

DOCUMENTATION CHECKLIST



POSITIVE AIRWAY PRESSURE (PAP) DEVICES FOR THE TREATMENT OF OSA

REQUIRED DOCUMENTATION

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

- Standard Written Order (SWO)**
 - The SWO contains all of the following elements:
 - Beneficiary's name or Medicare Beneficiary Identifier (MBI)
 - Order Date;
 - General description of the item
 - The description can be either a general description (e.g., wheelchair or hospital bed), a HCPCS code, a HCPCS code narrative, or a brand name/model number
 - For equipment - In addition to the description of the base item, the SWO may include all concurrently ordered options, accessories or additional features that are separately billed or require an upgraded code (list each separately)
 - For supplies – In addition to the description of the base item, the DMEPOS order/prescription may include all concurrently ordered supplies that are separately billed (list each separately)
 - Treating Practitioner Name or NPI
 - Treating Practitioner's signature
 - The treating practitioner's signature on the detailed written order meets **CMS Signature Requirements** <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf>
 - Any changes or corrections have been initialed/signed and dated by the treating practitioner.
- Delivery Documentation**

Direct Delivery	Shipped/Mail Order Tracking Slip	Shipped/Mail Order Return Post-Paid Delivery Invoice
<ul style="list-style-type: none"> <input type="checkbox"/> Beneficiary's name <input type="checkbox"/> Delivery address <input type="checkbox"/> Quantity delivered <input type="checkbox"/> A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. <input type="checkbox"/> Delivery date <input type="checkbox"/> Signature of person accepting delivery <input type="checkbox"/> Relationship to beneficiary 	<ul style="list-style-type: none"> <input type="checkbox"/> Shipping invoice <ul style="list-style-type: none"> <input type="checkbox"/> Beneficiary's name <input type="checkbox"/> Delivery address <input type="checkbox"/> A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. <input type="checkbox"/> Quantity shipped <input type="checkbox"/> Tracking slip <ul style="list-style-type: none"> <input type="checkbox"/> References each individual package <input type="checkbox"/> Delivery address <input type="checkbox"/> Package I.D. #number <input type="checkbox"/> Date shipped <input type="checkbox"/> Date delivered <input type="checkbox"/> A common reference number (package ID #, PO #, etc.) links the invoice and tracking slip (may be handwritten on one or both forms by the supplier) 	<ul style="list-style-type: none"> <input type="checkbox"/> Shipping invoice <ul style="list-style-type: none"> <input type="checkbox"/> Beneficiary's name <input type="checkbox"/> Delivery address <input type="checkbox"/> A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. <input type="checkbox"/> Quantity shipped <input type="checkbox"/> Date shipped <input type="checkbox"/> Signature of person accepting delivery <input type="checkbox"/> Relationship to beneficiary <input type="checkbox"/> Delivery date



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NOTE: If a supplier utilizes a shipping service or mail order, suppliers have two options for the DOS to use on the claim:

1. Suppliers may use the shipping date as the DOS. The shipping date is defined as the date the delivery/shipping service label is created or the date the item is retrieved by the shipping service for delivery. However, such dates should not demonstrate significant variation.
2. Suppliers may use the date of delivery as the DOS on the claim.

Medical Record Documentation

- Medical records include documentation of an in-person evaluation between the beneficiary and the ordering practitioner.
 - An in-person evaluation 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;
 - 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 Medicare-covered sleep test was performed and meets all of the following qualifications:
 - The sleep test (Type I, II, III, IV, Other) meets requirements of a valid sleep test as outlined in NCD 240.4.1 and the applicable A/B MAC LCD and Billing and Coding article,
 - Test was ordered by the beneficiary's treating practitioner,
 - 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,
 - The test is FDA-approved as a diagnostic device.
 - 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.



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- 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 in-person 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 than 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 than 3 months and the beneficiary is switched to an E0470, a new initial in-person 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 practitioner'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 practitioner reviewed written report of adherence data.
 - The clinical re-evaluation is documented in a detailed narrative note in the beneficiary's chart in the format the treating practitioner 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

- An SWO for the device
- An in-person evaluation by the treating practitioner that documents the beneficiary continues to use and benefit from the device.



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Beneficiaries Entering Medicare

(Continued Use of Existing Device or Replacement Device)

- An SWO for the device
- 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 an in-person evaluation by their treating practitioner 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.
- For items that the beneficiary obtains in-person at a retail store, the signed delivery slip or a copy of the itemized sales receipt is sufficient documentation of a request for refill.

Refill Request for Non-Consumable Supplies

- For items that are delivered to 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
- For items that the beneficiary obtains in-person at a retail store, the signed delivery slip or a copy of the itemized sales receipt is sufficient documentation of a request for refill.

Continued Medical Need for the equipment/accessories/supplies is verified by either:

- A refill order from the treating practitioner 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.

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.
- Items with no physician or other licensed health care provider order must be submitted with an "EY" modifier added to each affected HCPCS code.

ONLINE RESOURCES

- **DME MAC Supplier Manual**
 - **JB:** <https://www.cgsmedicare.com/jb/pubs/supman/index.html>
 - **JC:** <https://www.cgsmedicare.com/jc/pubs/supman/index.html>



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- **Local Coverage Determinations (LCDs) and Policy Articles**
 - **JB:** <https://www.cgsmedicare.com/jb/coverage/lcdinfo.html>
 - **JC:** <https://www.cgsmedicare.com/jc/coverage/lcdinfo.html>
- **Positive Airway Pressure Resources**
 - **JB:** <https://www.cgsmedicare.com/jb/mr/pap.html>
 - **JC:** <https://www.cgsmedicare.com/jc/mr/pap.html>
- **Positive Airway Pressure (PAP) Tool**
 - **JB:** https://www.cgsmedicare.com/medicare_dynamic/dme/jb_pap/pap.aspx
 - **JC:** https://www.cgsmedicare.com/medicare_dynamic/dme/jc_pap/pap.aspx

NOTE: It is expected that the beneficiary'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.

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 Supplier Manual* and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.