

Respiratory Assist Devices

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Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 7

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding 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

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary respiratory assist devices.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus LTSS (DSHP Plus LTSS) members.

Noninvasive positive pressure respiratory assistance (NPPRA) – The administration of positive air pressure, using a nasal and/or oral mask interface which creates a seal, avoiding the use of more invasive airway access (e.g., tracheostomy).

Respiratory assist device (RAD) without backup rate – Delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive interface (such as a nasal or oral facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs.

RAD with backup rate – Delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive interface (such as a nasal or oral facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs.

PROCEDURES

A prior authorization is required for items over \$500.00.

A RAD may be considered medically necessary for the first three (3) months of therapy for individuals with Restrictive Thoracic Disorders that meet **ALL** the following criteria:

- Individual has presence of a neuromuscular disease (e.g., amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (e.g., post-thoracoplasty for TB); **and**
 - An arterial blood gas PaCO₂, done while awake and breathing the individual's prescribed fractional concentration of oxygen (FIO₂), is greater than or equal to 45 mm Hg; **or**
 - Sleep oximetry demonstrates oxygen saturation level is equal to or less than 88% for at least five (5) minutes, done while breathing the individual's prescribed FIO₂; **or**
- Individual has presence of neuromuscular disease (only):
 - Maximal inspiratory pressure is less than 60 cm H₂O or forced vital capacity is less than 50% predicted; **and**
 - Chronic obstructive pulmonary disease (COPD) does not contribute significantly to the individual's pulmonary limitation.

A RAD not meeting the criteria as indicated in this policy is considered not medically necessary.

A RAD may be considered medically necessary for the first three (3) months of therapy for individuals with severe COPD when **ALL** the following criteria are met:

- An arterial blood gas PaCO₂, done while awake and breathing the individual's prescribed FIO₂, is equal to or greater than 52 mm Hg; **and**
- Sleep oximetry demonstrates oxygen saturation level equal to or less than 88% for at least five (5) minutes, done while breathing oxygen at two (2) liters per minute (LPM) or the individual's prescribed FIO₂, whichever is higher; **and**
- Prior to initiating therapy, obstructive sleep apnea (OSA) and treatment with continuous positive airway pressure (CPAP) has been considered and ruled out.

If a RAD with backup rate is billed, but the criteria for a RAD without backup rate device are met, payment will be based on the RAD without backup rate.

A RAD with backup rate device is considered not medically necessary for an individual with COPD during the first two (2) months.

Note: Therapy with a RAD without back-up device with proper adjustments of the settings, and patient accommodation to its use, will usually result in sufficient improvement without need of a back-up rate.

An RAD **with** back-up device may be considered medically necessary when **ALL** the following criteria have been met:

- The individual has used an RAD **without** back-up for 61 days; **and**
- An arterial blood gas PaCO₂ is repeated while the individual is awake and breathing their prescribed FIO₂ and the level remains 52 mm HG; **and**
- A sleep oximetry, while the individual is breathing with the RAD without back-up device demonstrates O₂ saturation of less than 88% for at least five (5) continuous minutes, done

while breathing oxygen at two (2) LPM or the individual's prescribed FIO₂, whichever is higher.

A RAD with a back-up device not meeting the criteria as indicated in this policy is considered not medically necessary.

A RAD may be considered medically necessary for the first three (3) months of therapy for those individuals with central sleep apnea (CSA) that have had an attended polysomnogram, performed on stationary equipment **and** meet **ALL** of the following criteria:

- The diagnosis of CSA; **and**
- The exclusion of OSA as the predominant cause of sleep-associated hypoventilation; **and**
- The ruling out of CPAP as effective therapy if OSA is a component of the sleep-associated hypoventilation; **and**
- Significant improvement of the sleep-associated hypoventilation with the use of either RAD device on the settings that will be prescribed for initial use at home, while breathing the individual's prescribed FIO₂.

A RAD not meeting the criteria as indicated in this policy is considered not medically necessary.

Heated and non-heated humidification may be considered medically necessary when prescribed by the treating physician to meet the needs of the individual **and** when the RAD meets the above criteria.

A noninvasive open ventilation (NIOV) system is/are considered experimental/investigational and, therefore, noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

If the device does not meet the criteria as indicated in this policy, the device and related accessories are considered not medically necessary.

For coverage beyond the initial three (3) months of therapy, medical necessity of continued coverage of these devices must occur within 61 to 90 days from the date the therapy was initiated.

Quantities of supplies greater than those identified as the usual maximum amounts are considered not medically necessary.

A physician must prescribe **ALL** equipment and accessory durable medical equipment (DME)

See table below for accessory quantity level limits.

<u>Accessory</u>	<u>Usual Maximum Replacement</u>	<u>Prepay Logic</u>
A4604**	1 per 3 months	1 per 80 floating days
A7027**	1 per 3 months	1 per 80 floating days
A7028**	2 per 1 month	6 per 80 floating days
A7029**	2 per 1 month	6 per 80 floating days
A7030**	1 per 3 months	1 per 80 floating days
A7031**	1 per 1 month	3 per 80 floating days

<u>A7032**</u>	<u>2 per 1 month</u>	<u>6 per 80 floating days</u>
<u>A7033**</u>	<u>2 per 1 month</u>	<u>6 per 80 floating days</u>
<u>A7034**</u>	<u>1 per 3 months</u>	<u>1 per 80 floating days</u>
<u>A7035*</u>	<u>1 per 6 months</u>	<u>1 per 170 floating days</u>
<u>A7036*</u>	<u>1 per 6 months</u>	<u>1 per 170 floating days</u>
<u>A7037**</u>	<u>1 per 3 months</u>	<u>1 per 80 floating days</u>
<u>A7038**</u>	<u>2 per 1 month</u>	<u>6 per 80 floating days</u>
<u>A7039*</u>	<u>1 per 6 months</u>	<u>1 per 170 floating days</u>
<u>A7044*</u>	<u>1 per 3 months</u>	<u>1 per 80 floating days</u>
<u>A7045*</u>	<u>1 per 3 months</u>	<u>1 per 80 floating days</u>
<u>A7046*</u>	<u>1 per 6 months</u>	<u>1 per 170 floating days</u>

* Allows for a 10-day delivery before run-out

** Allowing for a 3-month supply

Note:

Noninvasive open ventilation (NIOV) system is considered experimental/investigational and, therefore, non-covered and applies to Professional claims.

Total payments for a rental item may not exceed its allowable purchase price, except for those items identified as life sustaining DME.

For the purpose of this policy, arterial blood gas, sleep oximetry and polysomnographic studies may not be performed by a DME supplier. A DME supplier is not considered a qualified provider or supplier of these tests for purposes of this policy's coverage and payment guidelines. This prohibition does not extend to the results of studies conducted by hospitals certified to do such tests.

Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

Place of Service: Inpatient/Outpatient

Experimental/Investigational (E/I) services are not covered regardless of place of service.

The use of a RAD is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

Covered Codes

CPT code	Description
A4604	Tubing with integrated heating element for use with positive airway pressure device.
A7027	Combination oral/nasal mask, used with continuous positive airway pressure device, each.
A7028	Oral cushion for combination oral/nasal mask, replacement only, each.
A7029	Nasal pillows for combination oral/nasal mask, replacement only, pair.
A7030	Full face mask used with positive airway pressure device, each.
A7031	Face mask interface, replacement for full face mask, each.
A7032	Cushion for use on nasal mask interface, replacement only, each.
A7033	Pillow for use on nasal cannula type interface, replacement only, pair.
A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap.
A7035	Headgear used with positive airway pressure device.
A7036	Chinstrap used with positive airway pressure device.
A7037	Tubing used with positive airway pressure device.
A7038	Filter, disposable, used with positive airway pressure device.
A7039	Filter, non-disposable, used with positive airway pressure device.
A7044	Oral interface used with positive airway pressure device, each.
A7045	Exhalation port with or without swivel used with accessories for positive airway devices, replacement only.
A7046	Water chamber for humidifier, used with positive airway pressure device, replacement, each.
E0470	Respiratory assist device, bi-level pressure capability, without back up 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).
E0472	Respiratory assist device, bi-level pressure capability, with back up rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure).
E0561	Humidifier, non-headed, used with positive airway pressure device.
E0562	Humidifier, headed, used with positive airway pressure device.

Diagnosis Codes

Covered Diagnosis Codes for Procedure codes: E0470, E0471, E0472

E66.2	G12.0	G12.1	G12.20	G12.21	G12.22	G12.29
G12.8	G12.9	G35	G47.31	G47.32	G47.34	G47.35
G47.36	G47.37	G61.0	M41.00	M41.02	M41.03	M41.04
M41.05	M41.06	M41.07	M41.08	M41.112	M41.113	M41.114
M41.115	M41.116	M41.117	M41.119	M41.122	M41.123	M41.124
M41.125	M41.126	M41.127	M41.20	M41.22	M41.23	M41.24
M41.25	M41.26	M41.27	M41.30	M41.34	M41.35	M41.40
M41.41	M41.42	M41.43	M41.44	M41.45	M41.46	M41.47
Q31.0	Q31.1	Q31.2	Q31.5	Q31.8	Q31.9	Q32.0
Q32.1	Q32.2	Q32.3	Q32.4			

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

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POLICY UPDATE HISTORY

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