

January 2018

Positive Airway Pressure Devices

Dear Clinician,

Data from the Comprehensive Error Rate Testing (CERT) program projects that ~\$500M in inappropriate payments are made each year for positive airway pressure (PAP) devices used to treat obstructive sleep apnea (OSA). A significant proportion of the claim errors observed in the data relate to inadequate or missing documentation supporting the need for the PAP device and/or supplies. The information below is intended to assist you in documenting that your patient meets Medicare guidelines for replacement of a PAP device or supplies. A separate “Dear Clinician” letter addresses documentation necessary for your patient to receive their initial prescription of a PAP device.

There are two scenarios in which your patient diagnosed with OSA may qualify for a replacement device and/or supplies. First, they may have initially had their device paid for by Medicare. Alternatively, and more commonly, their device was initially prescribed prior to entering Medicare. The requirements for a replacement device differ for each of these scenarios and are described below.

Scenario 1: Initial Device Paid by Medicare

For your patient who was diagnosed with OSA while enrolled in Fee-For-Service (FFS) Medicare and Medicare paid for their PAP device, replacement of the device is based on the patient’s continuous use of the device and the statutory limitation for replacement based on a five (5) year reasonable useful lifetime (RUL) for the device. Medicare does not pay for routine replacement. Only if the device is lost, stolen or incurs irreparable damage due to a specific incident may a PAP device be replaced prior to the 5 year RUL. If the PAP device has exceeded the 5 year RUL, the patient may elect to receive a new device; however, there is no Medicare rule that requires the patient to do so.

Documentation requirements differ, depending on whether or not the patient is replacing their PAP device before or after the 5 year RUL:

- **Replacement before 5 years:** If a PAP device is replaced during the 5 year RUL because of loss, theft, or irreparable damage due to a specific incident, there is no requirement for a new sleep test or trial period; however, you must provide:
 - A new detailed written order obtained prior to delivery; and,
 - Face-to-face evaluation within six (6) months prior to the date of the order that documents the beneficiary has a condition that requires the use of the device (i.e., OSA).
- **Replacement after 5 years:** If a PAP device is replaced after the 5 year RUL, there is no requirement for a new sleep test or trial period; however, you must provide:
 - A new written order that must be received by the supplier prior to delivery; and,
 - Complete a face-to-face evaluation within six (6) months prior to the date of the written order that documents that your patient:

- Has a condition that requires the use of the PAP device (i.e., OSA); and,
- Continues to use the PAP device; and,
- Is benefitting from use of the PAP device.

Scenario 2: Initial Device Received Prior to Medicare

For your patient who received a PAP device prior to enrollment in Fee-For-Service Medicare and is now seeking Medicare coverage of either a replacement PAP device and/or accessories, the following coverage requirements must be met:

1. Sleep test – There must be documentation that the patient had a sleep test, prior to FFS Medicare, which meets the FFS Medicare AHI/RDI coverage criteria in effect at the time that your patient seeks a replacement PAP device and/or accessories. As a reminder, those current requirements are:
 - AHI or RDI is greater than or equal to 15 events per hour, with a minimum of 30 events; or,
 - AHI or RDI is 5-14 events per hour (minimum of 10 events) with documentation of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, or history of stroke.

(Note: For purposes of this policy, the calculation of the AHI or RDI includes only apneas and hypopneas. Respiratory effort-related arousals or RERAs must not be used in the calculation of the AHI or RDI. In addition, Medicare defines hypopnea as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.)

2. Clinical Evaluation – Following enrollment in FFS Medicare, the beneficiary must have a face-to-face evaluation with you to document in their medical record that:
 - a. They have a diagnosis of obstructive sleep apnea; and,
 - b. They continue to use and benefit from the PAP device.

Note that you must conduct the clinical evaluation face-to-face with your patient within six (6) months prior to the date of your order for the PAP device and the supplier must receive your written order prior to delivering the device to your patient.

Additional coverage and payment rules for sleep tests may be found in the LCDs for the applicable Medicare A/B MAC contractor. There may be differences between those LCDs and the DME MAC LCD. For the purposes of coverage of PAP therapy, the DME MAC coverage criteria take precedence.

The complete medical policy may be viewed on the DME MACS' individual websites or in the CMS Medicare Coverage Database. The Epworth Sleepiness Scale may be found in the Appendices section of the LCD. Clinicians are reminded that in order for these items to be reimbursed for your patients, the DME supplier may collect medical documentation including copies of your clinical evaluation and the report of the sleep study. Please cooperate with them so that they can provide the device that you have ordered for your patient.

Sincerely,

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