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POSITIVE AIRWAY PRESSURE (PAP) DEVICES: REPLACEMENT
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Dear Physician,

For Medicare to provide reimbursement for the replacement of positive airway pressure (PAP) devices used to treat obstructive sleep apnea (OSA), the medical necessity documentation requirements for coverage criteria must be met. The following information is intended to provide you with summary guidance on Medicare's coverage criteria and documentation requirements for the replacement of a PAP device or supplies.

A separate "Dear Physician" letter addresses documentation necessary for your patient to receive their initial PAP device.

There are two scenarios in which your patient diagnosed with OSA may qualify for a replacement device and/or supplies. First, the initial device was paid for by Medicare. Second, the initial device was paid prior to entering Medicare. The requirements for a replacement PAP 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. 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 the patient is replacing their PAP device before or after the 5-year RUL:

- Replacement **before** 5 years: If a PAP device is replaced before the 5-year RUL due to 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; and
    - A clinical evaluation: an in-person or Medicare-approved telehealth visit that documents your patient:
        - Has a diagnosis of OSA;
        - Continues to use the PAP device; and,
        - Is benefitting from use of the PAP device.

For the replacement of accessories or supplies (e.g., interfaces, tubing, filters, humidifier chambers), for a PAP device initially paid by Medicare, the medical necessity for the PAP device is assumed to have been established. Therefore, to make a payment determination for replacement accessories or supplies:

1. The treating practitioner's records must contain documentation that the PAP device continues to meet medical need; and,
2. The supplier's records must support the need to replace the accessory to maintain the equipment's functionality and meet the beneficiary's medical need.

CGS Administrators, LLC is a Medicare Part A, B, Home Health and Hospice, and DME Medicare Administrative Contractor for the Centers for Medicare & Medicaid Services.

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Scenario 2: Initial Device Received Prior to Medicare

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

1. A 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 your patient seeks a replacement PAP device and/or accessories. As a reminder, those current requirements are:
    - An AHI or RDI greater than or equal to 15 events per hour, with a minimum of 30 events; or,
    - An AHI or RDI of 5-14 events per hour, with a minimum of 10 events, and documentation of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia or 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 (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. A clinical evaluation: following enrollment in FFS Medicare, there must be an in-person or Medicare-approved telehealth evaluation that documents your patient:
    a. Has a diagnosis of OSA; and,
    b. Continues to use the PAP device.

This article is intended to be a general summary. It is not intended to take the place of the written law, regulations, national coverage determinations (NCDs) or local coverage determinations (LCDs). Coverage, coding and documentation requirements may be found in the Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea LCD (L33718) and LCD-Related Policy Article (A52467), located in the Medicare Coverage Database on the CMS website at https://www.cms.gov/medicare-coverage-database.

Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers are your partners in caring for your patient. They will not receive payment from Medicare for the items that are ordered for your patient if you do not provide information from the patient's medical record to the supplier when it is requested. Furthermore, if you do not provide the requested information to the supplier, your patient may have to pay for the item. Finally, your cooperation is a legal requirement as outlined in the Social Security Act which is the law governing Medicare. Help your DMEPOS supplier continue to provide the highest quality of service to your patient by promptly providing them with the requested information.

Your participation and cooperation with the supplier in this process will allow your patient to receive the most appropriate type of equipment. We appreciate all your efforts in providing quality services to your Medicare patients.

Sincerely,

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