



POSITIVE AIRWAY PRESSURE (PAP) DEVICES: COMPLYING WITH DOCUMENTATION & COVERAGE REQUIREMENTS

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Please note: The information in this publication applies only to the Medicare Fee-For-Service (FFS) Program (also known as Original Medicare).

This publication describes common Comprehensive Error Rate Testing (CERT) Program errors related to Positive Airway Pressure (PAP) devices and provides a checklist of the documentation needed to support a claim submitted to Medicare for PAPs.

The Centers for Medicare & Medicaid Services (CMS) developed the CERT Program to produce a national Medicare Fee-For-Service (FFS) error rate, as required by the Improper Payments Information Act. CERT randomly selects a small sample of Medicare FFS claims and reviews those claims and medical records from providers/suppliers who submitted them for compliance with Medicare coverage, coding, and billing rules.

In order to accurately measure the performance of the Medicare claims processing contractors and to gain insight into the causes of errors, CMS calculates both a national Medicare FFS paid claims error rate and a provider compliance error rate. The results of these reviews are published in an annual report and semi-annual updates.

CMS strives to eliminate improper payments in the Medicare Program to maintain the Medicare trust funds and protect patients.

Common PAP Device Errors

1. No documentation of the treating physician's initial face-to-face clinical evaluation conducted prior to the sleep study to assess the patient for obstructive sleep apnea (OSA).
2. No documentation of a Medicare-covered sleep study supporting medical necessity.
3. No documentation of the treating physician's signed and dated order describing the item(s) dispensed.
4. No documentation of the treating physician's face-to-face reevaluation, within the first 3 months of initiating therapy (but no sooner than the 31st day), which documents both improvement in subjective symptoms of OSA and objective data related to adherence to PAP therapy.

What Do I Need to Know to Prevent Errors?

1. Request the treating physician's initial face-to-face evaluation performed prior to the sleep study. This evaluation assesses the patient for OSA and is one of four criteria that may qualify the patient for PAP therapy.
2. Retain a copy of the Medicare-covered sleep study as soon as the order is received. The sleep study must meet certain conditions for coverage and is one of four criteria that may qualify the patient for PAP therapy.
3. Review the treating order to ensure that all equipment and supplies being dispensed are itemized on the order.
4. Remind the patient that a reevaluation is required for continuing PAP coverage beyond the initial three months. This reevaluation must document that the patient is benefiting from and adhering to the PAP therapy as ordered.

Documentation Requirements

PAP devices for the treatment of OSA are covered by Medicare only if the criteria in Table 1 and Table 2 are met.

Table 1. Initial Coverage for HCPCS Codes E0601 and E0470

Device	Criteria	Detailed Order
HCPCS code E0601	<p>A. A face-to-face clinical evaluation by the treating physician prior to the sleep study test to assess the patient for OSA.</p> <p>B. A Medicare-covered sleep test that meets either of the following:</p> <ol style="list-style-type: none"> 1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events with a minimum of 30 events; or 2. 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: <ol style="list-style-type: none"> a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or b. Hypertension, ischemic heart disease, or history of stroke. <p>C. The patient and/or their caregiver have received instruction from the supplier of the PAP device and accessories in the proper use and care of the equipment.</p>	<ul style="list-style-type: none"> • Patient name; • The description of item(s) to be dispensed; • The ordering physician's legible signature; and • The date of the ordering physician's signature.

Table 1. Initial Coverage for HCPCS Codes E0601 and E0470 (cont.)

Device	Criteria	Detailed Order
<p>HCPCS code E0470</p>	<p>Meets coverage criteria A–C, as outlined above, and criterion D:</p> <p>D. A HCPCS code E0601 device has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting.</p> <p>Note: Ineffective is defined as documented failure to meet therapeutic goals using a HCPCS code E0601 device during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings).</p>	<ul style="list-style-type: none"> • Patient name; • The description of item(s) to be dispensed; • The ordering physician’s legible signature; and • The date of the ordering physician’s signature. <p>Note: Orders for continuing supplies should include appropriate information on the quantity used, frequency of change, and duration of need. For additional information on detailed written orders, refer to the Medicare Program Integrity Manual (PIM), Chapter 5, section 5.2.3 at https://www.cms.gov/manuals/downloads/pim83c05.pdf.</p>

Table 2. Continued Coverage for HCPCS Codes E0601 and E0470 Beyond the First Three Months of Therapy

Device	Criteria	Detailed Order
HCPCS codes E0601 and E0470	<p>The treating physician must perform a clinical reevaluation no sooner than the 31st day, but no later than the 91st day after initiating therapy, which documents the following:</p> <ul style="list-style-type: none"> • A face-to-face clinical reevaluation by the treating physician with documentation that symptoms of OSA are improved; and • Objective evidence of adherence to use (defined as use of PAP devices for 4 or more hours per night on 70% of nights during a consecutive 30-day period anytime during the first 3 months of initial use) of the PAP device, reviewed by the treating physician. <p>Note: Documentation of adherence to PAP therapy shall be accomplished through direct download or visual inspection of usage data with documentation provided in a written report format to be reviewed by the treating physician and included in the patient's medical record.</p>	<ul style="list-style-type: none"> • Patient name; • The description of item(s) to be dispensed; • The ordering physician's legible signature; and • The date of the ordering physician's signature.

Table 2. Continued Coverage for HCPCS Codes E0601 and E0470 Beyond the First Three Months of Therapy (cont.)

Device	Criteria	Detailed Order
HCPCS codes E0601 and E0470	<p>Patients who fail the initial 12-week trial are eligible to requalify for a PAP device but must have both:</p> <ol style="list-style-type: none"> 1. Face-to-face clinical reevaluation by the treating physician to determine the etiology of the failure to respond to PAP therapy; and 2. Repeat sleep test in a facility-based setting (Type I study). <p>For patients who received a PAP device prior to enrollment in FFS Medicare and are seeking Medicare coverage of either rental of the device, a replacement PAP device, and/or accessories, both of the following coverage requirements must be met:</p> <ol style="list-style-type: none"> 1. The patient had a documented sleep test prior to FFS Medicare enrollment that meets the Medicare AHI/RDI coverage criteria in effect at the time that the patient seeks Medicare coverage of a replacement PAP device and/or accessories; and 2. The patient had a face-to-face clinical evaluation following FFS Medicare enrollment by the treating physician who documented in the patient's medical record that: <ol style="list-style-type: none"> a. The patient has a diagnosis of OSA, and b. The patient continues to use the PAP device. <p>If either criteria 1 or 2 above are not met, the claim will be denied as not medically necessary.</p> <p>In these situations, there is no requirement for a clinical reevaluation or for objective documentation of adherence to use of the device.</p>	<ul style="list-style-type: none"> • Patient name; • The description of item(s) to be dispensed; • The ordering physician's legible signature; and • The date of the ordering physician's signature.

Additional Documentation Requirements

- For long-term PAP therapy, documentation from the supplier or physician must support that the patient continues to use the PAP device.
- Proof of delivery of equipment and/or supplies is required.

Tips for Success

- Although medical records are not required to be submitted with a claim, they **must** be available upon request. We suggest that you consider gathering the relevant records at the time you dispense the item to the patient. This practice minimizes having to go back to the ordering physician at a later date. Please be aware that medical records are required to support the continued use of dispensed items.
- Clinical documentation submitted **must** support the medical necessity of the base item before payment may be considered for accessories and/or supplies.
- An order/prescription **must** be signed and dated by the treating physician who ordered the item in question. (Chapter 5, Section 5.2.3 of the Medicare PIM states: “Someone other than the physician may complete the detailed description of the item. However, the treating physician/practitioner must review the detailed description and personally sign and date the order to indicate agreement.”)

Learn More

Detailed education is available from the DME Medicare Administrative Contractors (MACs) serving Jurisdictions A, B, C, and D. Education is provided in a variety of formats including: self-paced online tutorials, podcasts, video education, and webinars. Additionally, each DME MAC jurisdiction staffs a Regional CERT Coordinator who can assist you with various CERT-related questions and/or concerns, such as:

- General CERT information;
- Detailed review results of a CERT claim;
- Explanation of a CERT-related overpayment;
- How to have a CERT overpayment re-reviewed;
- Clarification of the type of documentation CERT is requesting; and
- Why you may still be receiving request letters for medical records when you have already submitted the documentation.

DME MAC jurisdiction website addresses and contact information can be found in the Review Contractor Directory - Interactive Map at <https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-FFS-compliance-programs/review-contractor-directory-interactive-map>.

For a complete listing of all national educational products related to provider compliance, including CERT, please visit the Medicare Learning Network® (MLN) Products webpage at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts>.

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