



Helpful hints for filing

Respiratory Assist Devices

HCPCS Code E0470, ED471



Overview

The following information describes the DME Medicare Administrative Contractors' (DME MACs) medical policies for Respiratory Assist Devices (RAD). Coverage criteria for patients needing a RAD device who have a primary diagnosis of Obstructive Sleep Apnea (OSA) should reference the Positive Airway Pressure (PAP) Helpful Hint or PAP Medicare DME MAC policy. Information was obtained from the DMEPOS Supplier Manuals and Local Coverage Decisions from each region. Coding, coverage, payment, and documentation guidelines are listed on the following pages and are to be used as a guide. For specific instructions, please reference your Supplier Manual or contact your DME MAC medical director or provider helpline.

This information should not be considered to be either legal or reimbursement advice. Given the rapid and constant change in public and private reimbursement, Philips Respironics cannot guarantee the accuracy or timeliness of this information and urges you to seek your own counsel and experts for guidance related to reimbursement, including coverage, coding, and payment.

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RESPIRONICS

Definitions

Noninvasive Positive Pressure Respiratory

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

Respiratory assist device without backup rate (E0470) – 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.

Respiratory assist device with backup rate (E0471) – 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 air into the lungs. In addition, it has a timed backup feature to deliver this air pressure whenever sufficient spontaneous inspiratory efforts fail to occur.

FIO₂ – the fractional concentration of oxygen delivered to the patient for inspiration. A patient's usual FIO₂ refers to the oxygen concentration the patient normally breathes when not undergoing testing to qualify for a RAD device.

Polysomnography – the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with physician review, interpretation, and report. It must include sleep staging, which is defined to include a 1 to 4 lead electroencephalogram (EEG), an electrooculogram (EOG), and a submental electromyogram (EMG). It also must include at least the following additional parameters of sleep: airflow, respiratory effort, and oxygen saturation by oximetry. It may be performed as either a whole night study for diagnosis only or as a split night study to diagnose and initially evaluate treatment.

Beneficiary statement – a statement completed by the beneficiary, a family member, or caregiver at least 61 days after initiating use of the device. (Note: The patient is not required to see the treating physician within the same month that the Beneficiary Statement is completed.) Information captured on this statement must include: (1) patient's name; (2) date of birth; (3) telephone number; (4) confirmation that the Medicare beneficiary is using a device that helps him/her take breaths during sleep (separate from a machine providing oxygen or medicine);

(5) stated number of hours/day and number of months in total that machine has been used; (6) date of last visit with physician who prescribed the device; (7) confirmation that the device will continue to be used for treatment in the future; and (8) documentation of who is answering the questions. This statement must be signed and dated.

Physician's statement – a signed and dated statement completed by the treating physician no sooner than 61 days after initiating use of the device, declaring that the patient is compliantly using the device (an average of 4 hours per 24-hour period) and that the patient is benefiting from its use. An office visit is not required for statement completion if the physician is able to otherwise ascertain the facts needed to do so. (Facts regarding the progress of patient symptoms and patient usage of the device must be accurately reflected in the patient's medical record.)

General coverage guidelines

The treating physician must be one who is qualified – by virtue of experience and training in noninvasive respiratory assistance – to order and monitor the use of respiratory assist devices.

For the consideration of coverage, polysomnographic studies must be performed in a sleep study laboratory and not in a home or in a mobile facility. The laboratory also must comply with all applicable state regulatory requirements.

Arterial blood gas, overnight oximetry, and polysomnographic studies may not be performed by a DME supplier. The RAD device prohibition does not extend to results of studies conducted by hospitals certified to do such tests.

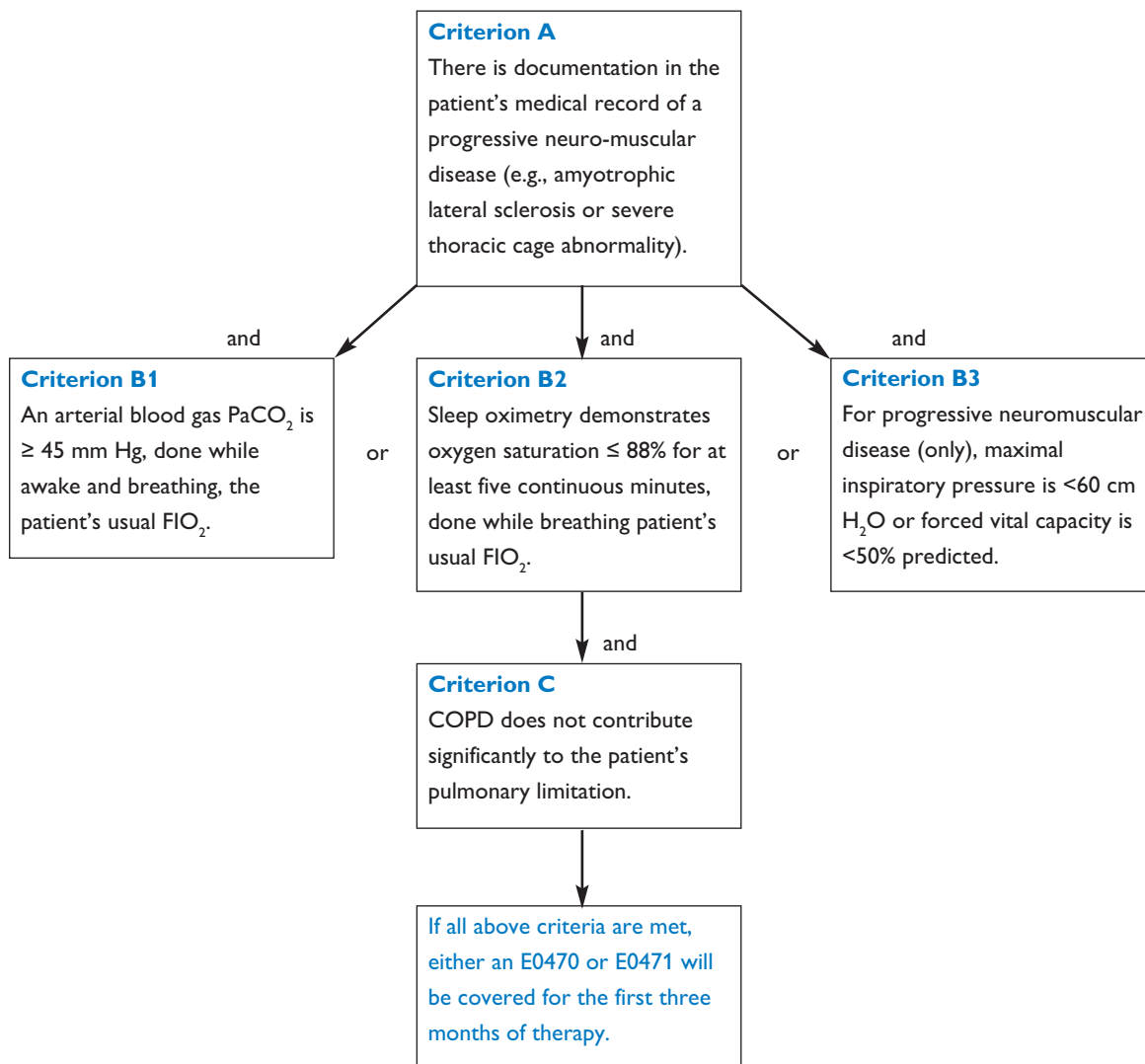
If at any time the patient discontinues use of E0470 or E0471, the supplier is expected to ascertain this and discontinue billing for the equipment and related accessories and supplies.

Clinical coverage guidelines

The treating physician must fully document in the patient's medical record the symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc. A RAD device (E0470 or E0471) is covered for patients with clinical disorder groups characterized as (I) restrictive thoracic disorders, (II) severe chronic obstructive pulmonary disease (COPD), (III) central sleep apnea (CSA), or complex sleep apnea (CompSA), and who also meet the criteria outlined in the following three flow charts.

Note: The following flow chart illustrates the clinical guidelines for coverage. For the documentation requirements for continued coverage, refer to the [Documentation section](#) on page 7.

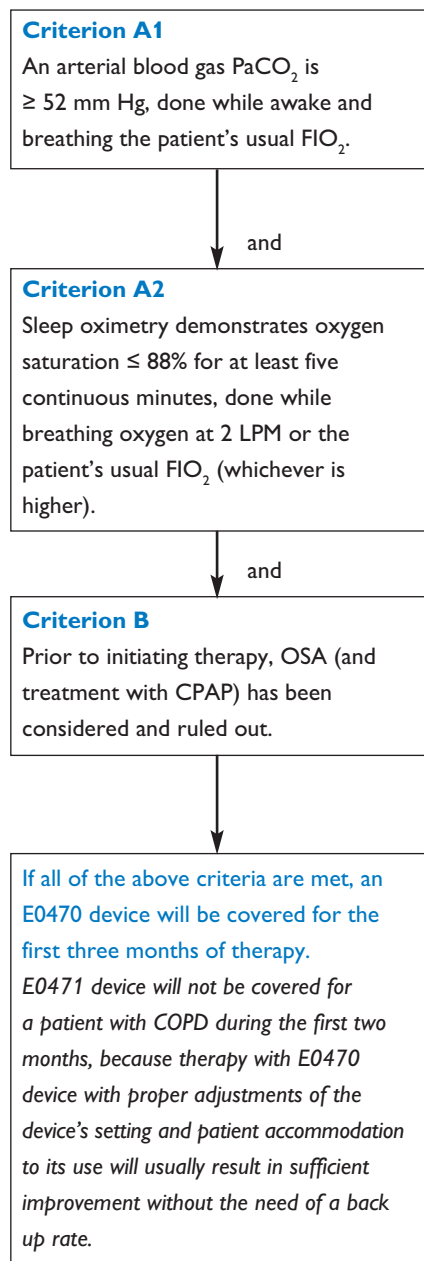
I. Restrictive thoracic disorders
(Progressive neuromuscular disease)



Note: The following flow chart illustrates the clinical guidelines for coverage. For the documentation requirements for continued coverage, refer to the [Documentation section](#) on page 7.

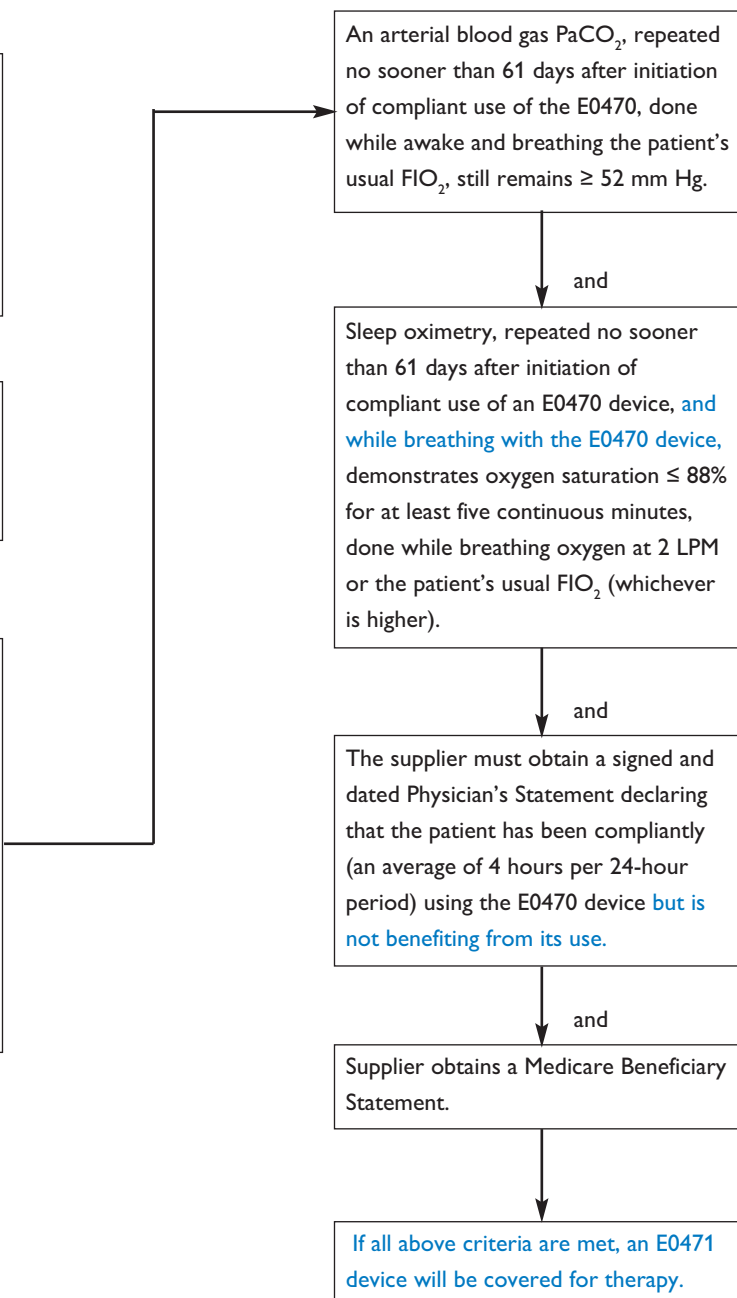
II. Severe COPD

Initial coverage criteria (first three months)



Continued coverage (beyond first three months)

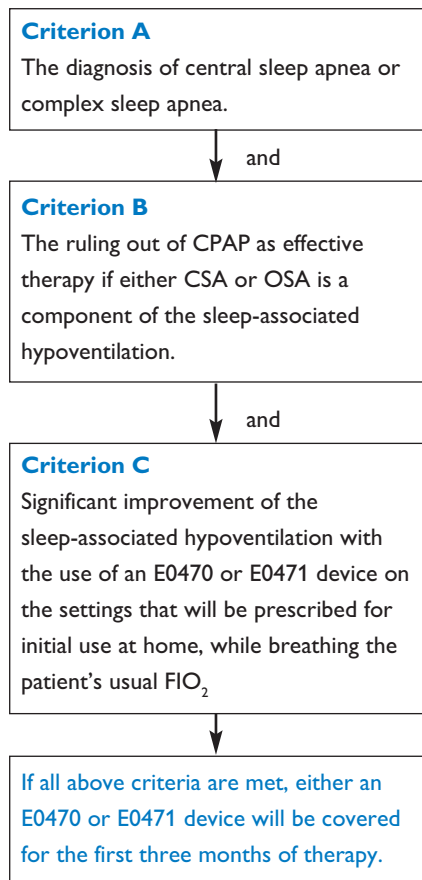
If at any time after initial issue the patient demonstrates compliant use of an E0470 device, and the treating physician believes that the patient requires an E0471 device, the following criteria must be met for coverage:



Note: The following flow chart illustrates the clinical guidelines for coverage. For the documentation requirements for continued coverage, refer to the [Documentation section](#) on page 7.

III. Central sleep apnea or complex sleep apnea

Prior to initiating therapy, a complete facility-based, attended PSG must be performed documenting the following criterion:



Central sleep apnea is defined as:

1. an apnea hypopnea index (AHI) greater than 5; and
2. central apneas/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. symptoms of either excessive sleepiness or disrupted sleep.

Complex sleep apnea is a form of central apnea specifically identified by the persistence or emergence of central apneas or hypopneas upon exposure to CPAP or an E0470 device when obstructive events have disappeared. These patients have predominately obstructive or mixed apneas during the diagnostic sleep study occurring at greater than or equal to 5 times per hour. With use of a CPAP or E0470, they show a pattern of apneas and hypopneas that meet the definition of CSA described previously.

Coding guidelines for equipment and accessories

	HCPCS code	Description	Payment category/maximum
Equipment*	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). BiPAP Auto and BiPAP Plus	Capped rental <ul style="list-style-type: none"> Rental payment can be made for up to 13 months of continuous use.
	E0471	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device). BiPAP ST and BiPAP autoSV	Capped rental only <ul style="list-style-type: none"> Rental payment can be made for up to 13 months of continuous use.
Accessories	A4604	Tubing with integrated heating element for use with positive airway pressure device	1 per 3 months
	A7030	Full face mask used with positive airway pressure device, each	1 per 3 months
	A7031	Face mask interface, replacement for full face mask, each	1 per 1 month
	A7032	Cushion for use on nasal mask interface, replacement only, each	2 per 1 month
	A7033	Pillow for use on nasal cannula type interface, replacement only, pair	2 per 1 month
	A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap	1 per 3 months
	A7035	Headgear	1 per 6 months
	A7036	Chin strap	1 per 6 months
	A7037	Tubing	1 per 3 months
	A7038	Filter, disposable	2 per 1 month
	A7039	Filter, nondisposable	1 per 6 months
	A7045	Exhalation port with or without swivel, replacement only	Not specified in current DMERC/DME MAC policy
	A7046	Water chamber for humidifier, replacement each	1 per 6 months
	A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified	No current fee schedule allowance
		E0561	Humidifier, nonheated
	E0562	Humidifier, heated	N/A purchase

*Please note that a -KX modifier is necessary to include when billing E0470 and E0471. The -KX modifier also should be added when billing accessories used with E0470 and E0471. Please see Documentation section on the next page for further details.

The DME MAC will reimburse separately for the accessory codes listed above when billed with a [capped rental item only](#). When billing for quantities of accessories greater than those described in the policy as the usual maximum amounts, each claim must include documentation supporting the medical necessity for the higher utilization. This information must be attached to the hard copy claim or entered in the HAO record of an electronic claim.

Either a nonheated (E0561) or heated (E0562) humidifier is covered and paid separately when prescribed by the treating physician for use with a covered E0470 or E0471 respiratory assist device.

Documentation

An order for the RAD device and accessories must be on file with the supplier and available to the DME MAC upon request. This order must be signed and dated by the treating physician. To support continued coverage for a respiratory assist device beyond the first three months of therapy, the supplier must obtain the treating physician's statement (signed and dated) and the Medicare beneficiary statement.

-EY modifier

Claims for RAD devices and accessories submitted to the DME MAC before a signed and dated order is on file with the supplier must include an -EY modifier attached to each affected HCPCS code.

-KX modifier

Appropriate documentation is a key component of the RAD policy. Therefore, a -KX modifier must be added to codes E0470 and E0471, and to codes for accessories used with E0470 and E0471. The -KX modifier must not be used until the required documentation has actually been obtained and entered into the supplier's files. The following table should be used as a guide to ensure appropriate use of the -KX modifier.

Claims submitted for the 1st through 3rd rental month	<ul style="list-style-type: none">• a physician's order is in the supplier's file• patient must meet the policy's coverage and payment guidelines
Claims submitted on the 4th rental month and thereafter	<p>Supplier has obtained:</p> <ul style="list-style-type: none">• the treating physician's statement• the beneficiary statement <p>Also, for COPD patients requiring a rate:</p> <ul style="list-style-type: none">• repeat arterial blood gas PaCO₂ AND• repeat sleep oximetry

If the completed and signed Beneficiary and Physician statements are not in the supplier's files in time for submission of the fourth or succeeding month's claims, the supplier may:

- Still submit a claim(s) but a -KX modifier must not be added.
- Choose to hold claims for the 4th and succeeding months until the completed and signed forms are obtained. Those claims may then be submitted with the -KX modifier, so long as their answers indicate continued compliant use of and benefit from the therapy, according to the coverage and payment rules outlined in the LCD.

Note: Inclusion or exclusion of a code for a specific product or supply does not imply any health insurance coverage or reimbursement policy. All referenced information and codes were taken from HCPCS. Please refer to DMEPOS Supplier Manual for complete explanations.

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