Sleep Apnea Treatment, Positive Airway Pressure Devices

Policy Number: MP-023
Last Review Date: 11/14/2019
Effective Date: 01/01/2020

Policy

Evolent Health considers **Positive Airway Pressure Devices for the treatment of Sleep Apnea** medically necessary for the following indications:

Continuous Positive Airway Pressure (CPAP) is covered for the treatment of obstructive sleep apnea (OSA) when all of the following indications are met:

1. A confirmed diagnosis of Obstructive Sleep Apnea (OSA) for the coverage of CPAP was done through one of the following:
   a) Attended Polysomnography (PSG) performed in a sleep laboratory (Type I)
   b) Unattended home sleep study test (HST) with a Type I, II, III or IV home sleep monitoring device.
2. The member's sleep test indicates any of the following:
   a) The Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events
   b) The AHI or RDI is greater than or equal to five and less than or equal to 14 events per hour with a minimum of 10 events AND documentation of:
      Excessive daytime sleepiness, Impaired cognition, Mood disorders, or Insomnia; OR
      - Hypertension, ischemic heart disease, or history of stroke
3. The member had a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the member for obstructive sleep apnea. The evaluation needs to include at least one of the following:
   a) Sleep history and symptoms of sleep disordered breathing including: snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches
   b) Duration of symptoms
   c) Validation of sleep hygiene inventory such as the Epworth Sleepiness Scale
   d) A physical examination that documents a focused cardiopulmonary and upper airway system evaluation, neck circumference and body mass index (BMI)
4. The member and/or their caregiver have received adequate instruction in the proper use and care of the equipment prior to its use.

PAP Devices for Children

PAP devices are covered for children when all of the following indications are met:

1. The PAP device is approved by the Food and Drug Administration (FDA) for the child's age
2. The child has been evaluated by an Ear, Nose and Throat (ENT) specialist prior to CPAP

3. Any of the following
   a) Surgery is contraindicated
   b) There is minimal adenotonsillar tissue
   c) OSA is persistent after adenotonsillectomy
   d) Member/parent(s) prefer non-surgical alternatives.

Automated Positive Airway Pressure (APAP, Auto-Titrating, Auto PAP, C-Flex)
Automated Positive Airway Pressure is considered medically necessary for the diagnosis of OSA for any one of the following indications:

1. When used during attended titration with Polysomnography to identify a single pressure for use with the standard CPAP for treatment of moderate to severe OSA
2. One of the following:
   a) When used in the self-adjusting mode for unattended treatment of members with moderate to severe OSA without significant comorbidities (i.e., congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), central sleep apnea syndromes, or hypoventilation syndromes)
   b) When used in an unattended way to determine a fixed CPAP treatment pressure for members with moderate to severe OSA without significant comorbidities (e.g., CHF, COPD, central sleep apnea or hypoventilation syndromes)
      Note: Members being treated with fixed CPAP on the basis of APAP titration or being treated with APAP must have close clinical follow-up to determine treatment effectiveness and safety. This is especially important during the first few weeks of PAP use.
3. A re-evaluation and, if necessary, a standard attended CPAP titration should be performed if symptoms do not resolve or if the APAP treatment otherwise appears to lack efficacy

Respiratory Assist Devices (RAD/BiPAP) without Backup Rate
RAD/BiPAP without backup rate is covered for the first three months for the diagnosis of obstructive sleep apnea (OSA) when both of the following indications are met:

1. The member meets the above indications for CPAP
2. A single level CPAP device has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting
   - "Ineffective" is defined as documented failure to meet therapeutic goals using a CPAP during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings)

   Note: If RAD/BiPAP without backup rate is billed and criteria in #2 above is not met, payment will be based on the allowance for the least costly medically appropriate alternative, CPAP single level.

Respiratory Assist Devices (RAD/BiPAP) with backup rate
(Refer to Limitations section)

New Insurance Services Division Members
The following indications for continued coverage apply to new [Client] members who own a CPAP/BiPAP machine:

- A baseline diagnostic sleep study needs to be on file and available when requested. If no baseline sleep study is available, a new sleep study must be done before continuation of coverage.

CONCURRENT USE OF OXYGEN WITH PAP THERAPY
Concurrent use of oxygen with PAP therapy is covered when the member meets all of the following indications:

1. The member must be in a "chronic stable state" (i.e. they are not experiencing an acute illness or an exacerbation of their underlying disease).
2. The member must have a severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm, or hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy.
3. All co-existing diseases or conditions that can cause hypoxia must be treated.
4. The OSA must be sufficiently treated such that the underlying severe lung disease is unmasked. This must be demonstrated before oxygen saturation results obtained during Polysomnography are considered qualifying for oxygen therapy.
5. A qualifying oxygen saturation test may only occur during a titration polysomnographic study (either split-night or stand-alone) if all of the following criteria are met:
   a) The titration is conducted over a minimum of two hours
   b) During titration, one of the following:
      - The AHI/RDI is reduced to less than or equal to an average of ten events per hour
      - If the initial AHI/RDI was less than an average of ten events per hour, the titration demonstrates further reduction in the AHI/RDI
   c) Nocturnal oximetry conducted for the purpose for oxygen reimbursement qualification may only be performed after optimal PAP settings have been determined and the beneficiary is using the PAP device at those settings
   d) The nocturnal oximetry conducted during the PSG demonstrates an oxygen saturation ≤ 88% for five minutes total (which need not be continuous).

CONTINUED COVERAGE:

Continued coverage of a PAP or RAD/BIPAP device beyond the first three months of therapy is covered for those members diagnosed with OSA whose OSA improves as a result of CPAP during the three month period as follows:

PAP Devices (Meets all indications)

1. The treating physician has conducted a clinical face to face re-evaluation and documents that the member's symptoms of obstructive sleep apnea are improved no sooner than the 61st day but no later than the 91st day after initiating therapy,
2. There is objective evidence of member adherence to therapy (use of the PAP device), reviewed by the treating physician.

    Note: Adherence to therapy is defined as use of PAP ≥ four hours per night on 70% of nights during a consecutive 30 day period anytime during the first three months of initial usage.

RAD/BiPAP (Meets all indications)

1. If a CPAP device is tried and found ineffective during the initial three month home trial, substitution of a RAD does not require a new initial face-to-face clinical evaluation or a new sleep test.
2. If a CPAP device has been used for more than three months and the member is switched to a RAD, a new initial face-to-face clinical evaluation is required, but a new sleep test is not required. A new three month trial would begin for use of the RAD.

CHANGING from CPAP to RAD/BiPAP WITHOUT BACK UP RATE DUE TO INEFFECTIVE THERAPY WHILE ON CPAP (either during a facility-based titration or in the home setting)

The treating physician must document the following issues were addressed prior to changing to a RAD without back device:

1. Interface fit and comfort. An appropriate interface has been properly fit and the beneficiary is using it without difficulty. This properly fit interface will be used with the RAD without back up rate device
2. CPAP pressure settings. The current pressure setting of the CPAP prevents the beneficiary from tolerating the therapy and lower pressure settings of the CPAP were tried but failed to help any of the following:
    a) Adequately control the symptoms of OSA
    b) Improve sleep quality
    c) Reduce the AHI/RDI to acceptable levels.

ACCESSORIES

1. Accessories used with a PAP device are covered when the coverage criteria for the PAP device are met.
2. For the usual maximum amount of accessories expected to be medically necessary, refer to the coding section of this policy.

LIMITATIONS

Limitations of PAP Therapy

1. Initial coverage of CPAP is limited to a 12 week period to identify members diagnosed with OSA who benefit from CPAP.

2. **Members who fail the initial 12 week trial** are eligible to re-qualify for a PAP device when they meet all of the following
   a) Have a repeat sleep test in a facility-based setting (Type I).
   b) Face-to face clinical re-evaluation by the treating physician to determine the cause of their failure to respond to PAP therapy
      Clinical Re-Evaluation
      - Re-evaluation must take place within the first three months of treatment.
      - Re-evaluation should document both member improvement in subjective symptoms of OSA and objective data related to member adherence to PAP therapy.
      - If the physician re-evaluation does not occur until after the 91st day but the evaluation demonstrates that the member is benefiting from PAP therapy, continued coverage of the PAP device will begin with the date of that re-evaluation.
   c) If a CPAP device is tried and found ineffective during the initial facility-based titration or home trial, substitution of a RAD without backup rate does not change the length of the trial unless there is less than 30 days remaining in the trial period.
   d) If less than 30 days remain in the trial period, the clinical re-evaluation (see above) and objective documentation of adherence must occur before the 120th day following the initiation of the CPAP.
   e) If more than 30 days remain in the trial period, the clinical re-evaluation would occur between the 31st and 91st days following the initiation of CPAP and objective documentation of adherence on the RAD without backup would need to occur prior to the 91st day following initiation of the CPAP.
   f) If a CPAP device has been used for more than 30 days and the member is switched to an RAD without back up rate,

- A new initial face-to-face clinical evaluation is required, but a new sleep test is not required.
- A new three month trial would begin for use of the RAD without back up rate.
- The clinical re-evaluation would occur between the 31st and 91st day following the initiation of the RAD. There would also need to be documentation of adherence to therapy during the three month trial with the RAD.

3. The PAP device must be FDA approved for the member's age.

4. **Discontinuation of Usage**- If there is discontinuation of usage of a PAP device at any time, the supplier is expected to confirm discontinuation and stop billing for the equipment and related accessories and supplies.

5. **Concurrent Use of Oxygen**
   - Documentation by the treating physician must clearly demonstrate that the indications for coverage and/or medical necessity above have been met.
   - Documentation by the treating physician should demonstrate that the indications for coverage of oxygen and oxygen equipment have been met.

6. **Auto-Titrating Continuous Positive Airway Pressure (APAP):**
   - Is not recommended for the diagnosis of obstructive sleep apnea (OSA).
   - Is not recommended for split-night titration.
   - APAP for continuous or long term use is considered not medically necessary.
   - Members with significant co-morbidities are not candidates for APAP titration or treatment. Co-morbidities include CHF, COPD, Central Sleep Apnea (Standard).

Exclusions
Respiratory Assist Devices (RAD) with backup rate: Is considered not medically necessary for the diagnosis of OSA and, therefore, **not covered** for this diagnosis.

Background
Sleep apnea is generally characterized by the disruption of breathing during sleep. Obstructive Sleep Apnea (OSA) is a type of sleep apnea characterized by the American Academy of Sleep Medicine (AASM) as the cessation of airflow for at least 10 seconds accompanied by an effort to breathe. According to the Centers for Medicare and Medicaid (CMS), apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with

at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.

OSA can be measured based on AHI and RDI among other measurement tools. AHI (apnea hypopnea index) is the average number of episodes of apnea and hypopanea per hour. RDI (respiratory disturbance index) is the average number of respiratory disturbances per hour. AHI and RDI are typically measured using a polysomnography during a sleep study.

CPAP (Continued Positive Airway Pressure) is one of the most common devices prescribed for treatment of OSA. CPAP is defined by CMS as a non-invasive technique for providing single levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep. This approach does not represent a cure, as CPAP must be administered every night.

The American Academy of Pediatrics (AAP) has established guidelines on the diagnosis and treatment of Obstructive Sleep Apnea Syndrome (OSAS) associated with adenotonsillar hypertrophy in children. If left untreated at a young age, OSAS can lead to further health complications. According to AAP, the common symptoms of OSAS include habitual snoring, disturbed sleep, day-time neurobehavioral problems, and occasionally day-time sleepiness. Conditions associated with OSAS include neurocognitive impairment, behavioral problems, hypertension, cardiac dysfunction and systemic inflammation.

The American Academy of Pediatrics (AAP) defines OSA in children as a disorder of breathing during sleep characterized by prolonged partial upper airway obstruction and/or intermittent complete obstruction (obstructive apnea) that disrupts normal ventilation during sleep and normal sleep patterns. The diagnosis of obstructive sleep-disordered breathing in most children is made through a thorough sleep-based history and physical examination. Adenoidectomy is the primary treatment for obstructed sleep-disordered breathing. CPAP, BiLevel PAP, and Auto PAP are used as a secondary treatment or as an adjunct therapy post tonsillectomy or adenoidectomy or as emergency treatment in severe cases.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description

Covered PAP Devices	
E0601	Continuous Airway Pressure (CPAP) device
E0470	Respiratory assist device (RAD), bi-level pressure (BiPAP) capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
ICD-10 codes covered if selection criteria are met:	
G47.30	Sleep apnea unspecified
G47.31	Primary central sleep apnea
G47.33	Obstructive sleep apnea
G47.37	Central sleep apnea in conditions elsewhere classified
Not Covered for the Diagnosis of OSA	
E0471	Respiratory assist device (RAD), bi-level pressure (BiPAP) capability, with backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)

Covered PAP Accessories		**Maximum Number Allowed**
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	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
A7044	Oral interface used with positive airway pressure device, each	No limitations
A7045	Exhalation port with or without swivel used with accessories for positive airway devices, replacement only	No limitations
A7046	Water chamber for humidifier, used with positive airway pressure device, replacement, each	1 per 6 months
E0561	Humidifier, non-heated, used with positive airway pressure device	No limitations
E0562	Humidifier, heated, used with positive airway pressure device	No limitations

Variations

Medicare Product

CPAP based on clinical diagnosis alone or using diagnostic procedure other than PSG or Type II, Type III or a Type IV HST measuring at least three channels is covered only when provided as a clinical study/trial and when that study meets clinical study/trial standards.

References

1. Benninger M, Walner D: Obstructive sleep-disordered breathing in children. Clin Cornerstone, 2007 Apr; 9(Suppl 1): S6-S12. http://www.ncbi.nlm.nih.gov/pubmed/?term=Benninger+M+%5Bau%5D+AND+breathing+%5Bti%5D
2. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) No. L33718 - Positive Airway Pressure System (PAP) Devices for the Treatment of Obstructive Sleep Apnea. (Contractor: CGS Administrators, LLC). Revision Effective Date: 01/01/2017.

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33718&ver=16&Date=&DocID=L33718&bc=iAAAABAAAAAA&

3. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) No. L33800 - Respiratory Assist Devices. (Contractor: CGS Administrators, LLC). Revision Effective Date: 01/01/2017. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33800&ver=13&Date=&DocID=L33800&bc=iAAAABAAAAAA&
4. Centers for Medicare and Medicaid Services (CMS). Medicare Learning Network (MLN). MLN Matters: # MM6048-Revised. Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA). Related CR Transmittal # R96NCD, Release date: 08/29/2008, Revised date 01/09/2018. http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6048.pdf
5. Centers for Medicare and Medicaid Services (CMS): National Coverage Determination (NCD) No. 240.4 - Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea. Effective Date: 03/13/2008 https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=226&ncdver=3&DocID=240.4&list_type=ncd&bc=gAAAAAgAAAAA&
6. Hayes Medical Technology Directory. Sleep Apnea Treatment, Devices. Publication Date: 09/16/1999. Annual Review Date: 03/14/2005. Archived: 01/01/2016
7. Hayes Medical Technology Directory. Bilevel Positive Airway Pressure for the Treatment of Obstructive Sleep Apnea in Adults. Publication Date: 11/26/2013. Annual Review Date: 10/09/2017.
8. Morgenthaler TI, Aurora RN, Brown T, et al. [Standards of Practice Committee of the AASM, American Academy of Sleep Medicine]. Practice parameters for the use of auto-titrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea syndrome: an update for 2007. An American Academy of Sleep Medicine Report. Sleep 2008 Jan; 31(1):141-147. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2225554/pdf/aasm.31.1.141.pdf
9. Nabili ST. Sleep Apnea. Available at: Medicinenet.com: Last reviewed: 09/05/2018. http://www.medicinenet.com/script/main/art.asp?articlekey=1982&pf=2
10. Marcus CL, Brooks LJ, Draper AK, et al. Clinical Practice Guideline: Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome. American

Academy of Pediatrics. August 2012. http://pediatrics.aappublications.org/content/pediatrics/early/2012/08/22/peds.2012-1671.full.pdf

11. NHIC Corp. DME MAC Jurisdiction A: PAP Documentation Requirement Revision - Ineffective Therapy on E0601., Posted 08/19/2010. http://www.medicarenhic.com/viewdoc.aspx?id=461
12. NHIC Corp. DME MAC Jurisdiction A : Positive Airway Pressure (PAP) Devices-Supplier Frequently Asked Questions, Revised: May 2012. Posted May 18, 2012. http://www.medicarenhic.com/viewdoc.aspx?id=837
13. Schwab RJ, Badr SM, Epstein LJ, et al. Continuous Positive Airway Pressure Adherence Tracking System. The optimal monitoring strategies and outcome measures in adults. Am J Respir Crit Care Med 2013 Sept; 188(5): 613-620. http://www.ncbi.nlm.nih.gov/pubmed/23992588