



Health & Human Services

RESPIRATORY ASSIST DEVICE (BIPAP)

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 RELATED TO OBSTRUCTIVE SLEEP APNEA (OSA):

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 ≥ 30 events without symptoms or ≥ 10 events with symptoms).

Indications and limitations of coverage and medical appropriateness:

Coverage is allowed if one of the following conditions are present:

- Symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc., **or**
- Restrictive thoracic disorders (i.e., progressive neuromuscular diseases or severe thoracic cage abnormalities), severe chronic obstructive pulmonary disease, central sleep apnea or obstructive sleep apnea, and the member's oxygen saturation drops below 88% on room air, **or**
- An E0470 device is covered for the treatment of obstructive sleep apnea (OSA) if criteria A – D are met:
 - A. Clinical evaluation by the treating practitioner prior to the sleep test to assess the member for obstructive sleep apnea **and**
 - B. The member has a sleep test (as defined below) that meets **either** of the following criteria (1 or 2) **and**
- The apnea-hypopnea index (AHI) is greater than or equal to 15 events per hour with a minimum of 30 events **or**



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- The AHI is greater than or equal to 5 and less than 15 events per hour with a minimum of 10 events and documentation of:
 - Excessive daytime sleepiness as documented by a score of greater than 10 on the Epworth Sleepiness Scale, impaired cognition, mood disorders, or insomnia; **or**
 - Hypertension, ischemic heart disease, or history of stroke.
- The member or their caregiver has received instruction from the durable medical equipment and supplies (DMEPOS) provider of the BIPAP device and accessories in the proper use and care of the equipment.
- An E0601 has been tried and proven ineffective based on a therapeutic trial conducted in a facility or during a home trial.

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 E0470, but it does not require a new sleep study.

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 cannulas, and repairs to equipment.
- Accessories used with the CPAP/ RAD device are covered when the coverage criteria for the device are met.



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CONTINUED RENTAL COVERAGE BEYOND THE FIRST THREE MONTHS OF THERAPY:

- Initial approval will be for three months of rental only. If documentation supports compliance and the therapy is effective a request for the remaining 9 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 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.

REPLACEMENT:

If a BIPAP device is replaced due to loss, theft, or irreparable damage caused by a specific incident, a new clinical evaluation, sleep test, or trial period is not required.

If a BIPAP device is replaced because it is unrepairable or obsolete, the member must be evaluated by their treating practitioner, who must document that the member continues to use and benefit from the PAP device.

A new sleep test or trial period is not required. However, a copy of the original sleep study must be submitted with the request.

If a BIPAP device is being replaced as irreparable/obsolete, there must be documentation from the manufacturer to support it.

A 12-month rental (up to purchase cost) will be approved. The rental period includes the compressor, manometer, CPAP Valve (if separate from the mask), filters, fuses, tubing, cushions, pillows, nasal cannulas, and chin straps.



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Supplies:

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

A non-heated (E0561) or heated (E0562) humidifier is covered and paid separately for use with a covered E0470.

The following table represents the usual maximum allowable number of accessories expected to be medically necessary for use with member-owned equipment:

A7030..... 1 per 6 months	A70341 per 6 months	A7038..... 2 per month
A7031..... 1 per month	A7035.....1 per 6 months	A70391 per 6 months
A7032..... 2 per month	A7036.....1 per 6 months	A70461 per 6 months
A7033..... 2 per month	A7037..... 1 per month	

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 (the 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.

Non-covered:

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



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Date Revised	Revisions
May 2017	Reformatted and revised. Added definition section. Updated compliance percentage. Added section III, 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.
June 11, 2020	Reviewed and revised. Revised A7034 to allow 1 per 6 months and A7039 to allow 1 per 6 months. Revised Documentation section first three bullets to: <ul style="list-style-type: none"> • A prescription from ordering physician/practitioner. • Physician/practitioner's documentation needs to address medical necessity. • Physician/practitioner exam within 90 days of the service authorization start date.
December 22, 2022	Replacement section deleted from line 1 and 2 "during the 5-year reasonable useful lifetime". Reformatted and updated with new logo.
August 1, 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 changes were made.
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.

