



Criteria for Determining the Medical Necessity for the Treatment of Sleep Disordered Breathing in Adults and Children

Effective Date: July 20, 2022

Next Review Date: July 2023

Policy Number: SLP022022

Clinical Guideline: Treatment of Sleep Disordered Breathing in Adults and Children

This is a guideline only. The guideline does not represent medical advice. Medical decisions are the responsibility of the member and the attending physician. Benefits are determined by the health plan and employer group contract and eligibility of the subscriber at the time services were rendered.

POSITIVE AIRWAY PRESSURE THERAPY

Obstructive Sleep Apnea (OSA)

Treatment for obstructive sleep apnea should be coordinated by a qualified healthcare professional who works with the member to identify an appropriate treatment plan. It is expected that members receive lifestyle counseling, where applicable, for treatment of underlying factors contributing to the obstructive sleep apnea symptoms. Educational interventions at the initiation of PAP therapy are considered a best practice.

Continuous Positive Airway Pressure (CPAP) and Auto titrating Positive Airway Pressure (APAP) (E0601) At an effective pressure level is a standard treatment for obstructive sleep apnea. The appropriate pressure setting for CPAP may be determined during an attended facility titration study. A sleep technologist manually adjusts the CPAP pressure to determine the optimal therapeutic pressure setting, which is then programmed into the CPAP so that a fixed airflow pressure is consistently administered during therapy. Auto-Titrating Positive Airway Pressure (APAP) devices vary the pressure during treatment, based on measurements of the patient's physiologic response, such as airflow, pressure fluctuations or measures of airway resistance. Auto-adjusting PAP devices apply constant pressure, or bi-level pressure changes, as in bi-level PAP.

For members without significant comorbidities (e.g., CHF, COPD, central or treatment-emergent sleep apnea, obesity hypoventilation syndrome, or other concomitant sleep disorders) APAP devices may be initiated in the home setting and used in the self-adjusting mode in lieu of an attended facility titration for treatment of patients with obstructive sleep apnea.

Clinical practice standards advise that patients being treated with fixed CPAP or APAP (E0601) therapy have close clinical follow up to determine the effectiveness of treatment, especially during the initial weeks of therapy. If obstructive sleep apnea symptoms are not resolved effectively with CPAP or APAP, a clinical reevaluation may be medically necessary.

Bi-level Positive Airway Pressure WITHOUT back-up rate (E0470)

A bi-level positive airway pressure device is a respiratory assist device that is able to deliver separate expiratory and inspiratory positive airway pressures for assisted ventilation and may improve results and comfort for some members with OSA as well as other sleep disordered and respiratory conditions.

Bi-level Positive Airway Pressure WITH back-up rate (E0471)

A bi-level positive airway pressure device with a back-up rate delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive interface to assist



spontaneous respiratory efforts and provide a device-delivered breath if a spontaneous breath is not sensed in a pre-specified time period.

I. Positive Airway Pressure for the Treatment of OSA

CPAP or APAP therapy with or without a humidifier (E0561 or E0562) **is considered medically necessary** for an initial period of 90 days for adult members who are diagnosed with obstructive sleep apnea, as evidenced by a positive facility-based polysomnogram PSG, or a positive Home Sleep Apnea HSAT, as defined by **either** of the following criteria:

- A. Apnea/Hypopnea (AHI), Respiratory Disturbance Index (RDI) or Respiratory Event Index (REI) greater than or equal to 15 events per hour, in adult members with symptomatic or asymptomatic OSA.
- B. AHI, RDI, or REI greater than or equal to 5 and less than 15 events per hour and at least one of the following is met:
 1. History of stroke
 2. Hypertension
 3. Ischemic heart disease
 4. Symptoms of impaired cognition, mood disorders or insomnia
 5. Excessive daytime sleepiness

CPAP or APAP with or without a humidifier (E0561 or E0562) for an initial 90-day period **is considered medically necessary** for the treatment of OSA in a child when ALL of the following criteria are met:

1. OSA diagnosis established by diagnostic sleep test
2. Child weighs 30 kilograms (66 pounds) or more
3. Adenotonsillectomy has been unsuccessful or is contraindicated, or when definitive surgery is indicated but must await complete dental and facial development

Treatment of snoring alone, without obstructive sleep apnea, **is not considered medically necessary**

Bi-level therapy without a backup rate feature (E0470) is considered medically necessary for an initial period of 90 days for the treatment of obstructive sleep apnea when:

- A. CPAP has been tried and proven ineffective or is not tolerated as documented by a qualified health professional.

II. Positive Airway Pressure for Treatment of Other Sleep Disordered Breathing Conditions

Bi-level therapy with or without a backup rate feature (E0470/E0471*) is considered medically necessary for an initial period of 90 days for members with clinical disorder groups (other than OSA) characterized as one of the following (see specific criteria for each specific disorder) conditions:

1. Restrictive thoracic disorder
2. Severe COPD with evidence of hypercapnia,
3. Central sleep apnea (CSA) or treatment-emergent central sleep apnea.



4. Hypoventilation syndrome

***NOTE:** Most titrations are started with Bi-level without a backup rate; the backup rate is added if incomplete resolution of the sleep disordered breathing. Most often, this is due to persistent CSA or in patients with insufficient (variable) respiratory pattern i.e. patients with neuromuscular diagnoses.

Restrictive Thoracic Disorders

An E0470 or E0471 device **is considered medically necessary** when all of the following criteria are met:

- A. One of the following:
 - 1. An arterial blood gas PaCO₂, done while awake and breathing the member's usual FIO₂ is greater than or equal to 45 mm Hg;
 - 2. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing the member's usual FIO₂;
 - 3. For a progressive neuromuscular disease (only), maximal inspiratory pressure is less than 60 cm H₂O or forced vital capacity (FVC) is less than 50% predicted;
- B. There is documentation that chronic obstructive pulmonary disease does not contribute significantly to the member's pulmonary limitation.

Severe COPD

An E0470 device **is considered medically necessary** when all of the following criteria are met:

- A. An arterial blood gas PaCO₂, done while awake and breathing the member's usual FIO₂, is greater than or equal to 52 mm Hg;
- B. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing oxygen at 2 LPM or the member's usual FIO₂ (whichever is higher);
- C. Prior to initiating therapy, Obstructive Sleep Apnea (OSA) and treatment with a continuous positive airway pressure device (CPAP) has been tried and failed, not tolerated or considered and ruled out.

An E0471 device **is considered medically necessary** for a member for either of the following A or B:

- A. For members with COPD who qualified for an E0470 device, an E0471 started any time after a period of initial use of an E0470 device **is considered medically necessary** when both criteria 1 and 2 are met.
 - 1. An arterial blood gas PaCO₂, done while awake and breathing the member's prescribed FIO₂, shows that the member's PaCO₂ greater than 52 or pre ABG PaCO₂ increase equal to or greater than 7 mm HG compared to the original result from criterion 1 (above).
 - 2. A facility-based PSG demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2



hours) while using an E0470 device that is not caused by obstructive upper airway events – i.e., AHI less than 5.

- B. Member's with COPD who are started on bi-level positive pressure (E0470, E0471) at discharge from hospitalization, can continue for up to 3 months to provide time to stabilize and/or complete re-evaluation

Central Sleep Apnea or Treatment-Emergent Central Sleep Apnea

An E0470 or E0471 device is **considered medically necessary** when:

- A. Prior to initiating therapy, a complete facility-based, attended polysomnogram must be performed documenting ALL of the following:
 - 1. The diagnosis of central sleep apnea (CSA) or treatment-emergent central sleep apnea;
 - 2. The ruling out of CPAP as effective therapy if either CSA or OSA is a component of the initially observed sleep-associated hypoventilation;
 - 3. Significant improvement of the sleep-associated hypoventilation with the use of a bi-level therapy on the settings that will be prescribed for initial use at home, while breathing the member's usual FIO₂.

NOTE: Adaptive Servo-Ventilation, auto SV/Bopp and auto SV advanced devices (E0471) should not be used in individuals with symptomatic chronic congestive heart failure (CHF) with reduced ejection fraction (LVEF less than or equal to 45%). Resumed Ltd[®] identified a significant increase in the risk of cardiovascular death in individuals with symptomatic, chronic heart failure (NYHA II – IV) with reduced ejection fraction (LVEF less than or equal to 45%) and moderate to severe predominant central sleep apnea (AHI greater than or equal to 15, CAHI/AHI greater than or equal to 50% and CAI greater than or equal to 10). Philips Respironics[®] issued the same warning for at-risk individuals using Bopp autoSV/Bopp auto SV Advanced devices. In individuals with LVEF greater than 45% or mild CHF-related central sleep apnea, ASV may be used as an option for treatment, at the clinical discretion of the prescribing qualified healthcare professional

Hypoventilation Syndrome

An E0470 device is **considered medically necessary** when both criteria A and B and either criterion C or D are met.

- A. An initial arterial blood gas PaCO₂, done while awake and breathing the member's prescribed FIO₂, is greater than or equal to 45 mm Hg
- B. Spirometry shows an FEV₁/FVC greater than or equal to 70%. (Refer to SEVERE COPD (above) for information about device coverage for members with FEV₁/FVC less than 70 %.)
- C. An arterial blood gas PaCO₂, done during sleep or immediately upon awakening, and breathing the member's prescribed FIO₂, shows the member's PaCO₂ worsened greater than or equal to 7 mm HG compared to the original result in criterion A (above).



- D. A facility-based PSG or HST while on CPAP and prescribed FiO₂ demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI less than 5.

If the above criteria are not met, E0470 and related accessories **will be considered not medically necessary**.

An E0471 device **is considered medically necessary** when both criteria A, B and either criterion C or D are met:

- A. A covered E0470 device is being used and found to be ineffective.
- B. Spirometry shows an FEV₁/FVC greater than or equal to 70%. (Refer to SEVERE COPD (above) for information about device coverage for members with FEV₁/FVC less than 70%).
- C. An arterial blood gas PaCO₂, done while awake, and breathing the member's prescribed FIO₂, shows that the member's PaCO₂ worsens greater than or equal to 7 mm HG compared to the ABG result performed to qualify the member for the E0470 device (criterion A under E0470).
- D. A facility-based PSG or HST while using E0470 and prescribed FiO₂ demonstrates oxygen saturation less than or equal 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI less than 5 while using an E0470 device.

If the criteria above are not met, an E0471 device **is considered not medically necessary**

Positive Airway Pressure Therapy Adherence

Treatment of obstructive sleep apnea with Positive Airway Pressure Therapy (PAP) therapy is dependent on patient adherence to the prescribed treatment. Close follow-up by a qualified healthcare professional and review of objective adherence data is recommended during PAP treatment to assure that the patient is prescribed the appropriate therapeutic pressure and is fit with an appropriate interface to encourage maximum use.

The first 90 days of PAP therapy are frequently considered an important trial period to assess patients' ability to comply with the treatment, and to evaluate the overall efficacy of PAP in resolving and/or minimizing the obstructive sleep apnea symptoms. If PAP is considered inadequate, based on objective adherence monitoring and symptom evaluation, efforts should be implemented to improve PAP adherence, or alternative therapies should be considered.

When PAP therapy is not successful, as evidenced by lack of patient adherence to prescribed therapy, and/or inadequate clinical response to therapy, the ordering qualified healthcare professional should discuss other treatment options with the patient.

CONTINUED COVERAGE BEYOND THE FIRST THREE MONTHS (90 days) OF THERAPY:

CPAP/APAP (E0601) Devices and Bi-level Device (E0470) for the treatment of Obstructive Sleep Apnea



Continued coverage of a PAP device beyond the first three months (90 days) of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy, there must be documentation the member is adhering to PAP therapy.

A. Objective evidence of adherence use of PAP therapy for the diagnosis of OSA is defined as:

1. Use of PAP ≥ 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.

Bi-level device (E0470 AND E0471) for the treatment of diagnoses other than Obstructive Sleep Apnea require the following documentation:

- A. Signed and dated statement completed by the treating practitioner no sooner than 61 days after initiating use of the device, declaring that the member is compliantly using the device (an average of 4 hours per 24 hour period) and that the member is benefiting from its use.

If the above criterion is not met, continued coverage of a PAP device and related accessories **is considered not medically necessary.**

In cases of lack of adherence, coverage of the PAP equipment and supplies may be discontinued based upon the health plan's coverage policy.

PAP REPLACEMENT

A replacement of a PAP device/supplies is considered medically necessary with a prescription from a qualified health professional. Confirmation must exist that the device is:

- nonfunctioning and out of warranty, or
- the device is greater than five years old

Documentation may come from the physician or rendering provider.

NOTE: *If above criteria are met and a previous diagnostic test is not available, physician attestation supporting a diagnosis of OSA will be accepted to support replacement device.*

Other:

Duplicate equipment is considered a convenience (e.g., travel PAP) and is not considered medically necessary. Replacement of a PAP device for the purposes of upgrading technology is not considered medically necessary.

Accessories and Supplies

The following accessories and supplies are considered medically necessary for members who meet criteria for PAP therapy. Guidelines for use and frequency of replacement should be based on industry standard practice and medical necessity, and are acceptable to most patients with normal usage. (See section titled **PAP Supply Guidance**)

- Chinstrap



- Disposable and/or non-disposable filters
- Nasal mask or oronasal mask (full face mask)
- Headgear
- Humidifier – heated or non-heated
- Replacement cushion or nasal pillows for nasal application device
- Replacement interface for oronasal mask
- Tubing - heated or non-heated

PAP Cleaning Machines or devices are considered items of convenience and not covered. In addition, the FDA has not evaluated the safety and effectiveness of ozone gas or UV light products claiming to clean, sanitize or disinfect CPAP machines and accessories in the home or healthcare setting.

Other non-surgical therapies

PAP therapy remains the “gold standard” for treatment for obstructive sleep apnea. However, other nonsurgical therapies may be considered when PAP cannot be tolerated or when an alternate therapeutic option is considered medically appropriate.

Coverage for oral appliances may be subject to the terms, conditions and limitations of the applicable benefit plan’s External Prosthetic Appliances and Devices (EPA) or Durable Medical Equipment (DME) benefit and schedule of copayments.

Over-the-counter (OTC) oral appliances obtained without a prescription are not considered medically necessary.

Experimental and Investigational

The following **OSA therapies** are considered experimental and investigational or unproven.

- Sleep Strip
- Oral pressure therapy (e.g., Winx[®] Sleep Therapy System)
- Provent[™] Professional Sleep Apnea Therapy Device
- Atrial overdrive pacing
- Cautery-assisted palatal stiffening operation (CAPSO)
- Electrical devices (e.g., Night Shift[™] Sleep Positioner, Night Balance) as therapy for positional obstructive sleep apnea
- Electrosleep therapy
- Injection Snoreplasty
- Laser-assisted uvulopalatoplasty (LAUP)
- Over-the-counter, non-customized mandibular appliances
- Pillar[™] Palatal Implant System
- Radiofrequency volumetric tissue reduction (RFVTR) of the soft palate, uvula, or tongue base (e.g., Coblation[®], Somnoplasty[®])



- Tongue-base suspension (e.g., AIRVance System)
- Transpalatal advancement pharyngoplasty
 - Diaphragmatic-Phrenic Nerve Stimulation for the treatment of CSA

REIMBURSEMENT INFORMATION:

NOTE: Services in excess of what is documented in this policy are subject to medical review of documentation that supports medical necessity. The following information is required to support medical necessity: physician history and physical, physician procedure note, treatment plan, plan of treatment, and sleep study results (PSG or HSAT as appropriate)

PAP SUPPLY GUIDANCE

The following supply table represents the usual maximum of supplies expected to be reasonable and necessary.

A4604	TUBING WITH INTEGRATED HEATING ELEMENT FOR USE WITH POSITIVE AIRWAY PRESSURE DEVICE	1 per 3 months
A7027	COMBINATION ORAL/NASAL MASK, USED WITH CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE, EACH	1 per 3 months
A7028	ORAL CUSHION FOR COMBINATION ORAL/NASAL MASK, REPLACEMENT ONLY, EACH	2 per 1 month
A7029	NASAL PILLOWS FOR COMBINATION ORAL/NASAL MASK, REPLACEMENT ONLY, PAIR	2 per 1 month
A7030	FULL FACE MASK USED WITH POSITIVE AIRWAY PRESSURE DEVICE, EACH	1 per 3 months
A7031	FACE MASK INTERFACE, REPLACEMENT FOR FULL FACE MASK, EACH	1 per 1 month
A7032	CUSHION FOR USE ON NASAL MASK INTERFACE, REPLACEMENT ONLY, EACH	2 per 1 month
A7033	PILLOW FOR USE ON NASAL CANNULA TYPE INTERFACE, REPLACEMENT ONLY, PAIR	2 per 1 month
A7034	NASAL INTERFACE (MASK OR CANNULA TYPE) USED WITH POSITIVE AIRWAY PRESSURE DEVICE, WITH OR WITHOUT HEAD STRAP	1 per 3 months
A7035	HEADGEAR USED WITH POSITIVE AIRWAY PRESSURE DEVICE	1 per 6 months
A7036	CHINSTRAP USED WITH POSITIVE AIRWAY PRESSURE DEVICE	1 per 6 months



A7037	TUBING USED WITH POSITIVE AIRWAY PRESSURE DEVICE	1 per 3 months
A7038	FILTER, DISPOSABLE, USED WITH POSITIVE AIRWAY PRESSURE DEVICE	2 per 1 month
A7039	FILTER, NON DISPOSABLE, USED WITH POSITIVE AIRWAY PRESSURE DEVICE	1 per 6 months
A7046	WATER CHAMBER FOR HUMIDIFIER, USED WITH POSITIVE AIRWAY PRESSURE DEVICE, REPLACEMENT, EACH	1 per 6 months

DEFINITIONS:

Apnea: temporary cessation of breathing and, therefore, of the body's intake of oxygen and release of carbon dioxide; cessation of airflow for 10 seconds or more

Apnea-Hypopnea Index (AHI): the total number of apneas and hypopneas per hour of sleep. AHI is an index of severity of obstructive sleep apnea. AHI is calculated by dividing the number of apneas plus the number of hypopneas by the number of hours of sleep.

If the AHI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events used to calculate the AHI must be at least the number of events that would have been required in a 2hour period (i.e., greater than or equal to 10 events).

Central Sleep Apnea (CSA): the repeated cessation of breathing caused by the temporary signal loss from the brain sent to the breathing muscles. CSA is most often seen in patients with neurologic disorders, congestive heart failure and in patients who take certain medications (e.g., opiates, benzodiazepines).

Hypersomnolence: excessive sleepiness during the typical period of wakefulness.

Hypopnea: an abnormal respiratory event lasting at least ten seconds with at least 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation, or a $\geq 3\%$ oxygen desaturation from pre-event baseline and/or the event is associated with an arousal.

Nocturnal: pertaining to, occurring at, or active at night.

O2 Saturation: percentage of oxygen carried by the blood.

Obstructive Sleep Apnea (OSA): characterized by repetitive apneas and/or hypopneas during sleep, caused by complete or partial collapse of pharyngeal airway during sleep. In adults, an apnea/hypopnea index (AHI) greater than or equal to 5 but less than 15 is considered mild OSA. AHI greater than or equal to 15 but less than 30 is considered moderate OSA. AHI greater than or equal to 30 is considered severe OSA. In pediatric patients, an AHI greater than or equal to 1 is considered abnormal.



Respiratory Disturbance Index (RDI): number of apneas + hypopneas + respiratory-related events during the sleep test divided by the total number of hours slept.

Respiratory-Event Index (REI); a measurement of sleep disordered breathing on home sleep apnea testing defined as number of apneas + hypopneas during the sleep test divided by the total sleep or recording time reported in hours.

Treatment-Emergent Central Sleep Apnea is a form of central sleep apnea specifically identified by the persistence or emergence of central apneas and/or hypopneas upon exposure to CPAP, bi-level therapy, or APAP, when obstructive events have disappeared. These members have predominately obstructive or mixed apneas during the diagnostic sleep study occurring at greater than or equal to 5 times per hour. With use of a CPAP, bi-level therapy, or APAP, they show a pattern of central apneas and/or central hypopneas that meets the definition of CSA described above.

References:

1. International Classification of Sleep Disorders – 3rd Edition (ICSD-3), American Academy of Sleep Medicine; 2014
2. Epstein LJ, Kristo D, Strollo PJ Jr, et al. Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med.* 2009 Jun 15; 5(3):263-76.
3. Collop NA, Anderson WM, Boehlecke B, Claman D, Goldberg R, Gottlieb DJ, Hudgel D, Sateia M, Schwab R; Portable Monitoring Task Force of the American Academy of Sleep Medicine. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. Portable Monitoring Task Force of the American Academy of Sleep Medicine. *J Clin Sleep Med.* 2007 Dec 15;3(7):737-47
4. Centers for Medicare and Medicaid Services National Coverage Decision for Sleep Testing for Obstructive Sleep Apnea (OSA) 240.4.1 Published 8/10/2009
5. Kushida CA; Littner MR; Morgenthaler T et al. Practice parameters for the indications for polysomnography and related procedures: An update for 2005. *Sleep* 2005; 28(4):499-521.
6. Centers for Medicare and Medicaid Services. National Coverage Determination for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA). NCD #240.4. Effective August 4, 2008.
7. Gay P, Weaver T, Loube D, Iber C. American Academy of Sleep Medicine (AASM). Positive Airway Pressure Task Force Standards of Practice Committee. Evaluation of positive airway pressure treatment for sleep-related breathing disorders in adults. *Sleep* 2006; 29(3):381
8. Kushida CA, Littner MR, Hirshkowitz M, et al. Practice parameters for the use of continuous and bi-level positive airway pressure devices to treat adult patients with sleep-related breathing disorders. *Sleep.* 2006; 29(3):375-380.



9. Kushida CA; Chediak A; Berry RB; Brown LK; Gozal D; Iber C; Parthasarathy S; Quan SF; Rowley JA; Clinical Guidelines for the Manual Titration of Positive Airway Pressure in Patients with Obstructive Sleep Apnea. Positive Airway Pressure Titration Task Force of the American Academy of Sleep Medicine. *Journal of Clinical Sleep Medicine*, Vol. 4, No. 2, 2008
10. Marcus CL, Brooks LJ, Ward SD, et al Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome. *Pediatrics* 2012 130(3) 715-755.
11. L J Gula, A D Krahn, A C Skanes, R Yee, and G J Klein. Clinical relevance of arrhythmias during sleep: guidance for clinicians. *Heart*. 2004 March; 90(3): 347–352.
12. Kribbs NB, Pack AI, Kline LR et al. Objective Measurement of Patterns of Nasal CPAP Use by Patients with Obstructive Sleep Apnea. *American Review of Respiratory Diseases* 1993;147(4): 887-895.
13. Sin DD, Mayers I, Man GCW, et al. Long-term Compliance Rates to Continuous Positive Airway Pressure in Obstructive Sleep Apnea. *Chest* 2002; 121(2); 430-435.
14. Fry JM. Current issues in the diagnosis and management of narcolepsy. *Neurology*. 1998; 50(2, suppl 1):S1–S48.
15. Kushida CA, Efron b, Guilleminault c. A Predictive Morphometric Model of the Obstructive Sleep Apnea Syndrome. *Ann Int Med* 127(8): 581-587.
16. Centers for Medicare and Medicaid Services LCD for Respiratory Assistive Devices (L33800) 1/1/2020.
17. Centers for Medicare and Medicaid Services LCD for Continuous Positive Airway Pressure System (CPAP) (L33718) Revision Effective Date 1/1/2020;
18. Mokhlesi B, Kryger MH, Grunstein RR. Assessment and management of patients with obesity hypoventilation syndrome. *Proc Am Thorac Soc* 2008; 5(2):218-225.
19. Mokhlesi B. Positive Airway Pressure Titration in Obesity Hypoventilation Syndrome. *Chest* 2007; 132(6):1624.
20. Mokhlesi B. Obesity Hypoventilation Syndrome: A State-of-the-Art Review. *Respir Care* 2010; 55(10)1347-1362.
21. Kaw R, Hernandez A, Walker E, Aboussouan L, Mokhlesi B. Determinants of Hypercapnia in Obese Patients With Obstructive Sleep Apnea: A Systematic Review and Metaanalysis of Cohort Studies. *Chest* 2009; 136(3):787-796
22. Banerjee D, Yee B, Piper A, Zwillich C, Grunstein R. Obesity Hypoventilation Syndrome: Hypoxemia During Continuous Positive Airway Pressure. *Chest* 2007; 131:1678-1684.
23. Resmed Ltd, Urgent: Field Safety Notice, Increased Risk of Cardiovascular Death with Adaptive ServoVentilation (ASV) Therapy for Patients with Symptomatic Chronic Heart Failure with Reduced Ejection Fraction; May 13, 2015.



24. Philips Response to Resmed Update on Phase IV SERVE-HF Study of Adaptive Servo-Ventilation (ASV) Therapy in Central Sleep Apnea and Chronic Heart Failure; May 15, 2015.
25. Tieder, Joel S., Joshua L. Bonkowsky, Ruth A. Etzel, Wayne H. Franklin, David A. Gremse, Bruce Herman, Eliot S. Katz, Leonard R. Krilov, J. Lawrence Merritt II, Chuck Norlin, Jack Percelay, Robert E. Sapién, Richard N. Shiffman, Michael B.H. Smith, for the SUBCOMMITTEE ON APPARENT LIFE THREATENING EVENTS, Brief, Unexplained Events in Newborns with No Underlying Health Problems or Risk for Sudden Infant Death, American Academy of Pediatrics, May 2016, VOLUME 137 / ISSUE 5, Clinical Practice Guideline
26. American Academy of Pediatrics, AAP Recommends New Term for Brief, Unexplained Events in Newborns with No Underlying Health Problems or Risk of Sudden Infant Death, 4/25/2016.
27. Michael R. Littner MD1; Clete Kushida MD, PhD2; Merrill Wise MD3; David G. Davila, MD4; Timothy Morgenthaler MD5; Teofilo Lee-Chiong MD6; Max Hirshkowitz PhD7; Daniel L. Loubé MD8; Dennis Bailey DDS9; Richard B. Berry MD10; Sheldon Kapen MD11; Milton Kramer MD1. Practice Parameters for Clinical Use of the Multiple Sleep Latency Test and the Maintenance of Wakefulness Test an American Academy of Sleep Medicine Report Standards of Practice Committee of the American Academy of Sleep Medicine
28. R. Nisha Aurora, MD, MHS1; Sabin R. Bista, MD2; Kenneth R. Casey, MD, MPH3; Susmita Chowdhuri, MD4; David A. Kristo, MD5; Jorge M. Mallea, MD6; Kannan Ramar, MD7; James A. Rowley, MD8; Rochelle S. Zak, MD9; Jonathan L. Heald, Journal of Clinical Sleep Medicine, Vol. 12, No. 5, 2016. Updated Adaptive Servo-Ventilation Recommendations for the 2012 AASM Guideline: "The Treatment of Central Sleep Apnea Syndromes in Adults: Practice Parameters with an Evidence-Based Literature Review and Meta- Analyses"
29. CDC Guideline for Prescribing Opioids for Chronic Pain United States, 2016 Morbidity and Mortality Weekly Report, March 15, 2016 <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf>
30. Aurora RN, Bista SR, Casey KR, Chowdhuri S, Kristo DA, Mallea JM, et al. Updated Adaptive Servo-Ventilation Recommendations for the 2012 AASM Guideline: "The Treatment of Central Sleep Apnea Syndromes in Adults: Practice Parameters with an Evidence-Based Literature Review and Meta- Analyses". J Clin Sleep Med. 2016 May 15; 12(5):757-6
31. Vishesh K. Kapur, MD, MPH; Dennis H. Auckley, MD; Susmita Chowdhuri, MD; David C. Kuhlmann, MD, Reena Mehra, MD, MS; Kannan Ramar, MBBS, MD; Christopher G. Harrod, MS Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline, Journal of Clinical Sleep Medicine, Vol. 13, No. 3, 2017
32. Clete A. Kushida, MD, PhD1; Michael R. Littner, MD; Timothy Morgenthaler, MD; Cathy A. Alessi, MD; Dennis Bailey, DDS; Jack Coleman, Jr., MD; Leah Friedman, PhD; Max Hirshkowitz, PhD; Sheldon Kapen, MD; Milton Kramer, MD; Teofilo Lee-Chiong, MD; Daniel L. Loubé, MD; Judith Owens, MD; Jeffrey P. Pancer, DDS; Merrill Wise, MD Practice Parameters for the Indications for Polysomnography and Related Procedures: An Update for 2005, J Clin Sleep Med. 2017; 13(3):479–504.
33. Susheel P. Patil, MD, PhD1; Indu A. Ayappa, PhD2; Sean M. Caples, DO3; R. John Kimoff, MD4; Sanjay R. Patel, MD5; Christopher G. Harrod, MS6. Treatment of Adult Obstructive Sleep Apnea



with Positive Airway Pressure: An American Academy of Sleep Medicine Clinical Practice Guideline, *Journal of Clinical Sleep Medicine*, Vol. 15, No. 2 Feb. 15, 2019

34. Ilene M. Rosen, MD, MS1; Douglas B. Kirsch, MD2; Ronald D. Chervin, MD, MS3; Kelly A. Carden, MD4; Kannan Ramar, MD5; R. Nisha Aurora, MD6; David A. Kristo, MD7; Raman K. Malhotra, MD8,9; Jennifer L. Martin, PhD10; Eric J. Olson, MD5; Carol L. Rosen, MD11; James A. Rowley, MD12; American Academy of Sleep Medicine Board of Directors Clinical Use of a Home Sleep Apnea Test: An Updated American Academy of Sleep Medicine Position Statement, *J Clin Sleep Med*. 2018;14(12):2075–2077.
35. Kirk V, Baughn J, et al. American Academy of Sleep Medicine Position Paper for the Use of a Home Sleep Apnea Test for the Diagnosis of OSA in Children. *J Clin Sleep Med*. 2017 Oct 15;13(10):1199-1203
36. Susheel P. Patil, MD, PhD1; Indu A. Ayappa, PhD2; Sean M. Caples, DO3; R. John Kimoff, MD4; Sanjay R. Patel, MD5; Christopher G. Harrod, MS6 Treatment of Adult Obstructive Sleep Apnea with Positive Airway Pressure: An American Academy of Sleep Medicine Clinical Practice Guideline, *J Clin Sleep Med*. 2019;15(2):335–343.
37. Certal VF, Zaghi S, Riaz M, et al. Hypoglossal nerve stimulation in the treatment of obstructive sleep apnea: A systematic review and meta-analysis. *Laryngoscope*. 2015 May;125(5):1254-64. Epub 2014 Nov 12
38. Strollo PJ Jr, Soose RJ, Maurer JT, et al. Upper-airway stimulation for obstructive sleep apnea. *N Engl J Med*. 2014 Jan 9; 370 (2):139-49
39. Woodson BT, Strohl KP, Soose RJ, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: 5-Year Outcomes. *Otolaryngol Head Neck Surg*. 2018;159(1):194. Epub 2018 Mar 27
40. Kent DT, Carden KA, Wang L, et al. Evaluation of Hypoglossal Nerve Stimulation Treatment in Obstructive Sleep Apnea. *JAMA Otolaryngol Head Neck Surg*. 2019 Sep 26. doi: 10.1001/jamaoto.2019.2723.
41. Kenneth D. Weeks, Jr., MD, FACC, The Basics of Obstructive Sleep Apnea Nov 30, 2012
<https://www.acc.org/latest-in-cardiology/articles/2014/08/21/14/05/the-basics-of-obstructive-sleep-apnea>
42. American Heart Association Ejection Fraction Heart Failure Measurement
<https://www.heart.org/en/health-topics/heart-failure/diagnosing-heart-failure/ejection-fraction-heart-failuremeasurement>, Accessed 6/3/2020
44. Roth GA, Poole JE, Zaha R, Zhou W, Skinner J, Morden NE. Use of Guideline-Directed Medications for Heart Failure Before Cardioverter-Defibrillator Implantation. *J Am Coll Cardiol*. 2016 Mar 8;67(9):1062-1069. doi: 10.1016/j.jacc.2015.12.046. PMID: 26940927; PMCID: PMC4780248.
<https://pubmed.ncbi.nlm.nih.gov/26940927/>
43. Mitchell T. Saltzberg, MD, FACC, FAHA, FHFA, [2016 Update to Heart Failure Clinical Practice Guidelines](#),
https://www.heart.org/idc/groups/heart-public/@wcm/@mwa/documents/downloadable/ucm_489089.pdf, Accessed 6/3/2020



44. Yancy, Clyde W. MD, MSC, MACC, Chair, James L. Januzzi, JR, MD, FACC, Vice Chair 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction
<https://www.fmda.org/Journal/OptimizationofHFTreatment.pdf>
45. Aubertin, G. Continuous positive airway pressure in childhood obstructive sleep apnea syndrome J Dentofacial Anom Orthod 2015;18:309, DOI: 10.1051/odfen/2018102
46. Michelle S. King, MD, Melissa S. Xanthopoulos, PhD, and Carole L. Marcus, MBBCh, Improving Positive Airway Pressure Adherence in Children, *Sleep Med Clin*. 2014 June 1; 9(2): 219–234. doi:10.1016/j.jsmc.2014.02.003 Sleep Center, The Children’s Hospital of Philadelphia, Perelman School of Medicine, University of Pennsylvania, 34th and Civic Center Boulevard, Philadelphia, PA 19104, USA <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4042088/pdf/nihms571573.pdf>
47. Shalini Paruthi, MD, Management of obstructive sleep apnea in children 2/4/2020.
<https://www.uptodate.com/contents/management-of-obstructive-sleep-apnea-in-children>
48. CLINICAL PRACTICE GUIDELINE, Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome, American Academy of Pediatrics, www.pediatrics.org/cgi/doi/10.1542/peds.2012-1671 doi:10.1542/peds.2012-1671
<https://pediatrics.aappublications.org/content/pediatrics/130/3/576.full.pdf>
49. Marcus, Carole L., Lee Jay Brooks, Kari A. Draper, David Gozal, Ann Carol Halbower, Jacqueline Jones, Michael S. Schechter, Stephen Howard Sheldon, Karen Spruyt, Sally Davidson Ward, Christopher Lehmann and Richard N. Shiffman, Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome, American Academy of Pediatrics, *Pediatrics* September 2012, 130 (3) 576-584; DOI: <https://doi.org/10.1542/peds.2012-1671>
50. Masip J. Non-invasive ventilation. *Heart Fail Rev*. 2007; 12(2):119-124. doi:10.1007/s10741-007-9012-7
<https://pubmed.ncbi.nlm.nih.gov/17492379/>
51. Chatburn RL. Which ventilators and modes can be used to deliver noninvasive ventilation? *Respir Care*. 2009;54(1):85-101. <https://pubmed.ncbi.nlm.nih.gov/19111109/>
52. Antonescu-Turcu A, Parthasarathy S. CPAP and bi-level PAP therapy: new and established roles. *Respir Care*. 2010;55(9):1216-1229. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3119924/>
53. Local Coverage Determination (LCD): Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387) effective 4/1/2020, National Government Services:
54. Local Coverage Determination (LCD): Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38385) effective 3/15/2020, Novitas Solutions
55. Local Coverage Determination (LCD): Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38398) effective 3/15/2020, First Coast Options,
56. Local Coverage Determination (LCD): Respiratory Assist Devices (L33800), 1/1/2020
<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33800&ContrID=140>

57. Amanda Piper, PhD, Brendon Yee, MBChB, PhD, Clinical manifestations and diagnosis of obesity hypoventilation syndrome, Aug 22, 2019. <https://www.uptodate.com/contents/clinical-manifestations-and-diagnosis-of-obesity-hypoventilationsyndrome#H717782162>
58. Global Strategy for the Diagnosis, Management and Prevention of Chronic Obstructive Pulmonary Disease (GOLD report 2020) Cloutier MM, Dixon AE, Krishnan JA, Lemanske RF, Pace W, Schatz M. Managing Asthma in Adolescents and Adults: 2020 Asthma Guideline Update From the National Asthma Education and Prevention Program. *JAMA*. 2020;324(22):2301–2317. doi:10.1001/jama.2020.21974 <https://jamanetwork.com/journals/jama/articleabstract/2773482>
59. American Heart Association AHA: <https://www.heart.org/en/health-topics/arrhythmia/symptoms-diagnosis-monitoring-of-arrhythmia> NHLBI: <https://www.nhlbi.nih.gov/health-topics/arrhythmia>
60. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016 US Department of Health and Human Services for Disease Control and Prevention, *MMWR* / March 15, 2016 / Vol. 65
61. American Academy of Sleep Medicine. (2007, February 12). Parasomnias Are Common And Frequent In Children, Study Finds. *ScienceDaily*. Retrieved April 11, 2021 from <https://www.sciencedaily.com/releases/2007/02/070201082519.htm>
62. Vishesh K. Kapur, MD, MPH1; Dennis H. Auckley, MD2; Susmita Chowdhuri, MD3; David C. Kuhlmann, MD4; Reena Mehra, MD, MS5; Kannan Ramar, MBBS, MD6; Christopher G. Harrod, MS7 Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline (page 490) <https://jcsmd.asm.org/doi/pdf/10.5664/jcsmd.6506>
63. Paruthi, Shalini, MD, [Evaluation of suspected obstructive sleep apnea in children](#). This topic last updated Feb 18, 2021. <https://www.uptodate.com/contents/evaluation-of-suspected-obstructive-sleep-apnea-in-children/print, accessed>
64. Verhulst SL, Schrauwen N, Haentjens D, Van Gaal L, De Backer WA, Desager KN. Reference values for sleep-related respiratory variables in asymptomatic European children and adolescents. *Pediatr Pulmonol*. 2007 Feb;42(2):159-67. doi: 10.1002/ppul.20551. PMID: 17186545.
65. Uliel S, Tauman R, Greenfeld M, Sivan Y. Normal polysomnographic respiratory values in children and adolescents. *Chest*. 2004 Mar;125(3):872-8. doi: 10.1378/chest.125.3.872. PMID: 15006944.
66. Technical Report: Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome Michael S. Schechter, Section on Pediatric Pulmonology, Subcommittee on Obstructive Sleep Apnea Syndrome *Pediatrics* Apr 2002, 109 (4) e69;
67. American Sleep Apnea Association <https://www.sleepapnea.org/treat/childrens-sleep-apnea/>, accessed 4/5/2021
68. Merrill S. Wise, MD1; Cynthia D. Nichols, PhD2; Madeleine M., et al, Respiratory Indications for Polysomnography in Children: An Evidence-Based Review, *SLEEP*, Vol. 34, No. 3, 2011 <https://aasm.org/resources/practiceparameters/reviewfullpolysomnographychild.pdf>



69. Optimal NIV Medicare Access Promotion: Patients with Hypoventilation Syndromes: A Technical Panel Report From the ACCP, AARC, AASM, and ATS Chest 160: No 5, November 2021, e377-e387
70. As relates just to Obesity Hypoventilation Syndrome. Evaluation and Management of OHS: An Official Am Thoracic Society Clinical Practice Guideline
71. Am Jr of Respiratory and Critical Care Medicine Vol 200, No 3, August 1 2019 p e6-e24.
72. Optimum NIV Medicare Access Promotion: Patients with COPD. A Technical Expert Panel Report from the Am College of Chest Physicians, the Am Association for Respiratory Care, the Am Academy of Sleep Medicine, and the Am Thoracic Society. Chest 2021; 160(5) e389-3397.
[https://journal.chestnet.org/article/S0012-3692\(21\)01481-1/fulltext](https://journal.chestnet.org/article/S0012-3692(21)01481-1/fulltext)
73. Morgenthaler TI, et al. Practice Parameters for the Use of Autotitrating Continuous Positive Airway Pressure Devices for Titrating Pressures and Treating Adult Patients with Obstructive Sleep Apnea Syndrome. An American Academy of Sleep Medicine Report (AASM). Sleep; 2008; 31(1):141-147

GUIDELINE UPDATE INFORMATION:

12/19/2013	New coverage guideline
5/22/2015	Scheduled review. Adherence criteria, criteria related to Adaptive Servo Ventilation and definitions added. Experimental/Investigational diagnostic tests updated: Actigraphy used alone, and use of Acoustic pharyngometry, or SNAP testing with fewer than three channels. Guideline reformatted, references updated
5/25/2016	Updated definitions of comorbid conditions and secondary sleep disorders Updated ASV indications with most current recommendations Expanded definition of MWT Provided list of standard PAP supply replacement schedule Added REI as a measurement of sleep disordered breathing Updated oxygen saturation requirements for PAP titration (CPT 95811) Extensive reformatting changes
3/28/2017	Sleep disorders without suspected OSA identified as criteria for in- facility testing
6/21/2017	Scheduled review: added PAP replacement language, in-facility diagnostic testing for sleep disorders not associated with OSA
8/9/2018	Scheduled review: describe snoring as habitual vs. disruptive as suggestive evidence of sleep disordered breathing; inclusion of chronic opioid use as a comorbid condition; expand measurement of compliance over a 24 hour period.



6/8/2020	<p>Scheduled Review:</p> <p>Sleep Testing Witnessed apnea as standalone risk condition for OSA Updated LVEF from 45 % to 40% for moderate to severe CHF OHS moved from sleep disordered breathing to comorbid condition list Align definition of PAP compliance with CMS Increase timeframe from 90 days to 1 year for allowance of HSAT Include implantation of hypoglossal nerve stimulator for testing reassessment of efficacy of device</p> <p>Treatment of OSA and Other Sleep Disordered Breathing Indication of bi-level therapy for non-OSA conditions Continued use criteria for bi-level therapy for non-OSA conditions Remove HNS from list of E/I</p> <p>Updated definitions Updated references</p>
5/24/2021	<p>Scheduled Review: Further defined the evidence supporting conditions requiring a lab based sleep study pertaining to: COPD Asthma Refractory cardiac arrhythmia Chronic opioid medication use Significant oxygen desaturations during diagnostic testing Update for requirements for replacement positive airway pressure devices (PAP) when broken and patient has been previously diagnosed with OSA and doing well on therapy. Streamline and clarify sleep study re-testing for adults and children Parasomnias in children</p> <p>Updated references Updated definitions</p>
7/20/2022	<p>Annual Review and Update Added replacement after 5 years</p>