Medical Policy

Respiratory Assist Device

Description

For purposes of this policy the following definitions are used:

FIO2 is the fractional concentration of oxygen delivered to the member for inspiration. The member's prescribed FIO2 refers to the oxygen concentration the member normally breathes when not undergoing testing to qualify for coverage of a Respiratory Assist Device (RAD). That is, if the member does not normally use supplemental oxygen, their prescribed FIO2 is that found in room air.

FEV1 is the forced expired volume in 1 second.

FVC is the forced vital capacity.

Central sleep apnea (CSA) is defined by all of the following:

1. An apnea-hypopnea index (AHI) greater than or equal to 5; and
2. The sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; and
3. A central apnea-central hypopnea index (CAHI) is greater than or equal to 5 per hour; and
4. The presence of at least one of the following:
    - Sleepiness
    - Difficulty initiating or maintaining sleep, frequent awakenings, or non-restorative sleep
    - Awakening short of breath
    - Snoring
    - Witnessed apneas
5. There is no evidence of daytime or nocturnal hypoventilation

Complex sleep apnea (CompSA) is a form of central apnea specifically identified by all of the following:

1. With use of a positive airway pressure device without a backup rate (E0601 or E0470), the polysomnogram (PSG) shows a pattern of apneas and hypopneas that demonstrates the persistence or emergence of central apneas or central hypopneas upon exposure to CPAP (E0601) or a bi-level device without backup rate (E0470) device when titrated to

the point where obstructive events have been effectively treated (obstructive AHI less than 5 per hour).

2. After resolution of the obstructive events, the sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; and
3. After resolution of the obstructive events, a central apnea-central hypopnea index (CAHI) greater than or equal to 5 per hour.

Apnea is defined as the cessation of airflow for at least 10 seconds.

Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.

The apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device.

For diagnosis of CSA, the central apnea-central hypopnea index (CAHI) is defined as the average number of episodes of central apnea and central hypopnea per hour of sleep without the use of a positive airway pressure device. For CompSA, the CAHI is determined during the use of a positive airway pressure device after obstructive events have disappeared.

If the AHI or CAHI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events used to calculate the AHI or CAHI must be at least the number of events that would have been required in a 2-hour period (i.e., greater than or equal to 10 events).

See below for a discussion of (PSG) and portable home sleep testing (HST).

If there is discontinuation of usage of an E0470 or E0471 device at any time, the supplier is expected to ascertain this and stop billing for the equipment and related accessories and supplies. The CMS break in service guidelines are followed; rental billing is not to exceed the capped rental period.

Policy

A respiratory assist device is considered reasonable and necessary when a member meets coverage criteria.

Policy Guidelines

Medicare Member Coverage Criteria:

Refer to Medicare policy (L33800) and article (A52517) for coverage criteria.

Respiratory Assist Device

Refer to National Coverage Determination (see NCD CAG-00465N) for additional coverage criteria.

Non-Medicare Member Coverage Criteria:

Coverage Criteria:

INITIAL COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES (when **not** being used to treat chronic respiratory failure due to COPD):

For an E0470 or an E0471 RAD to be covered (for conditions other than chronic respiratory failure due to COPD), the treating practitioner must fully document in the member's medical record symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea.

A RAD (E0470, E0471) is covered for those members with one of the following clinical disorders: restrictive thoracic disorders (i.e., neuromuscular diseases or severe thoracic cage abnormalities), severe chronic obstructive pulmonary disease (COPD), CSA or CompSA, or hypoventilation syndrome, or chronic respiratory failure due to COPD, as described in the following section.

Restrictive Thoracic Disorders

An E0470 or E0471 device is covered when criteria A – C are met.

A. There is documentation in the member's medical record of a neuromuscular disease (for example, amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (for example, post-thoracoplasty for TB).

B. One of the following:

    a. An arterial blood gas PaCO2, done while awake and breathing the member's prescribed FIO2 is greater than or equal to 45 mm Hg, or

    b. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the member's prescribed recommended FIO2, or

    c. For a neuromuscular disease (only), either i or ii,

        i. Maximal inspiratory pressure is less than 60 cm H20, or

        ii. Forced vital capacity is less than 50% predicted

C. Chronic obstructive pulmonary disease does not contribute significantly to the member's pulmonary limitation.

If all of the above criteria are met, either an E0470 or an E0471 device (based upon the judgment of the treating practitioner) will be covered for the first three months of therapy.

If all of the above criteria are not met, then E0470 or E0471 and related accessories will be denied as not reasonable and necessary.

See CONTINUED COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES BEYOND THE FIRST THREE MONTHS for information on more than three months' use.

Severe COPD

An E0470 device is covered if criteria A - C are met.

A. An arterial blood gas PaCO2, done while awake and breathing the member's prescribed FIO2, is greater than or equal to 52 mm Hg.

B. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the member's prescribed FIO2 (whichever is higher).

C. Prior to initiating therapy, sleep apnea and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out. (Note: Formal sleep testing is not required if there is sufficient information in the medical record to demonstrate that the member does not suffer from some form of sleep apnea (Obstructive Sleep Apnea (OSA), CSA and/or CompSA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation).

If all of the above criteria for members with COPD are met, an E0470 device will be covered for the first three months of therapy.

If all of the above criteria are not met, E0470 and related accessories will be denied as not reasonable and necessary.

An E0471 device will be covered for a member with COPD in either of the two situations below, depending on the testing performed to demonstrate the need.

<u>Situation 1</u>

For severe COPD members who qualified for an E0470 device, an E0471 started any time after a period of initial use of an E0470 device is covered if both criteria A and B are met.

A. An arterial blood gas PaCO2, done while awake and breathing the member's prescribed FIO2, shows that the member's PaCO2 worsens greater than or equal to 7 mm HG compared to the original result from criterion A, (above).

B. A facility-based PSG demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours) while using an E0470 device that is not caused by obstructive upper airway events – i.e., AHI less than 5. (Refer to the Positive Airway Pressure Devices policy for information about E0470 coverage for obstructive sleep apnea).

Situation 2

For severe COPD members who qualified for an E0470 device, an E0471 device will be covered if, at a time no sooner than 61 days after initial issue of the E0470 device, both of the following criteria A and B are met:

A. An arterial blood gas PaCO2 is done while awake and breathing the member's prescribed FIO2, still remains greater than or equal to 52 mm Hg.

B. Sleep oximetry while breathing with the E0470 device demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the member's prescribed FIO2 [whichever is higher].

If E0471 is billed but the criteria described in either situation 1 or 2 are not met, it will be denied as not reasonable and necessary.

See CONTINUED COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES BEYOND THE FIRST THREE MONTHS for information on more than three months' use.

Central Sleep Apnea or Complex Sleep Apnea

An E0470 or E0471 device is covered when, prior to initiating therapy, a complete facility-based, attended PSG is performed documenting the following (A and B):

A. The diagnosis of CSA or CompSA; and

B. Significant improvement of the sleep-associated hypoventilation with the use of an E0470 or E0471 device on the settings that will be prescribed for initial use at home, while breathing the member's prescribed FIO2.

If all of the above criteria are met, either an E0470 or an E0471 device (based upon the judgment of the treating practitioner) will be covered for members with documented CSA or CompSA for the first three months of therapy.

If all of the above criteria are not met, then E0470 or E0471 and related accessories will be denied as not reasonable and necessary.

See CONTINUED COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES BEYOND THE FIRST THREE MONTHS for information on more than three months' use.

Hypoventilation Syndrome

An E0470 device is covered if both criteria A and B and *either* criterion C *or* D are met.

A. An initial arterial blood gas PaCO2, done while awake and breathing the member's prescribed FIO2, is greater than or equal to 45 mm Hg.

B. Spirometry shows an FEV1/FVC greater than or equal to 70%. (Refer to Chronic Respiratory Failure Consequent to COPD for information about device coverage for beneficiaries with FEV1/FVC less than 70%.)

C. An arterial blood gas PaCO2, done while awake, and breathing the member's prescribed FIO2, shows the member's PaCO2 worsened greater than or equal to 7 mm HG compared to the original result in criterion A (above).

D. A facility-based PSG or HST demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI less than 5. (Refer to the Positive Airway Pressure Devices policy for information about E0470 coverage for obstructive sleep apnea.)

If the above criteria are not met, E0470 and related accessories will be denied as not reasonable and necessary.

An E0471 device is covered for a member with hypoventilation syndrome if both criteria A, B, and *either* criterion C *or* D is met:

A. A covered E0470 device is being used.

B. Spirometry shows an FEV1/FVC greater than or equal to 70%. (Refer to SEVERE COPD above for information about device coverage for members with FEV1/FVC less than 70%).

C. An arterial blood gas PaCO2, done while awake, and breathing the member's prescribed FIO2, shows that the member's PaCO2 worsens greater than or equal to 7 mm HG compared to the ABG result performed to qualify the member for the E0470 device (criterion A under E0470).

D. A facility-based PSG or HST demonstrates oxygen saturation less than or equal 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI less than 5 while using an E0470 device. (Refer to the Positive Airway Pressure Devices policy for information about E0470 coverage for obstructive sleep apnea.)

If the criteria above are not met, an E0471 device will be denied as not reasonable and necessary.

No aspect of a home sleep test, including but not limited to delivery and/or pickup of the device, may be performed by a DME supplier.

See CONTINUED COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES BEYOND THE FIRST THREE MONTHS for information on more than three months' use.

Chronic Respiratory Failure consequent to COPD

Initial Coverage Criteria

RAD with Backup Rate Feature

The RAD with backup rate feature to deliver high intensity noninvasive ventilation (NIV) as treatment for members with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD) is covered for home use. A RAD with backup rate feature is covered in the home for an initial 6-month period for members with COPD when *all the following* criteria are met:

A. The member exhibits hypercapnia as demonstrated by $PaCO2 \geq 52$ mmHg by arterial blood gas during awake hours while breathing his/her prescribed FiO2; *and*

B. Sleep apnea is not the predominant cause of hypercapnia (Formal sleep testing is not required if, per the treating practitioner, the member does not experience sleep apnea as the predominant cause of hypercapnia.); *and*

C. The member demonstrates *one of the following* characteristics:

    a. Stable COPD, without increase in or new onset of more than one respiratory symptom (cough, sputum production, sputum purulence, wheezing, or dyspnea) lasting 2 or more days and no change of pharmacological treatment during the 2-week period before initiation of NIV, *or*

    b. Hypercapnia present for at least 2 weeks post hospitalization after resolution of an exacerbation of COPD requiring acute NIV.

By the end of the initial 6-month period, a RAD with backup rate feature must be utilized as high intensity therapy, defined as a minimum IPAP ≥15 cm H2O and backup respiratory rate of at least 14 breaths per minute.

RAD without Backup Rate Feature

will cover in the home a RAD without backup rate feature for a member with CRF consequent to COPD who cannot tolerate high intensity NIV *or* for whom the backup rate feature is otherwise medically inappropriate. A RAD without backup rate feature is covered in the home for an initial 6-month period for members with COPD when *all of the following* criteria are met:

A. The member exhibits hypercapnia as demonstrated by PaCO2 ≥ 52 mmHg by arterial blood gas during awake hours while breathing his/her prescribed FiO2; *and*

B. Sleep apnea is not the predominant cause of the hypercapnia (Formal sleep testing is not required if, per the treating practitioner, the member does not experience sleep apnea as the predominant cause of the hypercapnia).

RAD Upon Hospital Discharge

Northwood will cover in the home a RAD with or without backup rate feature immediately upon hospital discharge for an initial 6-month period for members with acute on chronic respiratory failure due to COPD, if the member required either a RAD or ventilator within the 24-hour period prior to hospital discharge and the treating practitioner determines that the member is at risk of rapid symptom exacerbation or rise in PaCO2 after discharge.

Continuing Usage Criteria for a RAD

Members must be evaluated at least twice within the first year after initially receiving a RAD. Evaluations must occur by the end of the six-month initial coverage period and again during months 7-12.

First evaluation:
By 6 months after receiving initial coverage of a RAD, the treating practitioner must establish that usage criteria and clinical outcomes are being met. Specifically, the member must be determined by a treating practitioner to use the RAD at least 4 hours per 24-hour period, on at least 70% of days in a 30-day period and achieve *at least one* the following clinical outcomes:

A. Normalization (< 46 mmHg) of PaCO2, *or*

B. Stabilization of a rising PaCO2, *or*

C. 20% reduction in PaCO2 from baseline value, *or*

D. Improvement of *at least one* of the following member symptoms associated with chronic hypercapnia:

   a. headache

   b. fatigue

   c. shortness of breath

   d. confusion

   e. sleep quality

Second evaluation:
Between 7-12 months after initially receiving a RAD, the treating practitioner must establish the member is using the device at least 4 hours per 24-hour period on at least 70% of days in each paid rental month. After month 6, providers are required to document on a monthly basis that the member is using the device at least 4 hours per 24-hour period on at least 70% of days in each remaining paid rental month and any month in which accessories/supplies are dispensed.

CONTINUED COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES BEYOND THE FIRST THREE MONTHS OF THERAPY *WHEN USED TO TREAT CONDITIONS OTHER THAN CRF DUE TO COPD*

Members covered for the first three months of an E0470 or an E0471 device must be re-evaluated to establish the medical necessity of continued coverage beyond the first three months. While the member may certainly need to be evaluated at earlier intervals after this therapy is initiated, the re-evaluation upon which Northwood will base a decision to continue coverage beyond this time must occur no sooner than 61 days after initiating therapy by the treating practitioner. Northwood will not continue coverage for the fourth and succeeding months of therapy until this re-evaluation has been completed.

There must be documentation in the member's medical record about the progress of relevant symptoms and member usage of the device up to that time. Failure of the member to be consistently using the E0470 or E0471 device for an average of 4 hours per 24-hour period by the time of the re-evaluation (on or after 61 days after initiation of therapy) would represent non-compliant utilization for the intended purposes and expectations of benefit of this therapy. This would constitute reason for Northwood to deny continued coverage as not reasonable and necessary.

A signed and dated statement completed by the treating practitioner no sooner than 61 days after initiating use of the device, declaring that the member is compliantly using the device (an average of 4 hours per 24 hour period) and that the member is benefiting from its use must be obtained by the supplier of the device for continued coverage beyond three months.

If the above criteria are not met, continued coverage of an E0470 or an E0471 device and related accessories will be denied as not reasonable and necessary.

ACCESSORIES

The following table represents the usual maximum amount of accessories expected to be reasonable and necessary:

Code	Usual Maximum Amount
A4604	1 per 3 months
A7027	1 per 3 months
A7028	2 per 1 month
A7029	2 per 1 month
A7030	1 per 3 months
A7031	1 per 1 month
A7032	2 per 1 month
A7033	2 per 1 months
A7034	1 per 3 months
A7035	1 per 6 months
A7036	1 per 6 months
A7037	1 per 3 months
A7038	2 per 1 month
A7039	1 per 6 months
A7046	1 per 6 months

Billing for quantities of supplies greater than those described in the policy as the usual maximum amounts will be denied as not reasonable and necessary.

Either a non-heated (E0561) or heated (E0562) humidifier is covered and paid separately when ordered by the treating practitioner for use with a covered E0470 or E0471 RAD.

(The following code E0467 is not appropriate for the treatment of OSA – refer to Ventilator Policy).

Code E0467 (HOME VENTILATOR, MULTI-FUNCTION RESPIRATORY DEVICE, ALSO PERFORMS ANY OR ALL OF THE ADDITIONAL FUNCTIONS OF OXYGEN CONCENTRATION, DRUG NEBULIZATION, ASPIRATION, AND COUGH STIMULATION, INCLUDES ALL ACCESSORIES, COMPONENTS AND SUPPLIES FOR ALL FUNCTIONS) describes a ventilator that integrates the function of multiple types of equipment into a single device. Code E0467 combines the function of a ventilator with those of any combination of or all of the following:

· Oxygen equipment

· Nebulizer and compressor

· Aspirator (suction device)

· Cough stimulator (multiple products)

· Positive airway pressure devices (PAP and RAD)

· Custom fabricated oral appliances

If the multifunction ventilator does not include all of the functions listed above, then the ventilator must not be coded as E0467. Multifunction NCD that combine some but not all, of the listed functions must be coded as E1399 (DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS).

Positive airway pressure (PAP) devices, respiratory assist devices (RAD), and custom fabricated oral appliances, are considered same or similar to the features of products coded E0467.

The following positive airway pressure devices HCPCS codes for individual items are included in the functionality of code E0467:

- HCPCS codes E0470, E0471, E0472, E0561, E0562, E0601, A4604, A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, A7046.

Any claim for repair (HCPCS code K0739 for labor and any HCPCS code for replacement items) of beneficiary-owned equipment identified by HCPCS codes listed above is considered as unbundling if the date(s) of service for the repair overlaps any date(s) of service for code E0467.

Claims for code E0467 with a date(s) of service that overlaps date(s) of service in a rental month for any of the items listed above are considered as a claim for same or similar equipment.

Claims for A9279 (MONITORING FEATURE/DEVICE, STAND-ALONE OR INTEGRATED, ANY TYPE, INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED) are denied as non-covered. DME suppliers must not bill A9279 for remote monitoring services.

Northwood considers the Exsufflation Belt (K1021) **experimental and investigational** for pulmonary restrictive or pulmonary obstructive breathing because its effectiveness has not been established.

HCPCS Codes and Description

Respiratory Assist Device

CODE	DESCRIPTION
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)

ACCESSORIES

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
E0561 HUMIDIFIER, NON-HEATED, USED WITH POSITIVE AIRWAY PRESSURE DEVICE
E0562 HUMIDIFIER, HEATED, USED WITH POSITIVE AIRWAY PRESSURE DEVICE

NONCOVERED HCPCS CODES (experimental and investigational)

K1021 EXSUFFLATION BELT, INCLUDES ALL SUPPLIES AND ACCESSORIES

Documentation Requirements

Items in this policy may be subject to the Affordable Care Act (ACA) 6407 requirements.

The Affordable Care Act (ACA) 6407 requires that the treating physician conduct a face-to-face examination during the six month period preceding the written order. The documentation must be received by the provider prior to delivery for certain DME items. The documentation must describe a medical condition for which the DME is being prescribed.

Important Note:

Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary.

Northwood

Respiratory Assist Device

Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating practitioner in connection with diagnosis and treatment decisions.

Northwood follows all CMS National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), as applicable.

References

Centers for Medicare and Medicaid Services, Medicare Coverage Database, National Coverage Documents; https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=315&fromTracking=Y& Accessed and reviewed 12/15/25

CGS Administrators, LLC. Jurisdiction B DME MAC, Respiratory Assist Device. Local Coverage Determination No. L33800; Last accessed and reviewed December 15, 2025.

National Heritage Insurance Company (NHIC), Respiratory Assist Device. Local Coverage Determination No. L11504. Durable Medical Equipment Medicare Administrative Carrier Jurisdiction A. Chico, CA: NHIC; revised February 4, 2011.

Medical Policy

Northwood

Respiratory Assist Device

Aetna Noninvasive Positive Pressure Ventilation Clinical Policy Bulletin 0452, https://www.aetna.com/cpb/medical/data/400_499/0452.html Last accessed and reviewed 12/9/24.

Change/Authorization History

Revision Number	Date	Description of Change	Prepared / Reviewed by	Approved by	Review Date:	Effective Date:
A	11-20-06	Initial Release	Rosanne Brugnoni	Ken Fasse	n/a	
01	08-2007	Added quantities to full face mask codes	Rosanne Brugnoni	Ken Fasse	n/a	
02	01-2008	Revised least costly alternative statements for E0471 and E0470 to reflect changed payment category for E0471. Added: A7027 – A7029 to usual quantities table. Removed K0553 – K0555 from usual quantities table. Added E0471 to humidifier coverage statement. Added: A7027, A7028 and A7029. Removed K0553, K0554 and K0555	Susan Glomb	Ken Fasse		
03	3-13-08	Definitions added. Removed indication IV, Obstructive Sleep Apnea section and moved to Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea policy. Deleted NPPRA acronym. Removed: E0472	Susan Glomb	Ken Fasse		
04		Annual Review – no changes	Susan Glomb	Ken Fasse	Dec. 2008	
05	09-2009	Changed SADMERC to PDAC. GA and GZ modifiers added to policy in the event that they may be utilized in the future.	Susan Glomb	Ken Fasse		

06	Dec.15, 2009	Updated policy. Changed qty. of A7037 to 1 per 3 months. Added codes under accessories A7027, A7028, A7029.	Susan Glomb	Ken Fasse		
07	Dec.15, 2009	Annual review. No additional changes.	Susan Glomb	Ken Fasse	Dec. 2009	
08	12-03-10	Annual review – No changes	Susan Glomb	Ken Fasse	Dec.2010	
09	01-07-11	Delete; Least costly alternative language for E0471	Susan Glomb	Ken Fasse		
10	07-20-11	Added Important Note to all Medical Policies	Susan Glomb	Dr. B. Almasri		
11	11-10-11	Annual Review. Added References to Policy	Susan Glomb	Dr. B. Almasri	Nov. 2011	
12	04-04-12	Added reference to NH Medicaid	Susan Glomb	Dr. B. Almasri		
13	12-3-12	Annual Review – No changes	Susan Glomb	Dr. B. Almasri	Dec 12	
14	12-11-13	Annual review. No changes	Susan Glomb	Dr. B. Almasri		
15	12-4-14	Annual Review. Added: Items in this policy may be subject to the Affordable Care Act (ACA) 6407 requirements	Susan Glomb	Dr. B. Almasri		
16	12-10-15	Annual Review. Policy updated with Medicare policy guidelines. Member evaluation of RAD statement removed. References updated.	Susan Glomb	Dr. B. Almasri	12-10-15	
17	12-08-16	Annual Review. Updated HCPCS codes for ventilators referenced in policy.	Lisa Wojno	Dr. B. Almasri	December 2016	
18	12-19-17	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2017	

19	12-10-18	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2018	
20	12-05-19	Annual review. Added E0467 coding guidelines.	Carol Dimech	Dr. C. Lerchin	December 2019	December 2019
21	12-10-20	Annual review. Revised "physician" to "practitioner".	Carol Dimech	Dr. C. Lerchin	December 10, 2020	December 10, 2020
22	12-15-21	Annual review. Added NCD, LCD verbiage to "Important Note". Added: HCPCS code E0467 to ventilator code listings. Added: Language regarding no aspect of a home sleep test may be performed by a DME supplier. Revised: Coding instructions for multifunction ventilators (E0467). Claims for A9279 are denied as non-covered. DME suppliers must not bill A9279 for remote monitoring services.	Carol Dimech	Dr. C. Lerchin	December 15, 2021	December 15, 2021
23	9-15-22	Added new HCPCS code K1021, experimental and investigational. Added new reference.	Carol Dimech	Dr. C. Lerchin	9-15-21	10-1-21
24	12-15-22	Annual review. No further changes (see above).	Carol Dimech/Susan Glomb	Dr. C. Lerchin	12-15-22	
25	12-5-23	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	12-5-23	12-5-23
26	12-9-24	Annual review. No changes	Susan Glomb	Dr. C. Lerchin	12-9-24	12-9-24
27	7-17-25	Added new NCD coverage criteria for diagnosis of Chronic Respiratory Failure consequent to COPD.	Carol Dimech/Susan Glomb	Dr. C. Lerchin	7-17-25	7-17-25
28	12-15-2025	Annual review. Revised: "INITIAL COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES FOR	Susan Kazmierski	Dr. C. Lerchin	12-15-2025	12-15-

		THE FIRST THREE MONTHS OF THERAPY" to "INITIAL COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES" Revised Hypoventilation Syndrome: Refer to Chronic Respiratory Failure Consequent to COPD for information about device coverage for beneficiaries with FEV1/FVC less than 70%.) Revised C Hypoventilation Syndrome: done while awake				2025