cheyne-Stokes Breathing is defined as ALL of the following:

- 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
- Central apnea and/or central hypopnea index ≥ 5 per hour
- Central apneas plus central hypopneas 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 is defined as ALL of the following:

- 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 non-restorative sleep
 - Awakening short of breath
 - Witnessed apneas
- The predominately obstructive apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) on a PSG, or the apnea-hypopnea index (AHI) or respiratory event index (REI) on an HSAT is ≥ 5 events per hour.
- PSG during use of positive airway pressure without a backup rate shows ALL of the following:
 - Significant resolution of obstructive events
 - Central apnea plus central hypopnea index ≥ 5 per hour

- Central apneas plus central hypopneas are >50% of the total number of apneas and hypopneas

Sleep-related hypoventilation is defined as when EITHER of the following occur during sleep:

- Increase in arterial PCO₂, transcutaneous PCO₂, or end-tidal PCO₂ to a value >55mmHg for ≥10 minutes
- There is a ≥10mmHg increase in arterial PCO₂, transcutaneous PCO₂, or end-tidal PCO₂ during sleep (compared to awake supine value) to a value >50mmHg for ≥10 minutes

At Home Versus In Lab Sleep Testing Requests

Note:

For more information on technical policy requirements of HSAT and PSG as well as on scoring, see **Practice Notes (SL-1.1)**.

Note: For pediatric sleep study requests, see **Polysomnography in pediatrics (SL-3.1)**.

HSAT is medically necessary when clinical evaluation leads to concern for OSA in adults.

PSG (in lab full night diagnostic sleep study **OR** in lab split night sleep study) rather than HSAT is medically necessary when clinical evaluation leads to concern for sleep disordered breathing **AND ONE** of the following:

- Results of a validated questionnaire (STOP BANG or Berlin), or history and physical elements that would permit completion of the validated questionnaire, 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.
- Prior HSAT was non-diagnostic, defined as AHI < 5 scored with 3% hypopnea rule (per submitted report)
- Prior HSAT was technically inadequate due to a lack of at least 4 hours of adequate oximetry and flow data (per submitted report) .

PSG (in lab full night diagnostic sleep study **OR** in lab split night sleep study **OR** in lab full night PAP titration) is medically necessary when at least **ONE** of the following suspected or known co-morbid diagnoses or clinical scenarios is documented:

- **Obesity with ONE of the following:**
 - BMI ≥ 45
 - BMI $\geq 30\text{kg/m}_2$ plus **EITHER** awake arterial blood gas (ABG), end-tidal PCO₂ (EtPCO₂), or transcutaneous PCO₂ (TcPCO₂) with PCO₂ ≥ 45 **OR** venous blood gas (VBG) showing a PCO₂ $\geq 50\text{mmHg}$
 - BMI $\geq 30\text{kg/m}_2$ plus serum bicarbonate ≥ 27 with stated concern for obesity hypoventilation syndrome (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 PO₂ < 60 or PCO₂ ≥ 45
 - Documented pulmonary function tests demonstrating moderate to severe obstruction with forced expiratory volume in one second (FEV1) $\leq 69\%$ 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 cognitive or 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) due to known risk factor(s) described in clinical notes
- **Moderate to severe congestive heart failure:**
 - With documented pulmonary congestion or known left ventricular ejection fraction $< 45\%$
- **Atrial fibrillation:**
 - Atrial fibrillation alone, without an additional comorbid diagnosis, does not meet the criteria for an in-lab sleep study.
- **Pulmonary HTN:**
 - With documentation of a mean pulmonary artery pressure of $> 20\text{mmHg}$ 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 $\geq 2.9\text{m/s}$ **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 $> 105\text{msec}$ and/or midsystolic notching, pulmonary regurgitation velocity $> 2.2\text{m/sec}$)

- **Other critical illness that would prevent the individual from using the HSAT equipment**
 - As documented in the individual's 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 as demonstrated by ONE of the following:**
 - Daily use of long-acting opioids (e.g., Methadone®, Suboxone®, Fentanyl patch®, Oxycontin®, MS Contin®, extended release opioid formulations)
 - **BOTH** of the following:
 - Daily use of opioid
 - Stated concern for presence of central sleep apnea
- **Titration study (in lab full night PAP titration, only)** where bi-level positive airway pressure (HCPCS E0470 or E0471) is specifically requested for **EITHER** of the following:
 - CPAP or APAP has already been tried and proven ineffective or not tolerated due to pressure discomfort for an individual with OSA **OR**
 - The individual has been diagnosed with **ONE** of the following:
 - Central sleep apnea with or without Cheyne-Stokes Breathing
 - Treatment emergent central sleep apnea
 - Neuromuscular or restrictive thoracic disease
 - Severe COPD (arterial blood gas PaCO_2 is $\geq 52\text{mmHg}$ done while awake and breathing the individual's prescribed FiO_2)
 - Obesity hypoventilation syndrome (OHS) defined as BMI $\geq 30\text{kg/m}^2$ plus awake arterial blood gas (ABG), end-tidal PCO_2 (EtPCO_2), or transcutaneous PCO_2 (TcPCO_2) with $\text{PCO}_2 \geq 45$ OR venous blood gas (VBG) showing a $\text{PCO}_2 \geq 50\text{mmHg}$
 - Other Hypoventilation (defined awake arterial blood gas, end-tidal PCO_2 (EtPCO_2), or transcutaneous PCO_2 with $\text{PCO}_2 \geq 45$ OR venous blood gas showing a $\text{PCO}_2 \geq 50\text{mmHg}$)
 - Sleep-related hypoventilation as defined in **General Guidelines (SL-1.0)**.
- **Sleep related hypoxemia (in lab full night PAP titration, only)**
 - At least **ONE** of the following:
 - 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.

- In the presence of obesity, a diagnosis of obesity hypoventilation syndrome (OHS) must be confirmed as defined by BMI $\geq 30\text{kg/m}^2$ plus **EITHER** awake arterial blood gas (ABG), end-tidal PCO₂ (EtPCO₂), or transcutaneous PCO₂ (TcPCO₂) with PCO₂ ≥ 45 **OR** venous blood gas (VBG) showing a PCO₂ $\geq 50\text{mmHg}$
- **Documented OSA with unsuccessful APAP attempt (in lab full night PAP titration, only)**
 - Therapy trial of at least 30 days duration and **ANY of the following**:
 - APAP machine download with AHI $\geq 5/\text{hr}$ with ongoing symptoms of OSA
 - APAP use ≥ 4 hours per night on 70% of nights with continued symptoms
 - APAP intolerance despite DME or treating medical provider intervention which can include mask fittings, different masks, pressure changes or desensitization.
- **Titration study (in lab full night PAP titration, only) is medically necessary for ANY of the following sleep-related breathing disorders suggested on prior HSAT or diagnosed on prior PSG (as defined in the General Guidelines (SL-1.0)):**
 - Central sleep apnea
 - Central sleep apnea with Cheyne-Stokes Breathing
 - Treatment emergent central sleep apnea
- **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.
 - Polysomnography is not medically necessary for typical disorders of arousal (including but not limited to sleep terrors, confusional arousals, sleep walking, sleep-related eating disorder), recurrent isolated sleep paralysis, nightmares, exploding head syndrome, sleep-related hallucinations, sleep-related urologic dysfunction, sleep talking, sleep-related bruxism, or sleep starts (hypnic jerks) in the absence of stated concern for safety, or nocturnal seizures.
 - In the absence of comorbidities indicated in **General Guidelines (SL 1.0)** (At home versus in lab sleep testing requests), individuals who are undergoing initial diagnostic testing when there is a clinical suspicion of OSA should be evaluated for OSA with an HSAT when evaluating an uncomplicated parasomnia.

Note:

See **Polysomnography in pediatrics (SL-3.1)** for parasomnias in pediatric patients.

- **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 impaired daytime functioning (e.g., hypersomnia) not caused by another sleep disorder (such as untreated OSA, RLS, narcolepsy, REM sleep disorder), medical disorder, or mental disorder.
 - 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) (At home versus in lab sleep testing requests)**, individuals who are undergoing initial diagnostic testing when there is a clinical suspicion for OSA should be evaluated for obstructive sleep apnea with an HSAT before a diagnosis of PLMD is considered.
- **Suspected narcolepsy or idiopathic hypersomnia** with MSLT

Note: See **PSG and MSLT for Suspected Narcolepsy or Idiopathic Hypersomnia (SL-2.3)**

Background and Supporting Information

Serum bicarbonate ≥ 27 has a variable sensitivity of 86-92% and specificity of 50-90% with low positive predictive value of 69% and high negative predictive value of 96% for identifying obesity hypoventilation syndrome (OHS). A serum bicarbonate level < 27 mmol/L effectively rules out hypercapnea, irrespective of the prevalence of OHS. The American Thoracic Society (ATS) recommends using a serum bicarbonate level < 27 mmol/L to exclude the diagnosis of OHS in obese patients when suspicion for OHS is low to moderate (pretest probability $< 20\%$) but to measure the PaCO_2 in patients strongly suspected of having OHS. When pretest probability for OHS is low to moderate and the serum bicarbonate is ≥ 27 mmol/L, ATS recommends considering measuring PaCO_2 to confirm or rule out the diagnosis of OHS.

Though CSA is an independent predictor of incident atrial fibrillation and is found in higher prevalence in established atrial fibrillation, CSA is much less common than OSA in individuals with atrial fibrillation. Therefore, atrial fibrillation on its own is not an indication for an in-lab PSG.

Sleep apnea is prevalent after strokes and transient ischemic attacks (TIAs) with lower sleepiness and BMI as compared to the non-stroke/TIA population. The predominant sleep apnea type is obstructive. Dominant central apneas occur in much lower frequency (6% per a cross-sectional survey). Type, severity, and location of stroke do not correlate clearly with central apnea severity. Severity of both OSA and CSA

can reduce during the first six months post stroke/TIA. HSATs have been shown to be feasible and accurate in stroke patients during in-hospital rehabilitation.

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.

Necessity for preoperative sleep testing prior to bariatric surgery testing is based on these guidelines.

Practice Notes (SL-1.1)

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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 and 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
 - Facilities also typically record body position (with video) and snoring (via microphone).
- Calculations of the Apnea Hypopnea Index (AHI) and Respiratory Disturbance Index (RDI) 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

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Sleep Diagnostics-Coding (SL-1)

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The inclusion of any code in the below tables does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

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	G0398	Minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation
Home sleep test (HSAT) with type III portable monitor, unattended	G0399	Minimum of 4 channels: 2 respiratory movement/ airflow, 1 ECG/heart rate, and 1 oxygen saturation
Home sleep test (HSAT) with type IV portable monitor, unattended	G0400	Minimum of 3 channels Device type (airflow or peripheral arterial tone) not specified in HCPCS description

PSG procedure codes for unattended sleep studies

Unattended sleep studies	CPT®	Channels
Sleep study, unattended, simultaneous recording	95800	Minimum of 4 channels: heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time.
Sleep study, unattended, simultaneous recording	95801	Minimum of 3 channels: minimum of heart rate, oxygen saturation, and respiratory analysis (e.g., by airflow or peripheral arterial tone)
Sleep study, unattended, simultaneous recording Do not report CPT® 95806 in conjunction with any of the following codes: CPT® 93041-93229, 93268-93272, or 95800-95801	95806	Minimum of 4 channels: heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement)

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 (MSLT) or Maintenance of Wakefulness Testing (MWT), recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness. - Multiple sleep latency testing (MSLT) is performed prior to treatment when the requesting physician suspects narcolepsy. - MSLT must be requested with a facility sleep study performed the night before the CPT® 95805 (CPT® 95810 or CPT® 95811). CPT® 95805 is used to report MSLT or MWT - 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 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. CPT® 95810 is used to report in lab full night diagnostic sleep study - CPT® 93152 is used to report interrogation and programming of implanted phrenic nerve stimulator system during polysomnography (CPT® 95810)	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 • CPT® 95811 is used as EITHER an in lab 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 in lab full night 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. • CPT® 95782 is used to report an in lab full night diagnostic sleep study	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. • CPT® 95783 is used to report an in lab full night PAP titration	95783

Initial Sleep Diagnostic and Treatment Testing (SL-2.1)

SL.ST.200.A

v2.0.2026

Note: For more information on technical policy requirements of HSAT and PSG as well as on scoring, see [Practice Notes \(SL-1.1\)](#)

Note:

For pediatric sleep study requests, see [Polysomnography in Pediatrics \(SL-3.1\)](#).

Home Sleep Apnea Testing (HSAT)

- **HSAT** is medically necessary when clinical evaluation leads to concern for OSA in adults.

In-Laboratory Polysomnography- Sleep Disordered Breathing

PSG (in lab full night diagnostic sleep study **OR** in lab split night sleep study rather than HSAT is medically necessary when clinical evaluation leads to concern for sleep disordered breathing **AND ONE** of the following:

- Results of a validated questionnaire (STOP BANG or Berlin), or history and physical elements that would permit completion of the validated questionnaire, 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.
- Prior HSAT was non-diagnostic, defined as AHI < 5 scored with 3% hypopnea rule (per submitted report)
- Prior HSAT was technically inadequate due to a lack of at least 4 hours of adequate oximetry and flow data (per submitted report).

PSG (in lab full night diagnostic sleep study **OR** in lab split night sleep study **OR** in lab full night PAP titration) is medically necessary when at least **ONE** of the following suspected or known co-morbid diagnoses or clinical scenarios is documented:

- **Obesity with ONE of the following:**
 - BMI ≥45

- BMI $\geq 30\text{kg/m}^2$ plus **EITHER** awake arterial blood gas (ABG), end-tidal PCO₂ (EtPCO₂), or transcutaneous PCO₂ (TcPCO₂) with PCO₂ ≥ 45 **OR** venous blood gas (VBG) showing a PCO₂ ≥ 50 mmHg
- BMI $\geq 30\text{kg/m}^2$ plus serum bicarbonate ≥ 27 with stated concern for obesity hypoventilation syndrome (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 PO₂ < 60 or PCO₂ > 45
 - Documented pulmonary function tests demonstrating moderate to severe obstruction with forced expiratory volume in one second (FEV1) $\leq 69\%$ of predicted
- **Documented neurological disease:**
 - The neurological disease precludes the individual's ability to perform home sleep apnea testing due to cognitive or 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) due to known risk factor(s) described in clinical notes
- **Moderate to severe congestive heart failure:**
 - With documented pulmonary congestion or known left ventricular ejection fraction $< 45\%$
- **Atrial fibrillation:**
 - Atrial fibrillation alone, without an additional co-morbid diagnosis, does not meet the criteria for an in-lab sleep study.
- **Pulmonary HTN:**
 - With documentation of a mean pulmonary artery pressure of $> 20\text{mmHg}$ 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 $\geq 2.9\text{m/s}$ **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 >105msec and/or mid-systolic notching, pulmonary regurgitation velocity >2.2m/sec)

- **Other critical illness that would prevent the individual from using the HSAT equipment:**
 - As documented in the individual's record
- **Chronic severe insomnia:**
 - Documented by validated questionnaire (Insomnia Severity Index ≥ 22).
 - See **Questionnaires (SL 8)** for details regarding ISI.
- **Chronic daily opioid use as demonstrated by ONE of the following:**
 - Daily use of long acting opioids (e.g., Methadone®, Suboxone®, Fentanyl patch®, Oxycontin®, MS Contin®, extended-release formulations)
 - BOTH of the following:
 - Daily use of opioid
 - Stated concern for presence of central sleep apnea
- **Titration Study:**
 - Titration study (in lab full night PAP titration, only) where bilevel positive airway pressure (HCPCS E0470 or E0471) are specifically requested for **EITHER** of the following:
 - CPAP or APAP has already been tried and proven ineffective or not tolerated due to pressure discomfort for an individual with OSA **OR**
 - The individual has been diagnosed with **ONE** of the following:
 - Central sleep apnea
 - Central sleep apnea with Cheyne-Stokes Breathing
 - Treatment emergent central sleep apnea
 - Neuromuscular or restrictive thoracic disease
 - Severe COPD (arterial blood gas PaCO_2 is $\geq 52\text{mmHg}$ done while awake and breathing the individual's prescribed FiO_2)
 - Obesity hypoventilation syndrome (OHS) defined as BMI $\geq 30\text{kg/m}^2$ plus awake arterial blood gas (ABG), end-tidal PCO_2 (EtPCO_2), or transcutaneous PCO_2 (TcPCO_2) with $\text{PCO}_2 \geq 45$ **OR** venous blood gas (VBG) showing a $\text{PCO}_2 \geq 50\text{mmHg}$
 - Other hypoventilation (defined awake arterial blood gas, end-tidal PCO_2 (ET PCO_2), or transcutaneous PCO_2 with $\text{PCO}_2 \geq 45$ **OR** venous blood gas showing a $\text{PCO}_2 \geq 50\text{mmHg}$)
 - Sleep-related hypoventilation as defined in **General Guidelines (SL-1.0)**.
- **Sleep related hypoxemia (in lab full night PAP titration, only)**

- At least **ONE** of the following:
 - 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 $\leq 88\%$ lasting a minimum of 5 total minutes in the absence of apneas or hypopneas.
 - In the presence of obesity, a diagnosis of obesity hypoventilation syndrome (OHS) must be confirmed as defined by defined by BMI $\geq 30\text{kg/m}^2$ plus EITHER awake arterial blood gas (ABG), end-tidal PCO_2 (EtPCO_2), or transcutaneous PCO_2 (TcPCO_2) with $\text{PCO}_2 \geq 45$ OR venous blood gas (VBG) showing a $\text{PCO}_2 \geq 50\text{mmHg}$.
- **Documented OSA with unsuccessful APAP attempt (in lab full night PAP titration, only)**
 - Therapy trial of at least 30 days duration and **ANY** of the following:
 - APAP machine download with $\text{AHI} \geq 5/\text{hr}$ with ongoing symptoms of OSA
 - APAP use ≥ 4 hours per night on 70% of nights with continued symptoms
 - APAP intolerance despite DME or treating medical provider intervention which can include mask fittings, difference masks, pressure changes or desensitization.
- **Titration study (in lab full night PAP titration, only) is medically necessary for ANY of the following sleep-related breathing disorders suggested on prior HSAT or diagnosed on prior PSG (as defined in General Guidelines [SL-1.0]):**
 - Central sleep apnea
 - Central sleep apnea with Cheyne-Stokes Breathing
 - Treatment emergent central sleep apnea

In-Laboratory Polysomnography - Other Suspected Sleep Disorders

In lab full night diagnostic sleep study **OR** in lab split night sleep study **OR** in lab full night PAP titration study is medically necessary 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.
 - Polysomnography is not medically necessary for typical disorders of arousal (including but not limited to sleep terrors, confusional arousals, sleep walking, sleep-related eating disorder), recurrent isolated sleep paralysis, nightmares,

exploding head syndrome, sleep-related hallucinations, sleep-related urologic dysfunction, sleep talking, sleep-related bruxism or sleep starts (hypnic jerks) in the absence of stated concern for safety or nocturnal seizures.

- In the absence of comorbidities indicated in **General Guidelines (SL1.0 At home versus in lab sleep testing requests)**, individuals who are undergoing initial diagnostic testing when there is a clinical suspicion of OSA, should be evaluated for OSA with an HSAT when evaluating an uncomplicated parasomnias.

Note:

See **Polysomnography in pediatrics (SL-3.1)** for parasomnias in pediatric patients.

-
- **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 impaired daytime functioning (e.g., hypersomnia) not caused by another sleep disorder (such as untreated OSA, RLS, narcolepsy, REM sleep disorder), medical disorder, or mental disorder.
 - 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)** (at home versus in lab sleep testing requests), individuals who are undergoing initial diagnostic testing when there is a clinical suspicion of OSA should be evaluated for obstructive sleep apnea with an HSAT before a diagnosis of PLMD is considered.

- **Note:**

See **PSG and MSLT for Suspected Narcolepsy or Idiopathic Hypersomnia (SL-2.3)**

Split Night Study or Two Night Study

Split night study

- Split night study (in lab split night sleep study) is a single-night PSG + PAP trial, and typically is medically necessary if **BOTH** of the following are met:
 - Apnea Hypopnea Index (AHI) is ≥ 15 /hr during ≥ 2 hours of recording time on the diagnostic PSG
 - ≥ 3 hours are available for PAP titration

Note: Split night study (in lab split night sleep study) 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. Split night study (in lab split night sleep study) 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.

Titration study after attempted split night study

- In some cases, a split night study cannot be completed because the above criteria are not met
 - The first night study that met criteria for a sleep-related breathing disorder as defined in **General Guidelines (SL-1.0) Definitions** was performed as a diagnostic study (in lab full night diagnostic study)
 - Necessity of a second night PAP titration (in lab full night PAP titration) versus immediate treatment with E0601 APAP is determined by **General Guidelines (SL-1.0): At home versus sleep testing requests**.

PSG and Multiple Sleep Latency Testing for Suspected Narcolepsy or Idiopathic Hypersomnia (SL-2.3)

SL.ST.203.A

v2.0.2026

In lab overnight sleep study (PSG) followed by multiple sleep latency test (MSLT) – medical necessity criteria

- 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): At home versus in lab sleep testing requests.**
- MSLT must immediately follow a PSG
- MSLT cannot follow a split night or a PAP titration study where the plan is to adjust treatment settings
- Testing is medically necessary for suspected narcolepsy or idiopathic hypersomnia when ALL of the following are met:
 - 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
 - Excessive sleepiness is not better explained by ANY of the following:
 - OSA or other sleep disordered breathing
 - Circadian rhythm sleep-wake disorder
 - Insomnia
 - Inadequate sleep hygiene
 - Periodic limb movement disorder
 - Medication/substance use or withdrawal
 - Mental Disorder
 - Medical Disorder
 - Sufficient sleep must be demonstrated on most days for at least 3 months as defined by ONE of the following:
 - ≥7 hours per 24 hours for age ≥18 years
 - ≥8 hours per 24 hours for age 13-17 years

- ≥9 hours per 24 hours for age 6-12 years
- If OSA or other types of sleep disordered breathing is present on diagnostic testing **ALL** of the following must be met:
 - Therapy must be initiated prior to consideration of MSLT
 - MSLT is not requested to assess efficacy of PAP therapy for OSA or other types of sleep disordered breathing.
 - PSG (either CPT® 95810 or 95811) and MSLT should be done on optimal treatment settings for OSA or other types of sleep disordered breathing.
 - 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 **ALL** of the following:
 - PAP download shows AHI <5/hour
 - Currently using PAP ≥4 hours per night on 70% of nights during a consecutive thirty (30) day period 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 or other types of sleep disordered breathing, optimal efficacy and adherence has been achieved by demonstration of **ALL** of the following:
 - Efficacy confirmed on sleep testing where AHI <5/hour
 - Self-reported adequate use
 - Therapy has resolved symptoms of increased upper airway resistance (i.e., eliminated snoring)
- If repeat testing for suspected narcolepsy or idiopathic hypersomnia is requested, PSG followed by MSLT is medically necessary when EITHER of the following:
 - Previous testing did not confirm the diagnosis.
 - 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 an individual'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.

For individuals' with very mild OSA (AHI <10/hour, who are intolerant to therapy, consideration may be given to not use OSA therapy during the MSLT.

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:

- 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).
- "Individuals 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."

Per Recommended protocols for the Multiple Sleep Latency Test and Maintenance of Wakefulness Test in children: guidance from the American Academy of Sleep Medicine, *Journal of Clinical Sleep Medicine* 2024:

- "Symptoms of narcolepsy can present differently in children and adolescents compared to adults. First, daytime sleepiness may be expressed as inattentive, hyperactive, emotionally labile, and/or impulsive behavior in children and adolescents. Second, children and adolescents with NT1 can present initially with cataplectic facies (a static form of cataplexy presenting with ptosis, jaw lowering, and tongue protrusion) before more classic emotionally triggered cataplexy develops."
- "MSLT may not be appropriate in children <5 years of age due to lack of normative data in this age group. However, consideration may be given to performing MSLT in children <5 years of age in special circumstances such as classic symptoms of narcolepsy with cataplexy, and/or inability to obtain CSF orexin testing. Additional consideration should be given when interpreting MSLT results in prepubertal children, because prepubertal children are less likely to fall asleep during the day than older adolescents. Habitual naps are common in younger children and should be taken into account when interpreting MSLT data. Furthermore, mean sleep latencies tend to decrease with advancing Tanner stages in pubescent children."
- The MSLT should be performed following an attended PSG which allows a minimum of 8 hours time in bed with at least 7 hours of sleep, ideally meeting age-based needs.
- "Any home PAP/non-PAP therapies for sleep-disordered breathing patients should be used during the PSG and considered for use during MSLT naps based on clinical judgment. The therapeutic modality, PAP settings, and/or mask interface should match those used at home."
- Moderate to severe OSA should be treated prior to PSG-MSLT evaluation.

Evidence Discussion

In light of the relatively uncommon nature of narcolepsy, as compared to more common sleep and medical disorders, guidelines are meticulously followed to exclude these

common disorders before approval of testing for narcolepsy or idiopathic hypersomnia, treatment of which can be dangerous. To achieve a correct diagnosis of narcolepsy or idiopathic hypersomnia, the American Academy of Sleep Medicine (AASM) has published a protocol that requires the following:

- Adequate sleep documented by sleep diary or actigraphy for 2 weeks before testing
- Testing be performed when the individual is clinically stable and when treatment for existing sleep disorders are well-established and effective
- Medications that have alerting, sedating, and/or REM-sleep-modulating properties should be stopped at least 2 weeks before the Multiple Sleep Latency Test (MSLT)
- An overnight polysomnography (PSG) should be done on the night before the MSLT with optimal sleep apnea treatment (if applicable) for the purpose of documenting sufficient sleep, determining if a sleep-onset REM period (SOREMP) within 15 minutes of nighttime sleep onset occurred, and confirming the lack of any other sleep disorder that may be more common, such as sleep apnea. Split-night PSG should be avoided because it does not represent a full night of sleep uninterrupted by respiratory events and or PAP therapy adjustments

The test-retest reliability of the MSLT is low in narcolepsy type 2 and idiopathic hypersomnia (IH), with a confirmatory second MSLT in 18-47% of narcolepsy type 2 and 25% of idiopathic hypersomnia. Although a diagnosis of narcolepsy type 1 has a high rate of reproducibility on repeat MSLT, it can be missed on an initial MSLT and later confirmed in 20% of individuals' on a second MSLT who were not diagnosed during their first MSLT. Therefore repeat MSLT's can be done in the following circumstances:

- Narcolepsy and or idiopathic hypersomnia are still reasonably suspected but were not confirmed on the prior PSG/MSLT
- A previous diagnosis of narcolepsy or IH is now in question due to a change in symptoms

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

SL.ST.204.A

v2.0.2026

Maintenance of Wakefulness Testing-Indications

- Maintenance of Wakefulness Testing (MWT) using a 40-minute protocol is medically necessary 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)
 - The individual is stable with adherence to effective treatment for their sleep disorder
 - 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 **ALL** of the following:
 - PAP download shows AHI <5/hour
 - Currently using PAP ≥4 hours per night on 70% of nights during a consecutive thirty (30) day period during the preceding 6 months
 - Therapy has resolved symptoms of increased upper airway resistance (i.e., eliminated snoring).
 - If the individual is on treatment with non-PAP therapy for obstructive sleep apnea or other types of sleep disordered breathing, optimal efficacy and adherence has been achieved by demonstration of **ALL** of the following:
 - Efficacy confirmed on sleep testing with AHI <5/hour
 - Self-reported adequate use
 - 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) 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 individual's major sleep period. The MWT should be conducted when an individual 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 for adults indicate that:

- "Individuals 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 individuals 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 individual 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 individual should be instructed to consult with the clinician before starting a prescription or OTC medication prior to the test."

Evidence Discussion

The Maintenance of Wakefulness Test (MWT) is a series of wake trials used to measure the ability to stay awake during soporific conditions. The American Academy of Sleep Medicine (AASM) recommends four 40-minute wake trials with sleep onset defined as the first epoch of sleep. The AASM protocol requires the study to be done when an individual is clinically stable and when treatments of any known sleep disorders are well-established and effective. In individuals' with sleep-disordered breathing on positive airway pressure (PAP), downloaded data should show efficacy and adherence.

Guidance from federal and state government agencies regarding fitness to drive with regard to sleep disorders are poorly detailed or are found only by gathering information from several different sources in the system. The U.S. Department of Transportation (DOT) and Federal Motor Carrier Safety Administration (FMCSA) recommend only

repeat diagnostic testing for obstructive sleep apnea (OSA) if clinically indicated, but no recommendation on the use of the MWT. The Federal Aviation Administration (FAA) also does not require an MWT to evaluate for OSA treatment efficacy, but does include it as additional data when considering rescinding a prior diagnosis of narcolepsy or idiopathic hypersomnia.

The American Academy of Sleep Medicine (AASM) Practice Parameters recommends the MWT 40 minute protocol for when an individual's inability to remain awake constitute a public or personal safety issue. Consideration of public safety in certain fields of employment where MWT may be used, such as commercial driving or flying, should be taken into account. The AASM also recommends the MWT to assess response to treatment in some situations involving individuals with disorders of excessive sleepiness (e.g., medication response in individuals' with narcolepsy or idiopathic hypersomnia). However, the sleep clinician is advised not to rely on the MWT result as a single indicator of impairment or risk for accidents, but also to rely on clinical judgment including integration of clinical history and compliance with treatment.

Repeat sleep testing - Home or Attended Sleep Studies (SL-2.6)

SL.ST.206.A

v2.0.2026

Repeat Diagnostic Study

- Repeat diagnostic testing is not medically necessary only to supply new PAP equipment or other new treatment modality (e.g., oral appliance, surgery) for sleep apnea in the absence of a significant change in clinical status that might alter sleep disordered breathing type or severity resulting in a change in management
- 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 medically necessary for asymptomatic individuals on PAP or non-PAP therapy. However, individuals' with persistent or recurrent symptoms despite adherence with OSA therapy may require repeat testing.
- Home sleep apnea testing, in lab full night diagnostic sleep study, or in lab split night study, is medically necessary based on indications and comorbidities found in **General Guidelines (SL-1.0): At home versus in lab sleep testing requests** when there is documentation of **ANY** of the following:
 - Weight decreases by $\geq 10\%$ with a desire to discontinue PAP therapy and/or intolerance to PAP therapy and/or other planned change in management
 - Weight increases by $\geq 10\%$ when test results would lead to a significant change in management
 - To reassess for the continued presence of OSA after **ANY** of the following:
 - 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 currently treated with an oral appliance (OA) when there is documentation of **ANY** of the following:
 - New or replacement OA
 - Symptoms despite self-reported adequate use
 - $\geq 10\%$ weight change
 - Following adjustments to the OA setting

- 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)
- There have been changes in symptoms, medications, neurological status or cardiovascular status that warrants a re-evaluation for central sleep apnea which may result in a change in management.
- Results of previous medically necessary sleep test were not diagnostic (per submitted report).
 - To be considered not diagnostic, the study scored with 3% hypopneas should show an AHI or RDI on a PSG, or the AHI or REI on an HSAT, that is <5 events per hour.
- Previous HSAT was technically inadequate due to a lack of at least 4 hours of adequate oximetry and flow data (per submitted report)
- Previous in lab full night diagnostic sleep study or in lab split night study with AHI ≥ 5 was technically inadequate due to total sleep time < 2 hours (per submitted report)
- Previous in lab full night diagnostic sleep study or in lab split night study with AHI < 5 was technically inadequate due to a lack of 4 hours of adequate oximetry and flow data (per submitted report)
-
- 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)**

Evidence Discussion

Repeated routine sleep testing without positive impact on management of care, is not indicated. Aging as a sole indication for repeat diagnostic testing is not supported. In a subset of a large cohort of 427 randomly selected community-dwelling elderly subjects, age was found to have no statistically significant effect on RDI over an 18 year follow-up. RDI increase was associated with BMI increase and presence of self-reported high blood pressure. Supporting this association of RDI increase with BMI increase, and not age alone, was data from the Sleep Heart Health Study which showed a strong correlation between AHI and weight change.

When unnecessary repeat sleep testing is performed, a false negative result showing absence of sleep apnea may occur due to factors related to night to night variability.

This may result in loss of qualification for PAP therapy. Discontinuation of treatment would be harmful in this scenario, given the relationship between sleep apnea and neurocardiac morbidity and mortality. Significant time is saved in avoiding unnecessary testing and delay in re-initiation or continuation of treatment.

For some indications, a titration study is the best test, rather than a repeat diagnostic or split-night study. When a split night study is inappropriately performed instead of a titration study, the individual may be harmed during the study when a PAP machine is not being used and increases their risk of possible neurologic/cardiovascular adverse events. If a split night study is inappropriately performed, the individual would need to return to the laboratory for a full night titration, leading to a delay in care. Repeating a diagnostic study or diagnostic portion of a sleep study in lieu of a titration study creates a missed opportunity to obtain data about the titration of PAP therapy to make a decision on changes to therapy.

Repeat Titration

- A repeat titration study is not medically necessary only to supply new PAP equipment in the absence of a significant change in clinical status that might alter sleep disordered breathing type or severity resulting in a change in management
- 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 medically necessary for asymptomatic individuals' on PAP or non-PAP therapy. However, individuals' with persistent or recurrent symptoms despite adherence with OSA therapy may require repeat testing.
- A repeat titration study is not medically necessary 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 is medically necessary if **ANY** of the following criteria is met:

OSA currently on CPAP

- Re-assessment of treatment results with in lab full night PAP titration **OR** unattended APAP based on indications and comorbidities found in **General Guidelines (SL-1.0): At home versus in lab sleep testing requests** for an individual currently using CPAP ≥ 4 hours on 70% of nights during a consecutive 30 day period anytime during the past 1 year is medically necessary when **ANY** of the following has occurred:
 - Weight increases by $\geq 10\%$ with return of symptoms
 - Weight decreases by $\geq 10\%$ with 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 (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.

Sleep disordered breathing currently treated with bi-level PAP, APAP, ASV

- Re-assessment of treatment results with in lab full night PAP titration for an individual currently using bilevel PAP, APAP, ASV ≥ 4 hours on 70% of nights during a consecutive 30 day period anytime during the past 1 year is medically necessary when **ANY** of the following has occurred:
 - Weight increases by $\geq 10\%$ with return of symptoms
 - Weight decreases by $\geq 10\%$ with 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 (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)**

Evidence Discussion

The adverse outcomes of untreated sleep disordered breathing and benefits of treatment with positive airway pressure are well described in the literature. It is reasonable for a repeat titration/treatment study to be performed in certain clinical scenarios to optimize therapy.

Routine reassessment of asymptomatic individuals with OSA on PAP therapy is not medically necessary. There should be sufficient subjective and objective reason to suggest a retitration. Regular titration testing is unnecessary and possibly misleading and can result in inadequate titrations or the conclusion that Bilevel PAP is needed when CPAP therapy is sufficient.

In individuals with known OSA, appropriate redirection to a full night of titration from a requested diagnostic or split night study can be beneficial in terms of allowing extra time during the sleep period to find the optimal settings for the PAP therapy. Performing the requested diagnostic study instead of an appropriate titration study causes harm by potentially necessitating a further titration study in the future and thereby delaying optimal care. Performing a split night study instead of a full night titration study, in the appropriate circumstances, can be harmful to the individual, due to limitation of the amount of time allotted for acquisition of titration data, increasing the chances for an ineffective or indeterminate titration. This leads to delays in optimal care. Lack of effective titration data leads to PAP therapy non-compliance, which is harmful, as noted above.

Diagnostic Testing Pre- and Post-Hypoglossal Nerve Stimulator Implantation (SL-2.8)

SL.ST.208.A
v2.0.2026

Indications

PSG (in lab full night diagnostic sleep study) is medically necessary for the following:

Pre-implantation

No prior sleep testing:

- Individuals with a high pre-test likelihood for moderate to severe obstructive sleep apnea who have not undergone prior sleep testing should undergo home sleep apnea testing, if appropriate per guidelines, and a PAP trial before consideration of facility testing for possible hypoglossal nerve stimulator implantation. Please see section **General Guidelines (SL-1.0): At home versus in lab sleep testing requests.**

Prior diagnosis of OSA based on polysomnography or home sleep apnea testing:

- Pre-implant in lab full night diagnostic sleep study is medically necessary when:

ALL of the below are met:	AND	ONE of the below is met:
BMI ≤40		Individuals have never had an in lab full night diagnostic sleep study (diagnosis based on HSAT only)
AHI or REI ≤100		In lab full night diagnostic sleep study was performed >24 months ago
Continued PAP intolerance after attempting to use it during a minimum three month trial. This trial can include mask fittings, different masks, pressure changes, or desensitization.		In lab full night diagnostic sleep study was performed ≤24 months ago and there have been changes in weight or symptoms to suggest a clinically significant change in sleep study results

ALL of the below are met:	AND	ONE of the below is met:
Evaluation for HGNS should be performed by a board eligible or certified sleep physician or any provider in consultation with the sleep specialist.		

- For individuals age 13-18 years old with Down's Syndrome, pre-implant full night diagnostic sleep study is medically necessary when:

ALL of the below are met:	AND	ONE of the below is met:
AHI or REI <50		Individuals have never had an in lab full night diagnostic sleep study (diagnosis based on HSAT only)
Adenotonsillectomy is contraindicated or ineffective defined as residual AHI>10		In lab full night diagnostic sleep study was performed >6 months ago
Continued PAP intolerance after attempting to use it during a minimum three month trial. This trial can include mask fittings, different masks, pressure changes, or desensitization		In lab full night diagnostic sleep study was performed ≤6 months ago and there have been changes in weight or symptoms to suggest a clinically significant change in sleep study results
Evaluation for HGNS should be performed by a board eligible or certified sleep physician or any provider in consultation with the sleep specialist		

Post-implantation:

- As per the clinical trial, in lab full night diagnostic sleep study is medically necessary at least 2 months post-implantation for the purpose of fine-tuning device parameters and determining therapeutic stimulation settings.
- For individuals age 13-18 years old with Down Syndrome, an additional acclimation polysomnography (in lab full night diagnostic sleep study) can be performed the evening of device activation.
- Following the initial post-implantation study, repeat-in lab full night diagnostic sleep study is medically necessary if **ANY** of the following occurs:

- Clinical response is insufficient despite regular treatment with hypoglossal nerve stimulator
- Weight increases by $\geq 10\%$ with return of symptoms
- Results of previously medically necessary sleep test were inadequate (report of prior sleep testing is required)

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) $< 32 \text{ kg/m}^2$ 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 and 5 years. During the trial, a response to hypoglossal nerve stimulation at one year was defined as a reduction in baseline AHI by at least 50% with a final AHI of < 20 events per hour at one year (Sher's criteria for surgical success).

In 2017, the Food and Drug Administration revised the criteria to include individuals with AHI between 15 and 65. This was based on a prospective, single arm study conducted in Germany which utilized an inclusion criteria of AHI of 15 to 65 per hour and BMI $< 35 \text{ kg/m}^2$. 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 2020, the FDA added to its premarket approval individuals between the ages of 18 and 21 years old for whom adenotonsillectomy was not effective or contraindicated based on extrapolation from the STAR Trial and an ongoing pediatric Down Syndrome study. The BMI $\leq 32 \text{ kg/m}^2$ requirement did not apply, but the requirements of PAP failure/intolerance and lack of complete concentric collapse at the soft palate level on drug-induced sleep endoscopy (DISE) did apply to this new population. Very small studies of adults with OSA and tonsillar hypertrophy show mixed success after tonsillectomy (47.6–100% met Sher's criteria).

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

- Expansion of the upper limit baseline apnea-hypopnea index (AHI) from ≤ 65 to ≤ 100
- Expansion of the upper limit body mass index (BMI) from ≤ 32 to $\leq 40 \text{ kg/m}^2$
- Individuals with Down Syndrome between the ages of 13 and 18 years old with AHI > 10 and < 50 who qualify for the use of HGNS by the same indications as those between the ages of 18 and 21 years old. This was based on a 2022 trial of 42

individuals age 10 to < 22 years old with Down Syndrome who demonstrated safety and sustained efficacy at 12 months (65.9% met Sher's criteria).

The post-market approval ADHERE registry (5000 individuals enrolled since 10/2016) showed preliminary results of individuals implanted with higher AHI and BMI levels. 39 individuals with AHI > 65 and ≤ 100 showed a response rate of 66.7% per Sher's criteria. 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's criteria) between the subgroups. However, the conclusions are limited by small numbers, with only 33 subjects in the subgroup with AHI >65 events/ hr.

Preliminary results from the ADHERE registry showed 216 individuals with BMI >32kg/m² and ≤ 40 kg/m² who had a response rate of 60.6% per Sher's criteria. Some non-congruent data exist regarding the optimal BMI cutoff for HGNS therapy. A retrospective case-control study of 153 individuals comparing the clinical outcome between cohorts with BMI >32kg/m² and <32kg/m² showed comparable results. Previous data from the ADHERE registry noted a 8.5% reduced odds of treatment success for each unit increase in BMI. More than half of individuals with BMI >32kg/m² demonstrated AP collapse 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. Therefore, there are individuals with BMI >32kg/m² who may benefit from HGNS after a DISE showing AP collapse.

Clinical practice guidelines by the AASM and the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) specific to HGNS are not yet available. However, the German Society of Oto-Rhino-Laryngology, Head and Neck Surgery's 2021 Position Paper on HGNS recommends "besides suitable evaluation regarding any [HGNS], the reasons for PAP failure need to be documented during the screening process. It is, therefore, advisable to check for PAP optimization options and to evaluate other OSA treatment options in the individual decision-making process." In addition, sleep medicine expertise is recommended: "Ideally, individual selection, DISE, implantations, therapy adjustment and control are carried out in a department of otorhinolaryngology with profound sleep medicine knowledge or in a sleep medicine center under surveillance of the implanting surgeon."

A 2020 post-implant care pathway was produced by 5 high-volume HGNS centers in the US based on their experience. According to the 5-year STAR trial, residual disease burden may be reported anywhere from 10% (residual snoring) to 22% (residual AHI >15 or ESS >10) of HGNS individuals. Pathways were created for individuals with a combination of suboptimal adherence, suboptimal AHI, and/or suboptimal symptomatic response. Assessment and management recommendations require expertise of both sleep and surgical specialists.

Evidence Discussion

Hypoglossal nerve stimulation (HGNS) was demonstrated as safe and effective by the Stimulation Therapy for Apnea Reduction Trial (STAR) and was initially approved by the Food and Drug Administration (FDA) for use in adults 22 years of age and older.

FDA expanded approval for individuals ages 18-21 years old, pediatric individuals with Down Syndrome ages 13-18 years, and for individuals with BMI from <32 to <40 upper apnea-hypopnea index (AHI) limit from <65 to <100.

Post-implantation polysomnogram (PSG) testing is recommended by the American Academy of Sleep Medicine (AASM) for titration of stimulation parameters to optimized outcomes for OSA. The AASM also recommends periodic clinical assessment since OSA may recur postoperatively. In individuals treated with PAP, repeat titration is medically necessary in the setting of significant weight gain with re-emergence of symptoms. This recommendation can be extrapolated to individuals treated with HGNS.

Diagnostic Testing pre- and post transvenous phrenic nerve stimulator (TPNS) implantation (SL-2.9)

SL.ST.0002.9.A

v2.0.2026

Indications

In lab full night diagnostic sleep study is medically necessary for the following:

Pre-implantation

Prior diagnosis of CSA based on PSG done over 12 months ago or HSAT done at any time :

Polysomnography (in lab full night diagnostic sleep study) is medically necessary when **ALL** of the following are met:

- ≥ 18 years old
- Moderate to severe central sleep apnea seen on prior study as defined by central AHI ≥ 15 /hour
- CSA is not primarily attributed to opioid pain medications
- Absence of medical conditions that could transiently increase the severity of CSA on the PSG, including but not limited to:
 - Stroke or transient ischemic attack within the past 6 months
 - New diagnosis of heart failure less than 6 months ago
 - Left ventricular systolic dysfunction (EF $\leq 40\%$) not on optimal medical therapy (including a beta-blocker with **ONE** of the following: ACE inhibitor, angiotensin II receptor blocker or angiotensin receptor-neprilysin inhibitor) unless denoted contraindication to above
- Positive airway pressure contraindication, failure or intolerance after attempting to use it during a minimum three month trial. This trial can include mask fittings, different masks, pressure changes or desensitization.
- Supplemental oxygen therapy is contraindicated, ineffective, or not tolerated.
- Evaluation for TPNS should be performed by a board eligible or board certified sleep medicine physician or any provider in consultation with the sleep physician

Prior diagnosis of CSA based on PSG done within the past 12 months:

Repeat polysomnography (in lab full night diagnostic sleep study) is medically necessary when **ALL** of the following are met:

- There have been changes in weight, symptoms, medications, neurological status or cardiovascular status to suggest a clinically significant change in sleep study results.
- ≥ 18 years old
- Moderate to severe central sleep apnea seen on prior study as defined by central AHI ≥ 15 /hour
- CSA is not primarily attributed to opioid pain medications
- Absence of medical conditions that could transiently increase the severity of CSA on the PSG, including but not limited to:
 - Stroke or transient ischemic attack within the past 6 months
 - New diagnosis of heart failure less than 6 months ago
 - Left ventricular systolic dysfunction (EF $\leq 40\%$) not on optimal medical therapy (including a beta-blocker with **ONE** of the following: ACE inhibitor, angiotensin II receptor blocker or angiotensin receptor-neprilysin inhibitor) unless denoted contraindication to above
- Positive airway pressure contraindication, failure or intolerance after attempting to use it during a three month trial. This trial can include mask fittings, different masks, pressure changes or desensitization.
- Supplemental oxygen therapy is contraindicated, ineffective or not tolerated.
- Evaluation for TPNS should be performed by a board eligible or board certified sleep medicine physician or any provider in consultation with the sleep physician

Post-implantation

Polysomnography (in lab full night diagnostic sleep study) with interrogation and programming of the phrenic nerve stimulator system can be performed at least 2 months after implantation for the purpose of fine-tuning device parameters and determining therapeutic and tolerable stimulation settings.

Following the initial post-implantation study, retesting with an in lab full night diagnostic sleep study can be performed if **ANY** of the following occurs:

- Clinical response is insufficient despite compliant use
- Results of previously medically necessary sleep test were inadequate (report of prior sleep testing required)

Background and Supporting Information

Central sleep apnea (CSA) was found to be an independent risk factor for atrial fibrillation (AF) in the Sleep Heart Health Study. CSA demonstrated double the risk for AF. There is a strong association between CSA and AF both in congestive heart failure (CHF) and idiopathic CSA. Possible mechanisms include CSA as a marker for cardiac dysfunction and CSA induced carbon dioxide fluctuations with arousals and oxygen

desaturations leading to sympathetic over activation which then leads to arrhythmogenic structural and electrical remodeling. In a prospective observational cohort study of 784 hospitalized individuals with systolic heart failure, CSA was found in 165 individuals (21%) and was found to be a predictor of 6 month cardiac readmission.

A meta-analysis of 19 randomized studies that included individuals with AHI ≥ 10 /hour (predominantly CSA) and heart failure with reduced ejection fraction (HFrEF) $\leq 50\%$ showed short-term benefit of ASV, CPAP, and drug therapies on sleep, but long-term quality of life and cardiovascular benefit were lacking. Acetazolamide and theophylline require monitoring for use, and concerns exist with using these therapies in the HFrEF population. Transphrenic nerve stimulation (TPNS) demonstrated positive treatment outcomes on sleep and quality of life at 6 months with suggestion of improved cardiovascular outcomes. With ASV being contraindicated at this time for some heart failure individuals. TPNS is being considered for both these individuals and others who are not tolerating and or not experiencing benefit from non surgical therapies for CSA.

The Remede® System consists of a neurostimulator implanted into the right or left pectoral region and a combined stimulation and sensing lead implanted into the left pericardiophrenic vein or right brachiocephalic vein. There is an optional respiratory sensing lead placed in the azygos vein in older models where the stimulation lead did not sense respiration well. The stimulation lead transvenously stimulates only a single phrenic nerve, but both diaphragms move in response, resulting in a full breath.

The Pivotal Trial was a prospective, multicenter (31 hospital-based centers in Germany, Poland, USA) randomized trial that recruited treatment (n = 73) and control (n = 78) groups between 04/17/2013 and 05/28/2015. At baseline in both groups, the mean AHI was 46/hour, mean central apnea index (AI) was 24/hour, percent of sleep with O₂ saturation $\geq 90\%$ (T90%) was 10%, and Epworth Sleepiness Scale Score (ESS) was 8. 51% of the treatment group had an AHI reduction of 50% or greater at 6 months as compared to only 11% of the control group. At 5 year follow-up, pooled results of both treatment and control groups (activated 6 months later) showed sustained improvements in the AHI (24/hour), central AI (2/hour), T90% (3%), and ESS.

Analysis of subgroups showed similar sustained efficacy in PAP-treated versus PAP-naïve groups, 10 idiopathic central sleep apnea (16 participants which made up 11% of Pivotal Trial), and heart failure with either reduced or preserved ejection fraction (96 participants which made up 64% of the Pivotal Trial). Heart failure related hospitalization rates were 4.7% in the treatment group and 17.0% in the control group. There was no detectable difference in cardiovascular mortality in the first 6 months between the treatment and control groups. After 12 months of therapy, there was a statistically significant increase in left ventricular ejection fraction from 31.6% to 34.8% (p = 0.0004) as well as a statistically significant decrease in the Minnesota Living with Heart Failure score from 40.0 to 27.0 (p = 0.005).

The freedom from serious adverse events related to the implantation procedure, the system, or the delivered therapy was 91%. At 1, 3, and 5 years, 9%, 10%, and 14% of individuals had serious adverse events related to the implant procedure, device, or delivered therapy. These events were related to the implant site (impending erosion, hematoma, infection), lead failure/dislodgement/displacement, extra respiratory stimulation, concomitant device interaction, non-cardiac chest pain, and elevated transaminase. The two most frequent non-serious therapy-related complaints were abdominal discomfort near the diaphragm and sensation in areas remote from the diaphragm.

Based on sustained efficacy and low rate of serious adverse events, the Remede® System received FDA premarket approval on 10/06/2017 for the treatment of moderate to severe central sleep apnea (CSA) in adult individuals. Approval for adding MR Conditional labeling for 1.5T and 3T MRI scans to the implantable components was issued 03/28/2023.

The inclusion and exclusion criteria in the Pivotal Trial were extensive. Sleep study inclusion metrics were AHI ≥ 20 , central AI $\geq 50\%$ of all apneas with ≥ 30 central apnea events, and obstructive AI $\leq 20\%$ of the total AHI. In addition, there were numerous criteria for medical stability, including heart failure diagnosis being ≥ 6 months and systolic heart failure optimized with guideline-directed medical therapy (GDMT). Guideline-directed medical therapy (GDMT) is met when heart failure medications (e.g. beta-blockers, angiotensin-converting enzyme inhibitors, and others listed in the current guidelines) have been titrated up to trial defined target dosages as tolerated or are considered contraindicated or not medically necessary.

Stroke within 12 months of baseline testing was an exclusion criterion. Prospective studies and meta-analyses have shown a high prevalence of sleep apnea (both central and obstructive) after transient ischemic attacks (TIA's) and strokes without clear association with severity, neurological location, and vascular involvement. Central apneas have been shown to increase and decrease by 3 and 6 months post stroke/TIA. Therefore, stroke of any type and TIA within the prior 6 months was included in this guideline to ensure a PSG to qualify for the Remede® System was done when the CSA diagnosis was most stable.

CSA primarily attributed to opioids was an exclusion criterion. Although ASV is equally successful at reducing the CSA in opioid use and CHF, no randomized controlled trials have been done to assess the clinical benefits of opioid-induced CSA treatment such as reduction in morbidity and mortality. While a large cohort of 6002 CSA individuals at the VA showed all-cause CSA was associated with 1.5 times higher odds of cardiac hospital admission and chronic opioid users had 1.17 times increased odds, those opioid users with CSA did not. Increased morbidity and mortality in chronic opioid users has been demonstrated in multiple studies, but sleep disordered breathing was not assessed in these studies. A study of 50 methadone maintenance treatment individuals

found increased daytime sleep propensity and reduced daytime function, but multiple regression analysis showed that the severity of CSA did not contribute to either of these problems. Morbidity of untreated opioid induced CSA and clinical benefit from its treatment aside from AHI reduction has not been established in large studies.

The inclusion and exclusion criteria in the post-market reST Study were considerably simpler. The main inclusion criterion was moderate to severe central sleep apnea defined as AHI ≥ 15 /hour based on a PSG done within 12 months of the expected implant date and age ≥ 18 years old. The extensive exclusion criterion in the Pivotal Trial were limited to being able to do the study and not being or planning to become pregnant. Enrollment of up to 500 individuals in this multi-center, prospective, open label, non-randomized study started July 2019 and is estimated to be completed 6/2032. Safety and effectiveness data will be collected as well as heart failure specific outcomes in the heart failure subgroup.

ZOLL Medical's Patient Pathway Guide is based on the Pivotal Trial and reST Study protocols where the device is activated 1 month after implantation followed by office visits, PSG, or HSAT to assess efficacy and adjust therapy per each site's standard practice. PSG's and HSAT's for efficacy (not titration) at 6, 12, 18, and 24 months and HSAT at 36 and 60 months were specific to the trials. In ZOLL Medical's Patient Pathway Guide, 2-3 office visits occurring every 6-12 weeks to optimize therapy are done before usually PSG or HSAT is done to confirm efficacy and for final device optimization. HSAT's can report central apneas, but small studies show variable and low sensitivity. The American Academy of Sleep Medicine's 2017 Position Statement states that HSAT is an alternative to PSG for the diagnosis of OSA in uncomplicated individuals presenting with signs and symptoms that indicate an increased risk for moderate to severe OSA. Therefore, PSG and not HSAT for titration is included in this guideline.

Failure of nonsurgical therapies was not a requirement in either the Pivotal Trial or the reST study. However, the American Academy of Sleep Medicine (AASM) 2012 Practice Parameters on the Treatment of Central Sleep Apnea Syndromes (CSAS) in Adults recommended CPAP and nocturnal oxygen as standard treatment for CSAS related to CHF. After the SERVE-HF trial, an update in 2016 lowered the standard recommendation for adaptive servo-ventilation (ASV) to an option for CHF-associated CSAS in individuals with left ventricular ejection fraction $>45\%$ or mild CSAS. BPAP in spontaneous time (ST) mode is an option for CSAS related to CHF if there has been no response to adequate trials of CPAP, ASV, and oxygen therapies. Acetazolamide and theophylline are also only considered options for CSAS related to CHF and primary CSAS. Based on these practice parameters and a meta-analysis of CSA therapies, failure of mask based therapy and oxygen were included in this guideline, but not medication trials.

Experience with the hypoglossal nerve stimulator (HGNS) has shown that sleep medicine expertise is recommended for both individual selection and post implantation care. PAP failure despite optimization should be documented pre implantation. Suboptimal adherence, AHI, and symptomatic response may occur post implantation and requires expertise of both sleep and surgical specialists.

Diagnostic Testing Pre- and Post-Zepbound (SL-2.10)

SL.ST.0002.10.A

v2.0.2026

Pre-Treatment Sleep Testing

Home sleep apnea testing or polysomnography (in lab full night diagnostic sleep study or in lab split night sleep study) is medically necessary for **ANY** the following:

No prior sleep testing:

- Sleep testing of asymptomatic individuals prior to Zepbound treatment for OSA is not medically necessary.
- Either HSAT or PSG (in lab full night diagnostic sleep study or in lab split night sleep study) is medically necessary based on indications and comorbidities found in **(General Guidelines (SL-1.0): At home versus in lab sleep testing requests)** when **ALL** of the following are met:
 - ≥ 18 years old
 - BMI ≥ 30
 - **ONE OR MORE** of the following signs and symptoms of obstructive sleep apnea must be provided
 - Unexplained excessive daytime sleepiness or fatigue leading to impaired sleep-related quality of life
 - Sleep-related snoring, snorting, choking or gasping
 - Sleep-related witnessed apneas
 - The subjective sensation of awakening with breath-holding, shortness of breath, gasping, coughing or choking
 - Resistant hypertension defined as uncontrolled blood pressure despite the use of ≥ 3 antihypertensive agents of different classes
 - Refractory hypertension defined as uncontrolled blood pressure despite use of ≥ 5 antihypertensive agents of different classes
 - 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 or transient ischemic attack in the last 6 month

Prior PSG or HSAT showed AHI ≥ 15 :

A repeat HSAT or PSG (in lab full night diagnostic sleep study or in lab split night sleep study) is medically necessary based on indications and comorbidities found in **General Guidelines (SL-1.0): At home versus in lab sleep testing** when **ALL** of the following are met:

- ≥18 years old
- BMI ≥30
- **AT LEAST ONE** of the following are met:
 - ≥10% weight loss
 - There have been changes in symptoms, medications, neurological status or cardiovascular status to suggest a clinically significant change in sleep study results

Prior PSG showed AHI <15:

A repeat PSG (in lab full night diagnostic sleep study or in lab split night sleep study) is medically necessary when **ALL** of the following are met:

- ≥18 years old
- BMI ≥ 30
- The prior study (report of prior sleep testing required) showed an AHI <15 with **AT LEAST ONE** of the following:
 - ≥10% weight gain since the study
 - There have been changes in symptoms, medications, neurological status or cardiovascular status to suggest a clinically significant change in sleep study results

Prior PSG showed ≥ 50% CSA:

A repeat PSG (in lab full night diagnostic sleep study or in lab split night sleep study) is medically necessary when **ALL** of the following are met:

- ≥18 years old
- BMI ≥ 30
- The prior study (report of prior sleep testing required) showed **AT LEAST ONE** of the following:
 - Central apneas plus central hypopneas were ≥ 50% of the total number of apneas and hypopneas
 - Cheyne-Stokes Breathing
 - There have been changes in symptoms, medications, neurological status or cardiovascular status to suggest a clinically significant change in sleep study results

Prior HSAT showed AHI <15 and/or ≥50% CSA:

A PSG (in lab full night diagnostic sleep study or in lab split night sleep study) is medically necessary when **ALL** of the following are met:

- ≥ 18 years old
- BMI ≥ 30
- The prior study (report of prior sleep testing required) contained **AT LEAST ONE** of the following:
 - AHI < 15
 - Central apneas plus central hypopneas were $\geq 50\%$ of the total number of apneas and hypopneas
 - Cheyne-Stokes Breathing

Prior sleep study report is not provided:

Either HSAT or PSG (in lab full night diagnostic sleep study or in lab split night sleep study) is medically necessary based on indications and comorbidities found in **General Guidelines (SL-1.0)**: At home versus in lab sleep testing requests when **ALL** of the following are met:

- ≥ 18 years old
- BMI ≥ 30
- 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)**: Relevant diagnostic studies done in the past (prior sleep studies)

Post-treatment Sleep Testing

- A repeat sleep study is not medically necessary to continue or resume Zepbound.
- For reassessment of OSA severity while on or after Zepbound treatment, see **Repeat sleep testing-home or attended sleep studies (SL-2.6)**.

Background and Supporting Information

BMI reduction of 20% is associated with AHI reduction of 57% in obese individuals with moderate to severe OSA. The Wisconsin Sleep Cohort Study, which included participants with normal to obese BMI who had all severities of OSA including no OSA, showed a similar 48% AHI reduction associated with a 20% reduction in weight.

The American Thoracic Society (ATS) made a strong recommendation that patients with OSA who are overweight or obese (i.e., BMI > 25) be treated with comprehensive lifestyle intervention consisting of a reduced-calorie diet, exercise/increased physical activity, and behavioral counseling. For patients with OSA with a BMI > 27 whose weight had not improved despite a comprehensive weight-loss lifestyle program, a conditional recommendation was made for an evaluation for antiobesity pharmacotherapy.

The American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) made similar recommendations. Patients with overweight or

obesity and obstructive sleep apnea should be treated with weight-loss therapy including lifestyle interventions and additional modalities as needed, including phentermine/topiramate ER or bariatric surgery; the weight-loss goal should be at least 7% to 11% or more (Grade A).

Tirzepatide is a long-acting glucose-dependent insulintropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist that selectively binds to and activates both the GIP and GLP-1 receptors.

SURMOUNT-OSA was a phase 3, multicenter, randomized, parallel-arm, double-blind, placebo-controlled study to evaluate the efficacy and safety of a 52 week course of treatment with tirzepatide versus placebo in participants who had obesity and moderate-to-severe obstructive sleep apnea (OSA). Within the study, there were two trials: Trial 1 consisted of participants who were not receiving positive airway pressure (PAP) therapy at baseline and during the study; Trial 2 consisted of participants who were receiving PAP therapy at baseline and continued PAP throughout the study.

Inclusion criteria included age >18 years and AHI >15 per prior PSG or HSAT done at any time prior to the study. The AHI was confirmed on a PSG during the 4 week screening period prior to randomization. Key exclusion criteria were central or mixed sleep apnea defined as >50% mixed or central apneas/hypopneas, Cheyne-Stokes Respiration (not specifically defined), significant craniofacial abnormalities that may affect breathing, respiratory and neuromuscular disease that could interfere with results, active treatment of OSA with non PAP therapy, diabetes type 1 or 2, and significant renal and cardiovascular disease. Medications and disorders that would affect the study end points as well as complicate evaluation for gastrointestinal (GI) adverse effects were also exclusion criteria. Participants received regular lifestyle counseling sessions to assist in adherence to a 500 kcal/day deficit and at least 150 minutes per week of physical activity.

Trial 1 enrolled 234 participants, and Trial 2 enrolled 235 participants. There was a roughly 1:1 randomization between tirzepatide and placebo groups. The primary endpoint was the change in AHI from baseline to Week 52 as measured on a PSG. In Trial 1 (not on PAP), the mean change in AHI was -25.3 with tirzepatide and -5.3 with placebo, for an estimated treatment difference of -20. In Trial 2 (on PAP), the mean change in AHI was -29.3 with tirzepatide and -5.5 with placebo, for an estimated treatment difference of -23.8.

Significant improvements in the following key secondary endpoints were observed with tirzepatide as compared to placebo in both Trials: sleep apnea-specific hypoxic burden (a PSG calculated measure comprised of frequency, duration, and depth of oxygen saturation related to a respiratory event), percentage of participants who had an AHI reduction of >50% (61.2 – 72.4% versus 19 – 23.3%), percentage of participants who had an AHI < 5 or AHI 5-14 with Epworth Sleepiness Scale (ESS) score < 10 (42.2 – 50.2% versus 14.3 – 15.9%), PROMIS sleep impairment and sleep disturbance scores,

percent change in body weight (-17 to -19.6% versus -1.6 to -2.3%), systolic blood pressure (-7.6 to -9.5mmHg versus -1.8 to -3.9mmHg), and hsCRP concentration.

An admitted limitation of the study was that the effects of tirzepatide on OSA were not studied in participants with normal or overweight BMI. In addition, data analysis in SURMOUNT-OSA did not control for % change in body weight when reporting the AHI related end points.

The most frequently reported adverse events were gastrointestinal (diarrhea, nausea, vomiting and constipation in 9.2 – 26.3% of the tirzepatide group versus 0.9 – 12.5% of the placebo group). They were mild-to-moderate in severity and occurred most frequently during the dose-escalation phase. Serious adverse events were reported in 7.5% of participants in similar amounts between the tirzepatide and placebo groups. There were two adjudicated confirmed cases of acute pancreatitis in the Trial 2 tirzepatide group. No cases of medullary thyroid cancer were reported. Five cases of severe or serious depressive disorder or suicidal ideation or behavior events were reported across both Trials 1 and 2 (two with tirzepatide and three with placebo). Tirzepatide and other GLP-1 receptor agonist therapies contain a black box warning stating contraindication in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN-2). Participants with a family or personal history of MTC or MEN-2 were excluded from SURMOUNT-OSA.

The FDA approved Zepbound (tirzepatide) on 12/20/24 as the first and only prescription medication for treatment of moderate to severe OSA in adults with obesity. Zepbound had previously been approved for adults with obesity (BMI >30 or BMI >27 with at least one weight-related comorbid indication such as hypertension, dyslipidemia, type 2 diabetes, OSA, or cardiovascular disease) on 11/8/23. The FDA approval for obesity required Zepbound be used as an adjunct to a reduced-calorie diet and increased physical activity.

The American Academy of Sleep Medicine (AASM) released a statement on 12/23/24: "The AASM reminds patients that Zepbound is only effective for cases of sleep apnea that are related to obesity. While Zepbound can reduce the severity of sleep apnea, it may not cure the disease. Therefore, for some patients who have sleep apnea, combining another treatment with Zepbound may be ideal. Furthermore, weight loss from Zepbound must be maintained over time to continue experiencing a benefit for sleep apnea."

A longer treatment duration of tirzepatide was studied in SURMOUNT-4. 783 participants with BMI >30 or >27 with a weight related complication (excluding diabetes) were enrolled in a 36 week open label tirzepatide lead-in period. 670 participants continued in a 52-week, double-blind, placebo-controlled period. At 88 weeks, the 300 participants who received tirzepatide for the entire trial maintained at least 80% of the weight loss achieved during the lead-in period compared with 16.6% in those who had

been randomized to placebo. Safety profile was similar to SURMOUNT-OSA. However, AHI was not a measured endpoint.

Evidence Discussion

BMI and weight reduction in individuals with normal to obese BMI and no OSA to severe OSA are associated with significant AHI reduction. The American Thoracic Society (ATS), American Association of Clinical Endocrinologists (AACE), and American College of Endocrinology (ACE) recommend lifestyle intervention and consideration for antioesity pharmacotherapy in individuals who overweight or obese with OSA.

SURMOUNT-OSA was a phase 3, multicenter, randomized, parallel-arm, double-blind, placebo-controlled study to evaluate the efficacy and safety of a 52 week course of treatment with tirzepatide versus placebo in participants who had obesity and moderate-to-severe obstructive sleep apnea (OSA). Significant reductions in AHI were seen in the treatment arm (similar for participants both on and off PAP). Significant reductions were also seen in body weight, hypoxic burden, Epworth Sleepiness Scale score, PROMIS sleep impairment and disturbance scores, systolic blood pressure, and hsCRP.

The most frequently reported adverse events were mild to moderate gastrointestinal events, occurring most frequently during the dose-escalation phase. Serious adverse events were reported in 7.5% of participants in similar amounts between the tirzepatide and placebo groups. Participants with a family or personal history of MTC or MEN-2 were excluded from SURMOUNT-OSA.

The FDA approved Zepbound (tirzepatide) on 12/20/24 as the first and only prescription medication for treatment of moderate to severe OSA in adults with obesity. Zepbound had previously been approved for adults with obesity (BMI >30 or BMI >27 with at least one weight-related comorbid indication such as hypertension, dyslipidemia, type 2 diabetes, OSA, or cardiovascular disease) on 11/8/23. The FDA approval for obesity required Zepbound be used as an adjunct to a reduced-calorie diet and increased physical activity.

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A longer treatment duration of 88 weeks on tirzepatide was studied in SURMOUNT-4. Weight reduction and adverse events were similar to SURMOUNT-OSA. AHI as not measured.

Pediatric Guidelines

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Pediatric Sleep Guidelines (SL-3)

SL.ST.103.A
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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 CO₂ monitoring and arousal monitoring among other factors.

Pediatric definitions

Pediatric definitions for apneas, hypopneas, and obstructive sleep apnea differ compared with adults

Pediatric apnea

Drop in peak signal excursion by $\geq 90\%$ of pre-event baseline with an oronasal thermal sensor or alternative apnea sensor (diagnostic) or PAP device flow (titration study) for at least the duration of 2 breaths during the baseline portion of the study (obstructive or mixed events). **Note:** Duration criteria differ for central events.

Pediatric hypopnea

The peak signal excursion drops by $>30\%$ of the pre-event baseline using nasal pressure or alternative hypopnea sensor (diagnostic study) or PAP device flow (titration study) for ≥ 2 breaths.

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

Pediatric obstructive sleep apnea**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
 - Mild: 1 to <5
 - Moderate: ≥5 to <10
 - Severe: ≥10
 - A pattern of obstructive hypoventilation defined as at least 25% of total sleep time with hypercapnia (PaCO₂ >50mmHg) in association with **ONE OR MORE** of the following:
 - Snoring
 - Flattening of the inspiratory nasal pressure waveform
 - Paradoxical thoracoabdominal motion

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 (e.g., sleep terrors, sleep walking), nightmares, sleep talking, 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

In lab full night diagnostic sleep study (**See Polysomnography (facility-based-PSG) - coding (SL-1.4.2)** for age specific codes) is appropriate for children (17 years of age or younger) for the diagnosis 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:
 - Snoring
 - 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
 - Daytime sleepiness, tiredness, fatigue, or mood disturbances 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 in lab split-night testing (**See Polysomnography (facility-based-PSG) - coding (SL-1.4.2) for age specific codes**) 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 and documentation of the reason(s) for a split night PSG must be provided.

Initial polysomnography for positive airway pressure (PAP) titration

In lab full night PAP titration (**See Polysomnography (facility-based-PSG) - coding (SL-1.4.2) for age specific codes**) in children with obstructive sleep apnea syndrome is considered medically necessary when there is a diagnosis of pediatric obstructive sleep apnea as defined above.

Repeat polysomnography for diagnosis

- Repeat in lab full night diagnostic sleep study (**See Polysomnography (facility-based-PSG) - coding (SL-1.4.2) for age specific codes**) to assess for OSA is medically necessary in **ANY** of the following circumstances:
 - 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 (e.g., 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 **ONE** of the following criteria is met:
 - Residual symptoms of OSA are present with mild OSA (AHI 1-<5) preoperatively
 - Moderate to severe OSA (AHI ≥5)
 - Obesity
 - Craniofacial abnormalities that obstruct the upper airway
 - Neurological disorders such as Down Syndrome, Prader-Willi, and myelomeningocele

Special scenarios

In lab full night diagnostic sleep study and in lab full night PAP titration (**See Polysomnography (facility-based-PSG) - coding (SL-1.4.2) for age specific codes**) are considered medically necessary in **ANY** of the following circumstances:

- 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 in lab full night PAP titration (**See Polysomnography (facility-based-PSG) - coding (SL-1.4.2) for age specific codes**) is medically necessary 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:

In lab full night diagnostic sleep study should be performed in conjunction with an MSLT for diagnosis of narcolepsy or idiopathic hypersomnia. See **PSG and MSLT for Suspected Narcolepsy or Idiopathic Hypersomnia (SL-2.3)**

CPAP in Pediatrics (SL-3.2)

- CPAP is medically necessary 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

Treatment of Sleep-Related Breathing Disorders

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Treatment - General Information

SL.TX.101.A

v2.0.2026

Treatment Coding (SL-4.1.1)

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

The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

Treatment codes

Treatment codes	HCPCS and CPT®
Continuous airway pressure (CPAP/APAP) device	E0601
Respiratory assist device, bi-level pressure (BPAP) capability, WITHOUT backup rate feature, used with noninvasive interface, e.g. nasal or facial mask (intermittent assist device with continuous positive airway pressure device)	E0470
Respiratory assist device, bi-level pressure (BPAP) capability (including ASV), WITH backup rate feature, used with noninvasive interface, e.g. nasal or facial mask (intermittent assist device with continuous positive airway pressure device)	E0471
Respiratory assist device, bi-level pressure (BPAP) capability, WITH backup rate feature, used with invasive interface, e.g. tracheostomy tube (intermittent assist device with continuous positive airway pressure device)	E0472
Humidifier, non-heated, used with positive airway pressure (CPAP/BPAP/APAP) device	E0561

Treatment codes	HCPCS and CPT®
Humidifier, heated, used with positive airway pressure (CPAP/BPAP/APAP) device	E0562
Tubing with heating element	A4604
Combination oral/nasal mask	A7027
Replacement oral cushion combo mask	A7028
Replacement nasal pillow comb mask	A7029
CPAP full face mask	A7030
Replacement facemask interface	A7031
Replacement nasal cushion	A7032
Replacement nasal pillows	A7033
Nasal interface (mask or cannula type) used with PAP device	A7034
Positive airway pressure headgear	A7035
Positive airway pressure chinstrap	A7036
Positive airway pressure tubing	A7037
Positive airway pressure filter	A7038
Filter, non-disposable w/ PAP	A7039
PAP oral interface	A7044
Replace exhalation port	A7045
Replacement, water chamber, PAP device	A7046

Treatment codes	HCPCS and CPT®
Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified (this code relates to Compliance and the data download of an individuals PAP therapy).	A9279
CPAP initiation and management (code is used to report the initiation and instruction when a patient begins therapy)	CPT 94660

PAP - General Requirements (SL-4.1)

Orders for PAP and supplies can only be placed by a treating medical provider. This is defined as a licensed MD, DO, Nurse Practitioner, Clinical Nurse Specialist, or Physician Assistant.

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:

- The predominantly obstructive apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) on a PSG, or the apnea-hypopnea index (AHI) or respiratory event index (REI) on a HSAT is ≥ 15 events per hour; **OR**
- The predominantly obstructive apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) on a PSG, or the apnea-hypopnea index (AHI) or respiratory event index (REI) on a HSAT is ≥ 5 and < 15 events per hour with documentation of **ANY** of the following:
 - 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) is defined as ALL of the following:

- 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 apneas plus central hypopneas are $>50\%$ of the total number of apneas and hypopneas

Central sleep apnea (CSA) with Cheyne-Stokes Breathing is defined as ALL of the following:

- 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
- Central apnea and/or central hypopnea index ≥ 5 per hour
- Central apneas plus central hypopneas 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 is defined as ALL of the following:

- 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 non-restorative sleep
 - Awakening short of breath
 - Witnessed apneas
- The predominately obstructive apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) on a PSG, or the apnea-hypopnea index (AHI) or respiratory event index (REI) on an HSAT is ≥ 5 events per hour.
- PSG during use of positive airway pressure without a backup rate shows ALL of the following:
 - Significant resolution of obstructive events
 - Central apnea plus central hypopnea index ≥ 5 per hour

- Central apneas plus central hypopneas are >50% of the total number of apneas and hypopneas

Sleep-related hypoventilation is defined as when EITHER of the following occur during sleep:

- Increase in arterial PCO₂, transcutaneous PCO₂, or end-tidal PCO₂ to a value >55mmHg for ≥10 minutes
- There is a ≥10mmHg increase in arterial PCO₂, transcutaneous PCO₂, or end-tidal PCO₂ during sleep (compared to awake supine value) to a value >50mmHg 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 AASM Clinical Practice Recommendations for PAP Treatment of CSA with CHF (SL-4.1.2)

- CPAP (conditional recommendation, low certainty)
- BPAP with backup rate (conditional recommendation, very low certainty)
- ASV (conditional recommendation, low certainty)
 - In individuals with heart failure with reduced ejection fraction (HFrEF), ASV can be ordered if ALL of the following have been met:
 - The treating medical provider and patient have discussed the benefits and potential risks.
 - The treating medical provider must be a board-certified sleep medicine physician or a provider who is overseen by a board-certified sleep physician.
 - There must be a plan for follow-up while on treatment with ASV

Positive Airway Pressure Devices (SL-4.2)

SL.TX.102.A

v2.0.2026

Auto-Adjusting 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 Auto-Adjusting 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 individual's currently on fixed pressure treatment with CPAP) is medically necessary for **ALL** of the following:

- 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 **ALL** 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 Auto-Adjusting Positive Airway Pressure (APAP) Therapy (SL-4.2.2)

Note: For pediatric CPAP, see **CPAP in pediatrics (SL-3.2)**.

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)** or **Auto-Adjusting positive airway pressure (APAP) in unattended setting (SL-4.2.1)**
- The device is ordered by the treating provider following a clinical evaluation (either face to face or telehealth) where sleep disordered breathing and PAP treatment have been discussed.

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 a clinical reevaluation in the first three months since starting PAP to evaluate symptoms

Repeat initiation of APAP/CPAP HCPCS E0601 device after failing an initial trial period is medically necessary when:

- A clinical evaluation by a provider has occurred to determine the etiology of the failure to respond to PAP therapy with a support plan to address these causes.

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** of the following:
 - Diagnosis of OSA as defined in **General Guidelines (SL-1.0)**
 - CPAP or APAP (HCPCS E0601) have been tried and proven either ineffective or not tolerated, based on a therapeutic trial conducted in either a facility or a home setting
 - Neuromuscular disease or restrictive thoracic disorder when **BOTH** of the following:
 - 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 PaCO₂, done while awake and breathing the individual's prescribed FiO₂, is ≥45mmHg
 - End-tidal CO₂, transcutaneous CO₂, or venous blood gas ≥50mmHg
 - 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 ≤60cm of H₂O
 - Sniff nasal inspiratory pressure ≤40cm of water
 - Severe COPD when **BOTH** of the following:
 - An arterial blood gas PaCO₂ is ≥52mmHg done while awake and breathing the individual's prescribed FiO₂
 - OSA and CPAP treatment have been considered and ruled out (formal sleep testing not required)
 - Obesity hypoventilation syndrome (OHS) as defined by: :
 - BMI ≥30kg/m² plus **EITHER** awake arterial blood gas (ABG), end-tidal PCO₂ (EtPCO₂), or transcutaneous PCO₂ (TcPCO₂) with PCO₂ ≥45 **OR** venous blood gas (VBG) showing a PCO₂ ≥50mmHg
- Other hypoventilation syndrome (defined awake arterial blood gas, end-tidal PCO₂ (EtPCO₂), or transcutaneous PCO₂ with PCO₂ ≥45 **OR** venous blood gas showing a PCO₂ ≥50mmHg) 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 when **BOTH** 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 a clinical reevaluation in the first three months since starting PAP to evaluate symptoms

For **ALL** other indications:

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

Repeat initiation of Bilevel PAP HCPCS E0470 device after failing an initial trial period is medically necessary when:

- A clinical evaluation by a provider has occurred to determine the etiology of the failure to respond to PAP therapy with a support plan to address these causes

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 **BOTH** of the following:
 - Valid testing meeting criteria for central sleep apnea as defined in **PAP General Requirements (SL-4.1)** and **General Guidelines (SL-1.0)**
 - 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)**
 - 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 PaCO₂, done while awake and breathing the individual's prescribed FiO₂, is ≥45mmHg
 - End-tidal CO₂, transcutaneous CO₂, 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 H₂O
 - Sniff nasal inspiratory pressure ≤40cm of water
 - Severe COPD when **BOTH** of the following:
 - An arterial blood gas PaCO₂ is ≥52mmHg done while awake and breathing the individual's prescribed FiO₂
 - OSA and CPAP treatment have been considered and ruled out (formal sleep testing not required)

- Obesity hypoventilation syndrome as defined when **ALL** of the following:
 - BMI $\geq 30\text{kg/m}^2$ plus EITHER awake arterial blood gas (ABG), end-tidal PCO_2 (EtPCO_2) or transcutaneous PCO_2 (TcPCO_2) with $\text{PCO}_2 \geq 45$ OR venous blood gas (VBG) showing a $\text{PCO}_2 \geq 50\text{mmHg}$
 - ANY of the following:
 - 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 $\text{RDI} < 30$)
 - Individual has been diagnosed with severe OSA (AHI or $\text{RDI} \geq 30$) and has ongoing hypoventilation despite 3 months of compliant CPAP/APAP 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 $\text{PCO}_2 \geq 45$ OR venous blood gas showing a $\text{PCO}_2 \geq 50\text{mmHg}$) 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 a clinical reevaluation in the first three months since starting PAP 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 (either primary central sleep apnea or central sleep apnea with Cheyne-Stokes Breathing):

- Diagnosis of central sleep apnea as defined in **General Guidelines (SL-1.0) and PAP-General Requirements (SL-4.1)**
- In individuals with heart failure with reduced ejection fraction (HFrEF), ASV can be ordered if **ALL** of the following have been met:
 - The treating medical provider and patient have discussed the benefits and potential risks.
 - The treating medical provider must be a board-certified sleep medicine physician or a provider who is overseen by a board-certified sleep physician.
 - There must be a plan for follow-up while on treatment with ASV
- 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 or 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 a clinical reevaluation in the first three months since starting PAP 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

v2.0.2026

Coding

The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

Treatment codes for oral appliances

Treatment Description	HCPSC
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 medically necessary 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;
 - 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 treating medical provider 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 medical provider 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, stolen 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

- 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

Program Exclusions

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Sleep Apnea Treatment Program Exclusions (SL-5)

SL.TXS.105.A

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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
 - 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 PAP oxygen bleed-in adapter. E1399 may also 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, power adapter) 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

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Questionnaires (SL-8)

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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)	

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

Berlin Questionnaire scoring

Category 1: Items 1-5

- Item 1: if **Yes**, assign 1 point
- Item 2: if **c** or **d**, 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/m².

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 35kg/m²?

Age

6. Age over 50 years old?

Neck circumference

7. Neck circumference 16in/40cm 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)