Medical Policy
Management of Obstructive Sleep Apnea - OSA using Auto-Titrating Positive Airway Pressure - APAP and Continuous Positive Airway Pressure - CPAP Devices

Table of Contents
- Policy: Commercial
- Coding Information
- Information Pertaining to All Policies
- Policy: Medicare
- Description
- References
- Authorization Information
- Policy History
- Endnotes

Policy Number: 526
BCBSA Reference Number: NA

Related Policies
- Actigraphy, #533
- Bi-Level Positive Airway Pressure (BPAP) Devices, #527
- Home Apnea Monitoring, #224
- Management of Obstructive Sleep Apnea - OSA Oral Appliances, #529
- Multiple Sleep Latency Testing - MSLT and Maintenance of Wakefulness Testing - MWT, #534
- Polysomnography and Home Sleep Testing, #525
- Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome, #130

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Indications for Auto-titrating Positive Airway Pressure (APAP) or Continuous Positive Airway Pressure (CPAP)¹

Treatment with CPAP may be considered MEDICALLY NECESSARY for a patient aged 19 years or older when conditions A and B below are met:
A. Home or lab based sleep study demonstrates one of the following (1–2)
   1. AHI greater than or equal to 15
   2. AHI 5–14 with any of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, treatment-resistant hypertension, ischemic heart disease, history of stroke

AND
B. MEDICALLY NECESSARY CPAP level has been determined from one of the following (1–5):
   1. Split-night sleep study
   2. Whole-night lab based titration study following a study where the CPAP level was not determined during the therapeutic portion or the patient has OSA but did not meet criteria for PAP titration during the study
3. Whole-night lab based titration study in a patient in whom APAP is contraindicated (e.g., congestive heart failure [CHF], chronic obstructive pulmonary disease [COPD])
4. APAP titration trial
5. Whole-night lab based titration study when home, unmonitored APAP titration was unsuccessful.

Treatment with CPAP may be considered **MEDICALLY NECESSARY** for a patient aged 18 years or younger when conditions A and B below are met:
A. A lab-based sleep study demonstrating AHI of at least one (1) and appropriate CPAP titration has been performed
   **AND**
B. One of the following (1–4) is true:
   1. Adenotonsillectomy has been unsuccessful in curing OSA
   2. Adenotonsillectomy is not indicated because the patient has minimal adenotonsillar tissue
   3. Adenotonsillectomy is inappropriate because OSA is attributable to another underlying cause (e.g., craniofacial abnormality, morbid obesity)
   4. Adenotonsillectomy is contraindicated.

Treatment with APAP may be considered **MEDICALLY NECESSARY** when a patient meets conditions A and B below:
A. Home or lab based sleep study demonstrates one of the following (1–2):
   1. AHI greater than or equal to 15
   2. AHI 5–14 with any of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, treatment-resistant hypertension, ischemic heart disease, history of stroke
   **AND**
B. The patient has none of the following contraindications (1–4) to the use of APAP:
   1. Age 18 years or younger
   2. CHF
   3. COPD
   4. Central sleep apnea
   5. Neuromuscular disorders (e.g., muscular dystrophy, myasthenia gravis).

**Ongoing treatment with APAP or CPAP (adult and non-adult patients)**
Ongoing treatment may be considered **MEDICALLY NECESSARY** for patients who demonstrate compliance with therapy. Compliance is defined as:
1. *Use of the CPAP device for greater than or equal to four (4) hours per night on 70% of nights during a consecutive thirty (30) day period within the preceding 90 days*
   **OR**
2. There is clinical evidence submitted by the treating provider that demonstrates continued clinical benefit from use of the positive airway pressure device.

**Medicare HMO BlueSM and Medicare PPO BlueSM Members**
BCBSMA covers Continuous Positive Airway Pressure (CPAP) under the following situations for Medicare HMO Blue and Medicare PPO Blue members in accordance with CMS NCD:
1. For adult patients with OSA, initially limited to a 12-week period to identify beneficiaries who benefit from CPAP. CPAP is subsequently covered only for those beneficiaries who benefit from CPAP.
2. Members who have received education from the provider of CPAP prior to the use of the CPAP device to ensure the proper use of the device. A caregiver, for example a family member, may be compensatory, if consistently available in the beneficiary's home and willing and able to safely operate the CPAP device.
3. A positive diagnosis of OSA for the coverage of CPAP must include a clinical evaluation and a positive:
   a. Attended PSG performed in a sleep laboratory; or
   b. Unattended HST with a Type II home sleep monitoring device; or
c. Unattended HST with a Type III home sleep monitoring device; or
d. Unattended HST with a Type IV home sleep monitoring device that measures at least 3 channels.

4. The sleep test must have been previously ordered by the beneficiary’s treating physician and furnished under appropriate physician supervision.

5. An initial 12-week period of CPAP is covered in adult patients with OSA if either of the following criterion using the AHI or RDI are met:
   a. AHI or RDI greater than or equal to 15 events per hour, or
   b. AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

6. The AHI or RDI is calculated on the average number of events of per hour. If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing must be at a minimum the number of events that would have been required in a 2-hour period.

7. 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.

8. Coverage with Evidence Development (CED): Medicare provides the following limited coverage for CPAP in adult beneficiaries who do not qualify for CPAP coverage based on criteria 1-7 above. A clinical study seeking Medicare payment for CPAP provided to a beneficiary who is an enrolled subject in that study must address one or more of the following questions:
   a. In Medicare-aged subjects with clinically identified risk factors for OSA, how does the diagnostic accuracy of a clinical trial of CPAP compare with PSG and Type II, III & IV HST in identifying subjects with OSA who will respond to CPAP?
   b. In Medicare-aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or Type II, III & IV HST, does CPAP cause clinically meaningful harm?

The study must meet the following additional standards:
   c. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants’ health outcomes.
   d. The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
   e. The research study does not unjustifiably duplicate existing studies.
   f. The research study design is appropriate to answer the research question being asked in the study.
   g. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
   h. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is Food and Drug Administration-regulated, it also must be in compliance with 21 CFR Parts 50 and 56.
   i. All aspects of the research study are conducted according to the appropriate standards of scientific integrity.
   j. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.
   k. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.
   l. The clinical research study is registered on the ClinicalTrials.gov Web site by the principal sponsor/investigator prior to the enrollment of the first study subject.
   m. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured, including release of outcomes if outcomes are negative or study is
terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned for publication in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than 3 years after the end of data collection.

n. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

o. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.

BCBSMA does not cover other diagnostic sleep tests for the diagnosis of OSA for the following indication for Medicare HMO Blue and Medicare PPO Blue members in accordance with CMS NCD:
- Other diagnostic tests for the diagnosis of OSA, other than those noted above for prescribing CPAP.

National Coverage Determination (NCD) for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (240.4)


Prior Authorization Information

Commercial Members: Managed Care (HMO and POS)
Prior authorization is required through AIM Specialty Health.

Commercial Members: PPO, and Indemnity
Prior authorization is NOT required.

Medicare Members: HMO BlueSM and PPO BlueSM
Authorizations are required for all medically necessary services performed in the inpatient setting. Authorizations are NOT required for when these services are performed in the outpatient setting.

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>E0561</td>
<td>Humidifier, non-heated, used with positive airway pressure device</td>
</tr>
<tr>
<td>E0562</td>
<td>Humidifier, heated, used with positive airway pressure device</td>
</tr>
<tr>
<td>E0601</td>
<td>Single level continuous positive airway pressure device or auto-titrating continuous positive airway pressure</td>
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Description
This policy is applicable to use of auto-titrating (APAP) or continuous (CPAP) positive airway pressure systems and associated supplies in the management of obstructive sleep apnea (OSA). A separate document addresses the use of bi-level positive pressure (BPAP). Positive airway pressure treatment modalities and add-on devices (e.g. CPT code E1399) not addressed in this policy are considered to be not medically necessary.

Overview
Positive airway pressure (PAP), resulting in pneumatic splinting of the airway, is the mainstay of treatment of OSA. The pressure provided throughout the respiratory cycle may be constant (CPAP) or may vary between inspiration and expiration (bi-level PAP or BPAP). Auto-titrating positive airway pressure (APAP) supplies variable pressure in response to changes in various parameters e.g., sleeping position, sleep stages or changes in body habitus. Although APAP may be preferred by some patients, use of APAP has not increased compliance with therapy.

For patients requiring treatment with CPAP, pressure levels need to be titrated to each patient’s particular needs. For patients whose diagnostic sleep study is performed in a lab setting, it may be possible to diagnose OSA and perform the titration study in a single night. This approach, known as split-night study, may be used when AHI exceeds 20 per hour based on the first 2 hours of testing. Those who do not meet criteria for split-night protocol require either a second overnight titration study or temporary use APAP as a means of titrating CPAP. Titration is not required if APAP is selected as the long-term therapeutic approach. Other treatments for OSA (not addressed in this guideline) include positional therapy, non-surgical weight loss methods, oral appliances, oropharyngeal surgery or bariatric surgery. Tracheostomy should be considered when other measures fail and OSA is deemed severe enough to warrant this procedure. Adenotonsillectomy is the preferred initial approach to treatment of OSA in children. CPAP is reserved for those children who have an inadequate response to surgery, do not have enlarged tonsils or are not good surgical candidates.

In the management of patients with OSA, long-term compliance with positive airway pressure devices remains problematic. Adherence to therapy is defined by the Centers for Medicare & Medicaid Services (CMS) as use of PAP greater than or equal to 4 hours per night on 70% of nights during a consecutive thirty (30) day period. Compliance may be as low as 50% at one year and for this reason compliance monitoring is an important component of the management of patients with OSA. Every effort should be made to achieve compliance. Newer PAP devices record (and may
transmit) use times such that compliance monitoring may be performed remotely. Unless compliance is achieved and documented, the continued use of PAP devices (and the ongoing provision of associated supplies) cannot be considered to be medically necessary.

Policy History

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<tr>
<th>Date</th>
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<tbody>
<tr>
<td>9/2014</td>
<td>Coding information clarified</td>
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<tr>
<td>1/2013</td>
<td>Updated to add new CPT code 95782 and 95783.</td>
</tr>
<tr>
<td>9/1/2010</td>
<td>BCBSA National medical policy review. Changes to policy statements.</td>
</tr>
<tr>
<td>5/2009</td>
<td>Updated prior authorization information.</td>
</tr>
<tr>
<td>5/2007</td>
<td>Updated coverage and non coverage guidelines for oral appliances for sleep apnea.</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines
References


Endnotes

1 Based on AIM Specialty Health: Sleep Disorder Management Diagnostic & Treatment Guidelines Program - October 2013.