DOCUMENTATION CHECKLIST

CGS Administrators, LLC • DME MAC Jurisdiction C

POSITIVE AIRWAY PRESSURE (PAP) DEVICES FOR THE TREATMENT OF OSA QUALIFYING SLEEP TEST: HOME (TYPE II, III, IV & OTHER) STUDY

REQUIRED DOCUMENTATION IN SUPPLIER'S FILE

ALL E0601 (CPAP) AND E0470 (BIPAP WITHOUT BACKUP RATE) CLAIMS FOR OSA INITIAL COVERAGE (1ST THREE MONTHS)

☐ **DOCUMENTATION OF DISPENSING ORDER (PRELIMINARY WRITTEN OR VERBAL ORDER) THAT CONTAINS:**

☐ Description of the item ☐ Name of the beneficiary ☐ Name of the physician ☐ Date of the order
☐ Start date of the order (if different from date of the order) ☐ Physician signature (for written order) or supplier signature (for verbal order)

☐ **DETAILED WRITTEN ORDER THAT CONTAINS:**

- ☐ Beneficiary's name
- ☐ The treating physician's signature
- ☐ The date the treating physician signed the order
- ☐ The start date of the order - if the start date is different than the signature date
- ☐ Order for PAP with pressure setting
- ☐ List of all accessories/supplies to dispense with refill/replacement instructions
- ☐ Length of need

☐ **BENEFICIARY AUTHORIZATION**

☐ **REFILL REQUEST**

Items Were Obtained In Person at a Retail Store	Written Refill Request Received from the Beneficiary	Telephone Conversation Between Supplier and Beneficiary
☐ Signed delivery slip or copy of itemized sales receipt	☐ Name of beneficiary or authorized rep (indicate relationship) ☐ Statement that the beneficiary is requesting a refill ☐ Description of each item being requested ☐ Signature of requestor ☐ Date of request ☐ Quantity of each item beneficiary still has remaining ☐ Request was not received any sooner than 14 calendar days prior to the delivery/shipping date ☐ Shipment/delivery occurred no sooner than 10 calendar days prior to the end of usage for the current product	☐ Beneficiary's name ☐ Name of person contacted (if someone other than the beneficiary include this person's relationship to the beneficiary) ☐ Statement that the beneficiary is requesting a refill ☐ Description of each item being requested ☐ Date of contact ☐ Quantity of each item beneficiary still has remaining ☐ Contact was not made any sooner than 14 calendar days prior to the delivery/shipping date ☐ Shipment/delivery occurred no sooner than 10 calendar days prior to the end of usage for the current product

Revised May 24, 2012

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☐ **DELIVERY DOCUMENTATION**

Direct Delivery	Shipped/Mail Order Tracking Slip	Shipped/Mail Order Return Post-Paid Delivery Invoice
☐ Beneficiary's name	☐ Shipping invoice	☐ Shipping invoice
☐ Quantity delivered	☐ Beneficiary's name	☐ Beneficiary's name
☐ Detailed description of item(s)	☐ Delivery address	☐ Delivery address
☐ Brand	☐ Detailed description of item(s) shipped	☐ Detailed description of item(s) shipped
☐ Serial number	☐ Quantity shipped	☐ Quantity shipped
☐ Signature of person accepting delivery	☐ Brand	☐ Brand
☐ Relationship to beneficiary	☐ Serial number	☐ Serial number
☐ Signature date	☐ Tracking slip	☐ Date shipped
	☐ References each individual package	☐ Signature of person accepting delivery
	☐ Delivery address	☐ Relationship to beneficiary
	☐ Package I.D. #number	☐ Signature date
	☐ Date shipped	
	☐ Date delivered	
	☐ A common reference number links the invoice and tracking slip - may be entered by supplier	

BILLING REMINDER

- Direct Deliveries - the date the beneficiary received the DMEPOS supply shall be the date of service on the claim.
- Shipped or mailed – the date shipped shall be the date of service on the claim

☐ **Treating physician conducted a face-to-face clinical evaluation prior to the sleep test to assess the patient for OSA**.

☐ **Face-to-face clinical evaluation is documented in a detailed narrative note in the patient's chart in the format the physician uses for other entries.**

☐ **Clinical evaluation contains pertinent information about the following elements (evaluation may include other details and each element would not have to be addressed in every evaluation):**

- ☐ History
  - ☐ Signs and symptoms of sleep disordered breathing including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches
  - ☐ Duration of symptoms
  - ☐ Validated sleep hygiene inventory such as the Epworth Sleepiness Scale
- ☐ Physical Exam
  - ☐ Focused cardiopulmonary and upper airway system evaluation
  - ☐ Neck circumference
  - ☐ Body mass index (BMI)

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- ☐ **Medicare-covered sleep test that meets <u>all</u> of the following qualifications:**
  - ☐ Test was ordered by the beneficiary's treating physician.
  - ☐ Test was conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements.
  - ☐ Prior to the test, the beneficiary received instruction on how to properly apply the portable sleep monitoring device from the entity conducting the HST (may not be performed by DME supplier)
    - ☐ Face-to-face demonstration of the portable sleep monitoring device's application and use; **or**
    - ☐ Video or telephonic instructions, with 24 hour availability of qualified personnel to answer questions or troubleshoot issues with the device.
  - ☐ No aspect of the HST, including delivery and/or pickup of the device, was performed by the DME supplier.
  - ☐ The portable monitoring device used to conduct the HST met criteria for one of the devices listed in the PAP LCD.
  - ☐ The HST was interpreted by a physician who meets one of the following qualifications:
    - ☐ Current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); **or**,
    - ☐ Current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS); **or**,
    - ☐ 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**,
    - ☐ Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM), Accreditation Commission for Health Care (ACHC), or The Joint Commission (TJC, formerly the Joint Commission on Accreditation of Healthcare Organizations – JCAHO).
- ☐ **The sleep test results meet <u>either</u> of the following criteria:**
  - ☐ The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; **or**,
  - ☐ The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
    - ☐ Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; **or**,
    - ☐ Hypertension, ischemic heart disease, or history of stroke.

<u>NOTE:</u> The sleep test may be performed as either a whole night study for diagnosis only or as a split night study to diagnose and initially evaluate treatment. If the AHI or RDI is calculated based on less than 2 hours of sleep or recording time, the total number of recorded events used to calculate the AHI or RDI must be at least the number of events that would have been required in a 2 hour period.

- ☐ **The patient and/or their caregiver received instruction from the supplier of the PAP device and accessories in the proper use and care of the equipment.**

ADDITIONAL CRITERIA – E0470 (BIPAP WITHOUT BACKUP RATE)

- ☐ **The beneficiary meets all coverage criteria for a single level (E0601) positive airway pressure device.**
- ☐ **An E0601 was tried and proved ineffective based on a therapeutic trial conducted in either a facility or in a home setting.**
  - ☐ Interface fit and comfort was addressed and an appropriate interface has been properly fit and the beneficiary is using it without difficulty. This interface will be used with the E0470 device, and
  - ☐ Adjustments to the E0601 pressure settings were addressed. The current pressure setting of the E0601 prevents the beneficiary from tolerating the therapy and lower pressure settings of the E0601 were tried but failed to:
    - ☐ Adequately control the symptoms of OSA; or
    - ☐ Improve sleep quality; or,
    - ☐ Reduce the AHI/RDI to acceptable levels.

<u>NOTE:</u> If an E0601 device is tried and found ineffective during the initial facility-based titration or home trial, substitution of an E0470 device does not require a new initial face-to-face clinical evaluation or a new sleep test. During this time period, a change from an E0601 to an E0470 does not change the length of the trial unless there are less then 30 days remaining in the trial period. If more than 30 days remain in the trial period, the clinical re-evaluation would still occur between the 31st and 91st day following the initiation of the E0601 use and adherence documentation on the E0470 would need to occur prior to the 91st day following initial use of the E0601. If less than 30 days remain in the trial period, the clinical re-evaluation and adherence report must occur before the 120th day following initiation of the E0601.

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If an E0601 device has been used for more that 3 months and the patient is switched to an E0470, a new initial face-to-face clinical evaluation is required, but a new sleep test is not required. A new 3 month trial would begin for use of the E0470. A clinical re-evaluation must occur between the 31st and 91st day following initiation of the E0470 and there would also need to be documentation of adherence to therapy during the 3 month trial with an E0470.

All Claims for PAP Devices – Continued Coverage (Beyond the 1st Three Months of Therapy)

- ☐ **The treating physician's records document a clinical re-evaluation no sooner than the 31st day but no later than the 91st day after initiating therapy and documents that the beneficiary is benefiting from PAP therapy as demonstrated by:**
  - ☐ Improvement in the symptoms of obstructive sleep apnea; ***and***
  - ☐ Objective evidence of adherence to use of the PAP device.
    - ☐ Direct download or visual inspection of usage data verifies that the beneficiary has used PAP ≥ 4 hours per night on 70% of nights during a consecutive 30 day period anytime during the first three months of initial usage; and
    - ☐ Treating physician reviewed adherence data.
- ☐ **The re-evaluation is documented in a detailed narrative note in the patient's chart in the format the physician uses for other entries.**

* * *

- ☐ **Continued Use of the Equipment/Accessories/Supplies is Verified by Either**:
  - ☐ A medical record, dated within 12 months of the date of service under review, showing use; or
  - ☐ Valid proof of refill/replacement; or
  - ☐ Supplier records documenting beneficiary confirmation of continued use.
- ☐ **Continued Medical Need for the Equipment/Accessories/Supplies is Verified by Either:**
  - ☐ A refill order from the treating physician dated within 12 months of the date of service under review; or
  - ☐ A change in prescription dated within 12 months of the date of service under review; or
  - ☐ A medical record, dated within 12 months of the date of service under review, that shows usage of the item.

MODIFIER REMINDERS

- Suppliers should not submit claims to the DME MAC prior to obtaining a detailed written order. Items billed to the DME MAC before a signed and dated order has been received must be submitted with an EY modifier.
- For initial coverage (months 1-3), the KX modifier must not be used on claims unless all PAP coverage criteria are met.
- For continued coverage (4th month and thereafter), the KX modifier can only be used on claims if both the "Initial Coverage" criteria and "Continued Coverage" criteria have been met. See the PAP LCD for detailed information about use of the KX modifier.
- If all the coverage criteria have not been met, the GA or GZ modifier must be added to the code. When there is an expectation of a medical necessity denial, suppliers must enter GA on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or GZ if they have not obtained a valid ABN.
- Claim lines billed without a KX, GA, or GZ modifier will be rejected as missing information.

ADDITIONAL INFORMATION REFERENCES ON THE WEB

- Supplier Documentation Requirements
  http://www.cgsmedicare.com/jc/pubs/pdf/Chpt3.pdf
- Local Coverage Determinations (LCDs) and Policy Articles
  http://www.cgsmedicare.com/jc/coverage/LCDinfo.html
- Positive Airway Pressure Resources
  http://www.cgsmedicare.com/jc/coverage/mr/PAP.html

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Note: It is expected that the patient's medical records will reflect the need for the care provided. These records are not routinely submitted to the DME MAC but must be available upon request. Therefore, while it is not a requirement, it is a recommendation that suppliers obtain and review the appropriate medical records and maintain a copy in the beneficiary's file.

Many suppliers have created forms which have not been approved by CMS which they send to physicians and ask them to complete. Even if the physician completes this type of form and puts it in his/her chart, this supplier-generated form is not a substitute for the comprehensive medical record. Suppliers are encouraged to help educate physicians on the type of information that is needed to document a patient's need for PAP therapy.