Positive Airway Pressure (PAP) Devices:

For the Treatment of OSA Qualifying Sleep Test: Home (Type II, III, IV & Other) Study

MEDICAL REVIEW DOCUMENTATION CHECKLIST

REQUIRED DOCUMENTATION IN SUPPLIER'S FILE

All E0601 (CPAP) and E0470 (BiPAP without backup rate) Claims for OSA Initial Coverage (1st Three Months)

Detailed Written Order

- ☐ The DWO contains all of the following elements:
  - ☐ Beneficiary's name;
  - ☐ Prescribing physician's name;
  - ☐ The treating physician's NPI;
  - ☐ The treating physician's signature;
  - ☐ The date the treating physician signed the order (personally entered by the physician);
  - ☐ The date of the order;
  - ☐ Detailed description of the device being ordered; and
  - ☐ Detailed list of all accessories/supplies with quantity to dispense, number of refills and replacement frequency.
- ☐ The date of the order is on or after a face-to-face encounter between the ordering physician and the beneficiary.
- ☐ The DWO for the PAP device was obtained **prior to delivery**.
- ☐ The physician's signature on the detailed written order meets **CMS Signature Requirements** http://www.cgsmedicare.com/jc/pubs/news/2010/0410/cope12069.html
- ☐ Any changes or corrections have been initialed/signed and dated by the ordering physician.
- ☐ A date stamp (or similar) clearly indicates the supplier's date of receipt.

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

Medical Record Documentation

- ☐ Medical records include documentation of a face-to-face encounter between the beneficiary and the ordering practitioner.
  - ☐ F2F occurred within 6 months prior to completion of the detailed written order; and
  - ☐ F2F assesses the beneficiary for obstructive sleep apnea (OSA) by recording 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;

Created March 9, 2010
Revised January 25, 2016

- Physical Exam;
- Focused cardiopulmonary and upper airway system evaluation;
- Neck circumference; and
- Body mass index (BMI).

- Clinical evaluation was completed prior to the sleep test.
- A date stamp or similar indicator verifies that the supplier received a copy of the F2F note on or before the date of delivery.
- A Medicare-covered sleep test was performed and meets **all** 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 (http://www.cms.gov/medicare-coverage-database/indexes/lcd-list.aspx?Cntrctr=140&ContrVer=2&CntrctrSelected=140*2&name=CGS+Administrators%2c+LLC+(18003%2c+DME+MAC)&LCntrctr=140*2&bc=AgACAAAAAAAA&#ResultsAnchor).
  - The test 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 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 beneficiary 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.

Note: 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 is 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.

If an E0601 device has been used for more that 3 months and the beneficiary 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 $\geq$ 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 beneficiary's chart in the format the physician uses for other entries.

Replacement Device During Reasonable Useful Lifetime Due to Loss, Theft, or Irreparable Damage

- ☐ Documentation that verifies the reason for the replacement (police report, insurance report, fire report, etc.)

Replacement Device Following 5 year RUL

- ☐ A new detailed written order obtained prior to delivery
- ☐ Face-to-face evaluation by the treating physician that documents the beneficiary continues to use and benefit from the device
- ☐ Face-to-face was performed within six (6) months prior to the date of the order

Beneficiaries Entering Medicare (Continued Use of Existing Device or Replacement Device)

- ☐ Detailed written order obtained prior to delivery
- ☐ Sleep test – Documentation that the beneficiary had a sleep test, prior to FFS Medicare enrollment, that meets the Medicare AHI/RDI coverage criteria in effect at the time that the beneficiary seeks Medicare coverage of a replacement PAP device and/or accessories.
- ☐ Clinical Evaluation – Following enrollment in FFS Medicare, the beneficiary had a face-to-face evaluation by their treating physician who documents in the beneficiary's medical record that:
  - ☐ The beneficiary has a diagnosis of obstructive sleep apnea; and,
  - ☐ The beneficiary continues to use the PAP device.
- ☐ Face-to-face was performed within six (6) months prior to the date of the order.

Refill Request For Non-Consumable Supplies

- ☐ Beneficiary's name or authorized representative if different from the beneficiary
- ☐ A description of each item that is being requested

- ☐ Date of the request
- ☐ Documentation that describes the functional condition of the item(s) being refilled in sufficient detail to demonstrate the cause of the dysfunction that necessitates the replacement
- ☐ Contact did not take place sooner than 14 days prior to the delivery/shipping date
- ☐ Delivery was no sooner than 10 calendar days prior to end of usage for the current product

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

- 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

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

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.