Positive Airway Pressure (PAP) Devices

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

September 19, 2024

Disclaimer

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As a reminder, CMS does not allow recording of education opportunities such as this.

Participants

- CGS Administrators, LLC
- First Coast Service Options, Inc.
- National Government Services
- Noridian Healthcare Solutions, LLC
- Novitas Solutions
- Palmetto GBA
- WPS Government Health Administrators

Agenda

- Coverage Criteria
- Documentation Requirements
- References
- Resources

Acronyms

ABN: Advance Beneficiary Notice of Noncoverage

ACA: Affordable Care Act

AHI: Apnea-Hypopnea Index

CERT: Comprehensive Error Rate Testing

NSC: National Supplier Clearinghouse

OSA: Obstructive Sleep Apnea

PAP: Positive Airway Pressure Device

PSG: Polysomnogram

RAD: Respiratory Assist Device

RDI: Respiratory Disturbance Index

RUL: Reasonable Useful Lifetime

Coverage Criteria

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Initial Coverage

E0601 device covered for treatment of OSA if criteria A – C met:

A. In-person clinical evaluation by treating practitioner prior to sleep test to assess beneficiary for OSA

B. Sleep test that meets either one of following criteria:

1. AHI or RDI greater than or equal to 15 events per hour with minimum of 30 events; or
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:
   a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; OR
   b. Hypertension, ischemic heart disease, or history of stroke

C. Beneficiary or caregiver received instruction from supplier in proper use and care of PAP device

Treating Practitioner's Initial Evaluation

- For initial in-person evaluation, report would commonly document pertinent information about following elements:
  - History
    - 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 Epworth Sleepiness Scale
  - Physical Exam
    - Focused cardiopulmonary and upper airway system evaluation
    - Neck circumference
    - Body mass index (BMI)
- May include other details
- Each element would not have to be addressed in every evaluation

Sleep Tests

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

Coverage for RAD Without Backup (E0470)

E0470 device covered for beneficiaries with OSA who meet criteria A-C and D:

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

- Ineffective defined as documented failure to meet therapeutic goals using E0601 during titration portion of facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings)

Coverage for RAD Without Backup (E0470) 2

- If E0601 device tried and found ineffective during initial facility-based titration or home trial, substitution of E0470 does not require new initial in-person clinical evaluation or new sleep test
- If E0601 device used for more than 3 months and beneficiary switches to E0470, new initial in-person clinical evaluation required, but new sleep test not required
  - New 3-month trial would begin for use of E0470

Respiratory Assist Devices Policy

- Bi-level positive airway pressure device with back-up rate (E0471) not reasonable and necessary if primary diagnosis is OSA
  - If E0471 billed with OSA diagnosis, will deny as not reasonable and necessary
- Coverage, coding, and documentation requirements for use of E0470 and E0471 for diagnoses other than OSA addressed in Respiratory Assist Devices (RAD) LCD and related Policy Article

Continued Coverage: Beyond First Three Months of Therapy

Clinical re-evaluation between 31st and 91st day after initiating therapy

- Treating physician documents benefiting from therapy
  - Improvement in subjective symptoms of OSA
  - Objective data related to adherence
- Objective evidence of adherence reviewed by treating physician
  - Used at least four hours per night 70% of nights during consecutive thirty-day period anytime during first three months of initial usage

Re-evaluations Occurring After 91st Day

If re-evaluation does not occur until after 91st day:

- Continued coverage of PAP device will commence with date of re-evaluation if treating practitioner documents:
  - Beneficiary benefiting from PAP therapy, and
  - Objective evidence of adherence
    - Used greater than or equal to 4 hours per night 70% of nights during consecutive 30-day period anytime during first 3 months of initial usage

Failing Initial 12-Week Trial

Beneficiaries who fail initial 12-week trial eligible to re-qualify for PAP device but must have the following:

- In-person clinical re-evaluation by treating practitioner to determine etiology of failure to respond to PAP therapy; and,
- Repeat sleep test in facility-based setting; and,
  - May be repeat diagnostic, titration, or split-night study
- Begin a new timeframe for compliance to show adherence to therapy; and,
- Follow-up evaluation with treating practitioner that symptoms of OSA improved.
- Note: The DMEPOS supplier can resume billing the Medicare program for the PAP device and related accessories once all of the events above have occurred.

Ineffective Therapy: Switching From E0601 to E0470

Treating practitioner must document following issues were addressed prior to changing to E0470:

- Interface fit and comfort
  - Beneficiary using appropriately fit interface without difficulty
  - This appropriately fit interface will be used with E0470 device
- Pressure settings of E0601 prevents beneficiary from tolerating therapy and lower pressure settings of E0601 tried but failed to:
  - Adequately control symptoms of OSA; or,
  - Improve sleep quality; or,
  - Reduce AHI/RDI to acceptable levels

Ineffective Therapy: Switching From E0601 to E0470 [2]

If E0601 device tried and found ineffective during initial facility-based titration or home trial:

- More than 30 days remain:
  - Trial length remains same
  - Re-evaluation between 31st and 91st day
  - Adherence to therapy on RAD prior to 91st day
- Less than 30 days remain:
  - Re-evaluation must occur before 120th day
  - Adherence to therapy on RAD before 120th day

Ineffective Therapy: Switching From E0601 to E0470 [3]

After initial 3-month trial of E0601

- New evaluation
- New 3-month trial with RAD
  - Clinical re-evaluation between 31st and 91st day with RAD
  - Adherence to therapy with RAD

Concurrent Use of Oxygen With PAP Therapy

- Both oxygen LCD and PAP LCD must be followed
- OSA sufficiently treated and hypoxemia unmasked
- Overnight oximetry during home sleep test not eligible for oxygen qualification
- Testing may only occur during titration sleep study:
  - Minimum 2 hours
  - During titration specific reduction in AHI/RDI criteria met
  - Only performed after optimal PAP settings determined
  - Nocturnal oximetry conducted during PSG shows less than or equal to 88%

Replacement PAP

PAP initially provided and covered through Medicare Fee-for-Service (FFS):

- If PAP device replaced during 5-year RUL due to loss, theft, or irreparable damage:
  - No new clinical evaluation, sleep test, or trial
- If replaced following 5-year RUL, there must be in-person evaluation by treating practitioner that documents:
  - Beneficiary continues to use and benefit from device
  - No requirement for new sleep study or trial period

Beneficiaries Entering Medicare

Beneficiary seeking rental or replacement PAP and/or accessories must meet following requirements:

- Sleep test prior to Medicare FFS that meets AHI/RDI criteria in effect at time replacement PAP and/or accessories are needed, and
- In-person evaluation following enrollment in Medicare FFS by treating practitioner documenting:
  - Diagnosis of OSA; and
  - Beneficiary continues to use PAP device

Accessories for Beneficiary-Owned CPAP Devices

- If Medicare paid for base PAP initially (13 months rental), medical necessity for beneficiary-owned base PAP assumed to have been established
- Documentation needed:
  - Continued need for base item
  - Medical necessity of replacement of specific accessories or furnishing of new accessories and whether they are essential for effective use of base DME

Continued Medical Need

For ongoing supplies, accessories and PAP device rental:

- In addition to information justifying initial provision of item, there must be information in medical record to support that item continues to be reasonable and necessary
- Information used to justify continued medical need must be timely for date of service under review
- Documentation justifying continued medical need:
  - Recent order by treating practitioner for refills of supplies;
  - Recent order by treating practitioner for repairs;
  - Recent change in order;
  - Timely documentation in medical record showing usage of item
    - Record in preceding 12 months

Documentation Requirements

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Authorized to Order

Treating Practitioner:

- Doctor of Medicine (MD)
- Doctor of Osteopathy (DO)
- Nurse Practitioner (NP)
- Clinical Nurse Specialist (CNS)
- Physician Assistant (PA)

Treating practitioner must be enrolled in Medicare

Standard Written Order (SWO)

- Beneficiary's name or Medicare Beneficiary Identifier (MBI)
- Order date
- General description of item
- Quantity to be dispensed, if applicable
- Treating practitioner name or NPI
- Treating practitioner's signature

SWO must be completed and signed prior to billing Medicare

SWO: Description

- **Description** – General description (e.g., PAP device), 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 that are separately billed (List each separately)
- **For supplies** – In addition to description of base item, SWO may include all concurrently ordered supplies that are separately billed (List each separately)

SWO: PAP Mask Dear Physician Letter

Effective date February 1, 2024

Mask listed on SWO can be general description, such as:

- PAP mask
- Mask of choice
- Mask – fit for comfort
- Mask – one per three months

Eliminates need to get new SWO when beneficiary changes type of mask

May list multiple masks (i.e., full face and nasal masks both chosen on order template)

Also acceptable for other PAP accessories (cushions, pillows, tubing, and headgear)

New Order Required

- All claims for purchases or initial rentals
- Change in order for accessory, supply, drug, etc.
- On regular basis (even if there no change in order) only if specified in particular medical policy
- Item replaced
- Change in supplier and new supplier unable to obtain copy of valid order from original supplier
- Note: Be aware of state law/statute requirements

Documentation Requirements

For any DMEPOS item to be covered by Medicare, the medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement

- Detailed documentation in treating practitioner's records supporting:
  - Medical necessity of item billed
  - Diagnosis code that is billed on the claim
- Medical information intended to demonstrate compliance with coverage criteria may be included on prescription but must be corroborated by information contained in medical record

Resources

CMS

DME MACs

Other Related Contractors

NCD and LCD References

- National Coverage Determination for Positive Airway Pressure (PAP)
- Local Coverage Determination for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718)
- Related Policy Article for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (A52467)

Detailed Written Orders and Face-to-Face Encounters Resources

- MLN Matters Article MM8304:
- Dear Physician Letter: Face-to-Face and Written Order Requirements for Certain Types of DME

Thank you for attending!