Helpful hints for filing

Respiratory Assist Devices

HCPCS Code E0470 and E0471

Overview

The following information describes the Durable Medical Equipment Medicare Administrative Contractors' (DME MACs) medical policies for Respiratory Assist Devices (RAD). Coverage criteria for patients needing a RAD 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.

PHILIPS

RESPIRONICS

sense and simplicity

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.

FIO_2 – the fractional concentration of oxygen delivered to the patient for inspiration. A patient's prescribed FIO_2 refers to the oxygen concentration the patient normally breathes when not undergoing testing to qualify for a RAD. For example, if a patient does not normally use supplemental oxygen, their prescribed FIO_2 is that found in room air.

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.

FEV1 – the forced expired volume in 1 second

FVC – the forced vital capacity

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. However, results from studies conducted by hospitals (who may be a DME supplier) certified to do such tests are not subject to this exclusion.

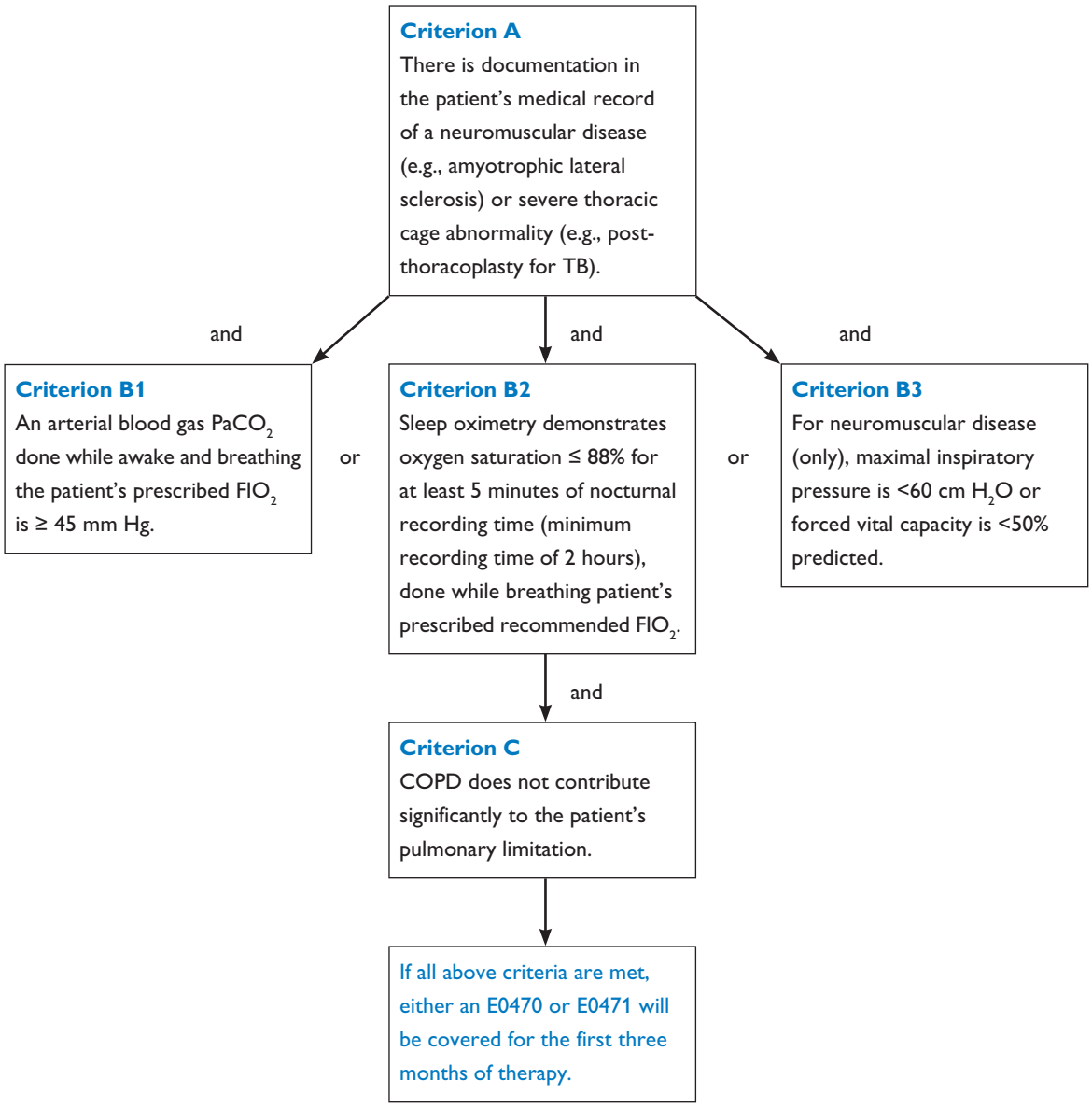
If at any time the patient discontinues use of E0470 or E0471, the supplier is expected to ascertain this and discontinue billing for the equipment and related accessories and supplies.

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 (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), complex sleep apnea (CompSA), or (IV) hypoventilation syndrome, and who also meet the criteria outlined in the following four 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 8.

I. Restrictive thoracic disorders



Note: The following flow charts illustrate the clinical guidelines for coverage. For the documentation requirements for continued coverage, refer to the Documentation section on page 8.

II. Severe COPD

Initial coverage criteria (first three months)

Criterion A
An arterial blood gas $PaCO_2$ done while awake and breathing the patient's prescribed FIO_2 is ≥ 52 mm Hg.

↓ and

Criterion B
Sleep oximetry demonstrates oxygen saturation is ≤ 88% for at least 5 minutes of nocturnal recording time (minimum recording time of 2 hours) done while breathing oxygen at 2 LPM or the patient's prescribed FIO_2 (whichever is higher).

↓ and

Criterion C
Prior to initiating therapy, OSA (and treatment with CPAP) has been considered and ruled out.

↓

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

Coverage for E0471

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

Scenario 1

For patients who qualify for an E0470, an E0471 started any time after a period of initial use of an E0470 is covered if both Criteria A and B are met.

Criterion A
An arterial blood gas $PaCO_2$ done while awake and breathing the patient's prescribed FIO_2 shows that the beneficiary's $PaCO_2$ worsens ≥ 7 mm Hg compared to the original result from Criterion A (initial coverage criteria).

↓ and

Criterion B
A facility-based PSG demonstrates oxygen saturation ≤ 88% for 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.

Scenario 2

For patients who qualified for an E0470, an E0471 will be covered if, at any time no sooner than 61 days after initial issue of the E0470, both Criterion A and B are met.

Criterion A
An arterial blood gas $PaCO_2$ is done while awake and breathing the patient's prescribed FIO_2 still remains ≥ 52 mm Hg.

↓ and

Criterion B
Sleep oximetry while breathing with the E0470 demonstrates oxygen saturation is ≤ 88% for 5 minutes of nocturnal recording time (minimum recording time of 2 hours) done while breathing oxygen at 2 LPM or the patient's prescribed FIO_2 (whichever is higher).

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 8.

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:

Criterion A
The diagnosis of central sleep apnea or complex sleep apnea.

↓ and

Criterion 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 patient's usual FIO_2

↓

If all above criteria are met, either an E0470 or E0471 will be covered for the first three months of therapy.

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 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.

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 8.

IV. Hypoventilation syndrome

An E0470 device will be covered if Criterion A, B and either C or D are met.

Criterion A
An initial arterial blood gas $PaCO_2$ done while awake and breathing the patient's prescribed FIO_2 is ≥ 45 mm Hg.

and

Criterion B
Spirometry shows an FEV1/FVC ≥ 70% and an FEV1 ≥ 50% of predicted.

and

Criterion C
An arterial blood gas $PaCO_2$ done during sleep or immediately upon awakening and breathing the patient's prescribed FIO_2 shows the beneficiary's $PaCO_2$ worsens ≥ 7 mm Hg compared to the original result in Criterion A.

or

Criterion D
A facility-based PSG demonstrates oxygen saturation ≤ 88% for 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events.

An E0471 device is covered for a patient with hypoventilation syndrome if Criterion A, B, and either C or D are met.

Criterion A
A covered E0470 device is being used.

and

Criterion B
Spirometry shows an FEV1/FVC ≥ 70% and an FEV1 ≥ 50% of predicted.

and

Criterion C
An arterial blood gas $PaCO_2$ done while awake and breathing the patient's prescribed FIO_2 shows that the beneficiary's $PaCO_2$ worsens ≥ 7 mm Hg compared to the ABG result performed to qualify the patient for the E0470 device.

or

Criterion D
A facility-based PSG demonstrates oxygen saturation ≤ 88% for 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events.

Continued coverage beyond the first three months of therapy

Patients covered for the first three months of an E0470 or an E0471 must be re-evaluated to establish the medical necessity of continued coverage by Medicare **beyond** the first three months. While the patient may certainly need to be evaluated at earlier intervals after 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 patient's medical record about the progress of relevant symptoms and patient usage of the device up to that time. Failure of the patient to be consistently using the E0470 or E0471 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. This would constitute reason for Medicare to deny continued coverage as not medically 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 patient is compliantly using the device (an average of 4 hours per 24-hour period) and that the patient is benefiting from its use, must be obtained by the supplier of the device for continued coverage beyond three months.

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 • 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 AVAPS, BiPAP ST, BiPAP autoSV and BiPAP autoSV Advanced	Capped rental • 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 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	N/A purchase
E0562	Humidifier, heated	N/A purchase

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.

* 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 page 8 for further details.

The DME MAC will reimburse separately for the accessory codes listed previously when billed with a capped rental item only. The supplier will be responsible for monitoring the amount of supplies and accessories a patient is actually using and assure that the patient has nearly exhausted the supply on hand prior to dispensing any additional items. See the CMS Program Integrity Manual for more details.

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 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 RAD beyond the first three months of therapy, the supplier must obtain the treating physician's statement (signed and dated).

-EY modifier

Claims for RADs 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 tables at the right should be used as a guide to ensure appropriate use of the -KX modifier.

-GA and -GZ modifiers

If all of the coverage criteria have not been met for use of the -KX modifier, the -GA or -GZ modifier must be added to a claim line for the RAD equipment (E0470 or E0471) and accessories when there is an expectation of a medical necessity denial. Suppliers must enter the -GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the -GZ modifier if they have not obtained a valid ABN. Claim lines billed without a -GA, -GZ or -KX modifier will be rejected as missing information.

Claims submitted for the 1st through 3rd rental month

- 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

- supplier has obtained the treating physician's statement
- patient must meet the policy's coverage criteria and indications and limitations and /or medical necessity guidelines

If the completed and signed Physician statement is not in the supplier's files in time for check submission of the 4th 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.

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