



Health & Human Services

## CONTINUOUS POSITIVE AIRWAY DEVICE (CPAP)

Service Authorization Required: Yes

CMN Required: No

### DURABLE MEDICAL EQUIPMENT MANUAL

POLICY COVERAGE AND LIMITATION CRITERIA

EFFECTIVE: March 2007

REVISED: July 2024

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### DEFINITIONS:

Apnea is defined as the cessation of airflow for at least 10 seconds.

Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline and with at least a 4% decrease in oxygen saturation.

Polysomnographic studies must be performed in a sleep study laboratory or accepted home studies code G0398, G0399, and G0400 (the submitting provider must clarify if the home sleep study used is accepted).

The apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device. For purposes of this policy, respiratory effort-related arousals (RERAs) are not included in the calculation of the AHI. Sleep time can only be measured in Type I (facility-based polysomnogram).

If the AHI is calculated based on less than 2 hours of sleep or recording time, 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 2-hour period (i.e., must reach  $\geq 30$  events without symptoms or  $\geq 10$  events with symptoms).

### Indications and limitations of coverage and medical appropriateness:

In this policy, the term CPAP (positive airway pressure) device will refer to both a single-level continuous positive airway pressure device (E0601) and a bi-level respiratory assist device without backup rate (E0470) when it is used in the treatment of obstructive sleep apnea.



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### INITIAL RENTAL COVERAGE OF THE FIRST THREE MONTHS OF THERAPY:

- Arterial blood gases, sleep studies, and sleep oximetry MUST NOT be performed by the DME supplier.
  - A heated (E0562) or non-heated (E0561) humidifier will be considered.
  - Included during rental: Compressor, manometer, CPAP Valve (if separate from the mask), fuses, nasal cannula's repairs to equipment.
  - Accessories used with the CPAP/ RAD device are covered when the coverage criteria for the device are met.
- I. An E0601 device is covered for the treatment of obstructive sleep apnea (OSA) if criteria A – C are met:
- A. Clinical evaluation by the treating practitioner prior to the sleep test to assess the member for obstructive sleep apnea.
  - B. The member has a sleep test (as defined below) that meets **either** of the following criteria (1 or 2)
    - 1. The apnea-hypopnea index (AHI) is greater than or equal to 15 events per hour with a minimum of 30 events or
    - 2. The AHI or RDI is greater than or equal to 5 and less than 15 events per hour with a minimum of 10 events and documentation of:
      - a. Excessive daytime sleepiness as documented by a score of greater than 10 on the Epworth Sleepiness Scale, impaired cognition, mood disorders, or insomnia; **or**
      - b. Hypertension, ischemic heart disease, or history of stroke.
  - C. The member or their caregiver has received instruction from the durable medical equipment (DMEPOS) provider of the CPAP device and accessories in the proper use and care of the equipment.
- II. An E0470 device is covered for those beneficiaries with OSA who meet criteria A-C above, in addition to criterion D:
- D. An E0601 has been tried and proven ineffective based on a therapeutic trial conducted in a facility or during a home trial.



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**Ineffective** is defined as one of the following:

- Documented failure to meet therapeutic goals using an E0601 during the titration portion of a facility-based study despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings) **or**,
- If a CPAP (E0601) device is tried and found ineffective **during** the initial three-month home trial, the substitution of a BIPAP (E0470) does not require a new sleep study. A new service authorization requesting a three-month trial for use of the E0470 is needed, **or**
- If a CPAP (E0601) device has been used for **more** than three months and the member is switched to a BIPAP (E0470), a clinical re-evaluation is required along with a new service authorization requesting a three-month trial for the use of the E0470 but **does not** require a new sleep study.

The Respiratory Assist Devices (RAD) policy addresses coverage, coding, and documentation requirements for the use of E0470 and E0471 for diagnoses other than OSA.

A bi-level positive airway pressure device with a backup rate (E0471) is **not** reasonable and necessary if the primary diagnosis is OSA.

### CONTINUED RENTAL COVERAGE BEYOND THE FIRST THREE MONTHS OF THERAPY:

- Initial approval will be for three months' rental only. If the documentation supports compliance and the therapy is effective, a request for the remaining nine months' rental will be considered.
- Accessories used with the CPAP device are covered when the coverage criteria for the device are met.
- Adherence to therapy is defined as the use of CPAP  $\geq 4$  hours per night on 70% of nights during a consecutive thirty (30) day period, anytime during the first three (3) months of initial usage.



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### REPLACEMENT:

If a CPAP device is replaced during its 5-year reasonable useful lifetime due to loss, theft, or irreparable damage due to a specific incident, a new clinical evaluation, sleep test, or trial period is not required.

If a CPAP device is replaced following the 5-year reasonable useful lifetime, the member must be evaluated by their treating practitioner, who must document that the member continues to use and benefit from the CPAP device.

There is no requirement for a new sleep test or trial period.

Replacement request: A sleep study from the original request is required.

If a CPAP device is being replaced as irreparable/obsolete, the manufacturer must provide documentation to support it.

12-month rental will be approved and included in the rental period: compressor, manometer, CPAP Valve (if separate from the mask), filters, fuses, tubing, cushions, pillows, nasal cannulas, and chin straps.

### **Documentation Requirements:**

- A prescription from an ordering physician/practitioner.
- Physician/practitioner's documentation needs to address medical necessity.
- Physician/practitioner exam within 90 days of the service authorization start date.
- Polysomnogram: **Initial Request:** must be within the last 12 months. Performed in a facility or in the home. Accepted home study codes G0398, G0399, and G0400 (submitting provider must clarify if the home sleep study used is accepted).

**Replacement Request:** A sleep study from the original request is required).

- Download to verify compliance for continued coverage.
- Documentation from the manufacturer to support the device if irreparable/obsolete.



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**Supplies:**

A mask (A7030) and headgear (A7035) will be paid separately during the rental period.

The following represents the usual maximum number allowed of accessories expected to be medically necessary:

A7030..... 1 per 6 months	A7034..... 1 per 6 months	A7038..... 2 per month
A7031..... 1 per month	A7035..... 1 per 6 months	A7039..... 1 per 6 months
A7032..... 2 per month	A7036..... 1 per 6 months	A7046..... 1 per 6 months
A7033..... 2 per month	A7037..... 1 per month	

**Non-covered:**

If the documents do not support the above policy criteria the accessories will be denied as not reasonable and necessary.

A bi-level positive airway pressure device with a back-up rate (E0471) is **not** reasonable and necessary if the primary diagnosis is OSA.



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Date Revised	Revisions
February 2017	Reformatted and revised. Added definition section. Updated compliance percentage. Added section II, E0470 coverage criteria/clarification. Added clarification for the E0471 as non-covered for OSA. Added clarification when the E0601 is not effective requiring the member to change to the E0470. Added the clarification for the acceptable Polysomnogram date span for initial/replacement request. Added clarification for the initial and continued coverage rental.
May 2017	Section D reformatted and added the word or after bullet 1 and 2. Also CONTINUED RENTAL COVERAGE BEYOND THE FIRST THREE MONTHS OF THERAPY: the bullet that stated Compliance is defined as using the device 4 out of 24 hours and 20 days out of the month was removed.
June 11, 2020	Reviewed and revised the logo to the new department logo. Revised Documentation Requirement section bullets 1-3 to <ul style="list-style-type: none"> <li>• A prescription from ordering physician/practitioner.</li> <li>• Physician/practitioner's documentation needs to address medical necessity.</li> <li>• Physician/practitioner exam within 90 days of the service authorization start date.</li> </ul>
December 27, 2022	Reviewed and reformatted. Added new logo.
August 1 <sup>st</sup> , 2023	Added to the Documents Required section Polysomnogram bullet - Accepted home studies codes: G0398, G0399, and G0400 (submitting provider must clarify if home sleep study used is accepted).
December 11, 2023	Reviewed and reformatted. No new changes.
July 1, 2024	Revised DEFINITIONS RELATED TO OBSTRUCTIVE SLEEP APNEA (OSA) by adding accepted home studies code: G0398, G0399, and G0400 (submitting provider must clarify if the home sleep study used is accepted). Removed the CMN required.