



A CELERIAN GROUP COMPANY

POSITIVE AIRWAY PRESSURE (PAP) DEVICES: REPLACEMENT

Replacement PAP - Revised April 2021

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Dear Physician,

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 Physician” 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, 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 year reasonable useful lifetime (RUL) for the device. Medicare does not pay for routine replacement. A PAP device may be replaced prior to the 5-year RUL only if the device is lost, stolen, or incurs irreparable damage due to a specific incident. 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 clinical evaluation, sleep test or trial period; however, you must provide
 - A new standard written order (SWO)
- 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 SWO
 - Complete an in-person visit that documents that your patient
 - Has a condition that requires the use of the PAP device (such as OSA)
 - Continues to use the PAP device
 - 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 FFS 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 apnea-hypopnea index (AHI)/respiratory disturbance index (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
 - o AHI or RDI is greater than or equal to 15 events per hour, with a minimum of 30 events; or
 - o 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 respiratory effort related arousals (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 an in-person evaluation with you to document in their medical record that
 - a. They have a diagnosis of obstructive sleep apnea.
 - b. They continue to use the PAP device.

Additional coverage and payment rules for sleep tests may be found in the LCDs for the applicable Medicare A/B MAC contractor. We recommend you read these for your state. There may be differences between those Local Coverage Determinations (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. Physicians 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 may provide the device that you have ordered for your patient.

Sincerely,

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