

Required Documentation in Supplier's File *

All E0601 (CPAP) Claims and E0470 (RAD 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
 - Start date of the 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 from 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
- Delivery Documentation

Direct Delivery	Shipped/Mail Order Tracking Slip	Shipped/Mail Order Return Post-Paid Delivery Invoice
<ul style="list-style-type: none"> • Beneficiary's name • Quantity delivered • Detailed description of item(s) • Brand • Serial number • Signature of person accepting delivery • Relationship to beneficiary • Signature date 	<ul style="list-style-type: none"> • Shipping invoice <ul style="list-style-type: none"> - Beneficiary's name - Delivery address - Detailed description of item(s) shipped • Tracking slip <ul style="list-style-type: none"> - References each individual package - Delivery address • A common reference number links the invoice and tracking slip – may be entered by supplier 	<ul style="list-style-type: none"> • Shipping invoice <ul style="list-style-type: none"> - Beneficiary's name - Delivery address - Detailed description of item(s) shipped - Quantity shipped - Brand - Serial number - Date shipped - Signature of person accepting delivery - Relationship to beneficiary - Signature date

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)

- Medicare-covered sleep test that meets **all** of the following qualifications:
 - Performed at a facility-based sleep laboratory
 - 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
 - Includes sleep staging (a 1-4 lead electroencephalogram [EEG], electro-oculogram [EOG], submental electromyogram [EMG] and electrocardiogram [ECG])
 - Also includes at least the following additional parameters of sleep: airflow, respiratory effort, and oxygen saturation by oximetry
 - The test (if performed on or after January 1, 2010) 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) or The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations – JCAHO).

- The sleep test results meet **either** 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.

NOTE: 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 (RAD 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

NOTE: If a CPAP device is tried and found ineffective during the initial 3 month home trial, substitution of a RAD does not require a new initial face-to-face clinical evaluation or a new sleep test.

If a CPAP device has been used for more that 3 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 3 month trial would begin for use of the RAD.

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 \geq 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 written report of 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.
- Supplier obtains current (at least every 4 months) documentation of on-going utilization.

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.

* **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.

There must be a specific request from a beneficiary or their caregiver before the supplier can dispense refills of PAP accessories. Refills cannot be automatically dispensed on a predetermined regular basis. Contact regarding refills should take place no sooner than approximately 7 days prior to the anticipated delivery/shipping date and delivery/shipping should be no sooner than approximately 5 days prior to the end of usage for the current product.

**Additional Information
References on the Web**

- Supplier Documentation Requirements
<http://www.cignagovernment.com/jc/pubs/pdf/Chpt3.pdf>
- Local Coverage Determinations (LCDs) and Policy Articles
<http://www.cignagovernment.com/jc/coverage/LCDinfo.html>

Disclaimer: This document was prepared as an educational tool and is not intended to grant rights or impose obligations. This checklist may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either written law or regulations. Suppliers are encouraged to consult the DME MAC Jurisdiction C Supplier Manual and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.