DOCUMENTATION CHECKLIST

POSITIVE AIRWAY PRESSURE (PAP) ACCESSORIES AND SUPPLIES

REQUIRED DOCUMENTATION

This Checklist only addresses accessories and supplies used with a PAP (E0601 or E0470) device – if a PAP device is also provided, refer to the appropriate PAP checklist.

- ☐ **Standard Written Order (SWO)** for any accessories/supplies:
  - ○ 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)
  - ○ Quantity to be dispensed, if applicable
  - ○ 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.
- ☐ **Refill Request**

For dates of service prior to January 1, 2024

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** ☐ Itemized Sales Receipt	☐ Name of beneficiary or authorized rep (indicate relationship) ☐ Description of each item being requested ☐ 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) ☐ 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
	NOTE: For non-consumable supplies i.e., those more durable items that are not used up but may need periodic replacement (e.g., PAP and RAD supplies) the supplier must assess whether the supplies remain functional, providing replacement (a refill) only when the supply item(s) is no longer able to function. The supplier must document the functional condition of the item(s) being refilled in sufficient detail to demonstrate the cause of the dysfunction that necessitates replacement (refill).	

For dates of service on and after January 1, 2024	
Items Were Obtained In Person at a Retail Store	**Delivered Refill Communications**
☐ Signed delivery slip or copy of itemized sales receipt ☐ Delivery slip/receipt should indicate items were picked up at store front	☐ Beneficiary name and/or authorized representative (Suggested: if someone other than the beneficiary include this person's relationship to the beneficiary) ☐ Date of Request ☐ Description of each item requested ☐ Documentation of affirmative response indicating a need for the refill ☐ Contact must occur no sooner than 30 calendar days prior to the expected end of the current supply ☐ Shipment/delivery occur no sooner than 10 calendar days prior to expected end of current supply

Medical Record Documentation

Beneficiaries Entering Medicare:

- ☐ Sleep test – There must be 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 must have 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.

Replacement of Accessories During the 13-month capped rental period for the PAP device:

- ☐ In-person clinical evaluation that occurred prior to the diagnostic sleep test and assessed the beneficiary for obstructive sleep apnea (OSA)
- ☐ Sleep test information that verifies the AHI/RDI coverage criteria located in the Positive Airway Pressure (PAP) Devices for Treatment of Obstructive Sleep Apnea LCD are met
- ☐ Documentation supporting that the diagnostic sleep test met coverage and reimbursement requirements, outlined in the CMS National Coverage Determination (NCD) 240.4.1 and A/B MAC LCDs and Billing and Coding articles
- ☐ Documentation of a diagnosis of OSA
- ☐ The beneficiary and/or caregiver received instructions 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.

The following additional criteria must be met when replacing accessories during months 4-13 of the capped rental period for the PAP device:

- ☐ In-person clinical re-evaluation that took place between the 31st and 91st day after initiating PAP therapy and that documents the beneficiary is benefitting 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 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 of Accessories for Medicare-Paid, Beneficiary-Owned PAP devices:

- ☐ For claims for replacement accessories (e.g., interfaces, tubing, filters, humidifier chambers), if Medicare paid for the base PAP device initially (i.e., for 13 months of continuous use), the medical necessity for the beneficiary-owned base PAP device is assumed to have been established.
- ☐ Documentation that the base DME item continues to meet medical need*
- ☐ The replacement of specific accessories or furnishing of new accessories remain medically necessary and are essential for the effective use of the base DME.

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

- ○ A recent order/prescription by the treating practitioner for refills of supplies;
- ○ A recent order/prescription by the treating practitioner for repairs;
- ○ A recent change in an order/prescription;
- ○ Timely documentation in the beneficiary's medical record showing usage of the item
  - ☐ Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in the policy.

- ☐ **Delivery Documentation**

Direct Delivery	**Shipped/Mail Order Tracking Slip**	**Shipped/Mail Order Return Post-Paid Delivery Invoice**
☐ Beneficiary's name ☐ Delivery address ☐ Quantity delivered ☐ 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. ☐ Delivery date ☐ Signature of person accepting delivery ☐ Relationship to beneficiary	☐ Shipping invoice ○ Beneficiary's name ○ Delivery address ○ 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. ○ Quantity shipped ☐ Tracking slip ○ References each individual package ○ Delivery address ○ Package I.D. #number ○ Date shipped ○ Date delivered ☐ 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)	☐ Shipping invoice ○ Beneficiary's name ○ Delivery address ○ 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. ○ Quantity shipped ○ Date shipped ○ Signature of person accepting delivery ○ Relationship to beneficiary ○ Delivery date

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.

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
- **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
- **MLN Matters® MM9741**
  - https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9741.pdf

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.