Name of Policy:
Noninvasive Positive Pressure Ventilation for Conditions Other Than Obstructive Sleep Apnea

Policy #: 203
Category: Durable Medical Equipment

Latest Review Date: April 2016
Policy Grade: Effective July 31, 2013:
Active Policy but no longer scheduled for regular literature reviews and updates.

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**
Nasal or oral continuous positive airway pressure (CPAP) or auto-titrating continuous positive airway pressure (APAP) is continuous positive airway pressure applied through the nose or via oral appliance. The continuous positive airway pressure is delivered by a flow generator through a mask to supply a pressure level sufficient to keep the upper airway patent. The pressure used is determined individually with a range of 3 to 15 centimeters of water. *(See Medical Policy #065: Medical Management of Obstructive Sleep Apnea Syndrome, for medical criteria coverage of CPAPs.)*

A respiratory assist device delivers two levels of positive airway pressure, both of which reach the patient through tubing connected to a full-face or nasal mask or through nasal pillows.

A bi-level respiratory assist device delivers alternating levels of positive airway pressure instead of the continuous pressure applied by CPAP. These machines function as a non-invasive ventilator. There are two set pressures, a higher pressure for inhalation and a lower pressure for exhalation, but some require a back up timed response in which a breath will be initiated if a breath is not taken within the set timed parameters. This feature may be useful in treating central sleep apnea and a number of pulmonary disorders.

The device cycles between a pre-determined inspiratory positive airway pressure (IPAP) phase—the pressure maintained during each inhalation—and a preset expiratory positive airway pressure (EPAP) phase. Each inspiration can be initiated by the patient or by the machine itself if it's programmed with a backup rate. The backup rate ensures that the patient will receive a set number of breaths per minute if he should become apneic. By helping to open up a patient's airways and alveoli, noninvasive positive pressure ventilation can enhance the patient's tidal volume—the amount of air passing in and out of the lungs per respiratory cycle. The expected improvement in tidal volume can be measured by looking at the difference between IPAP and EPAP.

These devices are in the FDA category of non-continuous ventilator, and as such, are primarily intended to augment patient ventilation. Bi-level positive airway pressure with back-up rate is not appropriate for obstructive sleep apnea but is appropriate for patients with neuromuscular respiratory insufficiency or restrictive lung disease from thoracic wall deformity and for some patients with central sleep apnea.

Adaptive servo-ventilation (ASV), a bilevel PAP system with a backup rate feature, uses an automatic, minute ventilation-targeted device that performs breath to breath analysis and adjusts its settings accordingly. Depending on breathing effort, the device will automatically adjust the amount of airflow it delivers in order to maintain a steady minute ventilation.
Policy:
Effective for dates of service on or after May 1, 2014:
Obstructive Sleep Apnea (OSA)*
Noninvasive Positive Pressure Ventilation Devices meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used by patients diagnosed with Obstructive Sleep Apnea (OSA) when prior to initiating therapy, a complete (full or split night), approved facility based, attended polysomnography has been performed and the test results have confirmed the diagnosis of OSA and ALL of the following criteria are met:

CPAP would have met the medical criteria for coverage as defined in medical policy Management of Obstructive Sleep Apnea Syndrome, Policy #065 and CPAP has been tried and proven ineffective.

Failed CPAP is defined as any of the following criteria documented in the medical record:

- Patient intolerance (claustrophobia, discomfort and/or pain due to pressure)
- Optimal PAP pressure has not been achieved, proven by evidence of respiratory events (apneas, hypopneas, etc) while on high pressures of CPAP (>10 cm H2O).

*Obstructive Sleep Apnea treatment is addressed in medical policy #065 Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome.

Noninvasive Positive Pressure Ventilation Devices meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for any one of the following disorders when the coverage criteria are met:

For Restrictive Thoracic Disorders / Neuromuscular Abnormalities when ALL of the following criteria are met:

- The member has been diagnosed with a progressive neuromuscular disease, (e.g., amyotrophic lateral sclerosis [ALS] or a severe thoracic cage abnormality, [e.g., post-thoracoplasty for TB]); AND
- COPD does not contribute significantly to the individual's pulmonary limitation; and ONE or more of the following criteria are met:
  - An arterial blood gas PaCO2 level is 45 mm Hg, done while awake and breathing the patient's usual FIO2 (fractionated inspired oxygen concentration); or
  - Sleep oximetry demonstrates an oxygen saturation 88% for at least five continuous minutes, done while breathing the patient's usual FIO2; or
  - Maximal inspiratory pressure is < 60 cm H2O or forced vital capacity is < 50% of predicted (for patients with a progressive neuromuscular disease only).
For Severe Chronic Obstructive Pulmonary Disease (COPD) when ALL of the following are met:

- An arterial blood gas PaCO2, done while awake and breathing the individual's usual FIO2, is 52 mm Hg or greater; OR
- Sleep oximetry demonstrates oxygen saturation 88% for at least five continuous minutes, done while breathing oxygen at 2 L/min. or the individual's usual FIO2 (whichever is higher); AND
- Prior to initiating therapy, obstructive sleep apnea and treatment with CPAP has been considered and ruled out.

For Hypoventilation Syndrome when ALL of the following criteria are met:

- An initial arterial blood gas PaCO2, done while awake and breathing the patient’s prescribed FIo2, is ≥ 45 mm Hg; AND
- Spirometry shows an FEV1/FVC ≥ 70% and an FEV1 ≥ 50% of predicted; OR
- An arterial blood gas PaCO2, done during sleep or immediately upon awakening, and breathing the patient’s prescribed FIO2, shows a PaCO2 worsened ≥ 7 mm HG compared to the original result in criterion 1 (above); OR
- An approved facility-based PSG demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours unless an emergency protocol was activated) that is not caused by obstructive upper airway events – i.e., AHI < 5.

For Noninvasive Positive Pressure Ventilation with back up when ALL the criteria are met:

- A covered E0470 device is being used; AND
- Spirometry shows an FEV1/FVC ≥ 70% and an FEV1 ≥ 50% of predicted; AND
- An arterial blood gas PaCO2, done while awake, and breathing the patient’s prescribed FIO2, shows that the beneficiary’s PaCO2 worsens ≥ mm HG compared to the ABG result performed to qualify the patient for the E0470 device; OR
- A facility-based PSG demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours unless an emergency protocol was activated) that is not caused by obstructive upper airway events – i.e., AHI < 5 while using an E0470 device.

For Central Sleep Apnea (CSA), (i.e., apnea not due to airway obstruction) when, prior to initiating therapy, a complete, (full or split night) approved facility based, attended polysomnography has been performed and the test results have revealed ALL of the following:

- The diagnosis of central sleep apnea (CSA) has been confirmed, defined as a AHI greater than 5, central apneas/hypopneas consist of 50% or more of the total apneas/hypopneas; AND
- The presence of obstructive sleep apnea (OSA) has been excluded, as the predominant cause of the sleep-associated hypoventilation; AND
• If OSA is a component of the sleep-associated hypoventilation, CPAP has been ruled out as an effective therapy; AND
• Significant clinical improvement of the patient's sleep-associated hypoventilation has been demonstrated with the use of a Bi-level positive pressure device, adjusted to the settings that will be prescribed for initial home use, while breathing the individual's usual FIO2.

A noninvasive positive pressure ventilation device with back-up would usually be the equipment used for this diagnosis.

**Noninvasive Positive Pressure Ventilation Device with a Back-up Rate**

Non-invasive positive pressure respiratory assist devices (BiPAP) which includes a Back-up Rate meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for any one of the above disorders when the coverage criteria are met AND BiPAP has failed as evidenced by continued hypoxemia or CO2 retention.

**Adaptive –Servoventilation bi-level devices meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the following conditions are met:

- The diagnosis of central sleep apnea (CSA) or Complex Sleep Apnea (CompSA) has been confirmed; AND
- Coverage criteria for BIPAP has been met as defined above; AND
- Patient has failed a BiPAP Trial

**Compliance Documentation**

Compliance documentation should be maintained in the supplier’s record. This documentation should include that the physician certifies the patient is compliant with the treatment and the sleep disorder has improved based on the treatment OR a recorded compliance document indicating proper utilization. (≥ 4 hours per night on 70% of the nights during a 30 consecutive day period during the initial 90 days of usage.) (Compliance documentation that extended beyond the 90 days will be reviewed on an individual basis … i.e. Accidents, change in physical status, surgery, etc.)

**Related Supply Coverage –** Supply information can be obtained by contacting our Customer Service department.

<table>
<thead>
<tr>
<th>Item</th>
<th>Code</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full face mask, each</td>
<td>A7030</td>
<td>1 in 180 days</td>
</tr>
<tr>
<td>Chinstrap</td>
<td>A7036</td>
<td>1 in 180 days</td>
</tr>
<tr>
<td>Combination Oral/Nasal Mask, each</td>
<td>A7027</td>
<td>1 in 180 days</td>
</tr>
<tr>
<td>Face Mask Interface, replacement for full face mask</td>
<td>A7031</td>
<td>1 in 180 days</td>
</tr>
<tr>
<td>Item Description</td>
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<td>1-in-90-days</td>
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<td>Headgear/Softcap</td>
<td>A7035</td>
<td>1-in-180-days</td>
</tr>
<tr>
<td>Nasal interface (mask or cannula type)</td>
<td>A7034</td>
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</tr>
<tr>
<td>Nose Pillows (Pair)</td>
<td>A7033</td>
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</tr>
<tr>
<td>Oral Interface Used With Positive Airway Pressure Device, Each</td>
<td>A7044</td>
<td>1-in-180-days</td>
</tr>
<tr>
<td>Replacement Cushion for nasal mask interface</td>
<td>A7032</td>
<td>1-in-180-days</td>
</tr>
<tr>
<td>Replacement Nasal Pillows for Combination Oral/Nasal Mask</td>
<td>A7029</td>
<td>1-in-180-days</td>
</tr>
<tr>
<td>Replacement Oral Cushion for Combination Oral/Nasal Mask</td>
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<td>1-in-180-days</td>
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<tr>
<td>Filter, non-disposable</td>
<td>A7039</td>
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<tr>
<td>Tubing/Hose</td>
<td>A7037</td>
<td>1-in-120-days</td>
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<td>Heated tubing</td>
<td>A4604</td>
<td>1-in-120-days</td>
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<tr>
<td>Non-heated humidifier</td>
<td>E0561</td>
<td>1-every-3-years</td>
</tr>
<tr>
<td>Heated humidifier</td>
<td>E0562</td>
<td>1-every-3-years</td>
</tr>
<tr>
<td>CPAP machine</td>
<td>E0601</td>
<td>1-every-3-years</td>
</tr>
</tbody>
</table>

Supplies are not covered separately in Alabama when billed during the 10 month rental period or within the first 10 months after the purchase.

Supplier should receive a request for additional supplies and should not automatically deliver supplies/accessories on a predetermined routine basis.

**Replacement Devices**

Previously covered devices meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage to be replaced when the following criteria are met: (Repeat sleep study is not required)

- The equipment has suffered irreparable damage (cost more to repair than to replace) and has been in the home for 3 years or longer; OR
- The patient’s condition has changed and a different piece of equipment is determined to be medically necessary.

Replacement devices will not be covered for replacing functioning equipment with a newer more advanced model. (Compliance documentation is not required on replacement equipment).

Replacement devices should be filed with modifier “RA” to indicate they are not the initial device but a replacement piece of equipment.
Effective for dates of service on October 1, 2010 through April 30, 2014:

Obstructive Sleep Apnea (OSA)

Noninvasive Positive Pressure Ventilation Devices meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used by patients diagnosed with Obstructive Sleep Apnea (OSA) when prior to initiating therapy, a complete (full or split night), approved facility based, attended polysomnography has been performed and the test results have confirmed the diagnosis of OSA and ALL of the following criteria are met:

CPAP would have met the medical criteria for coverage as defined in medical policy Management of Obstructive Sleep Apnea Syndrome, Policy #065 and CPAP has been tried and proven ineffective.

Failed CPAP is defined as any of the following criteria documented in the medical record:

- Patient intolerance (claustrophobia, discomfort and/or pain due to pressure)
- Optimal PAP pressure has not been achieved, proven by evidence of respiratory events (apneas, hypopneas, etc) while on high pressures of CPAP (>10 cm H2O).

Noninvasive Positive Pressure Ventilation Devices meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for any one of the following disorders when the coverage criteria are met:

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For **Noninvasive Positive Pressure Ventilation with back up** when **ALL** the criteria are met:

- A covered E0470 device is being used; **AND**
- Spirometry shows an FEV1/FVC ≥ 70% and an FEV1 ≥ 50% of predicted; **AND**
- An arterial blood gas PaCO2, done while awake, and breathing the patient’s prescribed FIO2, shows that the beneficiary’s PaCO2 worsens ≥ mm HG compared to the ABG result performed to qualify the patient for the E0470 device; **OR**
- A facility-based PSG demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours unless an emergency protocol was activated) that is not caused by obstructive upper airway events – i.e., AHI < 5.

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Related Supply Coverage
The following supplies meet Blue Cross and Blue Shield of Alabama’s criteria for coverage based on the following frequency when the above equipment is covered:

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**Filter, non-disposable**  
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**Tubing/Hose**  
*A7037*  
1 in 365 days

**Heated tubing**  
*A4604*  
1 in 365 days

**Non-heated humidifier**  
*E0561*  
1 every 3 years

**Heated humidifier**  
*E0562*  
1 every 3 years

**CPAP machine**  
*E0601*  
1 every 3 years

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Replacement devices should be filed with modifier “RA” to indicate they are not the initial device but a replacement piece of equipment.

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*
Key Points:
Patients with neuromuscular dysfunction, chest wall abnormalities, COPD, diaphragmatic dysfunction, and/or disorders of ventilatory control are susceptible to significant deterioration in oxygenation and ventilation during sleep. Nocturnal hypoventilation may be associated with cor pulmonale, nocturnal arrhythmias, morning headaches, impaired cognitive function, and reduced daytime vigilance. In addition to adversely impacting on the patient's health, significant deterioration in productivity and quality of life may follow. Although there are few randomized controlled trials on which to base recommendations, nocturnal noninvasive ventilatory assistance has been used to treat a number of disorders in an effort to improve the quality and duration of life in these patients.

A wide variety of restrictive thoracic diseases have been successfully treated with NPPV, including thoracic cage abnormalities (e.g., chest wall deformities, kyphoscoliosis, thoracoplasty, etc.) in addition to both rapidly and slowly progressive neuromuscular disorders (e.g., amyotrophic lateral sclerosis (ALS), neuropathies, myopathies, dystrophies, sequelae of polio, spinal cord injury, etc.). These conditions result in derangement of hypoventilation, and oxygen therapy alone is not only usually ineffective in relieving symptoms, but may also be dangerous and lead to a marked acceleration of carbon dioxide (CO₂) retention. NPPV is generally not indicated for patients who cannot cooperate with NPPV treatment or who need a protected airway to handle excessive secretions. (Patients who have impaired ability to protect the upper airway or excessive secretions are usually better managed with tracheostomy.) The availability of a full face mask, however, has made it possible to use NPPV even in patients with significant bulbar weakness.

Indications for noninvasive positive pressure ventilation (NPPV) are based on symptoms attributable to nocturnal hypoventilation and objective findings of nocturnal desaturation. The most common symptoms of chronic respiratory failure are associated with nocturnal sleep disruption, and include daytime hypersomnia, excessive fatigue, morning headache, cognitive dysfunction, and even dyspnea. A consensus conference suggested that any PaCO₂ > 45 mm Hg or abnormal nocturnal oxygen desaturation is a sufficient indication for NPPV. Clinically significant hypoxemia during sleep has been defined as an oxyhemoglobin saturation < 88% for at least 5 minutes. This criterion for clinically significant nocturnal hypoxemia was favored because it is relatively simple to determine and is consistent with established guidelines for determination of hypoxemia for oxygen therapy.

For patients with progressive neuromuscular disorders, the consensus panel concluded that pulmonary function test results may be an additional indicator of nocturnal desaturation. Most amyotrophic lateral sclerosis patients have a forced vital capacity (FVC) below 50% predicted before either the physician or patient actually becomes aware of any respiratory system involvement. Other measurements like maximal inspiratory pressure with a magnitude < 60 cm H₂O have been shown to be highly sensitive albeit less specific indicator of nocturnal desaturation.

What type of equipment and what specific ventilator settings should be chosen are controversial. Most studies of long-term NPPV for patients with neuromuscular disease have used volume-rather than pressure-targeted devices. More recent reviews have cited the advantages of...
pressure-targeted devices for comfort and in their ability to compensate for leaks. Volume-targeted equipment may be favorable for patients simply because triggering mechanisms are more adjustable and pressure-targeted systems are not able to guarantee minimum minute ventilation. The need for a mandatory backup rate, however, is more generally accepted because of the profound rapid eye movement (REM) desaturation that often occurs in patients with respiratory muscle weakness.

Nocturnal noninvasive positive pressure ventilatory assistance can effectively reduce daytime PaCO₂ in patients with neuromuscular/chest wall disorders who have chronic hypercapnia. Several authors have reported successful nocturnal noninvasive ventilatory assistance utilizing volume-cycled ventilators. Although the method of triggering these devices has not been specified consistently, use of both control and assist-control modes has been reported. Pressure-cycled positive pressure ventilators have also been employed, although inappropriate cycling of the ventilator due to leaky device-patient interfaces is a potential problem.

Recently, bilevel positive airway pressure via mask has been effectively utilized to provide nocturnal ventilatory assistance to patients with restrictive/neuromuscular disease or chest wall deformity who have chronic hypercapnia. Bilevel positive airway pressure provides inspiratory positive airway pressure (or inspiratory pressure support) and expiratory positive airway pressure, each of which can be independently adjusted to augment alveolar ventilation and maintain upper airway patency during sleep. Additionally, bilevel positive airway pressure devices are designed to compensate for mild-to-moderate mouth or interface leaks, which facilitate noninvasive application. Concern has been raised over the issue of CO₂ rebreathing when bilevel positive airway pressure is used with a high respiratory rate and low expiratory pressure. The possible clinical significance of CO₂ rebreathing through the standard exhalation valve is not clear, but can be eliminated by the use of a nonbreather valve. The available data support both bilevel positive airway pressure and conventional positive pressure ventilators as modes of noninvasive ventilatory assistance and an individualized approach to each patient are recommended.

When disorders of ventilatory control complicate neuromuscular, chest wall, and pulmonary parenchymal disorders, nocturnal noninvasive positive pressure ventilatory assistance may reverse components of the disease process and prevent or mitigate further deterioration. A recent report describing nocturnal noninvasive positive pressure ventilation in patients with chronic respiratory failure due to Duchenne's muscular dystrophy has suggested that there are advantages in survival and pulmonary function when treated patients are compared with patients who decline treatment. These patients were not randomized, and nocturnal noninvasive positive pressure ventilatory assistance was recommended to all patients on clinical grounds. In contrast, a randomized trial of preventive nocturnal noninvasive positive pressure ventilatory assistance in 70 patients with moderate pulmonary dysfunction due to Duchenne's muscular dystrophy showed, surprisingly and for unclear reasons that survival was significantly worse in patients receiving preventive nocturnal ventilatory assistance. Preventive nocturnal noninvasive positive pressure ventilatory assistance in these patients with moderate pulmonary dysfunction did not show a beneficial effect in terms of preservation of pulmonary function; however, the study methods have been criticized on the basis of patient selection (there was no confirmation of hypercapnic ventilatory failure in the study population), the method of determining and
monitoring ventilatory support (there was no objective assessment of adequacy of ventilatory support or therapeutic compliance), and the coexisting cardiac abnormalities that may have contributed to mortality. These studies in different patient groups show that nocturnal noninvasive positive pressure ventilatory assistance is likely to be beneficial when chronic respiratory failure complicates Duchenne's muscular dystrophy, but that the role of preventive nocturnal ventilatory assistance in patients with moderate pulmonary dysfunction is still not defined.

In contrast to the literature describing the benefits of nocturnal noninvasive positive pressure ventilatory assistance in patients with restrictive pulmonary disease and neuromuscular/chest wall disorders, there is relatively little information specifically addressing, its use in patients with COPD. Meecham Jones and coworkers reported results of a randomized, controlled trial of bilevel positive airway pressure plus oxygen vs. oxygen alone, in 14 subjects with chronic respiratory failure due to COPD. Their results showed significant improvement in daytime Pa₂ and PaCO₂, sleep time, sleep efficiency, and quality of life in the group receiving bi-level positive airway pressure. Only one subject withdrew from the study because of inability to tolerate positive airway pressure therapy. This study has not been validated by other researchers. Successful therapeutic results from nocturnal noninvasive positive pressure assistance in patients with COPD have not been uniformly reported in the literature. This may be related to patient intolerance of the interface or mode of positive pressure, or to variability in the severity of COPD among the study groups. Some studies suggest that there is physiologic and functional improvement in hypercapnic COPD patients after the initiation of nocturnal noninvasive positive pressure assistance, while other studies indicate that this therapy is not uniformly tolerated. Although the benefits of an in hospital acclimatization period to noninvasive positive pressure ventilatory assistance has not been evaluated specifically, a review of the literature suggests that providing an opportunity for acclimatization has a salutary effect on patient acceptance. In our unpublished clinical experience, a therapeutic trial of nocturnal noninvasive positive pressure ventilatory assistance in COPD patients whose conditions are clinically deteriorating despite optimal therapy may be of benefit if patients are highly motivated and consistently compliant. Given the large numbers of patients with COPD, the role and timing of nocturnal ventilatory assistance in COPD patients merit further study.

A variety of respiratory disorders have been shown to predispose patients to nocturnal hypoventilation. These include central (non-obstructive) sleep apnea and obstructive sleep apnea (OSA).

There are few reports on noninvasive ventilation in patients with other disorders leading to nocturnal hypoventilation that may be treated with NPPV. Furthermore, although there are many reports demonstrating the benefits of CPAP in patients with OSA, there are only limited data supporting the use of NPPV in these types of patients who fail to respond to CPAP therapy.

Based on available literature, certain general statements regarding indications for noninvasive positive pressure ventilation for other nocturnal hypoventilation syndromes can be made. Patients considered for this therapy should have the following: a disease known to cause hypoventilation; symptoms and signs of hypoventilation; failure to respond to first-line therapies in mild cases of hypoventilation (i.e., treatment of primary underlying disease with
bronchodilators, respiratory stimulants, weight loss, supplemental oxygen, CPAP); or have moderate-to-severe hypoventilation.

Potential side effects from NPPV include gastric distention, aspiration of gastric contents, conjunctivitis, facial abrasions from tight-fitting masks, hypotension, and mask dislocation leading to transient hypoxemia.

Adaptive servo-ventilation (ASV), a bi-level PAP system with a backup rate feature, uses an automatic, minute ventilation-targeted device that performs breath to breath analysis and adjusts its settings accordingly. Depending on breathing effort, the device will automatically adjust the amount of airflow it delivers in order to maintain a steady minute ventilation. Most studies on the use of ASV have investigated its use for heart failure patients with central apnea or Cheyne-Stokes respiration.

Morrell, et al (2007) stated that hypercapnic cerebral vascular reactivity (HCVR) is reduced in patients with CHF and sleep-disordered breathing (SDB) and that this may be associated with an increased risk of stroke. These researchers tested the hypothesis that reversal of SDB in CHF patients using ASV would increase morning HCVR. A total of 10 CHF patients with SDB, predominantly OSA, were included in this study. The HCVR was measured from the change in middle cerebral artery velocity, using pulsed Doppler ultrasound. HCVR was determined during the evening (before) and morning (after) one night of sleep on ASV and one night of spontaneous sleep (control). Compared with the control situation, ASV decreased the AHI (group mean +/- SEM, control: 48 +/- 12, ASV: 4 +/- 1 event per hour). HCVR was 23% lower in the morning, compared with the evening, on the control night (evening: 1.3 +/- 0.2, morning: 1.0 +/- 0.2 cm/sec per mm Hg, p < 0.05) and 27% lower following the ASV night (evening: 1.5 +/- 0.2, morning: 1.1 +/- 0.2 cm/sec per mm Hg, p < 0.05). The effect of ASV on the evening-to-morning reduction in HCVR was not significant, compared with the control night (0.02 cm/sec per mm Hg, 95% confidence interval: -0.28, 0.32 p = 0.89). The authors concluded that in CHF patients with SDB, HCVR was reduced in the morning compared with the evening. However, removal of SDB for one night did not reverse the reduced HCVR. The relatively low morning HCVR could be linked with an increased risk of stroke.

Hastings, et al (2008) assessed the use of ASV in CHF patients with all types of sleep apnea. Eleven male patients with stable CHF and sleep apnea (AHI > 15 events/h) were treated with six months optimized ASV and compared to eight patients not receiving ASV. At baseline, both groups were comparable for New York Heart Association class, left ventricular ejection fraction (LVEF), plasma brain natriuretic peptide (BNP) concentrations and AHI. All patients were receiving optimal medical therapy. At six months, the authors reported that ASV significantly reduced AHI with improvement in LVEF and aspects of quality of life.

Definitions

AASM recommended definitions

1. Apnea is defined as the cessation of airflow for 10 seconds or longer.

1. Hypopnea is defined as a recognizable transient reduction (but not complete cessation) of breathing for 10 seconds or longer, a decrease of 30% excursion of nasal pressure signal
from baseline, with a greater than or equal to 4% oxygen saturation from baseline. An arousal is unnecessary to score a hypopnea using the recommended definition.

2. Obstructive apneas and hypopneas are typically distinguished from central events by the detection of respiratory efforts during the event.

3. The RDI is defined as the number of obstructive apneas, hypopneas, and respiratory effort related arousals (RERAs) per hour.

4. An RERA is an event characterized by increasing respiratory effort for 10 seconds or longer leading to an arousal from sleep but one that does not fulfill the criteria for a hypopnea or apnea. The criterion standard to measure RERAs is esophageal manometry, as the AASM recommends. However, esophageal manometry is uncomfortable for patients and impractical to use in most sleep centers.

5. A reliable and valid way to measure RERAs is with the use of a nasal cannula and pressure transducer. Results obtained with this transducer are reliable (intraclass correlation of 0.96). With regard to the diagnosis of OSA, this method does not differ from esophageal manometry in a clinically significant manner. With either method, the RDI is greater than 5 and the normal RDI cutoff is greater than 15.

**AASM Alternative Definition**

Hypopnea is defined as a recognizable transient reduction (but not complete cessation) of breathing for 10 seconds or longer, a decrease of 50% or greater in the amplitude of a validated measure of breathing, or a reduction in amplitude of less than 50% associated with a greater than or equal to 3% oxygen desaturation or the event is associated with an arousal.

**Key Words:**

BiPap® ST, Synchrony® S/T, respiratory assist devices with backup rate feature, noninvasive positive pressure respiratory assistance (NPPRA), BiPap®, Adaptive –Servoventilation bilevel devices, BiPap AUTO SV, VPAP, Variable PAP, VPAP ST, VPAP adapt SV

**Approved by Governing Bodies:**

FDA approved

**Benefit Application:**

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP contracts: FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.
**Coding:**

**HCPCS codes:**

**E0470**  
Respiratory assist device, bi-level pressure capability, without backup rate feature, used with non-invasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)

**E0471**  
Respiratory assist device, bi-level pressure capability, with backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure)

**E0472**  
Respiratory assist device, bi-level capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure)

**E0561**  
Humidifier, non-heated, used with positive airway pressure device

**E0562**  
Humidifier, heated, used with positive airway pressure device

**A7030**  
Full facemask used with positive airway pressure device, each

**A7031**  
Face mask, interface, replacement for full-face mask, each

**A7032**  
Replacement cushion for nasal application device, each

**A7033**  
Replacement pillows for nasal application device, pair

**A7034**  
Nasal interface (mask or cannula type), used with positive airway pressure device, with or without head strap

**A7035**  
Headgear

**A7036**  
Chin strap

**A7037**  
Tubing

**A7038**  
Filter, disposable

**A7039**  
Filter, non-disposable

**References:**


8. www.respironics.com
10. www.focusonals.com/respiratory.htm

Policy History:
Medical Policy Group, June 1998
Medical Policy Group, May 2001
Medical Policy Group, August 2004 (2)
Medical Policy Administration Committee, September 2004
Available for comment November 2-December 16, 2004
Medical Policy Group, February 2006 (1)
Medical Policy Group, April 2007 (2)
Medical Policy Administration Committee, April 2007
Available for comment April 20-June 4, 2007
Medical Policy Group, October 2008 (1)
Medical Policy Group, March 2010 (3)
Medical Policy Administration Committee, April 2010
Available for comment March 24-May 7, 2010
Medical Policy Group, June 2010 (3)
Medical Policy Administration Committee, July 2010
Medical Policy Group, July 2010 (3)
Medical Policy Administration Committee, August 2010
Available for comment August 6-September 18, 2010
Medical Policy Group, July 2013 (3): 2013 Update – no updated literature to add; no change in policy statement
Medical Policy Group, July 2013: Effective July 31, 2013 this policy will remain active but will no longer be scheduled for regular literature updates and reviews.
Medical Policy Group, October 2013 (3): Corrected error in policy statement – no change in content of coverage
Medical Policy Group, April 2014 (5): Updated Maximums for tubing.
Medical Policy Administration May 2014
Available for comment May 6 through June 19, 2014
Medical Policy Group, April 2016 (6): Removed policy statement regarding non-invasive pressure ventilation for obstructive sleep apnea and moved to policy #065 Diagnosis and
Medical Management of Obstructive Sleep Apnea Syndrome and removed table with supply maximums. Policy name changed for clarification to Non-invasive Positive Pressure Ventilation for Conditions Other Than Obstructive Sleep Apnea; no changes to policy intent.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.