

# 2024 Sleep Program

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## *Sleep Studies and Devices*

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Guideline	Protocol ID	Previous Review Date	Last Review Date
Polysomnography (PSG)	P_11472, P_11825	07/01/2024	08/01/2024
Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness (MWT)	P_11796	08/04/2023	07/01/2024
Automatic Positive Airway Pressure (APAP), Biventricular Positive Airway Pressure (BPAP), Continuous Positive Airway Pressure (CPAP) Devices	P_11473	10/11/2023	07/01/2024
Oral Appliance	P_11141	08/04/2023	07/01/2024

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## Sleep Testing

### Polysomnography (PSG)

#### Sleep Program: Sleep Studies

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**Last Review Date: 08/01/2024**

Previous Review Date: 07/01/2024

Guideline Initiated: 06/02/2021

### Contraindications or Exclusions to Unattended Home Sleep Study (HSS)

Contraindications or exclusions to home sleep testing may include **ANY** of the following: [9] [19]

1. Clinical condition includes **ANY** of the following:
  - a. BMI more than 50 kg/m<sup>2</sup> [15]
  - b. Heart failure, New York Heart Association (NYHA) Class III or IV, or LVEF is 45% or less. [3]
  - c. Neuromuscular disease or impairment
  - d. Opioid use is chronic.
  - e. Pulmonary disease is characterized by forced expiratory volume/forced vital capacity (FEV1/FVC) 0.7 and FEV1 less than 60% predicted, oxygen use or daytime hypercapnia or hypoxemia.
  - f. Sleep disorder (other than OSA) is suspected (eg, central sleep apnea, idiopathic hypersomnia, narcolepsy, nocturnal seizure activity, parasomnia, periodic limb movement disorder, rapid-eye movement [REM] behavior disorder, sleep-related hypoventilation). [3]
  - g. Stroke
2. Individual or available caregiver is unable to carry out home instructions. [3]
3. Obstructive sleep apnea (OSA) is asymptomatic, regardless of comorbidities.

### Contraindications or Exclusions to Attended In-Laboratory Polysomnography (PSG)

Contraindications or exclusions for an attended in-laboratory polysomnography (PSG) may include of **ANY** of the following: [9]

1. Bruxism
2. Insomnia with **NO** other symptoms of obstructive sleep apnea or other sleep disorders (eg, restless leg, nocturia, fatigue, difficulty concentrating, heavy habitual snoring).
3. Restless leg syndrome (RLS) primary diagnostic testing<sup>1</sup>
4. Rhythmic movement disorder (RMD)
5. Sleep related leg cramps
6. Sleep related myoclonus

## Polysomnography (PSG)



### NCD 240.4.1

See also, **NCD 240.4.1**: Sleep Testing for Obstructive Sleep Apnea (OSA) at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.

## Attended In-Lab Polysomnography (PSG) Guideline

An attended, in-laboratory polysomnography (PSG) is considered medically appropriate when the documentation demonstrates **ANY** of the following:

1. Non-obstructive sleep apnea (OSA) disorder is suspected or known and **ANY** of the following: [18]
  - a. Central sleep apnea (CSA) (Types of CSA: Cheyne-Stokes breathing, drug-induced apnea, high-altitude periodic breathing, idiopathic central sleep apnea, medical condition-induced central sleep apnea, treatment-emergent central sleep apnea. Symptoms of CSA: difficulty falling asleep, excessive daytime sleepiness, frequent nighttime awakening, pause in breathing, snoring and waking up short of breath, etc.)
  - b. Medications are used that predispose to central sleep apnea (eg, opioids).
  - c. Narcolepsy or idiopathic hypersomnia
  - d. Parasomnia, characterized by atypical or violent episodes. [9] [19]
  - e. Seizure activity, nocturnal, and electroencephalogram (EEG) is abnormal, non-diagnostic or indeterminate.

<sup>1</sup>PSG is generally not a direct indication for diagnosing RLS. PSG is useful for measuring periodic limb movements (PLMS), which *contributes* to the RLS diagnosis.

- f. Periodic limb movement disorder (PLMD) and **ALL** of the following: [18] [19]
  - i. Clinical status includes **ANY** of the following:
    - A. Antidepressant medication usage
    - B. Antipsychotic medication usage
    - C. Hypersomnia persists **AND** prior home sleep study has ruled-out sleep disordered breathing.
    - D. Iron-deficiency anemia
    - E. Peripheral neuropathy
    - F. Pregnancy
    - G. Pulmonary hypertension
    - H. Renal failure
  - ii. Repetitive limb movement is reported.
  - iii. Sleep disruptions are characterized by **EITHER** of the following:
    - A. Difficulty remaining asleep/frequently waking.
    - B. Excessive daytime sleepiness (EDS)
- 2. Obstructive sleep apnea (OSA) is known and **ALL** of the following: [9] [19]
  - a. An attended study is required to support advanced positive airway pressure (PAP) titration (eg, adaptive servo ventilation [ASV]).
  - b. **Contraindication to an unattended home sleep study** (*see section: Contraindications to Home Sleep Study [HSS]*) **OR** prior sleep testing is negative, non-diagnostic, indeterminate or incomplete **AND** symptoms persist.
  - c. Sleep evaluation is complete (eg, body mass index (BMI), cardiopulmonary assessment, comorbidity evaluation, neck circumference, sleep history).
- 3. Obstructive sleep apnea is suspected and **ALL** of the following:
  - a. Evaluation of **ANY** of the following:
    - i. Excessive daytime sleepiness (EDS) (measured by a combination of tests including those for medical and psychiatric co-morbidities and the Epworth Sleepiness Scale [ESS]) **AND ANY TWO** of the following: [3] [9] [19]
      - A. BMI is 30 kg/m<sup>2</sup> or higher **OR** large neck circumference (17 inches or more in men or 16 inches or more in women).
      - B. Hypertension

- C. Snoring is loud and habitual.
- D. Symptoms of apnea, choking or gasping are present.
- ii. High-risk with **EITHER** of the following: [3]
  - A. Central sleep apnea (CSA) is suspected with comorbidities associated with respiratory impairment (eg, chronic opioid use, neurological disorders).
  - B. Heart failure with New York Heart Association (NYHA) Class III, NYHA Class IV or left ventricular ejection fraction (LVEF) is 45% or less.
- iii. Safety evaluation for professions that have a direct impact on public-safety (eg, bus drivers, pilots, truck drivers). [9] [6]
- b. **Contraindication to an unattended home sleep study** (see section: Contraindications to Home Sleep Study [HSS]) **OR** prior sleep testing is negative, non-diagnostic, indeterminate or incomplete **AND** symptoms persist.
- c. Sleep evaluation is complete (eg, body mass index (BMI), cardiopulmonary assessment, comorbidity evaluation, neck circumference, sleep history).
- 4. Titration after a hypoglossal nerve stimulator (HNS) implant [22]

## Unattended Home Sleep Study (HSS) Guideline

An unattended home sleep study is considered medically appropriate when the documentation demonstrates that **ALL** of the following criteria are met: [3]

1. **NO** contraindications to an unattended, home sleep study exist (see section Contraindications to Unattended, Home Sleep Study [HSS]).
2. Obstructive sleep apnea symptoms (eg, BMI 30 m<sup>2</sup> or higher, choking or gasping during sleep, habitual loud snoring, large neck circumference [17 inches or more in men, or 16 inches or more in women], observed apneas) **AND** fatigue and/or excessive daytime sleepiness (measured by a combination of test including those for medical and psychiatric co-morbidities and the Epworth Sleepiness Scale [ESS]). [9] [19]
3. Sleep evaluation is complete (eg, body mass index (BMI), cardiopulmonary assessment, comorbidity evaluation, neck circumference, sleep history).

## Repeat In-Lab Polysomnography (PSG) Guideline

A repeat in-lab polysomnography (PSG) is considered medically appropriate when the documentation demonstrates **ANY** of the following: [7]

1. Assessment of response to treatment with non-positive airway pressure (PAP) interventions, when clinically significant weight loss or gain has occurred since diagnosis of obstructive sleep apnea (OSA) or initiation of its treatment.
2. Attended study is required to support PAP titration.
3. Change in cardiovascular disease
4. Current treatment for OSA with development of unexplained symptoms of obstructive sleep apnea syndrome (OSAS).
5. Reassessment of sleep-related hypoxemia and/or sleep-related hypoventilation following initiation of treatment for OSA

### Repeat Home Sleep Study (HSS) Guideline

A repeat home sleep study (HSS) is considered medically appropriate when the documentation demonstrates an unattended study is required for **ANY** of the following: [7]

1. Obstructive sleep apnea (OSA) diagnosis re-evaluation when an assessment is needed for positive airway pressure adjustment or discontinuation (eg, weight or symptom changes)
2. Post-treatment evaluation for surgery or oral appliance device efficacy

### Split-Night Study Guideline

A split-night attended in-lab sleep study is considered medically appropriate when the documentation demonstrates that **ALL** of the following criteria are met: [9] [19]

1. In-lab, attended polysomnography (PSG) indications are met (see section: Attended In-lab Polysomnography).
2. Sleep study is diagnostic and 3 hours are left to complete continuous positive airway pressure (CPAP) titration.



#### **LCD 33405**

See also, **LCD 33405**: Polysomnography and Sleep Testing at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.



#### **LCD 34040**

See also, **LCD 34040**: Polysomnography and Other Sleep Studies at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.

**LCD 35050**

See also, **LCD 35050**: Outpatient Sleep Studies at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.

**LCD 36593**

See also, **LCD 36593**: Polysomnography at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.

**LCD 36902**

See also, **LCD 36902**: Polysomnography and Other Sleep Studies at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.

**LCD 36861**

See also, **LCD 36861**: Polysomnography and Other Sleep Studies at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.

**LCD 36839**

See also, **LCD 36839**: Polysomnography and Other Sleep Studies at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.

## **Bilevel positive airway pressure/Continuous positive airway pressure BPAP/CPAP Titration**

### **BPAP/CPAP Guideline**

An in-laboratory bilevel positive airway pressure/continuous positive airway pressure (BPAP/CPAP) titration study is considered medically appropriate when the documentation demonstrates **ANY** of the following: [7]



1. BPAP or other advanced positive airway pressure (PAP) modalities (eg, adaptive servo-ventilation [ASV], average volume-assured pressure support [AVAPS] or intelligent volume assured pressure support [iVAPS]) are indicated.
2. CPAP therapy is adhered to and symptoms of sleep apnea remain or recur.
3. Oxyhemoglobin desaturation occurs while on PAP therapy.

## Sleep Study, Pediatric/Young Adult

### Attended In-Lab Polysomnography (PSG) Guideline

An attended, in-laboratory polysomnography is considered medically appropriate when the documentation demonstrates **ANY** of the following: [2] [5] [14] [20]

1. Adenotonsillectomy for peri-operative monitoring when obstructive sleep apnea (OSA) is suspected or known.
2. Apparent life-threatening event (ALTE) is suspected in an infant with a sleep related breathing disorder (eg, apnea, change in color or muscle tone, coughing, gagging).
3. Chest wall deformities are suspected.
4. Congenital central alveolar hypoventilation syndrome is suspected.
5. Neuromuscular disorders are known and hypoventilation is suspected.
6. Positive airway pressure (PAP) evaluation or titration
7. Symptom evaluation for **ANY** of the following:
  - a. Hypersomnia or parasomnia
  - b. Learning problems during the daytime (eg, behavioral issues, inattention, neurocognitive issues)
  - c. Periodic limb movement disorder (PLMD)
  - d. Restless leg syndrome
  - e. Seizures are nocturnal.
  - f. Sleep disturbance with frequent gasps, labored breathing, pauses or snorts

### In Home Sleep Study Guideline

An in home pediatric sleep study: [5] [20]

- The role of this therapy is uncertain/unclear in the current evidence. Requests for this therapy require review by a physician reviewer, medical director and/or the individual's healthplan.

## PSG Procedure Codes

**Table 1. Sleep Studies, Polysomnography (PSG) Associated Procedure Codes**

CODE	DESCRIPTION
95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
95808	Polysomnography; any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist
95810	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95811	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 bilevel ventilation, attended by a technologist

## PSG Summary of Changes

The polysomnography (PSG) sleep clinical guidelines from 2023 to 2024 had the following version changes:

- Added BMI > 50 kg/m<sup>2</sup> to contraindication to unattended home sleep study.
- Added the following definitions:
  - Adaptive servo-ventilation (ASV)
  - Average volume-assured pressure support (AVAPS)
  - Intelligent volume assured pressure support (iVAPS)
  - Neuromuscular disease
  - Oxyhemoglobin saturation
- Added "Insomnia with **NO** other symptoms of obstructive sleep apnea or other sleep disorders (eg, restless leg, nocturia, fatigue, difficulty concentrating, heavy habitual snoring)." under contraindications to attended in lab PSG.
- "Contraindication to unattended home sleep study (see section: Contraindications to Home Sleep Study [HSS]) OR prior home sleep study is positive (eg, apnea-hypopnea index [AHI] over 5)" was updated to "Contraindication to an unattended home sleep study (see section: Contraindications to Home Sleep Study [HSS]) OR prior sleep testing is indeterminate, incomplete OR negative and symptoms persist" under the known OSA section to match the indication under suspected OSA.
- "Current treatment for OSA with development" was updated to "Current treatment for OSA with development of unexplained symptoms of OSAS"
- Repeat Home Polysomnography (PSG) title changed to Repeat Home Sleep Study (HSS).

- Removed "Obesity Hypoventilation Syndrome (BMI of at least 30 kg/m<sup>2</sup> and elevated pCO<sub>2</sub> of 45 mmHg or more)" per current research.
- "Sleep evaluation is complete with sleep history, body mass index (BMI), neck circumference, cardiopulmonary assessment, sleep disorder history and comorbidity evaluation" was updated to "Sleep evaluation is complete (eg, sleep history, body mass index (BMI), neck circumference, cardiopulmonary assessment, comorbidity evaluation)".
- Citations updated per the evidence.

## Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness (MWT)

### Sleep Program: Sleep Studies

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**Last Review Date: 07/01/2024**

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Guideline Initiated: 06/02/2021

## Contraindications or Exclusions to Multiple Sleep Latency Test (MSLT)

Contraindications or exclusions to multiple sleep latency test (MSLT) include **ANY** of the following:

1. Circadian rhythm disorders
2. Insomnia
3. Neurological (other than narcolepsy) or medical disorders for the routine assessment of sleepiness.
4. Obstructive sleep apnea (OSA) is suspected, for initial evaluation.
5. OSA is known, for treatment planning (eg, positive airway pressure [PAP]).

**Reference:** [ 2023 Assessment of Vigilance and Fatigue ]

## Maintenance of Wakefulness Test (MWT)



### IMPORTANT

Polysomnography (PSG) must be done on the night preceding MWT to rule out other sleep disorders and to document adequate nocturnal sleep time (6 hours).

## MWT Guideline

An in-lab, supervised maintenance of wakefulness test (MWT) is considered medically appropriate when the documentation demonstrates **ANY** of the following: [10]

1. Narcolepsy or idiopathic hypersomnia for monitoring of treatment response.
2. Safety concerns: assessment of ability to stay awake when being awake is necessary for personal or public safety.



### LCD 35050

See also, **LCD 35050**: Outpatient Sleep Studies at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.



### LCD 36593

See also, **LCD 36593**: Polysomnography at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.



### LCD 36902

See also, **LCD 36902**: Polysomnography and Other Sleep Studies at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.



### LCD 36861

See also, **LCD 36861**: Polysomnography and Other Sleep Studies at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.



### LCD 34040

See also, **LCD 34040**: Polysomnography and Other Sleep Studies at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.

**LCD 36839**

See also, **LCD 36839**: Polysomnography and Other Sleep Studies at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.

**LCD 33405**

See also, **LCD 33405**: Polysomnography and Sleep Testing at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.

## Multiple Sleep Latency Test (MSLT)

**NOTE**

Polysomnography (PSG) must be done on the night preceding MSLT to rule out other sleep disorders and to document adequate nocturnal sleep time (6 hours).

### MSLT Guideline

An in-lab supervised multiple sleep latency test (MSLT) to evaluate hypersomnia is considered medically appropriate when the documentation demonstrates that **ANY** of the following criteria are met: [10]

1. Idiopathic hypersomnia, that is characterized by excessive daytime sleepiness or hypersomnolence that has been present for 8 weeks or more, and **ANY** of the following:  
**\*NOTE:** *The American Academy of Sleep Medicine (AASM) Clinical Practice Guideline recommends actigraphy to monitor total sleep time prior to testing with MSLT in patients with suspected central disorders of hypersomnolence.*
  - a. Prior testing did **NOT** include polysomnography confirmation.
  - b. Prior testing is non-diagnostic or indeterminate.
  - c. Symptoms persist and/or narcolepsy is suspected.
2. Narcolepsy is characterized by **ANY** of the following :[18]
  - a. Cataplexy (weakness/muscle tone loss without consciousness loss)
  - b. Excessive daytime sleepiness (EDS)

- c. Hypnagogic hallucinations (sleep-related hallucinations when falling asleep)
- d. Hypnopompic hallucinations (sleep-related hallucinations when awakening)
- e. Sleep paralysis
- f. Sleep is disrupted or fragmented.



**LCD 35050**

See also, **LCD 35050**: Outpatient Sleep Studies at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.



**LCD 36593**

See also, **LCD 36593**: Polysomnography at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.



**LCD 36902**

See also, **LCD 36902**: Polysomnography and Other Sleep Studies at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.



**LCD 36861**

See also, **LCD 36861**: Polysomnography and Other Sleep Studies at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.



**LCD 34040**

See also, **LCD 34040**: Polysomnography and Other Sleep Studies at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.



#### **LCD 36839**

See also, **LCD 36839**: Polysomnography and Other Sleep Studies at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.



#### **LCD 33405**

See also, **LCD 33405**: Polysomnography and Sleep Testing at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.

## **MSLT/MWT Procedure Codes**

**Table 1. Multiple Sleep Latency Testing (MSLT) or Maintenance of Wakefulness Testing (MWT) Associated Procedure Codes**

<b>CODE</b>	<b>DESCRIPTION</b>
95805	Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness

## **MSLT/MWT Summary of Changes**

The MSLT/MWT clinical guidelines from 2023 to 2024 had the following version changes:

- Citations updated per the evidence.
- Evidence reviewed and indications remained the same.

## **Sleep Devices**

### **Automatic Positive Airway Pressure (APAP) • Bilevel Positive Airway Pressure (BPAP) • Continuous Positive Airway Pressure (CPAP) Devices**

#### **Sleep Program: Airway Pressure Devices**

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Guideline Initiated Date: 05/01/2021

## Contraindications or Exclusions to Continuous or Bi-Level Positive Airway Pressure (CPAP) or (BPAP)

Contraindications or exclusions to continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BPAP) may include **ANY** of the following:

1. Air leak syndrome (eg, pneumothorax with bronchopleural fistula)
2. Anastomoses, esophageal, gastric or duodenal that are recent (positive pressure can increase upper gastrointestinal [GI] insufflation).
3. Facial deformities that prevent application of CPAP mask.
4. Mental status is altered and unable to protect the airway.
5. Post-procedure facial, esophageal or gastric transsphenoidal surgery
6. Vomiting copious emesis or excessive secretions complicating use.

**Reference:** [8]

## Contraindications or Exclusions to Automatic Positive Airway Pressure (APAP)

Contraindications or exclusions to automatic positive airway pressure (APAP) may include **ANY** of the following:

1. Age is less than 18 years.
2. Chronic obstructive pulmonary disease (COPD)
3. Heart failure with NYHA Class III, NYHA Class IV, or left ventricular ejection fraction (LVEF) is 45% or less.
4. Neuromuscular disorder with elevated daytime  $pCO_2$
5. Obesity hypoventilation syndrome
6. Opioid/narcotic use is chronic.

**References:** [13] [19]



## Automatic Positive Airway Pressure (APAP) • Bilevel Positive Airway Pressure (BPAP) • Continuous Positive Airway Pressure (CPAP)

**NCD 240.4**

See also, **NCD 240.4**: Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.

### Automatic Positive Airway Pressure (APAP) Guideline

An automatic positive airway pressure (APAP) treatment is considered medically appropriate when the documentation demonstrates **ALL** the following: [16] [13]

- I. Age is 18 years or older.
- II. Obstructive sleep apnea is known from in-person, clinical evaluation.
- III. Sleep study demonstrates **ANY** of the following:
  - A. Apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is 15 events or more per hour, with a minimum of 30 events.
  - B. AHI (or RDI) is 5 or more events and less than 15 events per hour, with a minimum of 10 events **AND** documentation includes **ANY** of the following:
    1. Cognition impaired or mood disorders
    2. Excessive daytime sleepiness (Epworth Sleepiness Scale more than 10) or daytime somnolence/fatigue interfering with daily activities
    3. Hypertension, arrhythmia, ischemic heart disease or stroke history
    4. Pulmonary hypertension

### CPAP Initial Treatment Guideline

Continuous positive airway pressure (CPAP) treatment is considered medically appropriate when the documentation demonstrates **ANY** of the following: [13] [16]

- I. Polysomnography (PSG), diagnostic, is completed and **ANY** of the following:
  - A. Automatic positive airway pressure (APAP) **FAILURE**
  - B. Obstructive sleep apnea (OSA) is mild (eg, Apnea-hypopnea index [AHI] is between 5 and 15 events) and **ANY** of the following: [21]

1. Excessive daytime sleepiness (EDS)
  2. Hypertension
  3. Quality of life decline due to sleep-related symptoms (eg, headaches, insomnia, snoring).
- C. OSA is moderate to severe (eg, AHI is 15 or more events). [21]
- II. Prior split night study does **NOT** support moderate or severe OSA (eg, AHI is 15 or more events) **AND** additional apnea events are noted later in the study.

### BPAP Initial Treatment Guideline

Bilevel positive airway pressure (BPAP) treatment is considered medically appropriate when the documentation demonstrates **ANY** of the following: [13] [16]

1. Central sleep apnea (CSA) treatment during titration study<sup>2</sup>.
2. Continuous positive airway pressure (CPAP) is **NOT** tolerated due to high pressures.
3. Polysomnography (PSG), diagnostic, is completed and **ANY** of the following:
  - a. Automatic positive airway pressure (APAP) **FAILURE**
  - b. Obstructive sleep apnea (OSA) is mild (eg, Apnea-hypopnea index [AHI] is between 5 and 15 events) and **ANY** of the following: [21]
    - i. Excessive daytime sleepiness (EDS)
    - ii. Hypertension
    - iii. Quality of life decline due to sleep-related symptoms (eg, snoring, insomnia, headaches).
  - c. OSA is moderate to severe (eg, AHI is 15 or more events). [21]
4. Prior split night study does **NOT** support moderate or severe OSA (eg, AHI is 15 or more events) **AND** additional apnea events noted later in the study.

### BPAP/CPAP Continuation of Treatment Guideline

An evaluation to continue bilevel positive airway pressure/continuous positive airway pressure (BPAP/CPAP) is considered medically appropriate when the documentation demonstrates **ANY** of the following conditions: [7]

1. Evaluation for effectiveness and adherence (at least 4 hours use per night for at least 70% of all nights within one month)
2. Prior home sleep study is positive (eg, Apnea-hypopnea index [AHI] is over 15 events) **AND** an attended, in-lab sleep study is required to support BPAP/CPAP titration.

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<sup>2</sup>BPAP is used with back-up rate for the treatment of CSA.

## Positive Airway Pressure (PAP) Device Guideline

Positive airway pressure (PAP) device (only) **AND following an in-lab study**<sup>3</sup>, is considered medically appropriate when the documentation demonstrates **ANY** of the following:

1. Automatic positive airway pressure/bilevel positive airway pressure/continuous positive airway pressure (APAP/BPAP/CPAP) treatment is adhered to, and sleep apnea symptoms persist or recur.
2. APAP treatment is **NOT** tolerated or **FAILED**.
3. CPAP control of obstructive apneas and hypopneas, and oxyhemoglobin desaturations persist.
4. CPAP treatment is **NOT** tolerated due to high pressure, and BPAP or other advanced modalities are indicated.
5. Obstructive sleep apnea (OSA) is moderate/severe (eg, Apnea-hypopnea index [AHI] of 15 or more events).
6. Prior split night study does **NOT** support moderate or severe OSA (eg, AHI is 15 or more events) **AND** additional apnea events noted later in the study.
7. Professional physical evaluation requirement for jobs involving public safety (eg, Department of Transportation physical for truck-drivers or pilots)
8. Titration study demonstrated at 15 cm of H<sub>2</sub>O of CPAP with continued respiratory events.

**References:** [13] [7] [16] [6]



### LCD 33800

See also, **LCD 33800:** Respiratory Assist Devices at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.

## APAP/BPAP/CPAP Procedure Codes

**Table 1. PAP Associated Procedure Codes**

CODE	DESCRIPTION
E0601	Continuous positive airway pressure (CPAP) device
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)

<sup>3</sup>In-lab study must be completed prior to initial device authorization.

CODE	DESCRIPTION
E0471	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)

## APAP/BPAP/CPAP Summary of Changes

The APAP/BPAP/CPAP clinical guidelines from 2023 to 2024 had the following version changes:

- Added definitions for hypopnea and insufflation.
- Citations updated per the evidence.
- Evidence reviewed and indications remained the same.
- Removed L33718 and L33800 from guideline per CMS.

## Oral Appliance

### Sleep Program: Sleep Devices

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**Last Review Date: 07/01/2024**

Previous Review Date: 08/04/2023

Guideline Initiated: 05/01/2021

## Contraindications or Exclusions to Mandibular Repositioning Appliance (MRA)

Contraindications or exclusions to mandibular advancement device (MAD) include **ANY** of the following: [4] [11] [17]

- Teeth are insufficient to support the device.
- Teeth/oral health problems (eg, loose teeth, periodontitis, significant cavities)

## Oral Appliance

### Oral Appliance Guideline

An oral device (mandibular advancement device [MAD] or tongue retaining device [TRD]) is considered medically indicated when the documentation demonstrates **ANY** of the following conditions: [13] [17]

1. Primary snoring is present and obstructive sleep apnea (OSA) is **ABSENT**.
2. OSA is known **AND** continuous positive airway pressure (CPAP) intolerant or preference is an alternative to CPAP.



#### LCD 33428

See also, **LCD 33428: Cosmetic and Reconstructive Surgery** at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.



#### LCD 33611

See also, **LCD33611: Oral Appliances for Obstructive Sleep Apnea** at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.

## Oral Appliance Procedure Codes

**Table 1. Oral Devices Associated Procedure Codes**

CODE	DESCRIPTION
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment

## Oral Appliance Summary of Changes

The Oral Appliance clinical guideline from 2023 to 2024 had the following version changes:

- Citations updated per the evidence.
- Evidence reviewed and indications remained the same.
- Removed L33611 from guideline per CMS.

## Sleep Definitions

**Adaptive servo-ventilation (ASV)** is a type of positive airway pressure (PAP) device. For some people with sleep apnea, especially central sleep apnea, ASV machines can promote stable and consistent breathing during sleep by sending pressurized air through a mask and into the upper airway. Distinct from other PAP devices, ASV machines make real-time adjustments to air pressure based on built-in sensors that track breathing

**Apnea** is the temporary cessation of breathing, especially during sleep.

**Apnea/Hypopnea Index (AHI)** is the number of apneas and hypopneas per hour (hr) of sleep, and is used to classify obstructive sleep apnea (OSA) severity. AHI may be interpreted as follows:

- AHI less than 15/hr is mild OSA.
- AHI 16-30/hr is moderate OSA.
- AHI over 30/hr is severe OSA.

**Apparent life-threatening event (ALTE)** refers to a sudden event often characterized by apnea or other abrupt changes in a child's behavior. Symptoms of an ALTE include: apnea, change in color or muscle tone, coughing or gagging.

**Average volume-assured pressure support (AVAPS)** is a modality of noninvasive ventilation that provides a targeted tidal volume by automatically adjusting the inspiratory pressure support within a set range. AVAPS provides the advantage of delivering a fixed tidal volume, which is kept constant due to changes in the levels of inspiratory pressures.

**Automatic positive airway pressure (APAP)** is one of the three main forms of positive airway pressure that opens the airway during sleep. Instead of operating at a set pressure, APAP monitors respiratory activity in order to provide the lowest level of PAP necessary to eliminate respiratory disturbances.

**Body Mass Index (BMI)** is a weight to height ratio, calculated by dividing one's weight in kilograms by the square of one's height in meters and used as an indicator of obesity and underweight.

**Bi-level positive airway pressure (BiPAP)** is one of the three main forms of positive airway pressure. It senses inspiration and expiration. It is able to provide a different pressure during inspiration and it cycles between two levels of continuous positive airway pressure.

**Central sleep apnea (CSA)** is a breathing disorder that causes the body to decrease or stop the effort of breathing during sleep. It is usually caused by an issue in the brain or heart. Certain medications (like pain medications) can cause this breathing pattern too. It is different from obstructive sleep apnea (OSA) because the problem is not caused by a blockage of the airway. Types of central sleep apnea include Cheyne-Stokes breathing, drug-induced apnea, high-altitude periodic breathing, idiopathic central sleep apnea, medical condition-induced central sleep apnea and treatment-emergent central sleep apnea. Symptoms of central sleep apnea include difficulty falling asleep, excessive daytime sleepiness (EDS), frequent nighttime awakening, pause in breathing, and waking up short of breath.

**Cheyne-Stokes breathing** is a type of breathing disorder characterized by cyclical episodes of apnea and hyperventilation.

**Chronic opiate use** is the filling of three or more sequential prescriptions for opioid medicine, or tolerance/dependence/addiction to opiate substances.

**Congenital central hypoventilation syndrome (CCHS)** is a rare neurological disorder characterized by inadequate breathing during sleep and in more severely affected individuals, during waking periods as well. This disorder is associated with a malfunction of the nerves that control involuntary body functions and abnormal development of early embryonic cells that form the spinal cord.

**Continuous positive airway pressure (CPAP)** is one of the three main forms of positive airway pressure that opens the airway during sleep. It provides a continuous, steady flow of air at a single pressure. This pressure setting is the exact level of air pressure required to keep the airway clear of obstructions.

**Electroencephalogram (EEG)** is a recording of electrical activity in the brain.

**Epworth sleepiness scale (ESS)** is a self-administered tool to evaluate the severity of excessive daytime sleepiness (EDS) on a subjective scale. An ESS score of 10 or higher indicates a possible sleep disorder. ESS scores may be interpreted as follows:

- 0-5 is Lower Normal Daytime Sleepiness.
- 6-10 is Higher Normal Daytime Sleepiness.
- 11-12 is Mild Excessive Daytime Sleepiness.
- 13-15 is Moderate Excessive Daytime Sleepiness.
- 16-24 is Severe Excessive Daytime Sleepiness.

**Excessive daytime sleepiness (EDS)** is sleepiness that occurs during normal wake-hours that may have a number of causes including, but not limited to, insufficient sleep, a sleep disorder, and/or a circadian rhythm disorder or circadian misalignment. It is measured by tools such as the Epworth Sleepiness Scale (ESS).

**Forced expiratory volume in 1 second (FEV1)** is a measurement in liters taken from a pulmonary function test (PFT) (a noninvasive test that measures lung volume, capacity, rates of flow and gas exchange). It calculates the amount of air that a person can force out of their lungs in 1 second.

**Hypopnea:** a short period during which a person experiences a reduction in breathing as they sleep. Different technical definitions of hypopnea have been used over time. Currently, the American Academy of Sleep Medicine (AASM) outlines three criteria that must be met for a breathing event to be considered a hypopnea:

- Airflow must decrease by at least 30%.
- This decrease must last for 10 or more seconds.
- Blood oxygen levels must drop by at least 3% or 4% during this event, or brain waves must demonstrate an arousal, which signals a brief awakening or a transition to a lighter sleep stage.

Reference: [<https://www.sleepapnea.org/hypopnea/>]

**Idiopathic hypersomnia** is a central disorder of hypersomnolence causing a state of constant and severe excessive sleepiness with unrefreshing naps, and often with post-awakening confusion (sleep drunk). Idiopathic hypersomnia with long sleep time includes a sleep episode of at least 10 hours and is considered uncommon.

**Insufflation:** the act of blowing something (such as a gas, powder, or vapor) into a body cavity.



**Intelligent volume assured pressure support definition (iVAPS)** is a mode of non-invasive ventilation (NIV), which relies on applying an alveolar target volume and adjusts pressure and respiratory rate automatically to achieve optimal ventilatory support.

**Narcolepsy** is a chronic neurological disorder that affects the brain's ability to control sleep-wake cycles. People with narcolepsy may feel rested after waking, but then feel very sleepy throughout much of the day.

**Neuromuscular disease** is a disease (eg, amyotrophic lateral sclerosis [ALS], muscular dystrophy, myasthenia gravis) that affects the function of muscles due to problems with the nerves and muscles in the body. The most common finding of these diseases is muscle weakness.

**Table 1. New York Heart Association (NYHA) Functional Classification for Heart Failure**

CLASS	SYMPTOMS EXPERIENCED
Class I (Mild)	Cardiac disease, but no symptoms and no limitation in ordinary physical activity (eg, shortness of breath when walking, climbing stairs).
Class II (Mild)	Mild symptoms (eg, mild shortness of breath and/or angina) and slight limitation during ordinary activity.
Class III (Moderate)	Marked limitation in activity due to symptoms, even during less-than-ordinary activity, (eg, walking short distances [20–100 m]). Comfortable only at rest. Class IIIa: no dyspnea at rest. Class IIIb: recent dyspnea at rest.
Class IV (Severe)	Severe limitations. Experience symptoms while at rest. Unable to carry on any physical activity without discomfort.

**Obesity hypoventilation syndrome** is the presence of a body mass index (BMI) over 30 kg/m<sup>2</sup> and elevated pCO<sub>2</sub> 45 mmHg or greater, which cannot be solely attributed to other conditions (eg, pulmonary disease, skeletal restriction, neuromuscular weakness, hypothyroidism, pleural pathology or medications).

**Obstructive sleep apnea (OSA)** is a sleep-related breathing disorder that involves a decrease or complete halt in airflow despite an ongoing effort to breathe. It occurs when the muscles and soft tissues in the upper airway relax during sleep, causing soft tissue in the back of the throat to collapse and block the upper airway. Some common symptoms of sleep apnea include: daytime sleepiness or fatigue, gasping for breath during sleep, silent pauses in breathing, snoring and snorting.

**Oxyhemoglobin saturation:** Oxygen saturation is a measure of how much hemoglobin is currently bound to oxygen compared to how much hemoglobin remains unbound.

**Parasomnia** Parasomnia is a "catchall" term for unusual behaviors that people experience either as they are falling asleep, while asleep, or during the arousal period between sleep and wakefulness. Some examples include sleepwalking, sleep talking, REM sleep behavior disorder and night terrors.

**Periodic limb movement disorder (PLMD)** is characterized by periodic episodes of repetitive limb movements during sleep that are **NOT** caused by another sleep disorder (such as obstructive sleep apnea [OSA]), and cause daytime symptoms such as excessive daytime sleepiness.



**Peri-operative** relates to the time before, during, and after a surgical operation.

**Polysomnogram (PSG) or sleep study/test** is a test that electronically transmits and records specific physical activities during sleep. The recordings are analyzed to determine whether a sleep disorder exists.

**Positive airway pressure (PAP)** treatment uses a machine to pump air under pressure into the lungs. The forced air delivered by continuous positive airway pressure (CPAP) prevents episodes of upper airway collapse that block the breathing in people with obstructive sleep apnea and other breathing problems.

**Pulmonary hypertension** is a type of high blood pressure that affects the arteries in the lungs and the right side of the heart.

**Respiratory distress index (RDI)** is the number of respiratory disturbances (apneas, hypopneas, and respiratory effort related arousals [RERAs]) per hour of sleep.

**Restless leg syndrome (RLS)** is a condition that causes an uncontrollable urge to move the legs, usually because of an uncomfortable sensation. It typically happens in the evening or nighttime hours while sitting or lying down. Moving eases the unpleasant feeling temporarily.

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