

**Policy terminated because coverage is provided under
NCHC Durable Medical Equipment and Supplies**

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1.0 Description of the Procedure, Product, 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 recipient 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:

- a. Bilevel positive airway pressure (BiPAP), which delivers a higher inspiratory PAP (IPAP) than expiratory PAP (EPAP);
- b. 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
- c. 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 recipients 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 recipients who do not benefit from CPAP therapy.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

Note: Most recipients will be able to get all the services they need under the core (basic) plan of NC Health Choice. A recipient who qualifies as having special needs may be able to receive additional services not covered by the core plan.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

- a. Noninvasive respiratory assist devices are covered under the NCHC Program when they are determined to be medically necessary because the criteria and guidelines shown below are met:
- b. Any recipient who 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 Program 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.
- c. The NCHC Program considers noninvasive positive pressure ventilation with bilevel positive airway pressure devices medically necessary durable medical equipment for recipients who have one of the conditions listed below and who meet the medical necessity criteria for these conditions.
- d. Polysomnography data must include a summary with, at minimum, the following information:
 1. Total sleep time for the study;
 2. Total RDI or AHI for the study;
 3. Average and lowest recorded oxygen saturation;
 4. For any desaturations below 90%, the length of time at the abnormally low saturation level or range;
 5. Obstructive event indices for supine and non-supine positions, along with total sleep time spent supine;
 6. 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.

- e. 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.
1. A bilevel PAP device is considered medically necessary when the following criteria are met:
 - (a) The recipient has been diagnosed with a progressive neuromuscular disease (e.g., amyotrophic lateral sclerosis) or a severe thoracic cage abnormality;
 - (b) COPD does not contribute significantly to the recipient's pulmonary limitation;
 - (c) The recipient has clinically significant respiratory insufficiency, as indicated by ANY of the following:
 - (i) An arterial blood gas PaCO₂ level is ≥ 45 mm Hg, done while awake and breathing the recipient's usual FIO₂ (fractionated inspired oxygen concentration);
 - (ii) Sleep oximetry demonstrates an oxygen saturation $< 88\%$ for at least five continuous minutes, done while breathing the recipient's usual FIO₂;
 - (iii) For progressive neuromuscular disease only, maximal inspiratory pressure < 60 cm H₂O or forced vital capacity (FVC) $< 50\%$ of predicted.
 - (d) 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.
- f. Severe COPD: The most common obstructive lung diseases include chronic bronchitis, emphysema, bronchiectasis, and cystic fibrosis.
1. A bi-level PAP device without a back-up rate feature is considered medically necessary when one of the following two criteria is met:
 - (a) Hypercapnia exists as shown by an arterial blood gas PaCO₂ done while awake and breathing the recipient's usual FIO₂ is > 52 mm Hg; OR
 - (b) Sleep oximetry demonstrates an oxygen saturation $< 88\%$ for a least five continuous minutes, done while breathing oxygen at 2 LPM or the recipient's usual FIO₂ (whichever is higher).
 2. A bi-level PAP device with the back-up rate feature will be considered medically necessary for severe COPD if the recipient continues to meet the criteria in 3.2.2.b.1 above, despite at least two months of compliant use (an average of 4 hours per 24 hour period) of a bi-level PAP without a back-up rate feature. Clinical documentation from the treating physician to indicate recipient compliance with the initial device and the lack of desired therapeutic effect from use of this device may be requested.

- g. 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.
- h. 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 noted above.
- i. Obstructive Sleep Apnea (OSA): A bilevel PAP device without back-up rate may be considered medically necessary when the criteria below are met:
1. The recipient meets the criteria for OSA
 2. The recipient failed medical management as appropriate.
 3. The recipient 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.
- j. 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 recipients who have demonstrated obstructive sleep apnea either at initial polysomnography or during an unattended (unsupervised) home sleep study.
- 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 control apneas have failed to respond to:
1. Reduction in the administered CPAP or bilevel pressures in the sleep lab ('down titration'); AND
 2. 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
 3. 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 show to be effective in the sleep lab.
- k. Obesity Hypoventilation Syndrome (aka Pickwickian Syndrome)
1. The use of bilevel PAP is appropriate when necessary in recipients 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.

3.3 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 recipients 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:

- a. Because recipients 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 Program for medical necessity review.
- b. Equipment will be rented with rental fees applied to purchase price for a trial period of three months to document recipient compliance, recipient tolerance, and clinical benefits prior to purchase. After 90 days of coverage a decision regarding the medical necessity of purchase will be made.
- c. 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.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

- a. Noninvasive respiratory assist devices are not covered for indications other than those listed in **Subsection 3.2**.
- b. 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.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

- a. Prior approval is required for noninvasive respiratory assist devices.
- b. 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.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010	Throughout	Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.
October 31, 2011	Throughout	Policy Termination. Coverage for this policy is provided by NCHC policy 2011.09, Medical Equipment and Supplies.

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

HCPCS Codes				
A4604	A7027	A7028	A7029	A7030
A7031	A7032	A7033	A7034	A7035
A7036	A7037	A7038	A7039	A7044
A7045	A7046	E0470	E0471	E0472
E0561	E0562			

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital, Outpatient Hospital and Office

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges..