



Helpful hints for filing

Positive Airway Pressure (PAP) devices (E0601 and E0470) and related accessories

Overview

The following information describes coverage and payment information regarding positive airway pressure (PAP) devices and accessories. Coverage criteria for a respiratory assist device (RAD) used for the treatment of obstructive sleep apnea (OSA) are now reflected in this Helpful Hints and the Medicare Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) PAP Local Coverage Decision (LCD). Coding, coverage, payment, and documentation guidelines are listed on the following pages. This is to be used as a guide. For an item to be covered by Medicare, the following conditions apply: (1) item must be eligible for a defined Medicare benefit category; (2) item must be reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member; and (3) the item must meet all applicable Medicare statutory and regulatory requirements.¹ Please refer to your supplier manual or contact your DME MAC medical director or provider helpline for specific instructions.

CPAP, Auto CPAP, and CPAP with C-Flex devices (HCPCS E0601) are classified in the payment policy category "Capped Rental." Medicare will pay on a rental basis for continuous use up to 13 months, after which the title and ownership of the equipment will pass to the beneficiary. Accessories required for items in the "Capped Rental" category are reimbursed separately by Medicare unless specifically noted otherwise.

General coverage guidelines

On March 13, 2008, the National Coverage Decision (NCD) was updated, allowing coverage of a PAP device based upon a diagnosis of OSA

by home sleep testing (HST). Additionally, the NCD was updated to remove the requirements that an individual have moderate-to-severe OSA and that surgery is a likely alternative.

¹Section 1862 (a)1(A) of Title XVIII of the Social Security Act.

PHILIPS

RESPIRONICS

Definitions

- Apnea – A cessation of airflow for at least 10 seconds.
- Apnea-Hypopnea Index (AHI) – Average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device.
- Continuous Positive Pressure Airway device (CPAP) – A device which provides a flow of positive pressure air at a constant level to the upper airway by way of tubing and a noninvasive interface to splint the airway open during sleep.
- Home Sleep Test (HST) – Is performed unattended in a home using a portable monitoring device, and must monitor and record a minimum of three channels that allow for direct calculation of AHI or RDI.
- Hypopnea – An abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.
- Nasal application device – Nasal, nasal/oral, or facial mask.
- Obstructive Sleep Apnea (OSA) – Frequent and prolonged episodes in which breathing stops during sleep. Diagnosis is confirmed by monitoring the patient during sleep for periods of apnea and lowered blood oxygen levels. OSA results from the obstruction of the upper airway.
- Polysomnography (PSG) – A polysomnography is distinguished from a sleep study by the inclusion of sleep staging. Sleep staging is defined to include a 1-4 lead electroencephalogram (EEG), an electrooculogram (EOG), a submental electromyogram and a electrocardiogram (ECG). This study may either be conducted as a whole-night or split-night study.
- Respiratory Distress Index (RDI) – Average number of apneas plus hypopneas per hour of recording, without the use of a positive airway pressure device.
- Sleep study – Continuous and simultaneous recording of physiological and pathophysiological parameters of sleep with physician review, interpretation, and report. The recorded parameters are airflow, respiratory effort, and oxygen saturation by oximetry.

General coverage guidelines

For the purpose of the policy, a Medicare-covered sleep test must be either:

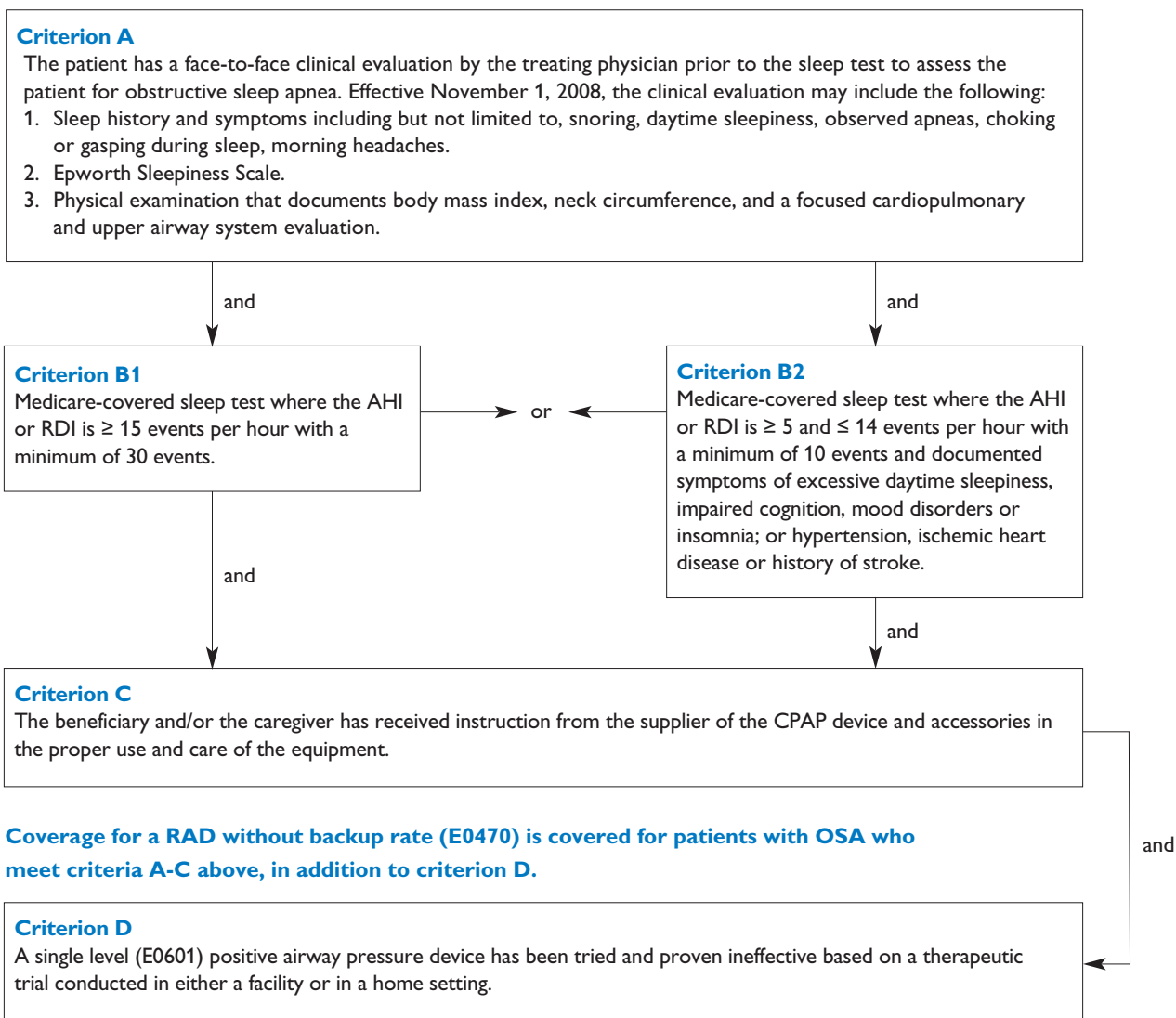
- A polysomnogram performed in a facility-based sleep laboratory or unattended using a home sleep monitoring device of Types II, III and IV (must monitor and record at least three channels that allow for direct calculation of AHI or RDI). The test must be ordered by the beneficiary's treating physician and conducted by a laboratory that qualifies as a Medicare provider of sleep tests and complies with all applicable state regulatory requirements.
- Not be performed by a DME supplier or any entity with a significant financial relationship to the DME supplier. This exclusion does not apply to results of studies from hospitals certified to perform such tests.

If a patient discontinues usage of an E0601 or E0470 device at any time, the supplier is expected to ascertain the device, and stop billing for the equipment and related accessories and supplies.

Clinical coverage guidelines

Initial coverage: PAP devices are covered under Medicare when ordered and prescribed by the licensed treating physician to be used for adult patients with OSA or for beneficiaries diagnosed with OSA whose OSA improved as a result of CPAP therapy during the initial 12-week period. Criteria A-C as outlined on the following page must be met in order to be considered for coverage.

I. Initial coverage criteria for CPAP (first three months)



If a CPAP device is tried and found to be ineffective during the initial three-month home trial, substitution of a RAD does not require a new initial face-to-face clinical evaluation or a new sleep test. Please refer to the detailed criteria provided in the Continued Coverage: Failure of CPAP section of this Helpful Hints.

If a CPAP device has been used for more than three months and the patient is switched to a RAD, a new initial face-to-face clinical evaluation is required, but a new sleep test is not required. A new three-month trial would begin for use of the RAD.

Payment: least costly alternative

If E0470 is billed and criterion D is not met, payment will be based on the allowance for the least costly medically appropriate alternative, E0601. A RAD with backup rate (E0471) is not medically necessary if the primary diagnosis is OSA; therefore, if E0471 is billed with a diagnosis of OSA, the following two payment rules apply:

If criteria A-D above are met, payment will be based on the allowance for the least costly medically appropriate alternative, E0470.

or

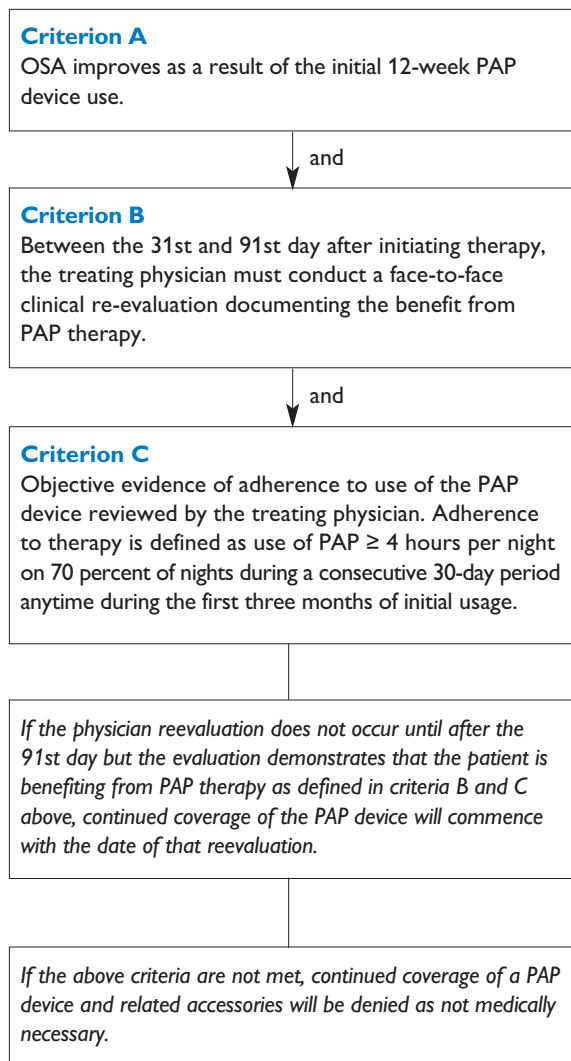
If criteria A-C above are met but not criterion D, payment will be based on the allowance for the least costly medically appropriate alternative, E0601.

Coverage, coding, and documentation requirements for the use of a RAD device for diagnoses other than OSA are addressed in the RAD Helpful Hints and Medicare policy.

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

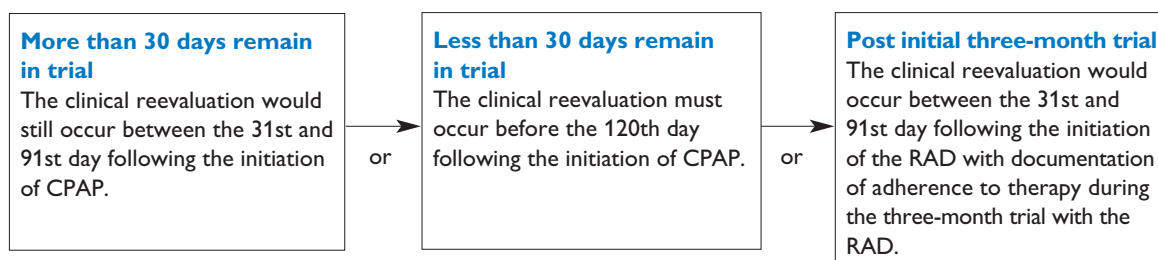
II. Continued coverage of CPAP (beyond first three months)

Continued coverage of a PAP device (E0470 or E0601) may continue for beneficiaries who meet the following criteria:



Initiation to RAD for the treatment of OSA

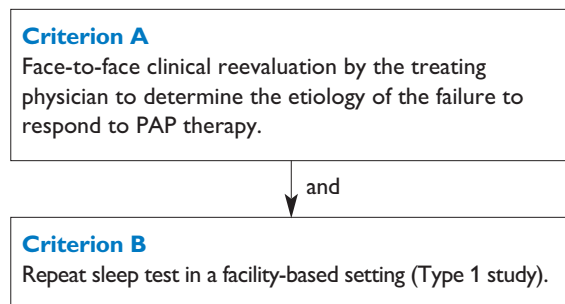
If a CPAP device is tried and found ineffective during the initial three-month home trial, substitution of a RAD (E0470) does not change the length of the trial (three months) unless



For a PAP device dispensed prior to November 1, 2008, if the initial coverage criteria in effect at that time was met, and the criteria for coverage after the first three months in effect were met, coverage for the PAP device will continue on or after November 1, 2008, assuming patient compliance with the PAP device.

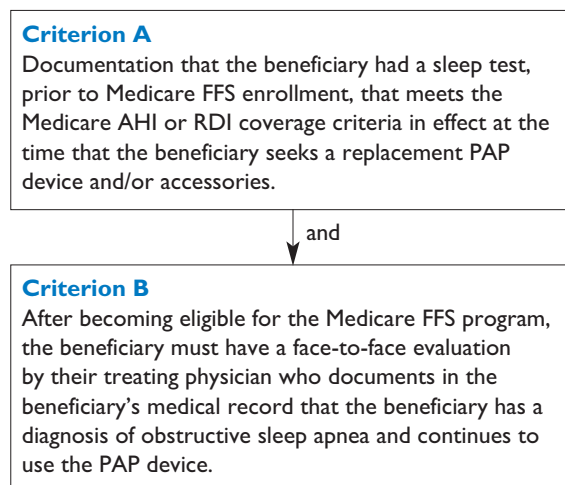
III. Failure of CPAP: continued coverage (beyond first three months)

Beneficiaries who fail the initial 12-week trial are eligible to requalify for a PAP device but must have both:



IV. New Medicare beneficiaries: continued coverage

For new Medicare Fee-for-Service (FFS) beneficiaries who received a PAP device prior to becoming eligible for Medicare, and need coverage for either a replacement PAP device and/or accessories, both of the following requirements must be met:



there are less than 30 days remaining in the trial period. Depending upon where the beneficiary is in the trial, the following criteria would apply for a clinical reevaluation:

Sleep tests

Coverage of a PAP device for the treatment of OSA is limited to claims where the diagnosis of OSA is based upon a Medicare-covered sleep test (Type I, II, III, or IV). A Medicare-covered sleep test must be either a polysomnogram performed in a facility-based laboratory (Type I study) or a home sleep test (HST) (Types II, III, or IV). The test must be ordered by the beneficiary's treating physician and conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements.

Facility-based sleep test

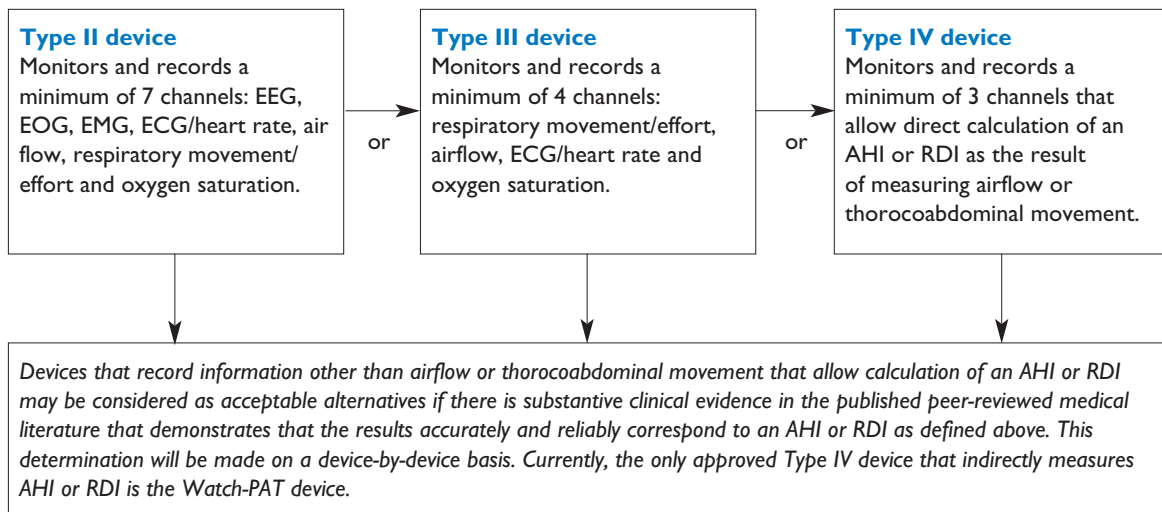
A Type I sleep test is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with physician review, interpretation, and report. It is facility-based and

must include sleep staging, which is defined to include a 1-4 lead electroencephalogram (EEG), electrooculogram (EOG), submental electromyogram (EMG) and electrocardiogram (ECG). It must also include at least the following additional parameters of sleep:

- Airflow
- Respiratory effort
- Oxygen saturation by oximetry
- Performed as either a whole night study for diagnosis only or a split night study to diagnose and initially evaluate treatment

Home Sleep Test (HST)

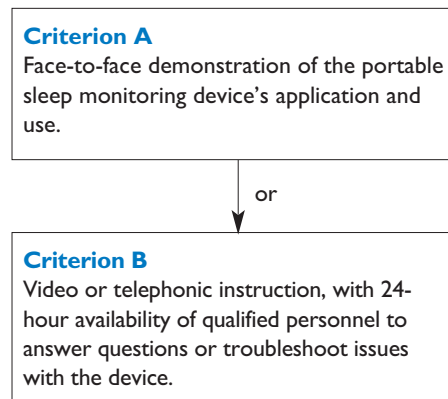
A HST is performed unattended in the beneficiary's home using a portable monitoring device. A portable monitoring device for conducting an HST must meet one of the following criteria:



HST requirements

For PAP devices with initial dates of service on or after November 1, 2008, all beneficiaries who undergo a HST must, prior to having the test, receive instruction on how to properly apply a portable sleep monitoring device.

This instruction must be provided by the entity conducting the HST and may not be performed by a DME supplier. Patient instruction may be accomplished by either:



Physician credentials

For PAP devices with initial dates of service on or after November 1, 2008, all HSTs (Type II, III, or IV) must be interpreted by a physician who holds either:

1. Current certification in sleep medicine by the American Board of Sleep Medicine (ABSM); or,
2. Current subspecialty certification in sleep medicine by a member board of the American Board of Medical Specialties (ABMS); or,
3. Completed residency or fellowship training by an ABMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the physician is eligible; or,
4. Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM) or The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations – JCAHO).

For PAP devices with initial dates of service on or after January 1, 2010, physicians interpreting facility-based polysomnograms (Type I) must meet one of the physician credential requirements (1-4) for credentialing.

No aspect of a HST, including but not limited to delivery and/or pickup of the device, may be performed by a DME supplier. This prohibition does not extend to the results of studies conducted by hospitals certified to do such tests.

Billing for CPAP accessories

Accessories are separately reimbursable according to the frequencies outlined below.

| HCPSC code | Description | Maximum replacement allowance* |
|------------|---|--------------------------------|
| 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 |

| HCPSC code | Description | Maximum replacement allowance* |
|------------|--|-----------------------------------|
| A7036 | Chinstrap | 1 per 6 months |
| A7037 | Tubing | 1 per 3 months |
| A7038 | Filter, disposable | 2 per 1 month |
| A7039 | Filter, non-disposable | 1 per 6 months |
| A7045 | Exhalation port with or without swivel, replacement | Not specified in 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, non-heated | N/A; purchased item |
| E0562 | Humidifier, non-heated | N/A; purchased item |

*Quantities of supplies greater than those outlined in DME MAC policy as the usual maximum amounts will be denied as not medically necessary, in the absence of clear documentation supporting the medical necessity for the higher utilization. This information must be attached to a hard copy claim or entered into the narrative field of an electronic claim. Documentation in the patient record must corroborate the order and medical necessity of the items and quantities billed.

Humidifier coverage

Either a non-heated (E0561) or heated (E0562) humidifier is covered when ordered by the treating physician for use with a covered PAP (E0470 or E0601) device.

Suggestions include:

- Document medical necessity and maintain in patient file
- Candidates for heated humidity may include:
 - Patients prone to mouth leaks
 - Patients with chronic nasal symptoms (including conditions existing prior to initiation of CPAP treatment)
 - Elderly patients; as a person ages, the likelihood of nasal complaints, increased nasal resistance and/or impairment of the mucociliary function of the nose increases
 - Patients taking medications that may result in dryness of the nasal mucosa (i.e., anti-hypertensives, antidepressants)

Documentation requirements

A Certificate of Medical Necessity (CMN) is not required for PAP claims. However, the supplier is required to keep appropriate documentation on file, including:

- An order for all equipment and accessories signed and dated by the treating physician
- Documentation of medical necessity

–EY modifier

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items billed before a signed and dated order has been received by the supplier must be submitted with an –EY modifier added to each affected HCPCS code.

–KX modifier

On claims for the first through third months, suppliers must add a –KX modifier to codes for PAP equipment (E0470 or E0601) and accessories only if all of the criteria have been met.

Continued coverage (beyond first three months)

For claims beginning with the fourth month of rental, and including all subsequent monthly rental claims, the supplier must add a –KX modifier to codes for equipment (E0470 or E0601) and accessories only if both the initial coverage and continued coverage criteria have been met. Suppliers must maintain documentation in their records that these criteria have been met and this must be available to the DME MAC upon request.

- If the supplier does not obtain information from the physician that the beneficiary has demonstrated improvement in their OSA symptoms and is adhering to PAP therapy in time for submission of the fourth or succeeding months' claims, the supplier may still submit the claims, but a –KX modifier must not be used.
- Claims may be held for the fourth and succeeding months pending receipt of information from the treating physician that the beneficiary received a clinical reevaluation between the 31st and 91st day, had documented improvement in OSA symptoms, and is adhering to PAP therapy, with the –KX modifier. However, if the beneficiary received a clinical reevaluation at a later date (after the 91st day), claims can be submitted with the –KX modifier for dates of service following the date of clinical reevaluation.
- For a PAP device dispensed prior to November 1, 2008, if initial coverage criteria in effect at the time were met and criteria for coverage after the first three months of initial coverage was met, the –KX modifier may be added to the claim on or after November 1, 2008, if the beneficiary continues to use the device.
- For beneficiaries who received a PAP device prior to enrollment in the Medicare FFS program and are seeking Medicare coverage of either a replacement PAP device and/or accessories, the supplier may add the –KX modifier only if all of the criteria have been met. The supplier may hold claims, pending confirmation that the requirements were met, and may submit claims with the –KX modifier beginning with the date of enrollment.

**Philips Healthcare is part of
Royal Philips Electronics**

How to reach us

www.philips.com/healthcare
healthcare@philips.com
fax: +31 40 27 64 887

Asia
+852 2821 5888

Europe, Middle East, Africa
+49 7031 463 2254

Latin America
+55 11 2125 0744

North America
+1 425 487 7000
800 285 5585 (toll free, US only)

Philips Respironics
1010 Murry Ridge Lane
Murrysville, PA 15668

Customer Service
+1 724 387 4000
800 345 6443 (toll free, US only)

Respironics Asia Pacific
+65 6298 1088

Respironics Australia
+61 (2) 9666 4444

Respironics Deutschland
+49 8152 93 06 0

Respironics Europe, Middle East, Africa
+33 1 47 52 30 00

Respironics France
+33 2 51 89 36 00

Respironics Italy
+39 03 62 63 43 1

Respironics Sweden
+46 8 120 45 900

Respironics Switzerland
+41 6 27 45 17 50

Respironics United Kingdom
+44 800 1300 845

www.philips.com/respironics

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.

For more information from Philips Respironics

| Reimbursement | Customer service | Website |
|--|--|--|
| Information & fee schedules Educational materials & questions (coding, coverage and payment) | 1-800-345-6443; listen to the instructions and follow prompts to select the insurance reimbursement information option | www.philips.com/respironics |

Respironics is a trademark of Respironics, Inc. and its affiliates. All rights reserved. The C-Flex mark is used under license. Watch-PAT is a trademark of Itamar Medical Ltd.



©2009 Koninklijke Philips Electronics N.V. All rights are reserved.

Philips Healthcare reserves the right to make changes in specifications and/or to discontinue any product at any time without notice or obligation and will not be liable for any consequences resulting from the use of this publication.

CAUTION: US federal law restricts these devices to sale by or on the order of a physician.

Hoehc KW 08/10/09 MCI 4102396 PN 1036650