CLINICAL MEDICAL POLICY and PRIOR-AUTHORIZATION POLICY	
Policy Name:	Noninvasive Positive Pressure Intermittent Ventilation in the Home Setting
Policy Number:	MP-002-MD-PA
Approved By:	Medical Management
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Application:	All participating hospitals and providers
Page Number(s):	1 of 9

Disclaimer

Gateway Health℠ (Gateway) medical payment and prior-authorization policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT:

This policy applies to all Gateway Health Pennsylvania Medicaid members whose clinical situation does not warrant an inpatient admission but may need to be evaluated and/or treated within 48 hours and/or the treating physician believes that allowing the patient to leave the facility would likely put the member at serious risk. The member may be admitted to the facility for an observation period or an extended assessment and management encounter. Observation Services are those services furnished on a hospital's premises, including use of a bed and periodic monitoring by a hospital's nurse or other staff. Observation stays do not require authorization from the health plan.

DEFINITIONS:

Apnea - The cessation of airflow for at least ten seconds.

Apnea-Hypopnea Index (AHI) -

The average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device.

Bi-level Positive Airway Pressure (BiPAP, Bi-level positive airway pressure) - Bi-level positive airway pressure is a type of noninvasive ventilation that helps keep the upper airways of the lungs open by providing a flow of air delivered through a face mask. The air is pressurized by a machine, which delivers alternating levels of positive airway pressure, to the face through long plastic hosing.

Central Sleep Apnea - A sleep related disorder in which the effort to breathe is diminished or absent, typically for 10 to 30 seconds, either intermittently, or in cycles and is usually associated with reduction in blood oxygen saturation.

Chronic Obstructive Pulmonary Disease (COPD) - A group of progressive diseases with chronic inflammation and obstruction/constriction of the small airways leading to severe dyspnea, reduced health-related quality of life and high mortality rates. The disease is classified as mild, moderate or severe. Examples of COPD include chronic bronchitis, emphysema, bronchiectasis and cystic fibrosis.

Fi02 - The fractional concentration of oxygen delivered for inspiration or the percent of oxygen a patient is inhaling. A 'prescribed Fi02' is the oxygen concentration the patient normally breathes when not undergoing testing to qualify for coverage of a Respiratory Assist Device (RAD).

FEV1 - The forced expired volume in one second

FVC - The forced vital capacity.

Hypopnea - An abnormal respiratory event lasting at least ten seconds and is associated with at least a 30% reduction in thoracoabdominal movement or airflow compared to baseline, and at least a 4 % decrease in oxygen saturation.

Hypoventilation Syndrome/Obesity Hypoventilation Syndrome - A chronic condition in which obesity (body mass index greater than or equal to 30 kg/m (2)) and chronic hypoventilation during waking hours are combined. Hypoventilation is defined as insufficient ventilation leading to hypercapnia, which is an increase in the partial pressure of carbon dioxide as measure by arterial blood gas analysis. This condition can result in pulmonary hypertension, cor pulmonale and probable early mortality. The condition is associated with respiratory, metabolic, hormonal and cardiovascular impairments.

Noninvasive positive pressure ventilation/assistance (NIPPV/NPPV/NPPRA) - A form of ventilatory assistance delivered via a noninvasive interface (i.e., full face mask, nasal mask/pillows), as opposed to invasive ventilation that is delivered through an endotracheal tube or tracheostomy.

Obstructive Sleep Apnea - The most common form of sleep apnea caused by complete or partial obstruction of the upper airway. It is characterized by repetitive episodes of shallow or paused breathing during sleep, despite the effort to breathe, and is usually associated with a reduction of blood oxygen saturation.

PaO2 - The level of oxygen in the blood obtained via arterial blood gas.

Prior Authorization Review Panel (PARP) — A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Positive airway Pressure (PAP) - A mode of mechanical respiratory ventilation

Respiratory Assist Devices (RADs) - Devices that are capable of operating in numerous modes, from basic continuous positive pressure to traditional pressure and volume ventilator modes.

Restrictive Thoracic Disorders - Lung diseases that are a category of extra-pulmonary, pleural or parenchymal respiratory diseases that restrict lung expansion, resulting in a decreased lung volume, an increased work of breathing, and inadequate ventilation and/or oxygenation. Examples of Restrictive Thoracic Disorders include amyotrophic lateral sclerosis, Duchenne muscular dystrophy, myasthenia gravis, post-polio syndrome, spinal cord injuries and severe thoracic cage abnormality (e.g., kyphoscoliosis).

SpO2 - Measurement of how saturated hemoglobin is with oxygen.

PROCEDURES

A. Coverage shall be provided per this policy for members who have been diagnosed with:
   a. Restrictive Thoracic Disorders; OR
   b. Severe Obstructive Pulmonary Disease (COPD); OR
   c. Central Sleep Apnea; OR
   d. Obstructive Sleep Apnea; OR
   e. Hypoventilation Syndrome

B. The following medical necessity criteria for each condition above demonstrates medical necessity:
   a. **Restrictive Thoracic Disorders**
      i. COPD does not contribute significantly to the member's pulmonary limitation; AND
      ii. The member has a progressive neuromuscular disease (such as amyotrophic lateral sclerosis or a severe thoracic cage abnormality (such as post-thoracoplasty for tuberculosis); AND
      iii. The member has symptoms of sleep-associated hypoventilation (nocturnal hypoxemia), such as daytime hypersomnolence, excessive fatigue, dyspnea, morning headache, cognitive dysfunction, etc.; AND
      iv. The member has clinically significant hypoxemia, as indicated by the following:
         1. Arterial blood gas PaC02 is greater than or equal to 45 mm Hg, performed while the member is awake and breathing their prescribed Fi02 (fractional inspired oxygen concentration); *OR*
         2. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least 5 continuous minutes of nocturnal recoding time (minimum recording time of two hours), performed while breathing the member's prescribed Fi02; *OR*
         3. For progressive neuromuscular diseases:
            a. The maximal inspiratory pressures are less than 60 cm H2O, or
            b. Forced vital capacity (FVC) less than 50% of predicted.
      v. If all of the above criteria are met, then E0470 or E0471 devices and related accessories will be covered as medically necessary.
   b. Severe Chronic Obstructive Pulmonary Disease (COPD)
      i. Coverage criteria for E0470, a bi-level pressure respiratory assist device *without* a backup rate feature using a noninvasive interface (intermittent assist device with continuous positive pressure) when all the following criteria are met:
         1. The member has symptoms of sleep-associated hypoventilation (nocturnal hypoxemia), such as daytime hypersomnolence, excessive fatigue, dyspnea, morning headache, cognitive dysfunction, etc.; AND
         2. Arterial blood gas PaC02 of 52 mmHg or greater, done while awake and breathing using the member's prescribed Fi02; AND
         3. Sleep oximetry documents an oxygen saturation less than or equal to 88% for greater than or equal to a cumulative five minutes of nocturnal recording time (minimum

recording time of two hours), done while breathing oxygen at 2 LPM or the prescribed Fi02, whichever one is higher; AND

4. Documentation related to recurrent hospitalizations for hypercapnic respiratory failure (greater than or equal to two admissions within a twelve month period); AND
5. Prior to initiating NPPV therapy, sleep apnea and treatment with a continuous positive pressure device (CPAP) has been considered and ruled out.

ii. Documented formal sleep apnea testing is not needed if there is sufficient information in the medical record that demonstrates that the member does not suffer from some form of sleep apnea as the primary cause of awake hypercapnia or nocturnal arterial oxygen desaturation.

iii. If all of the above criteria are met for patients with COPD, the E0470 device and related accessories will be covered as medically necessary. If all the above criteria are not met, requests for the E0740 device and related accessories will require case-by-case review.

c. The E0471 device (respiratory assist device, bi-level pressure capability, with back up rate feature, used with noninvasive interface) will be considered eligible for coverage for patients with COPD when the member has demonstrated at least two months of compliant use of E0740 (expected use on average of four hours in a 24 hour time period), and in either of the two following situations:

i. For those patients who qualified for an E0470 device, an E0471 initiated any time after a period of initial use of an E0470, is covered if an arterial blood gas PaC02, performed on the member while awake and on prescribed Fi02, shows the PaC02 worsened greater than or equal to 7 mmHG compared to the original result; AND if a past facility polysomnography demonstrated an oxygen saturation less than or equal to 88% for greater than or equal to a cumulative five minutes of nocturnal recording (minimum recording time of two hours) while using the E0470 device that is not caused by obstructive upper airway events.

ii. For members who qualified for an E0470 device, the E0471 will be covered if, at a time no sooner than 61 days after the initial issue of the E0470 device, when an arterial blood gas PaC02 is done while awaken and the member is breathing with prescribed Fi02, still remains greater than or equal to 52 mmHg; AND sleep oximetry while breathing with the E0470 demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative of five minutes of nocturnal recording time (minimum recording time of two hours), done while breathing oxygen at two LPM of the prescribed Fi02, whichever is higher.

d. Central Sleep Apnea or Complex Sleep Apnea

i. In order to provide noninvasive positive pressure ventilation device (either the E0470 or the E0471) for a patient with Central Sleep Apnea, the following criteria must be met as confirmed by a polysomnography:

1. An AHI greater than 5; AND
2. Central apneas or hypopneas greater than 50% of the total apneas/hypopneas; AND
3. Central apneas or hypopneas greater than or equal to 5 times per hour; AND
4. The presence of at least one of the following: sleepiness, difficulty initiating or maintaining sleep, frequent awakenings, or no-restorative sleep, awakening short of breath, snoring or witnessed apneas: AND
5. There is no evidence of daytime or nocturnal hypoventilation
6. If all of the criteria above are met, then E0470 or E0471 and related supplies will be approved as medically necessary

e. Obstructive Sleep Apnea (OSA)

i. Noninvasive positive pressure ventilation device (E0470) may be considered eligible for patients who:

1. Have been diagnosed with OSA; AND

2. Have failed medical management; AND
3. A CPAP (E0601) has been tried and been proven ineffective or is not tolerated based on therapeutic trial in either a facility or during a three month trial in the home setting.

ii. If the criteria are met, an E0470 Respiratory Assist Device (RAD) will be considered medically necessary. The use of an E0471 Respiratory Assist Device (RAD) has not been proven to be of value for patients with a primary diagnosis OSA and will be considered not medically necessary.

f. Hypoventilation Syndrome
   i. Coverage for E0470 will be considered medically necessary when both A & B criterion **AND** either C OR D are met:
      1. Arterial blood gas PaC02 is greater than 45 mmHg done while the patient is awake and breathing the prescribed Fi02; AND
      2. There is a 70% or greater spirometry FEV1/FVC: AND ONE OF THE FOLLOWING:
         a. Arterial blood gas PaC02 has worsened greater than or equal to seven mmHg compared to the original results outlined in criterion A, performed during sleep or immediately upon wakening while breathing the patient's prescribed Fi02; or,
         b. Polysomnography or home sleep study documents an oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of two hours) that is not caused by obstructive upper airway events (e.g., AHI less than 5).
   ii. If the above criteria are met, the E0470 device and related supplies will be approved as medically necessary.

g. Coverage for E0471 is available for patients when both A & B criterion AND either C or D are met:
   i. A covered E0470 Respiratory Assist Device (RAD) device is currently being used; AND
   ii. FEV1/FVC per spirometry is greater than or equal to 70%; AND
   iii. Arterial blood gas PaC02 performed while the patient is awake and breathing the prescribed Fi02, has worsened greater than or equal to 7 mm Hg compared to the arterial blood gas result performed for the qualifying criteria for the E0470 device; OR
   iv. A polysomnography or home sleep study demonstrates an 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 airway events (e.g., AHI less than 5 while using an E0470 device).
   v. If all the above criteria are met, the E0471 device and related supplies will be approved as medically necessary.

C. For continuation of coverage of either the E0470 or E0471 there must be:
   a. A re-evaluation after three months of therapy to assess the continued medical necessity for NPPV.
   b. Medical records must contain physician documentation that the member has been compliant with the device in a face-to-face clinical evaluation (an average of four hours per 24-hour period during a 30 consecutive day period) and that the member is benefiting from the therapy.
   c. Compliance documentation will be reviewed on an individual basis for situations in which the member has been in an accident, change in physical status, surgery etc.

D. Pediatric Use
   a. Requests for the pediatric use of bi-level Respiratory Assist Devices will be considered on an individual case basis and require at a minimum, a complete evaluation by, and a recommendation from, a specialist such as a pediatric pulmonologist or cardiothoracic surgeon.

E. Contraindications for NIPPV Therapy:
   a. Inability to fit or tolerate noninvasive interface
   b. Facial trauma or facial, esophageal or gastric surgery

c. Cardiovascular instability
d. Excessive and/or viscous secretions
e. Recent gastro-esophageal surgery
f. Severely impaired mental status
g. Reduced consciousness

F. When Noninvasive Respiratory Assist Devices are considered not medically necessary:
   a. For indications other than those listed above the scientific evidence has not been established.

G. All equipment and accessories must be prescribed by a physician with detailed written orders. Accessories requested for greater than the outlined quantity limits will be need to be reviewed for medical necessity. *Refer to Attachment A: Table of Accessories and Quantities Limits*
   a. Either a heated or non-heated humidifier (E0561, E0562) is considered medically necessary for use with NIPPV.
   b. Compliance monitoring equipment are considered an integral component of the function of the device and are not eligible for separate reimbursement.
   c. There is no additional payment for the liners (A9999) used with the RADs, which are made of cloth, silicone, or other materials and are place between the skin and the mask interfaces because they are not medically necessary.

H. Audit Statement
   a. The medical record should include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health Plan® at any time pursuant to the terms of your provider agreement.

I. Place of Service for the administration to occur is in an outpatient setting

J. Length of Coverage
   a. Length of initial and continuation of coverage is 3 months

K. Governing Bodies Approval
   a. U.S. Food and Drug Administration (FDA)
      i. The FDA has approved several types of single level continuous positive airway pressure (CPAP), auto-adjusting CPAP RAD's, and bi-level positive pressure (PAP) RADs for obstructive sleep apnea and/or respiratory insufficiency caused by central and/or mixed apneas and periodic breathing.

AUTHORIZATION and CODING REQUIREMENTS

Authorization from Gateway is required for NPPV therapy performed on an outpatient basis.

Table of Accessories and Quantities Limits

A4604	1 per 3 months (4 per calendar year)	Tubing with integrated heating element for use with positive airway pressure device
A7027	1 per 3 months (4 per calendar year)	Combination oral/nasal mask, used with continuous positive airway pressure device, each
A7028	2 per 1 month (24 per calendar year)	Oral cushion for combination oral/nasal mask, replacement only, each
A7029	2 per 1 month (24 per calendar year)	Nasal pillows for combination oral/nasal mask, replacement only, pair

A7030	1 per 3 months (4 per calendar year)	Full face mask used with positive airway pressure device, each
A7031	1 per 1 month (12 per calendar year)	Face mask interface, replacement for full face mask, each
A7032	2 per 1 month (24 per calendar year)	Cushion for use on nasal mask interface, replacement only, each
A7033	2 per 1 month (24 per calendar year)	Pillow for use on nasal cannula type interface, replacement only, pair
A7034	1 per 3 months (4 per calendar year)	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap
A7035	1 per 6 months (2 per calendar year)	Headgear used with positive airway pressure device
A7036	1 per 6 months (2 per calendar year)	Chinstrap used with positive airway pressure device
A7037	1 per 3 months (4 per calendar year)	Tubing used with positive airway pressure device
A7038	2 per 1 month (24 per calendar year)	Filter, disposable, used with positive airway pressure device
A7039	1 per 6 months (2 per calendar year)	Filter, non-disposable, used with positive airway pressure device
A7046	1 per 6 months (2 per calendar year)	Water chamber for humidifier, used with positive airway pressure device, replacement, each
A7044	1 per 3 months (4 per calendar year)	Oral interface used with positive airway pressure device, each
E0561	Rental only	Humidifier, non-heated, used with positive airway pressure devices
E0562	Rental only	Humidifier, heated, used with positive airway pressure devices
S8186		Swivel adaptor

PROCEDURE CODES

E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive 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 back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (Intermittent assist device with continuous positive airway pressure device)

DIAGNOSIS CODES

B91	Sequelae of poliomyelitis
E66.2	Morbid (severe) obesity with alveolar hypoventilation
G12.1 - G12.9	Spinal muscular atrophy and related syndromes
G14	Post-polio syndrome
G47.31	Primary central sleep apnea
G47.33	Obstructive sleep apnea (adult) (pediatric)
G47.34	Idiopathic sleep related non-obstructive alveolar hypoventilation
G47.35	Congenital central alveolar hypoventilation syndrome
G47.36	Sleep related hypoventilation in conditions classified elsewhere
G47.37	Central sleep apnea in conditions classified elsewhere
G54.0 - G54.9, G55	Nerve root and plexus disorders
G70.00 - G73.7	Diseases of myoneural junction and muscle
J40 - J44.9, J47.0 - J47.9	Chronic lower respiratory system diseases
J67.0 - J67.9	Respiratory diseases due to external agents
J80, J96.00 - J96.92, J98.4	Other diseases of the respiratory system
M41.00 - M41.9, M96.5	Scoliosis
M95.4	Acquired deformity of chest and rib
R06.00, R06.3,R06.09 R06.83 - R06.89	Other dyspnea and respiratory abnormalities
R06.81	Apnea, not elsewhere classified
R09.02	Hypoxemia
R53.0 - R53.1, R53.81, R58.83 G93.3	Other malaise and fatigue
Numerous options	Late effect of spinal cord injury or injury to nerve root(s), spinal plexus (es), and other nerves of trunk [Codes not listed due to expanded specificity]

REIMBURSEMENT

Participating providers will be reimbursed per their Gateway Health Plan® contract.

POLICY SOURCES

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Marcus CL, Brooks LJ, Draper KA, et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*. 2012;130(3):576-84.