Positive Airway Pressure Devices (PAP)

A Collaboration Webinar presented by the A/B and DME Medicare Administrative Contractors

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- WPS Government Health Administrators: https://www.wpsgha.com/

Agenda

- Patient Care is a Partnership
- Definitions and Acronyms
- Coverage Criteria
- Replacement
- Standard Written Order (SWO)
- Comprehensive Error Rate Testing (CERT)
- Resources
- Questions

Partners in Patient Care

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DMEPOS Suppliers Need Your Help

- DMEPOS suppliers are your partners in caring for your patient
- Information contained directly in the contemporaneous medical record is the source required to justify payment for DMEPOS
- Suppliers will not receive payment from Medicare for the items that are ordered if they do not receive authenticated medical records to support medical need
- Not providing this information may result in patients having to pay for the item themselves
- When you write orders or make referrals to another provider, be sure to include all the necessary information to support medical necessity of the items ordered

HIPAA Privacy Rules

- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits disclosure of protected health information without beneficiary authorization to carry out treatment, payment or health care operations.
- The DME MAC, UPIC and CERT perform health care operations as agents of the Centers for Medicare and Medicaid Services (CMS). Providing the requested documentation is in keeping with the HIPAA Privacy Rule.
- Help DMEPOS suppliers continue to provide good service to patients by promptly providing the information to support medical necessity
- “Collaborative Patient Care is a Provider Partnership” MLN Fact Sheet https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Caring-for-Medicare-Patients-is-a-Partnership.pdf

Definitions and Acronyms

Acronyms

- **ABN:** Advance Beneficiary Notice of Noncoverage
- **AHI:** Apnea-Hypopnea Index
- **CERT:** Comprehensive Error Rate Testing
- **OSA:** Obstructive Sleep Apnea
- **PAP:** Positive Airway Pressure Device
  Note: PAP refers to both a single-level continuous positive airway pressure device (E0601) and a bi-level respiratory assist device without back-up rate (E0470) when it is used in the treatment of obstructive sleep apnea.
- **PSG:** Polysomnogram
- **RAD:** Respiratory Assist Device
- **RDI:** Respiratory Disturbance Index
- **RUL:** Reasonable Useful Lifetime
- **SWO:** Standard Written Order

Obstructive Sleep Apnea

- Apnea
  - Cessation of airflow for at least 10 seconds
- Hypopnea
  - Abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoraco-abdominal movement or air flow as compared to baseline and with at least a 4% decrease in oxygen saturation

Apnea/Hypopnea Index
Respiratory Disturbance Index

- Apnea-Hypopnea Index (AHI)
  - The average number of episodes of apnea and hypopnea per hour of **sleep** without the use of a positive airway pressure device
- Respiratory Disturbance Index (RDI)
  - The average number of apneas plus hypopneas per hour of **recording** without the use of a positive airway pressure device

Note: For the purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of either AHI or RDI

Continuous Positive Airway Pressure Device (E0601)

- Delivers a constant level of positive air by way of tubing and a noninvasive interface.
  - Within a single respiratory cycle
    - An inspiration followed by an expiration
  - Assists spontaneous respiratory efforts
  - Supplements volume of inspired air in the lungs
- Includes auto-titrating single-level CPAP device

Respiratory Assist Devices (RAD)

- RAD with backup (E0471) delivers adjustable, variable levels of positive air pressure by way of tubing and a noninvasive interface
  - Within a single respiratory cycle
  - Assists spontaneous respiratory efforts
  - Supplements volume of inspired air in the lungs
  - Includes a timed backup feature when spontaneous inspiratory efforts fail to occur
- **E0471 is denied as not reasonable and necessary if the primary diagnosis is OSA**
- RAD without backup (E0470) delivers adjustable, variable levels of positive air pressure by way of tubing and a noninvasive interface
  - Within a single respiratory cycle
  - Assists spontaneous respiratory efforts
  - Supplements volume of inspired air in the lungs

Sleep Tests

- Coverage of a PAP device for the treatment of OSA is limited to claims where the diagnosis of OSA is based on:
  - A sleep test (Type I, II, III, IV, Other) that meets the Medicare requirements for a valid sleep test as outlined in NCD 240.4.1 and the applicable A/B MAC LCD and Billing and Coding article; and,
  - A sleep test that is approved by the Food and Drug Administration (FDA) as a diagnostic device; and,
  - The sleep test results meet the coverage criteria in effect for the date of service of the claim for the PAP device; and,
  - The sleep test is ordered by the beneficiary's treating practitioner; and,
  - The sleep test is conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements.

Coverage Criteria

Overview of Medicare's PAP Coverage

- In-person evaluation to discuss sleep-related issues
- Following the in-person evaluation, order a facility-based PSG, or an inpatient hospital-based or home-based sleep test that meets coverage and payment requirements
- Sleep study must show minimum AHI or RDI requirements are met to demonstrate diagnosis of OSA
- SWO for device and accessories
- Instructions on proper use and care of the device (from the supplier, usually at delivery)
- Initial 3-month trial begins at delivery

Overview of Continued Coverage Beyond 3 Months

- In-person evaluation conducted between 31st and 91st day after initiating therapy
  - Benefiting from therapy
  - Adherence/Compliance regimen
- Additional coverage guidelines for E0470 when an E0601 has been tried and proven ineffective
- Completion of PAP device rental (13 months of total rental)
- Medicare will pay for related accessories during the reasonable useful lifetime (5 years)

Initial Coverage Criteria – E0601

- An E0601 device is covered for OSA if criteria A-C are met:

  A. Beneficiary has in-person clinical evaluation by the treating practitioner prior to sleep test to assess them for OSA

  B. Beneficiary has sleep test that meets either criteria 1 or 2:

     1. AHI or RDI is greater than or equal to15 events per hour with minimum 30 events

     2. AHI or RDI greater than or equal to 5 and less than or equal to 14 events per hour with minimum of 10 events and documentation of:

        - Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia, or
        - Hypertension, ischemic heart disease, or history of stroke.

  C. Beneficiary and/or caregiver has received instruction from the supplier of the device in proper use and care of the equipment.

Initial Coverage Criteria – E0470

- RAD without backup rate (E0470) covered for those beneficiaries with OSA who meet criteria A-C, in addition to criterion D:

  D. An E0601 has been tried and proven ineffective based on therapeutic trial conducted in facility or home setting

  – **Note:** Ineffective is defined as documented failure to meet therapeutic goals using an E0601 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)

Coverage of RAD

- E0601 tried and found ineffective during initial facility-based titration or home trial:
  - Substitution of RAD does not require new in-person clinical evaluation exam or sleep test
  - Trial length extended to 120 days if <30 days remaining
- E0601 used more than 3 months and beneficiary switched to RAD
  - New in-person clinical evaluation required
  - No new testing required
  - New 3-month trial begins for RAD
    - Require re-evaluation between 31st and 90th day

In-Person Clinical Evaluation

- History should include:
  - Signs and symptoms of sleep disordered breathing including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches
  - Duration of symptoms
  - Validated sleep hygiene inventory such as the Epworth Sleepiness Scale
- Physical exam should include:
  - Focused cardiopulmonary and upper airway system evaluation
  - Neck circumference
  - Body Mass Index (BMI)

Continued Coverage Beyond First 3 Months

- Clinical re-evaluation by the treating practitioner:
  - No sooner than the 31st day but no later than the 91st day after initiating therapy
  - Document that the beneficiary is benefiting from PAP therapy
    - Symptoms of obstructive sleep apnea are improved; and
    - Objective evidence of adherence to use of the PAP device, reviewed by the treating practitioner

Adherence to Therapy

- Use of PAP ≥ 4 hours per night on 70% of nights during consecutive 30-day period
- Documented through direct download or visual inspection of usage data
- Documentation provided in a written report format to be reviewed by the treating practitioner and included in the beneficiary's medical record

Effects of Late Re-Evaluations

- **Scenario 1:** In-person clinical re-evaluation demonstrating continued coverage criteria occurred before the 91st day, but the supplier was not provided the documentation of the visit.
  - Subsequent supplier claims must be held until documentation is received
- **Scenario 2:** In-person clinical re-evaluation does not occur by 91st day and subsequent re-evaluation demonstrates continued coverage criteria is met:
  - Coverage resumes beginning with the date of re-evaluation.

Failed Initial Trail

- Beneficiaries who fail the initial 12-week trial are eligible to re-qualify for a PAP device if:
  1. In-person clinical re-evaluation by the treating practitioner to determine the etiology of the failure to respond to PAP therapy; and,
  2. Repeat sleep test in a facility-based setting (Type 1 study).
     - This may be a repeat diagnostic, titration or split-night study.

Continued Medical Need for PAP Devices, Supplies, and Accessories

- For ongoing supplies and rented DME items, in addition to information that justifies the initial provision of the PAP device and supplies, there must be information in the beneficiary's medical record to support that the item continues to remain reasonable and necessary.
- Information used to justify continued medical need must be timely for the date of service under review:
  - A record in the preceding 12 months
- Any of the following may serve as documentation justifying continued medical need:
  - A recent order/prescription by the treating practitioner for refills
  - A recent change in an order/prescription
  - Timely documentation in the beneficiary's medical record showing usage of the item

Replacement

Initial Device Paid by Medicare

Initial Device Received Prior to Medicare

Replacement: Initial Device Paid by Medicare

- Replacement is based on:
  - The patient's continuous use of the device
  - Statutory limitation for replacement based on a 5-year reasonable useful lifetime (RUL)
- Medicare does not pay for routine replacement
- May be replaced prior to 5-year RUL only if device is lost, stolen, or incurs irreparable damage due to a specific incident
- Patient may elect to receive a new device after 5-years

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:
  - No requirement for a new clinical evaluation, sleep test or trial period;
  - New SWO required

Replacement After 5 Years

- If replaced after 5-year RUL, the following is required:
  - A new SWO
  - In-person visit that documents 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 the use of the PAP device
- No requirement for new sleep test or trial period

Beneficiaries Entering Medicare

- For beneficiaries who received a PAP device prior to enrollment in Fee for Service (FFS) Medicare and are seeking Medicare coverage of a PAP device:

  1. Sleep test – There must be documentation that the beneficiary had a sleep test, prior to FFS Medicare enrollment, that meets the Medicare AHI/RDI coverage criteria in effect at the time that the beneficiary seeks Medicare coverage of a replacement PAP device and/or accessories; and,

  2. Clinical Evaluation – Following enrollment in FFS Medicare, the beneficiary must have an in-person evaluation by their treating practitioner who documents in the beneficiary's medical record that:

     – The beneficiary has a diagnosis of obstructive sleep apnea; and,

     – The beneficiary continues to use the PAP device.

Standard Written Order

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Who Can Order PAP Devices

- The following practitioners may order PAP equipment and accessories:
  - Doctor of Medicine (MD)
  - Doctor of Osteopathy (DO)
  - Physician Assistant (PA)
  - Nurse Practitioner (NP)
  - Clinical Nurse Specialist (CNS)
- Must be enrolled in the Medicare Provider Enrollment, Chain and Ownership System (PECOS)

SWO Elements

- Beneficiary's name or Medicare Beneficiary Identifier (MBI)
- Order date
- General description of item
  - Description can be either general description (e.g., PAP), HCPCS code, HCPCS code narrative, or brand name/model number
  - For equipment – In addition to description of base item, SWO may include all concurrently ordered options, accessories, or additional features separately billed or require upgraded code (list each separately)
  - For supplies - In addition to description of base item, DMEPOS order/prescription may include all concurrently ordered supplies separately billed (list each separately)
- Quantity to be dispensed, if applicable
- Treating practitioner name or National Provider Identifier (NPI)
- Treating practitioner's signature

Comprehensive Error Rate Testing (CERT)

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2020 Improper Payment Rates and Projected Improper Payment: https://www.cms.gov/files/document/2020-medicare-fee-service-supplemental-improper-payment-data.pdf

Service Type	Improper Payment Rate	Projected Improper Payment Amount
Overall	6.27%	$25.74 B
Part A Providers (excluding Hospital Inpatient Prospective Payment System (IPPS))	6.15%	$10.92 B
Part B Providers	8.09%	$8.44 B
Hospital IPPS	3.00%	$3.61 B
DMEPOS	31.80%	$2.77 B

Improper Payment Rates for CPAP by Referring Provider

Referring Provider Type	Improper Payment Rate
Internal Medicine	29.1%
Family Practice	42.3%
Nurse Practitioner	33.9%
Neurology	25.5%
Physician Assistant	23.1%
No Referring Provider Type	27.1%

Top Errors Related to Medical Record Documentation

- Documentation does not include a clinical evaluation by the treating practitioner prior to sleep test to assess for OSA
- Documentation does not include a valid sleep study that meets LCD requirements
- Documentation was not timely (within preceding 12 months) to support continued need
- Medical record documentation is not authenticated (handwritten or electronic) by the author
- Medical record documentation does not document a confirmed diagnosis of OSA

Resources

CMS

DME MACs

Other Related Contractors

NCD and LCD References

- National Coverage Determination for Positive Airway Pressure (PAP)
  - National Coverage Determination for Positive Airway Pressure (PAP): https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf
- Local Coverage Determination for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718)
  - CGS Medicare: https://www.cgsmedicare.com/
  - Noridian Medicare: https://www.noridianmedicare.com/
- Related Policy Article for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (A52467)
  - CGS Medicare: https://www.cgsmedicare.com/
  - Noridian Medicare: https://www.noridianmedicare.com/

Noridian Healthcare Solutions Jurisdiction A Resources

- **Website:** Noridian JA (https://med.noridianmedicare.com/web/jadme)
- **IVR, Supplier Contact Center, and Telephone Reopenings:** 1.866.419.9458
- **Noridian Medicare Portal:** NMP (https://med.noridianmedicare.com/web/jadme/topics/nmp)
- **LCDs and Policy Articles:** Noridian Medicare (https://med.noridianmedicare.com/web/jadme/policies/lcd/active)

CGS Administrators, LLC Jurisdiction B Resources

- **Website:** CGS JB (http://www.cgsmedicare.com/jb)
- **IVR Unit:** 1.877.299.7900
- **myCGS Web Portal:** CGS Portal (http://www.cgsmedicare.com/jb/mycgs/index.html)
- **Customer Service:** 1.866.590.6727
- **Telephone Re-openings:** 1.844.240.7490
- **LCDs and Policy Articles:** CGS Medicare (http://www.cgsmedicare.com/jb/coverage/lcdinfo.html)

CGS Administrators, LLC Jurisdiction C Resources

- **Website:** CGS JC (http://www.cgsmedicare.com/jc)
- **IVR Unit:** 1.866.238.9650
- **myCGS Web Portal:** CGS Portal (http://www.cgsmedicare.com/jc/mycgs/index.html)
- **Customer Service:** 1.866.270.4909
- **Telephone Re-openings:** 1.866.813.7878
- **LCDs and Policy Articles:** CGS Medicare (http://www.cgsmedicare.com/jc/coverage/lcdinfo.html)

Noridian Healthcare Solutions Jurisdiction D Resources

- **Website:** Noridian JD (https://med.noridianmedicare.com/web/jddme/)
- **IVR, Supplier Contact Center and Telephone Reopenings:** 1.877.320.0390
- **Noridian Medicare Portal:** NMP (https://med.noridianmedicare.com/web/jddme/topics/nmp)
- **LCDs and Policy Articles:** Noridian Medicare (https://med.noridianmedicare.com/web/jddme/policies/lcd/active)

Other Contractor Resources

- Pricing, Data Analysis and Coding Contractor (PDAC)
  - 1.877.735.1326
  - PDAC (http://www.dmepdac.com/)
- National Supplier Clearinghouse
  - 1.866.238.9652
  - Palmetto GBA (http://www.palmettogba.com/nsc)
- CEDI
  - 1.866.311.9184
  - CEDI (http://www.ngscedi.com/ngs/portal/ngscedi)
  - E-mail: CEDI Email (NGS.CEDIHelpdesk@anthem.com)

Questions?

Thank you for attending this A/B and DME MAC collaborative education.

Thank you for attending!