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2023 Sleep Program Clinical Guidelines

Sleep Studies and Devices

Guideline	Protocol ID	Previous Review Date	Last Review Date
Polysomnography (PSG)	P_11140, P_11159, P_11165	03/03/2023	08/04/2023
Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness (MWT)	P_11142	08/08/2022	08/04/2023
Automatic Positive Airway Pressure (APAP), Biventricular Positive Airway Pressure (BPAP), Continuous Positive Airway Pressure (CPAP) Devices	P_11100	01/31/2023	10/11/2023
Oral Appliance	P_11141	08/08/2022	08/04/2023

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Sleep Testing

Polysomnography (PSG)

Sleep Program: Sleep Studies

P_11140, P_11159, P_11165
Guideline Initiated Date: 05/01/2021
Previous Review Date: 03/02/2023
Last Review Date: 08/04/2023

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:

I. Non-obstructive sleep apnea disorder (NON-OSA) is suspected or known and **ANY** of the following: [17]

   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 predispose to central sleep apnea (eg, opioids).

   C. Narcolepsy or idiopathic hypersomnia

   D. Parasomnia, characterized by atypical or violent episodes. [10] [18]

   E. Seizure activity, nocturnal, and electroencephalogram (EEG) is abnormal or inconclusive.

F. Periodic limb movement disorder (PLMD) and **ALL** of the following: [17] [18]

1. 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

2. Repetitive limb movement is reported.

3. Sleep disruptions are characterized by **ANY** of the following:

a. Difficulty remaining asleep/frequently waking.

b. Excessive daytime sleepiness (EDS)

II. Obstructive sleep apnea (OSA) is known and **ALL** of the following: [10] [18]

A. An attended study is required to support advanced positive airway pressure (PAP) titration (eg, adaptive servo ventilation [ASV])

B. 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)

C. Sleep evaluation is complete with sleep history, body mass index (BMI), neck circumference, cardiopulmonary assessment, sleep disorder history and comorbidity evaluation.

III. Obstructive sleep apnea is suspected and **ALL** of the following:

A. Evaluation of **ANY** of the following:

1. 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] [10] [18]

a. BMI 30 or higher **OR** large neck circumference (17 inches or more in men or 16 or more inches in women)

b. Hypertension

c. Snoring is loud and habitual.

d. Symptoms of apneas, choking or gasping are present.

2. High-risk with **ANY** 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) 45% or less.

3. Safety evaluation for professions that have a direct impact on public-safety (eg, bus drivers, pilots, truck drivers). [10] [6]

B. 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.

C. Sleep evaluation is complete with sleep history, body mass index (BMI), neck circumference, cardiopulmonary assessment, sleep disorder history and comorbidity evaluation.

IV. Titration after a Hypoglossal Nerve Stimulator (HNS) implant [21]

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]

I. **NO** contraindications to an unattended, home sleep study exist (see section Contraindications to Unattended, Home Sleep Study [HSS]).

II. Obstructive sleep apnea symptoms (eg, BMI 30 or higher, choking or gasping during sleep, habitual loud snoring, large neck circumference [17 inches or more in men, or 16 or more inches in women], observed apneas) **AND** excessive daytime sleepiness (measured by a combination of test including those for medical and psychiatric co-morbidities and the Epworth Sleepiness Scale [ESS]). [10] [18]

III. Sleep evaluation is complete with sleep history, body mass index (BMI), neck circumference, cardiopulmonary assessment, sleep disorder history and comorbidity evaluation.

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]

I. Assessment of response to treatment with non-PAP interventions, when clinically significant weight loss or gain has occurred since diagnosis of OSA or initiation of its treatment.

II. Attended study is required to support advanced positive airway pressure (PAP) titration.

III. Change in cardiovascular disease

IV. Current treatment for OSA with development

V. Reassessment of sleep-related hypoxemia and/or sleep-related hypoventilation following initiation of treatment for OSA

Repeat Home Polysomnography (PSG) Guideline

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

I. OSA diagnosis re-evaluation when an assessment is needed for positive airway pressure adjustment or discontinuation (eg, weight or symptom changes)

II. 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: [10] [18]

I. In-lab, attended polysomnography (PSG) indications are met (see section: Attended In-lab Polysomnography).

II. 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*.

BPAP/CPAP Titration

Guideline

An in-laboratory BPAP/CPAP titration study may be indicated with **ANY** of the following: [7]

- Bilevel positive airway pressure (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.

- CPAP therapy is adhered to and symptoms of sleep apnea remain or recur.
- Oxyhemoglobin desaturation occurs while on PAP therapy.

Sleep Study, Pediatric (under 18)

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] [15] [19]

I. Adenotonsillectomy for perioperative monitoring when OSA is suspected or known.

II. 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).

III. Chest wall deformities are suspected.

IV. Congenital central alveolar hypoventilation syndrome is suspected.

V. Neuromuscular disorders are known and hypoventilation is suspected.

VI. Positive airway pressure (PAP) evaluation or titration

VII. Symptom evaluation for **ANY** of the following:

A. Hypersomnia or parasomnia

B. Learning problems, daytime (eg, behavioral issues, inattention, neurocognitive issues)

C. Periodic limb movement disorder (PLMD)

D. Restless leg syndrome

E. Seizure, nocturnal

F. Sleep disturbance with frequent gasps, labored breathing, pauses, or snorts

In Home Sleep Study Guideline

An in home pediatric sleep study: [5] [19]

- 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.

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

Contraindications or exclusions for an attended in-laboratory polysomnography (PSG) includes of **ANY** of the following: [10] [8]

- Bruxism
- Restless leg syndrome (RLS) primary diagnostic testing[1]
- Rhythmic movement disorder (RMD)
- Sleep related leg cramps
- Sleep related myoclonus

Contraindications or Exclusions to Unattended Home Sleep Study (HSS)

Contraindications or exclusions to home sleep testing include **ANY** of the following: [10] [18]

I. Clinical condition includes **ANY** of the following:

A. Heart failure, New York Heart Association (NYHA) Class III or IV, or LVEF of 45% or less. [3]

B. Neuromuscular disease or impairment

C. Obesity hypoventilation syndrome (BMI of at least 30 kg/m2 and elevated pCO2 of 45 mmHg or more).

D. Opioid use, chronic

E. Pulmonary disease is characterized by 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

II. Individual or available caregiver unable to carry out home instructions. [3]

III. Obstructive sleep apnea (OSA) is asymptomatic, regardless of comorbidities.

[1]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.

Procedure Codes

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

CODE	DESCRIPTION
95782	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95783	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
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
95800	Sleep study, unattended simultaneous recording heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time
95801	Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation and respiratory analysis (e.g., by airflow or peripheral arterial tone)
95806	Sleep study, unattended, simultaneous recording of heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)
G0398	Home sleep study with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation
G0399	Home sleep study with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation
G0400	Home sleep study with type IV portable monitor, unattended; minimum of 3 channels

Summary of Changes

The polysomnography (PSG) sleep clinical guidelines from 2022 to 2023 had the following version changes:

- "Neuromuscular disease" was updated to "neuromuscular disease or impairment" under the Contraindications or exclusions to unattended HSS.
- Repeat in-lab PSG had the following additions:
  - "Assessment of response to treatment with non-PAP interventions, when clinically significant weight loss or gain has occurred since diagnosis of OSA or initiation of its treatment"
  - "Current treatment for OSA with development OR change in cardiovascular disease."
  - "Reassessment of sleep-related hypoxemia and/or sleep-related hypoventilation following initiation of treatment for OSA"

- Sleep study, pediatric had the following changes:
  - "Hypoventilation is suspected due to neuromuscular disorders" was updated to "Neuromuscular disorders are known and hypoventilation is suspected".
  - "Obstructive sleep apnea syndrome (OSAS) is suspected or known, perioperatively during adenotonsillectomy" as updated to "Adenotonsillectomy for perioperative monitoring when OSA is suspected or known"

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

Sleep Program: Sleep Studies

P_11142
Guideline Initiated: 06/02/2021
Previous Review Date: 08/08/2022
Last Review Date: 08/04/2023

Maintenance of Wakefulness Test (MWT)

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

Maintenance of Wakefulness Test Guideline

An in-lab, supervised maintenance of wakefulness test (MWT) is considered medically appropriate when the documentation demonstrates **ANY** of the following: [11]

- Narcolepsy or idiopathic hypersomnia for monitoring of treatment response.
- 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
PSG must be done on the night preceding MSLT to rule out other sleep disorders and to document adequate nocturnal sleep time (6 hours).

Multiple Sleep Latency Test (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: [11]

I. 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 polygraphy confirmation.

   B. Prior testing is indeterminate.

   C. Symptoms persist with continued suspicion of narcolepsy.

II. Narcolepsy is characterized by **ANY** of the following :[17]

   A. Cataplexy (weakness/muscle tone loss without consciousness loss)

   B. Excessive daytime sleepiness (EDS)

   C. Hypnogogic 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*.

Contraindications or Exclusions to Multiple Sleep Latency Test (MSLT)

Contraindications or exclusions to multiple sleep latency test (MSLT) include **ANY** of the following: [13]

- Circadian rhythm disorders
- Insomnia
- Neurological (other than narcolepsy) or medical disorders for the routine assessment of sleepiness.
- Obstructive sleep apnea (OSA) is suspected, for initial evaluation.
- Obstructive sleep apnea (OSA) is known, for treatment planning (eg, PAP).

Procedure Codes

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

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

Summary of Changes

The MSLT/MWT clinical guidelines from 2022 to 2023 had the following version changes:

- Information and references were verified as up to date.

Sleep Devices

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

Sleep Program: Airway Pressure Devices

P_11100
Last Review Date: 10/11/2023
Previous Review Date: 08/04/2023
Guideline Initiated Date: 05/11/2021

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 may be appropriate when the medical record demonstrates **ALL** the following: [16] [14]

I. Age 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 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 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 may be indicated with **ANY** of the following: [14] [16]

I. Polysomnography (PSG), diagnostic, is completed and **ANY** of the following:

A. Automatic positive airway pressure (APAP) failure

B. OSA is mild (eg, AHI is between 5 and 15) and **ANY** of the following: [20]

1. Excessive daytime sleepiness (EDS)

2. Hypertension
3. 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). [20]

II. Prior split night study does **NOT** support moderate or severe OSA (eg, AHI is 15 or more) **AND** additional apnea events noted later in the study.

BPAP Initial Treatment Guideline

Bilevel positive airway pressure (BPAP) treatment may be indicated with **ANY** of the following: [14] [16]

I. Central sleep apnea (CSA) treatment during titration study.[2]

II. Continuous positive airway pressure (CPAP) is **NOT** tolerated due to high pressures.

III. Polysomnography (PSG), diagnostic, is completed and **ANY** of the following:

A. Automatic positive airway pressure (APAP) failure

B. OSA is mild (eg, AHI is between 5 and 15) and **ANY** of the following: [20]

1. Excessive daytime sleepiness (EDS)
2. Hypertension
3. 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). [20]

IV. Prior split night study does **NOT** support moderate or severe OSA (eg, AHI is 15 or more) **AND** additional apnea events noted later in the study.

BPAP/CPAP Continuation of Treatment Guideline

An evaluation to continue BPAP/CPAP may be indicated for **ANY** of the following conditions: [7]

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

Positive Airway Pressure (PAP) Device Guideline

Positive airway pressure (PAP) device (only) **AND following an in-lab study**[3], is considered medically appropriate when the documentation demonstrates **ANY** of the following: [14]

[2]BPAP is used with back-up rate for the treatment of CSA.

- APAP/BPAP/CPAP treatment is adhered to, and sleep apnea symptoms persist or recur. [7]
- APAP treatment is **NOT** tolerated or has failed. [16]
- CPAP control of obstructive apneas and hypopneas, and oxyhemoglobin desaturations persist.
- CPAP treatment is **NOT** tolerated due to high pressure, and BPAP or other advanced modalities are indicated. [16]
- Obstructive sleep apnea (OSA) is moderate/severe (eg, AHI of 15 or more).
- Prior split night study does **NOT** support moderate or severe OSA (eg, AHI is 15 or more) **AND** additional apnea events noted later in the study.
- Professional physical evaluation requirement for jobs involving public safety (eg, Department of Transportation physical for truck-drivers or pilots) [6]
- Titration study demonstrated at 15 cm of H2O of CPAP with continued respiratory events.

LCD 33718
See also, **LCD 33718**: Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea at https://www.cms.gov/medicare-coverage-database/search.aspx *if applicable to individual's healthplan membership*.

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*.

Contraindications or Exclusions to Automatic Positive Airway Pressure (APAP)

Contraindications or exclusions to automatic positive airway pressure (APAP) include **ANY** of the following: [14] [18]

- Age less than 18 years
- Chronic obstructive pulmonary disease (COPD)
- Chronic opioid/narcotic use

[3]In-lab study must be completed prior to initial device authorization.

- Heart failure with NYHA Class III, NYHA Class IV, or left ventricular ejection fraction (LVEF) 45% or less
- Neuromuscular disorder with elevated daytime pCO2
- Obesity hypoventilation syndrome

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) include **ANY** of the following: [9]

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

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)
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)

Summary of Changes

The APAP/BPAP/CPAP clinical guidelines from 2022 to 2023 had the following version changes:

- Positive Airway Pressure (PAP) Device guideline changes:
  - Removed "and there is NO prior split-night or titration study" from "Obstructive sleep apnea (OSA) is moderate/severe (eg, AHI of 15 or more) and there is NO prior split-night or titration study" indication.
- APAP/BPAP/CPAP guideline changes:

- Removed "AND there is NO past split-night study" from the "OSA is moderate to severe (eg, AHI is 15 or more)" indication under BPAP/CPAP initial treatment.

Oral Appliance

Sleep Program: Sleep Devices

P_11141
Guideline initiated: 05/01/2021
Previous Review Date: 08/08/2022
Last review Date: 08/04/2023

Oral Appliance

Oral Appliance Guideline

An oral device (mandibular advancement device [MAD] or tongue retaining device [TRD]) may be indicated for **ANY** of the following conditions: [12] [14]

- **ABSENT** obstructive sleep apnea (OSA) and snoring (primary)
- Obstructive sleep apnea is known **AND** CPAP intolerant or preference is an alternative to CPAP.

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*.

Contraindications or Exclusions to Mandibular Repositioning Appliance (MRA)

Contraindications or exclusions to mandibular advancement device (MAD) include **ANY** of the following: [4] [12]

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

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

Summary of Changes

The Oral Appliance clinical guideline from 2022 to 2023 had the following version changes:

- Information and references were verified as up to date.

Definitions/Key Terms

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.

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.

Bi-level positive airway pressure (BiPAP) is one of the three main forms of positive airway pressure. It cycles between two levels of continuous positive airway pressure.

Central sleep apnea (CSA) is a breathing disorder that causes your 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, snoring, and waking up short of breath.

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.

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 be a result of circadian dysrhythmia and disruption of the body's homeostasis. It is measured by tools such as the Epworth Sleepiness Scale (ESS).

Forced expiratory volume (FEV1) is a measurement 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.

Idiopathic hypersomnia is 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.

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/m2 and elevated pCO2 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 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, silent pauses in breathing, snoring and snorting.
Parasomnia is an abnormal disruption of sleep such as sleep walking, sleep talking, nightmares, bedwetting, sleep apnea (problems with breathing that cause loud snoring) or nighttime seizures.
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 OSA).
Perioperative 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 airway of the lungs. The forced air delivered by continuous positive airway pressure (CPAP) prevents episodes of 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, hypo-pneas, 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 night-time hours while sitting or lying down. Moving eases the unpleasant feeling temporarily.

Reference Section

[1] Almeida, F. R. & Lettieri, C. J. (2022). Oral Appliances for the Treatment of Sleep -Disordered Breathing. M. Kryger, T. Roth, . . . W. C. Dements (Eds.). *Principles and Practice of Sleep Medicine* (7), (pp. 1657-1670.e5). Philadelphia, PA: Elsevier
[2] Aurora, R.N., Zak, R.S., . . . Ramar, K. (2011). Practice parameters for clinical use of the multiple sleep latency test and the maintenance of wakefulness test. *Sleep, 32*(3), 379-388.
[3] Avidan, A. (2022). Sleep and Its Disorder. *Bradley and Daroffs Neurology in Clinical Practice, 101* (2022), 1664-1744.e9.

[4] Basyuni, S., Barabas, M. & Quinnell, T. (2018). An update on mandibular advancement devices for the treatment of obstructive sleep apnoea hypopnoea syndrome. *Journal of Thoracic Disease, 10*(Suppl 1), S48-S56.

[5] Baughn, J.M. (2023). Pediatric Sleep Disorders. R.D. Kellerman & D.P. Rakel (Eds.). *Conn's Current Therapy 2023*, (pp. 1362-1367). Philadelphia, PA: Elsevier

[6] Brown, D.B. (2022). Legal Aspects of Fatigue- and Safety-Sensitive Professions. M. Kryger, T. Roth, . . . W.C. Dement (Eds.). *Principles and Practice of Sleep Medicine* (7), (pp. 723-726.e4). Philadelphia, PA: Elsevier, Inc.

[7] Caples, S. M., Anderson, W. M., . . . Hasmi, S. D. (2021). Use of polysomnography and home sleep apnea tests for the longitudinal management of obstructive sleep apnea in adults: an American Academy of Sleep Medicine clinical guideline statement. *Journal of Clinical Sleep Medicine, 17* (6), 1287-1293.

[8] Gerstenslage, B. & Slowik, J.M. (2021). Sleep Study. *StatPearls,* . Retrieved: July 2023. https://www.ncbi.nlm.nih.gov/books/NBK563147/

[9] Gill, H.S. & Marcolini, E.G. (2022). Noninvasive Mechanical Ventilation. *Emergency Medicine Clinics of North America, 40*, 603-613.

[10] Kimoff,R. J., Kaminska, M. & Pamidi, S. (2022). Obstructive Sleep Apnea. V. C. Broaddus. (Eds.). *Murray & Nadel's Textbook of Respiratory Medicine* (7), (pp. 1654-1669.e.14). Philadelphia: Elsevier.

[11] Krahn, L. E., Arand, D. L., . . . Harrod, C. G. (2021). 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, 17*(12), 2489-2498.

[12] Lavigne, G. J., Babiloni, A. H,... Cistulli, P. A. (2020). Critical Issues in Dental and Medical Management of Obstructive sleep Apnea. *Journal of Dental Research, 99*, 26-35.

[13] Littner, M.R., Kushida, C., . . . Kramer, M. (2005). Practice parameters for clinical use of the multiple sleep latency test and the maintenance of wakefulness test. *Sleep, 28*(1), 113-21.

[14] Liu, S. Y-C., May, A. M., . . . Mehra, R. (2022). Sleep-Disorder Breathing Treatment. B. V. Broaddus (Ed.). *Murray's & Nadel's Textbook of Respiratory Medicine* (7), (pp.1687-1702e.6). Philidelphia: Elsevier.

[15] Marcus, C.L., Brooks, L.J., . . . Shiffman, R.N. (2012). Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome. *Pediatrics, 130*(3), 576-584.

[16] Patil, S.P., Ayappa, I.A., . . . Harrod, C.G. (2019). Treatment of Adult Obstructive Sleep Apnea with Positive Airway Pressure: An Academy of Sleep Medicine Clinical Practice Guideline. *Journal of Clinical Sleep Medicine, 15*(2), 335-343.

[17] Rosenberg, R., Hirshkowitz, M., . . . Kryger, M. (2019). The role of home sleep testing for evaluation of patiens with excessive daytime sleepiness: focus on obstructive sleep apnea and narcolepsy. *Sleep Medicine, 56*(2019), 80-89.

[18] Sarber, K.M., Lam, D.J. & Ishman, S.L. (2021). Sleep Apnea and Sleep Disorders. P.W. Flint & H.W. Francis (Eds.). *Cummings Otolaryngology: Head and Neck Surgery* (7), (pp. 215-235 e4). Philadelphia, PA: Elsevier

[19] Stowe, R.C. & Afolabi-Brown, O. (2020). Pediatric polysomnography- A review of indications, technical aspects, and interpretations. *Paediatric Respiratory Reviews, 34*, 9-17.

[20] (2021). Always tired? You may have sleep apnea. *U.S. Food and Drug Administration (FDA)* Retrieved: July 2023. https://www.fda.gov/consumers/consumer-updates/always-tired-you-may-have-sleep-apnea?you may have sleep apnea#subscribe

[21] Weeks, B., Bao, G., . . . Emdur, L. (2018). Hypoglossal Nerve Stimulator Implantation in a Non-Academic Setting: Two-Year Result. *Laryngoscope Investigative Otolaryngology, 3*, 315-318.

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