Bi-level Positive Airway Pressure (BPAP/NPPV)

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<thead>
<tr>
<th>Type:</th>
<th>Policy Specific Section:</th>
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<tr>
<td>Medical Necessity/Not Medical Necessity</td>
<td>Durable Medical Equipment</td>
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<table>
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<tr>
<th>Original Policy Date:</th>
<th>Effective Date:</th>
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<tbody>
<tr>
<td>October 1, 2010</td>
<td>January 21, 2013</td>
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Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Description**

Bi-level positive airway pressure (BPAP) is a mode of non-invasive positive pressure ventilation (NPPV). The BPAP respiratory assist device utilizes a full-face or nasal mask to deliver different levels of inspiratory and expiratory positive airway pressure (PAP), instead of the continuous pressure applied by continuous positive airway pressure (CPAP) devices. Bi-level PAP devices
provide NPPV therapy for hospital or in-home use and PAP therapy for patients with sleep-disordered breathing who do not benefit from CPAP therapy.

Bi-level PAP devices are available with or without a back-up rate feature. Devices that have the back-up rate feature, (usually called S/T or Spontaneously Timed), will initiate a breath if none is detected within a specific time period.

Note: This policy addresses the medical necessity criteria for the in-home use of BPAP respiratory assist devices only.

**Policy**

*Reimbursement for the following durable medical equipment (DME) will initially be limited to a three month rental period when the service is determined to be medically necessary based on the criteria listed below. Subsequent reimbursement will be provided when documentation substantiates patient compliance and clinical benefit from the device. (See continued coverage criteria beyond the first three months of therapy listed below).*

**Restrictive Thoracic Disorders**

A BPAP device with or without a back-up rate (HCPCS code E0470 or E0471) is considered medically necessary when all of the following criteria are met:

- Symptoms characteristic of sleep associated hypoventilation
- Diagnosis of a progressive neuromuscular condition or a severe thoracic cage abnormality
- Chronic obstructive pulmonary disease (COPD) does not contribute significantly to the patient's pulmonary limitation
- Clinically significant hypoxemia evidenced by any of the following:
  - Arterial blood gas PaCO2 done while awake and breathing the patient's prescribed FIO2 (fractional inspired oxygen concentration), is greater than or equal to 45 mm Hg
  - Sleep (nocturnal) oximetry demonstrates an oxygen saturation less than or equal to 88% for at least five continuous minutes, measured while breathing patient's prescribed FIO2
  - Maximal inspiratory pressure less than 60 cm H2O or forced vital capacity (FVC) less than 50% of predicted, for neuromuscular disease only

**Severe Chronic Obstructive Pulmonary Disease (COPD)**

A BPAP device without a back-up rate (HCPCS code E0470) is considered medically necessary when all of the following criteria are met:

- Symptoms characteristic of sleep associated hypoventilation
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- Arterial blood gas PaCO₂, done while awake and breathing the patient's prescribed FIO₂, is greater than or equal to 52 mm Hg
- Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing oxygen at two liters per minute (LPM) or the patient's prescribed FIO₂ (whichever is higher)
- Prior to initiating therapy, obstructive sleep apnea (OSA) and treatment with continuous positive airway pressure (CPAP) has been considered and ruled out

A BPAP device with a back-up rate (HCPCS code E0471) is considered **medically necessary** for COPD patients who qualified for BPAP without a back-up rate (HCPCS code E0470) and meet the specific criteria in one of the following:

- Any time after a period of initial use of the BPAP without a back-up rate device (HCPCS code E0470) and **both** of the following criteria are met:
  - Arterial blood gas PaCO₂, done while awake and breathing the patient's prescribed FIO₂, shows the PaCO₂ worsens more than or equal to 7 mm Hg compared to the original results from criteria for the BPAP without a back-up rate device (HCPCS code E0470)
  - Polysomnography in a sleep-laboratory demonstrates oxygen saturation less than 88% for greater than or equal to five minutes of nocturnal recording time (minimum recording time of two hours) while using the BPAP without a back-up device that is not caused by obstructive upper airway events* (i.e., AHI less than 5)

- At a time no sooner than 61 days after initial issue of the BPAP without a back-up rate device (HCPCS code E0470) when **both** of the following criteria are met:
  - Arterial blood gas PaCO₂ done while awake and breathing the patient's prescribed FIO₂, still remains greater than or equal to 52 mm Hg
  - Sleep oximetry while breathing with the BPAP without a back-up rate device (HCPCS code E0470), demonstrates oxygen saturation less than or equal to 88% for greater than or equal to five continuous minutes of nocturnal recording time (minimum recording time of two hours), done while breathing oxygen at two liters per minute or the patient's prescribed FIO₂ (whichever is higher)

*Note: For obstructive upper airway information refer to the Blue Shield of California (BSC) Medical Policy: Obstructive Sleep Apnea - Diagnosis and Management.

**Central Sleep Apnea (CSA) or Complex Sleep Apnea (CompSA)**

A BPAP device with or without a back-up rate (HCPCS code E0470 or E0471) is considered **medically necessary** when **all** of the following criteria are met:

- Prior to initiating therapy, a complete polysomnogram in a sleep laboratory confirms the primary diagnosis of CSA or CompSA (see definitions in policy guideline)
- Presence of OSA has been excluded as the predominant cause of the sleep-associated hypoventilation
• Significant improvement of the sleep-associated hypoventilation with the use of a BPAP device with or without a back-up rate (HCPCS code E0470 or E0471) adjusted to the settings that will be prescribed for initial home use, while breathing the patient's prescribed FIO2

Obstructive Sleep Apnea (OSA)
A BPAP device without a back-up rate (HCPCS code E0470) is considered medically necessary when both of the following criteria are met:
- Criteria for continuous positive airway pressure (CPAP) met as established in BSC Medical Policy: Obstructive Sleep Apnea - Diagnosis and Management
- Trial failure or intolerance to CPAP or auto-adjusting CPAP (APAP) (See Policy Guideline)

A BPAP device with a back-up rate (HCPCS code E0471) is considered not medically necessary for the treatment of the primary diagnosis of OSA.

Hypoventilation Syndrome
A BPAP device without a back-up rate (HCPCS code E0470) is considered medically necessary when both of the following criteria are met:
- Initial arterial blood gas PaCO2, done while awake and breathing the patient's prescribed FIO2, is greater than or equal to 45 mm Hg
- Spirometry shows an FEV1/FVC greater than or equal to 70% and an FEV1 greater than or equal to 50% of predicted* and one of the following:
  - An arterial blood gas PaCO2, done during sleep or immediately upon awakening, and breathing the patient's prescribed FIO2, shows the PaCO2 worsened more than or equal to 7 mm Hg compared to the initial result as above
  - Polysomnography in a sleep laboratory demonstrates oxygen saturation less than or equal to 88% for greater than or equal to five minutes of nocturnal recording time (minimum recording time of two hours) that is not caused by obstructive upper airway events (i.e., AHI less than 5)

A BPAP device with a back-up rate (HCPCS code E0471) is considered medically necessary when both of the following criteria are met:
- BPAP without a back-up rate (HCPCS code E0470) is being used
- Spirometry shows an FEV1/FVC greater than or equal to 70% and an FEV1 greater than or equal to 50% of predicted* and one of the following:
  - Arterial blood gas PaCO2, done while awake and breathing the patient's prescribed FIO2, shows the PaCO2 worsens more than or equal to 7 mm Hg compared to the arterial blood gas result performed to qualify the patient for the BPAP without a back-up rate device (HCPCS code E0470)
Polysomnography in a sleep laboratory demonstrates oxygen saturation less than or equal to 88% for greater than or equal to five minutes of nocturnal recording time (minimum recording time of two hours) that is not caused by obstructive upper airway events (i.e., AHI less than 5)

*Refer to Severe COPD section above for information about device coverage for patients with FEV1/FVC less than 70% and FEV1 less than 50% of predicted.

**Continued coverage criteria beyond the first three months of therapy**

Continued coverage of a BPAP device beyond the first three months of therapy is considered **medically necessary** if the following criteria are met:

- Documented patient adherence/tolerance to therapy defined as use of PAP >/= four (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
- Documentation of therapeutic benefit from use of the device

A heated or non-heated humidifier is considered **medically necessary** for use with any BPAP device.

Note: Blue Shield of California follows the Medicare Durable Medical Equipment Regional Carrier (DMERC) rules with respect to the usual medically necessary quantity of supplies for respiratory assist devices (Refer to Tables Section below).

**Policy Guideline**

Note: Patients hospitalized and sent home on a BPAP device who do not meet the specific medically necessary criteria (i.e., no history of prior PSG or sleep study, CPAP trial or sleep oximetry) may be approved for a three month trial. Continuation of a BPAP device requires a new initial face-to-face clinical evaluation and the above diagnosis-specific medically necessary criteria be met.

**Examples of qualified conditions:**

- Hypoventilation syndromes (insufficient ventilation leading to an increase in PaCO2) include but are not limited to: central alveolar hypoventilation, obesity hypoventilation syndrome, and chronic obstructive pulmonary disease (COPD)
- Symptoms characteristic of sleep associated hypoventilation include, but are not limited to, daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea etc.
- Neuromuscular conditions include but are not limited to: amyotrophic lateral sclerosis (ALS), neuropathies, myopathies, dystrophies, sequelae of polio, and spinal cord injury
- Severe thoracic cage abnormalities include but are not limited to: post-thoracoplasty for tuberculosis, chest wall deformities, kyphoscoliosis, and fibrothoraces and intractable pleural effusions causing restrictive pulmonary disease
• COPD conditions include, but are not limited to: chronic bronchitis, emphysema, bronchiectasis, and cystic fibrosis
• Central sleep apnea (CSA) is defined as all of the following:
  o An apnea hypopnea index (AHI) greater than 5
  o Central apneas/hypopneas greater than 50% of the total apneas/hypopneas
  o Central apneas or hypopneas greater than or equal to five times per hour
  o Symptoms of either excessive sleepiness or disturbed sleep
• Complex sleep apnea (CompSA) is a form of central apnea specifically identified by persistence or emergence of central apneas or hypopneas upon exposure to CPAP (HCPCS code E0601) or BPAP without a back-up rate device (HCPCS code E0470) when obstructive events have disappeared. These patients have predominantly obstructive or mixed apneas during the diagnostic sleep study occurring at greater than or equal to five times per hour. With use of CPAP or E0470, they show a pattern of apneas and hypopneas that meet the definition of CSA described above.

Information on obstructive upper airway events refer to the Blue Shield of California (BSC): Obstructive Sleep Apnea - Diagnosis and Management.

**Examples of failed CPAP** include, but are not limited to:

• Claustrophobia
• Inability to breathe through the nose
• Patient intolerance
• Discomfort or pain
• Patients requiring high pressures of CPAP (>10 cm H₂O) complaining of pressure discomfort

Reimbursement for maintenance of positive airway pressure (PAP) devices is included in the monthly rental allowance for the device.

If a CPAP device has been tried and found ineffective during the initial three-month trial, substitution of a BPAP device does not require a new clinical evaluation or a new sleep test if the medical necessity criteria are met initially.

If a CPAP device has been used for more than three months and is switched to a BPAP device, a new initial face-to-face clinical evaluation is required and the criteria above must be met, but a new sleep test is not required. A new three-month trial would begin for BPAP.

If a BPAP device is replaced during the three year reasonable useful lifetime because of loss, theft or irreparable damage due to a specific incident, there is no requirement for a new clinical evaluation, sleep test, or trial period.

**Coding for BPAP devices:**

• HCPCS code E0470 describes BPAP devices *without a back-up rate* (e.g., VPAP Auto, VPAP S, BiPAP)
• HCPCS code E0471 describes BPAP devices *with a back-up rate* (e.g., VPAP ST, VPAP Adapt SV, VPAP III ST-A)
**Documentation Required for Clinical Review**

<table>
<thead>
<tr>
<th>Initial request:</th>
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<tbody>
<tr>
<td>• History and physical or progress notes including: prior treatment responses</td>
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<tr>
<td>• Complete polysomnogram, sleep oximetry, arterial blood gas (ABG), or spirometry results/reports (if applicable)</td>
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<th>Re-evaluation:</th>
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<td>• Documentation of patient adherence/tolerance to therapy defined as use of PAP ( \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 (e.g., direct download from the device or Smart Card or other data card)</td>
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<tr>
<td>• Documentation of therapeutic benefit from use of the device</td>
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The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.