DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

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Continuous and Bi-level Positive Airway Pressure (CPAP/BPAP) Devices:

Complying with Documentation & Coverage Requirements

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

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

The Centers for Medicare & Medicaid Services (CMS) developed the CERT Program to produce a national Medicare Fee-For-Service (FFS) improper payment rate, as required by the Improper Payments Information Act of 2002, as amended by the Improper Payments Elimination and Recovery Improvement Act of 2012. CERT randomly selects a statistically-valid, stratified sample of Medicare FFS claims and reviews those claims and related medical records for compliance with Medicare coverage, payment, coding, and billing rules.

To accurately measure the performance of the Medicare claims processing contractors and gain insight into the causes of errors, CMS calculates a national Medicare FFS improper payment rate and improper payment rates by claim type. The results of these reviews are reported annually. In 2012, the improper payment rate for PAP devices was 56 percent. The projected improper payment amount for PAP devices during the 2012 report period was approximately $356 million.

CMS strives to eliminate improper payments in the Medicare Program to maintain the Medicare Trust Fund while protecting patients from medically unnecessary services or supplies.

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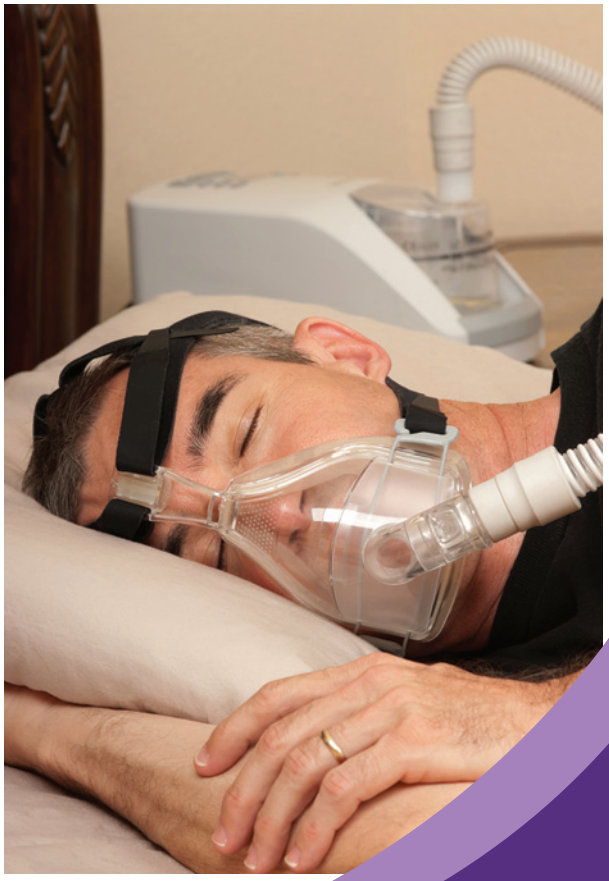
Common PAP Device Errors

1. No documentation of the treating physician's initial face-to-face clinical evaluation conducted before the sleep study to assess the patient for Obstructive Sleep Apnea (OSA).
2. No physician documentation that a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist has had a face-to-face encounter with the individual involved during the 6-month period preceding such written order.
3. No documentation of a Medicare-covered sleep study supporting medical necessity.
4. No documentation of the treating physician's signed and dated order describing the item(s) dispensed.
5. No documentation of the treating physician's face-to-face re-evaluation, within the first three months of initiating therapy (but after the 31st day), which documents both improvement in subjective symptoms of OSA and objective data related to adherence to PAP therapy.
6. No documentation of continued need and continued use.

What Do I Need to Know to Prevent Errors?

1. Request the treating physician's initial face-to-face evaluation performed before 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 dispensed are itemized on the order. Ensure that there has been a face-to-face encounter during the 6 months prior to the written order.
4. Remind the patient that a re-evaluation is required for continuing PAP coverage beyond the initial 3 months. This re-evaluation must document that the patient is benefiting from, and adhering to, the PAP therapy as ordered (that is, continued need and continued use). This requirement may be facilitated by the use of compliance cards/memory cards in the PAP device.



Documentation Requirements

Use the following Healthcare Common Procedure Coding System (HCPCS) codes, listed in Table 1, to report a PAP device.

Table 1. HCPCS Codes for PAP Devices

HCPCS Code	Code Descriptor
E0601	Continuous positive airway pressure (CPAP) device
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g. nasal or facial mask (intermittent assist device with continuous positive airway pressure device)

PAP devices for the treatment of OSA are covered by Medicare only if they meet the criteria in Tables 2 and 3 on pages 4 and 5. For additional information on detailed written orders, visit the Medicare Program Integrity Manual (PIM), Chapter 5, Section 5.2.3 at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c05.pdf on the CMS website.

Table 2. Initial Coverage for HCPCS Codes E0601 and E0470

Device	Code Criteria	Detailed Order
HCPCS code E0601	A. A face-to-face clinical evaluation by the treating physician before the sleep test to assess the patient for OSA. B. A Medicare-covered sleep test that meets one of the following: 1. 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** 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: a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or b. Hypertension, ischemic heart disease, or history of stroke. C. The patient and/or their caregiver received instructions from the supplier of the PAP device and accessories in the proper use and care of the equipment. D. A face-to-face encounter during the 6-month period preceding the written order. E. Objective evidence of continued need and continued use.	• Patient name; • Description of item(s) to be dispensed; • Prescribing practitioner's National Provider Identifier (NPI); • Ordering physician's legible signature; and • Date of the ordering physician's signature.
HCPCS code E0470	Meets coverage criteria A-E, as outlined above, and criterion A, below: A. A HCPCS code E0601 device has been tried and proven ineffective based on a therapeutic trial conducted either in a facility or in a home setting. **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 (such as, proper mask selection and fitting and appropriate pressure settings).	• Patient name; • Description of item(s) to be dispensed; • Prescribing practitioner's NPI; • Ordering physician's legible signature; and • Date of the ordering physician's signature.

Table 3. Continued Coverage for HCPCS Codes E0601 and E0470 Beyond the First 3 Months of Therapy

Device	Code Criteria	Detailed Order
HCPCS codes E0601 and E0470	The treating physician must perform a clinical re-evaluation after the 31st day, but before the 91st day after initiating therapy, which documents the following: • A face-to-face clinical re-evaluation 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. **NOTE:** Documentation of adherence to PAP therapy must be determined through direct download or visual inspection of usage data with written documentation provided in a report to be reviewed by the treating physician and included in the patient's medical record. **Patients who fail the initial 12-week trial** are eligible to re-qualify for a PAP device but must have both: 1. A face-to-face clinical re-evaluation by the treating physician to determine the etiology of the failure to respond to PAP therapy; and 2. A repeat sleep test in a facility-based setting (Type I study). **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: 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: a. The patient has a diagnosis of OSA; and b. The patient continues to use the PAP device. If either criterion 1 or 2 above is not met, the claim will be denied as not medically necessary. In these situations, there is no requirement for a clinical re-evaluation or for objective documentation of adherence to use of the device.	• Patient name; • Description of item(s) to be dispensed; • Ordering physician's legible signature; and • Date of the ordering physician's signature.

NOTE: Orders for continuing supplies should include appropriate information on the quantity used, frequency of change, and duration of need.

Additional Documentation Requirements

1. For long-term PAP therapy, documentation from the supplier or physician must support that the patient continues to use the PAP device.
2. 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 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 later. Please be aware that medical records are required to support the continued use of dispensed items.
- Submitted clinical documentation must support the medical necessity of the base item before payment may be made 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 must review the detailed description and personally sign and date the order to indicate agreement.”)

Resources

Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) serving Jurisdictions A, B, C, and D provide detailed education in a variety of formats including: self-paced online tutorials, podcasts, video education, and webinars. Each DME MAC jurisdiction staffs a Regional CERT Coordinator who can assist you with various CERT-related questions or concerns, such as:

- Basic CERT information;
- Clarification of the type of documentation requested by CERT;
- Detailed review results of a CERT claim;
- Explanation of a CERT-related overpayment;
- Explanation of why you continue receiving request letters for medical records when you have already submitted the documentation; and
- How to have a CERT overpayment re-reviewed.

You can find DME MAC jurisdiction website addresses and Regional CERT Coordinator contact information in Table 4.

Table 4. Website Addresses and Regional CERT Coordinators for Each DME MAC

Jurisdiction	Website Address	Regional CERT Coordinator
Jurisdiction A: NHIC, Corp.	http://www.medicarenhic.com	Alina Jimenez 323-432-7840 alina.jimenez@hp.com
Jurisdiction B: National Government Services (NGS)	http://www.ngsmedicare.com	Stacie McMichel 317-841-4612 Stacie.McMichel@wellpoint.com
Jurisdiction C: CGS Administrators, LLC (CGS)	http://www.cgsmedicare.com/jc	Brenda Normandia 615-782-4485 Brenda.Normandia2@cigna.com
Jurisdiction D: Noridian Administrative Services, LLC (NAS)	https://www.noridianmedicare.com/dme	Jennifer Huber 701-433-3064 jennifer.huber@noridian.com and Melissa Gordon 701-433-3092 melissa.gordon@noridian.com

For more information on Medicare coverage of PAP devices, refer to the resources listed in Table 5.

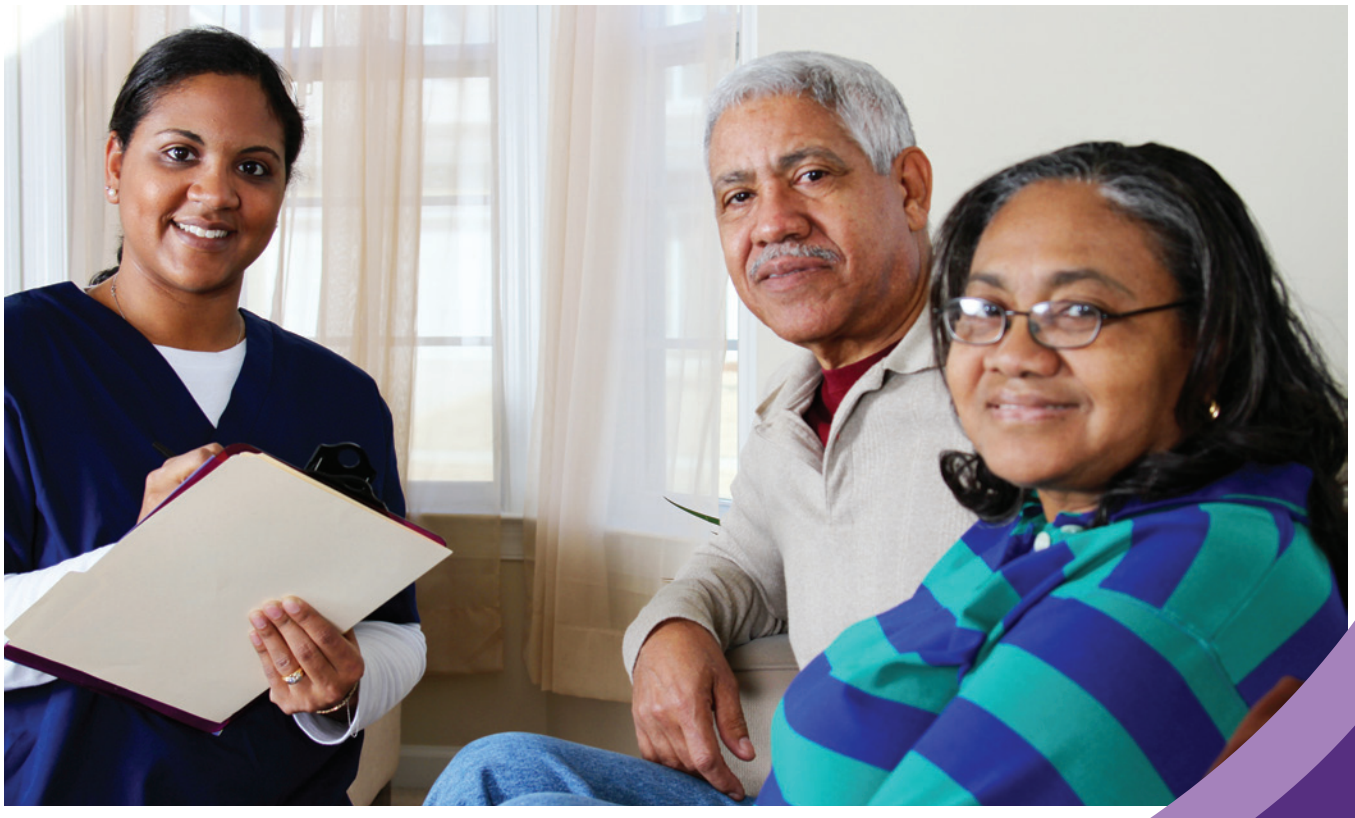


Table 5. Resources

Resource	Website and Description
CMS Internet-Only Manual, "Medicare Claims Processing Manual" (Publication 100-04), Chapter 20	The "Medicare Claims Processing Manual" describes basic billing requirements. Chapter 20 focuses on DME billing. Chapter 20 of this manual is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf on the CMS website.
Medicare Coverage Database	The Medicare Coverage Database permits searching of National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and DME MAC provider education articles regarding coverage policies. This database is available at http://www.cms.gov/medicare-coverage-database on the CMS website.
Medicare Learning Network® (MLN) Podcast, "Positive Airway Pressure (PAP) Devices: Complying with Documentation & Coverage Requirements"	This podcast is designed to provide education on the documentation and coverage requirements needed to submit Medicare claims for PAP devices. This podcast is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Multimedia-Items/CMS1252820.html on the CMS website.
MLN Guided Pathways to Medicare Resources	The MLN Educational Web Guides MLN Guided Pathways to Medicare Resources helps health care professionals gain knowledge on resources and products related to Medicare and the CMS website. For more information, please refer to the section about your provider type in the "MLN Guided Pathways to Medicare Resources Provider Specific" booklet available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/Guided_Pathways_Provider_Specific_Booklet.pdf on the CMS website. All other "Guided Pathways" resources are available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Guided_Pathways.html on the CMS website.
MLN Products	The MLN Products web page provides a complete listing of all national educational products related to provider compliance, including CERT. These products are available at http://go.cms.gov/MLNProducts on the CMS website.
PAP Devices - Required Documentation	The links below lead directly to the PAP documentation requirement pages for each DME MAC Jurisdiction A - D: Jurisdiction A: http://www.medicarenhic.com/dme/articles/050109_certchecklist.pdf Jurisdiction B: http://www.ngsmedicare.com/ngs/wcm/connect/9df9410044ba0c9da079bd55559be69e/894_0812_PAP.pdf?MOD=AJPERES Jurisdiction C: http://www.cgsmedicare.com/jc/coverage/mr/PDF/MR_checklist_PAP1.pdf Jurisdiction D: https://www.noridianmedicare.com/dme/coverage/docs/checklists/positive_airway_pressure_pap_devices.html
Provider Compliance	For more information about provider compliance, visit http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html on the CMS website, or scan the Quick Response (QR) code on the right with your mobile device.

This fact sheet was current at the time it was published or uploaded onto the web. Medicare policy changes frequently so links to the source documents have been provided within the document for your reference.

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