

Corporate Medical Policy

Noninvasive Respiratory Assist Devices

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Description of Procedure or Service

Over the past decade, noninvasive positive pressure ventilation (NPPV, sometimes NIPPV) delivered by a nasal or face mask has gained increasingly widespread acceptance for the support of both chronic and acute ventilatory failure. The development of improved masks and ventilatory technology which eliminate the need for endotracheal intubation, made this mode of ventilation acceptable. Respiratory Assist Devices (RADs) are more complex than continuous positive airway pressure (CPAP) devices. CPAP devices deliver a single, fixed pressure to the patient during the night. Some sleep breathing disorders do not benefit from CPAP and require treatment with devices that recognize the breathing patterns and adjust pressure during the respiratory cycle.

Noninvasive respiratory assist devices are divided into three basic types depending on their pressure delivery system:

Bilevel positive airway pressure (BiPAP), which delivers a higher inspiratory PAP (IPAP) than expiratory PAP (EPAP);

Auto-titrating positive airway pressure (APAP), which automatically increases BiPAP (IPAP/EPAP) as needed to maintain airway patency and then decreases the pressure if no abnormal respiratory events are detected within a set period of time. (APAP devices can be set at BiPAP mode as well as CPAP mode.); and

Adaptive servo-ventilation (ASV), which uses a servocontroller that automatically adjusts pressure by breath-by-breath analysis to maintain a steady minute ventilation especially in heart failure patients with central sleep apnea and/or Cheyne-Stokes respiration.

The primary noninvasive positive pressure ventilation mode is bilevel positive airway pressure. The term BiPAP[®] is a registered trademark held by Respironics, Inc., but is widely used to describe any bilevel positive airway pressure device. Bilevel devices serve two primary purposes. They provide noninvasive positive pressure ventilation therapy for hospital or in-home use and they provide positive airway pressure therapy for some sleep-disordered breathing patients who do not benefit from CPAP therapy.

This policy addresses the medical necessity criteria for the home use of noninvasive positive pressure respiratory assist devices. This policy does not address the use of these devices as part of the treatment of the acutely ill, hospitalized patient.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for noninvasive respiratory assist devices when they are determined to be medically necessary because the medical criteria and guidelines shown below are met.

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Please refer to Corporate Medical Policy titled, **Diagnosis and Medical Management of Sleep Apnea, for medical criteria and guidelines for continuous positive airway pressure (CPAP).**

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Noninvasive respiratory assist devices are covered under the DME benefits. Please refer to Certificate for availability of benefits and any prior review requirements regarding the rental/purchase of equipment. See Covered Services, Durable Medical Equipment.

DME Supplier must meet eligibility and/or credentialing requirements as defined by the Plan to be eligible for reimbursement.

When Noninvasive Respiratory Assist Devices are covered

Any patient that needs a device other than CPAP (e.g., cannot be successfully treated via auto-titrating CPAP) or needs surgery must be evaluated with a supervised polysomnography in a sleep laboratory with appropriate monitoring by skilled personnel. The Plan will give primary consideration to data from in-lab polysomnography and pressure titrations in evaluating requests for coverage of bi-level pressure, adaptive servo-ventilation, and sleep apnea surgery.

BCBSNC considers noninvasive positive pressure ventilation with bilevel positive airway pressure devices medically necessary durable medical equipment for patients who have one of the conditions listed below and who meet the medical necessity criteria for these conditions.

- Polysomnography data must include a summary with, at minimum, the following information:
- Total sleep time for the study;
- Total RDI or AHI for the study;
- Average and lowest recorded oxygen saturation;
- For any desaturations below 90%, the length of time at the abnormally low saturation level or range;
- Obstructive event indices for supine and non-supine positions, along with total sleep time spent supine;
- Periodic leg movement (PLM) index.

A polysomnogram that does not distinguish between supine and non-supine obstructive events, to the extent that any possible positional predisposition to obstruction can be determined, is not complete and may not be sufficient to support a request for surgery or pressure therapy.

For review of requests for respiratory assist devices, the submitted record must include details of the titration studies including measured indices for all modalities and pressure levels recorded. A summary or interpretation of findings alone is not adequate.

1. **Restrictive Thoracic Disorders:** The most common restrictive thoracic disorders include sequelae of polio, spinal cord injury, neuropathies, myopathies and dystrophies, ALS, chest wall deformities and kyphoscoliosis.
 - a. A bilevel PAP device is considered medically necessary when the following criteria are met:
 - i. The patient has been diagnosed with a progressive neuromuscular disease (e.g., amyotrophic lateral sclerosis) or a severe thoracic cage abnormality; **and**
 - ii. COPD does not contribute significantly to the patient's pulmonary limitation; **and**

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- iii. The patient has clinically significant respiratory insufficiency, as indicated by any of the following:
 - 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**
 - For progressive neuromuscular disease only, maximal inspiratory pressure < 60 cm H₂O or forced vital capacity (FVC) $< 50\%$ of predicted.
 - iv. In order for bilevel PAP with a backup rate or servocontroller feature to be covered, there must be medical record evidence that bilevel PAP without a backup rate is ineffective.
2. **Severe COPD:** The most common obstructive lung diseases include chronic bronchitis, emphysema, bronchiectasis, and cystic fibrosis.
 - a. A bilevel PAP device without a back-up rate feature is considered medically necessary when one of the following two criteria is met:
 - i. Hypercapnia exists as shown by an arterial blood gas PaCO₂ done while awake and breathing the patient's usual FIO₂ is > 52 mm Hg; **OR**
 - ii. Sleep oximetry demonstrates an oxygen saturation $< 88\%$ for a least five continuous minutes, done while breathing oxygen at 2 LPM or the patient's usual FIO₂ (whichever is higher)
 - b. A bilevel PAP device with the back-up rate feature will be considered medically necessary for severe COPD if the patient continues to meet the criteria in B.1 above, despite at least two months of compliant use (an average of 4 hours per 24 hour period) of a bilevel PAP without a back-up rate feature. Clinical documentation from the treating physician to indicate patient compliance with the initial device and the lack of desired therapeutic effect from use of this device may be requested.
 3. **Central Sleep Apnea:** Central sleep apnea may be treated with CPAP, bilevel PAP, or bilevel PAP with a back-up rate or servocontroller features. Prior to initiating therapy, complete facility based attended polysomnography must be performed documenting the primary diagnosis of central sleep apnea (CSA).

If central sleep apnea requires pressure therapy and is not adequately controlled with CPAP or standard bilevel PAP, then bilevel PAP with a back-up rate or a servocontroller feature will be covered upon a demonstration of effectiveness.
 4. **Cheyne-Stokes Breathing:** CSB is characterized by cyclic reductions or cessations of airflow, due to decreased or absent respiratory effort. It is considered a type of central sleep apnea. Indications for therapy are the same as C. above.
 5. **Obstructive Sleep Apnea (OSA):** A bilevel PAP device *without* back-up rate may be considered medically necessary when the criteria below are met:
 - a. The patient has met the criteria for OSA as outlined in Corporate Medical Policy for Diagnosis and Medical Management of Sleep Apnea, and
 - b. The patient failed medical management as appropriate (See Corporate Medical Policy for Diagnosis and Medical Management of Sleep Apnea, policy number MED1394); and
 - c. The patient has tried and failed CPAP therapy (as documented in the medical records after titration and appropriate acclimation measures) or when CPAP has been shown to be ineffective in the sleep lab. In either case, it must be shown that bilevel PAP is more effective or better tolerated in the sleep lab.
 6. **Complex Sleep Apnea:**

"Complex Sleep Apnea" as used in this policy is defined as a clinical syndrome where central apneas develop during pressure titrations in the sleep lab in patients who have demonstrated obstructive sleep apnea either at initial polysomnography or during an unattended (unsupervised) home sleep study.

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Coverage of bilevel PAP device with a backup rate or an adaptive servo-ventilation (ASV) device may be considered medically necessary in patients with Complex Sleep Apnea syndrome when the central apneas have failed to respond to:

- a. Reduction in the administered CPAP or bilevel pressures in the sleep lab ('down titration'); and
 - b. Acclimation/desensitization to pressure therapy by a trial of auto bilevel PAP in the home setting with appropriate, gradual acclimation measures for a period of at least four weeks, followed by a bilevel PAP titration in the sleep lab for determination of definitive treatment pressures; and
 - c. Evaluation and treatment of underlying medical conditions or etiologies (e.g., thyroid disease, opiate use, renal failure, etc.);
and when the back-up rate or ASV device has been shown to be effective in the sleep lab.
7. **Obesity Hypoventilation Syndrome** (aka Pickwickian Syndrome):
- a. The use of bilevel PAP is appropriate when necessary in patients with Obesity Hypoventilation Syndrome. The use of back-up rate or ASV devices will be covered only when bilevel PAP has been shown to be ineffective and the requested device has been shown to be more effective in the sleep lab.

When Noninvasive Respiratory Assist Devices are not covered

Noninvasive respiratory assist devices are not covered for indications other than those listed above.

A bilevel PAP device *with* a back-up rate feature and related accessories for the primary diagnosis of OSA are considered not medically necessary and, therefore, not covered.

Policy Guidelines

Medical therapy, when appropriate to the clinical situation, includes: weight loss, avoidance of alcohol, sedatives and caffeine consumption, especially before bedtime, allowing adequate sleep time, maintenance of appropriate body position during sleep (side versus back), oral appliances, positive airway pressure devices and a medically supervised smoking cessation program.

Pressure therapy such as described in this coverage policy may be medically necessary in patients with clinically significant OSA or other respiratory conditions referenced above documented by supervised polysomnography. Prior to initiation of pressure therapy, medical therapy as described in the preceding paragraph must be considered and applied as appropriate to the clinical situation.

Requests for coverage of Bilevel PAP devices will be handled as follows:

- Because patients who require bilevel PAP, bilevel PAP with a back-up rate, or adaptive servo-ventilation frequently have significant underlying disease other than OSA, medical necessity for requested pressure therapy may not always be determined from polysomnography data alone. In these circumstances, supporting medical records should be submitted along with titration data and may be required by the Plan for medical necessity review.
- Equipment will be rented with rental fees applied to purchase price for trial period of three months to document patient compliance, patient tolerance, and clinical benefits prior to purchase. After 90 days of coverage a decision regarding the medical necessity of purchase will be made.
- Payment for the device includes payments for the provision of all necessary accessories, i.e., mask, tubing, or cannula. Separate charges for replacement of masks, tubing, cannula or for respiratory equipment maintenance services are not covered since they are included in the rental payment.

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Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: A4604, A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, A7046, E0470, E0471, E0472, E0561, E0562

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Kushida CA, Littner MR, Hirshkowitz M, et al. Practice Parameters for the Use of Continuous and bilevel Positive Airway Pressure Devices to Treat Adult Patients with Sleep-Related Breathing Disorders. American Academy of Sleep Medicine Report. *Sleep*. 2006; 29(3):375-380. Retrieved on August 28, 2007 from http://216.21.56.228/Resources/PracticeParameters/PP_PositiveAirwayPressure.pdf

Centers for Medicare and Medicaid Services, Region C DMERC Local Carrier Determination (LCD) L5023 for Respiratory Assist Devices, (07/01/07). Retrieved on August 28, 2007 from http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=5023&lcd_version=30&show=all

Morgenthaler T; Gay P; Gordon N et al. Adaptive servoventilation versus noninvasive positive pressure ventilation for central, mixed, and complex sleep apnea syndromes. *SLEEP* 2007;30(4):468-475. Retrieved on August 28, 2007 from <http://www.journalsleep.org/Articles/300412.pdf>

No authors listed. National Association for Medical Direction of Respiratory Care (NAMDRC). Clinical indications for noninvasive positive pressure ventilation in chronic respiratory failure due to restrictive lung disease, COPD, and nocturnal hypoventilation-A consensus conference report. *Chest*. 1999; 116(2):521-534. Retrieved on April 22, 2008 from <http://www.chestjournal.org/cgi/content/full/116/2/521>

Kushida CA; Chediak A; Berry RB; Brown LK; Gozal D; Iber C; Parthasarathy S; Quan SF; Rowley JA; Positive Airway Pressure Titration Task Force of the American Academy of Sleep Medicine. Clinical guidelines for the manual titration of positive airway pressure in patients with obstructive sleep apnea. *J Clin Sleep Med* 2008;4(2):157-171. Retrieved on March 6, 2009 from <http://www.aasmnet.org/Resources/ClinicalGuidelines/040210.pdf>

Specialty Matched Consultant Advisory Panel review - 3/2/09.

Specialty Matched Consultant review (2) - 10/2009

Senior Medical Director Review - 12/2009

Policy Implementation/Update Information

12/21/09 Notification of new policy entitled Noninvasive Respiratory Assist Devices. **THIS POLICY IS NOT EFFECTIVE UNTIL MARCH 30, 2010.** Prior to March 30, 2010 refer to policy number OTH8138, Sleep Apnea and Breathing Related Sleep Disorders in Adults. The policy entitled Sleep Apnea and Breathing Related Sleep Disorders in Adults has been separated into three policies and will be archived on March 30, 2010. Notification given December 21, 2009. Effective date March 30, 2010. (pmo)

4/13/10 Item C. Central Sleep Apnea, in the When Not Covered section revised: If central sleep apnea

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requires pressure therapy and is not adequately controlled with CPAP or standard bilevel PAP, ~~at the initial titration and bilevel PAP re-titration after a one month trial of auto titrating bilevel PAP in the home,~~ then bilevel PAP with a back-up rate or a servocontroller feature will be covered upon a demonstration of effectiveness. (adn)

3/15/11 Specialty Matched Consultant Advisory Panel review 2/23/11. No change to policy statement or coverage criteria. (adn)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.