Medical Policy

Respiratory Assist Devices

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 the Sleep Tests section 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.

INITIAL COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES FOR THE FIRST THREE MONTHS OF THERAPY:

For an E0470 or an E0471 RAD to be covered, the treating physician 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, etc.

A RAD (E0470, E0471) is covered for those Member's 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, 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 physician) 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 Member's 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.

Situation 1. For Group II Member's (COPD) 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 LCD for information about E0470 coverage for obstructive sleep apnea).

Situation 2. For Group II Member's (COPD) 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 physician) will be covered for Member's 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 SEVERE COPD (above) for information about device coverage for Member's with FEV1/FVC less than 70%.)

C. An arterial blood gas PaCO2, done during sleep or immediately upon awakening, 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 LCD 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 are 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 Member's 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 LCD 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.

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

VENTILATOR WITH NOINVASIVE INTERFACES

The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations Manual (Internet-Only Manual, Publ. 100-03) in Chapter 1, Part 4, Section 280.1 stipulates that ventilators (E0465 and E0466) are covered for the following conditions:

"[N]euromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease."

Each of these disease categories are comprised of conditions that can vary from severe and life-threatening to less serious forms. These disease groups may appear to overlap conditions described in the Respiratory Assist Devices LCD but they are not overlapping. Choice of an appropriate device i.e., a ventilator versus a bi-level PAP device is made based upon the severity of the condition. CMS distinguished the use of respiratory product types in a National Coverage Analysis Decision Memo (CAG-00052N) in June 2001 saying that RAD is "distinguished from ventilation in a patient for whom interruption or failure of respiratory support leads to death."

The conditions described in the Respiratory Assistance Devices (RAD) local coverage determination are not life-threatening conditions where interruption of respiratory support would quickly lead to serious harm or death. These policies describe clinical conditions that require intermittent and relatively short durations of respiratory support. Thus, any type ventilator would not be eligible for reimbursement for any of the conditions described in the RAD LCD even though the ventilator equipment may have the capability of operating in a bi-level PAP (E0470, E0471) mode. Bi-level PAP devices (E0470, E0471) are considered as reasonable and necessary in those clinical scenarios.

Claims for ventilators (E0465 and E0466) used for the treatment of conditions described in the RAD LCD will be denied as not reasonable and necessary.

CONTINUED COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES BEYOND THE FIRST THREE MONTHS OF THERAPY

Member's 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 by Medicare 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 Medicare will base a decision to continue coverage beyond this time must occur no sooner than 61 days after initiating therapy by the treating physician. Medicare 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 Medicare to deny continued coverage as not reasonable and necessary.

A signed and dated statement completed by the treating physician 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 physician for use with a covered E0470 or E0471 RAD.

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. 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 physician in connection with diagnosis and treatment decisions.

References

Centers for Medicare and Medicaid Services, Medicare Coverage Database, National Coverage Documents; October 2015.

National Government Services, Inc. Jurisdiction B DME MAC, Respiratory Assist Device. Local Coverage Determination No. L33800; revised date October 1, 2015.

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.

Applicable URAC Standard

Core 8	Staff operational tools and support

Change/Authorization History

Revision Number	Date	Description of Change	Prepared / Reviewed by	Approved by	Review 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