Medicare explained for PAP, RAD, Ventilators and Oxygen

Presented by
Noridian Provider Outreach and Education
Jurisdiction D DME MAC
February 2017
Disclaimer

This information release is the property of Noridian Healthcare Solutions, LLC. It may be freely distributed in its entirety, but may not be modified, sold for profit or used in commercial documents.

The information is provided “as is” without any expressed or implied warranty. While all information in this document is believed to be correct at the time of writing, this document is for educational purposes only and does not purport to provide legal advice. All models, methodologies and guidelines are undergoing continuous improvement and modification by Noridian and the Centers for Medicare & Medicaid Services (CMS). The most current edition of the information contained in this release can be found on the Noridian website and the CMS website.

The identification of an organization or product in this information does not imply any form of endorsement. CPT codes, descriptors, and other data only are copyright 2017 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS apply.

- Noridian Medicare Website (https://med.noridianmedicare.com)
- CMS Website (https://www.cms.gov)
Agenda

- Positive Airway Pressure Devices (PAP)
- Respiratory Assist Devices (RAD)
- Non-Invasive Ventilators
- Nocturnal Oxygen Testing Requirements
- Affordable Care Act Impact
- Medical Records
- Resources
Positive Airway Pressure Devices (PAP)
Initial Coverage
12 Week Trial

A. FTF clinical evaluation by treating physician prior to a sleep test to assess patient for OSA

B. Medicare covered sleep test that meets either one of the following criteria
   1. AHI or RDI ≥ 15 events per hour with a minimum of 30 events or
   2. AHI or RDI ≥ 5 – 14 events per hour with a 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. Patient or caregiver received instruction from the supplier in the proper use and care of CPAP (E0601)
Treating Physician’s Initial Evaluation

• Physician FTF initial evaluation
  – Written in the same format that are used for other entries and may include:
    • History
      – Signs and symptoms of sleep disordered breathing including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches
      – Duration of symptom
      – Validated sleep hygiene inventory such as the Epworth Sleepiness Scale (see Appendices)
    • Exam
      – Focused cardiopulmonary and upper airway system evaluation
      – Neck circumference
      – Body mass index (BMI)
Sleep Test

- Payment and coverage guidelines for the test are found in the LCD for the appropriate Medicare Part A or local Part B contractor
- Those LCDs may be different from the DME MAC LCD
- Coverage for PAP is based on the DME MAC policy and takes precedence
- Four acceptable Medicare-covered sleep tests
  - Type I, II, III or IV
FAQ

Q: When do sleep studies expire?

A: Sleep studies do not expire, however studies used to qualify a beneficiary under Medicare, must meet Medicare guidelines as outlined in the PAP policy at the time the beneficiary enters Medicare. In the case of an initial study performed for the purposes of diagnosis after Medicare eligibility, it is preferred that therapy be initiated within three months of the study, but in no case would longer than 12 months be considered.
Continued Coverage Beyond 12 Weeks

- Face to Face clinical re-evaluation between 31st and 91st day after initiating therapy
  - Treating physician documents benefiting from therapy
  - Objective evidence of adherence reviewed by treating physician
    - Used ≥ 4 hours per night 70% of nights during a consecutive thirty day period anytime during the first three months of initial usage
Treating Physician’s Re-evaluation

• May not be documented before the 31st day
• Must document
  – Improvement in subjective symptoms of OSA
  – Objective data related to adherence
    • Through direct download or visual inspection of usage data
      with documentation provided in a written report format to be
      reviewed by the treating physician and included in the
      beneficiary’s medical record
Re-evaluations Occurring After 91st Day

- Physician documents benefiting from therapy and
- Objective evidence of adherence reviewed by treating physician
  - Used $\geq$ 4 hours per night 70% of nights during a consecutive thirty day period anytime during the first three months of initial usage
- Continued coverage begins with the date of re-evaluation
Failing the 12 Week Trial Period

• May re-qualify
• New FTF re-evaluation by treating physician
  – Determine the etiology of the failure to PAP therapy
• Repeat sleep test
  – Facility-based setting only – Type I study
    • Diagnostic
    • Titration
    • Split – night
• Obtain the documentation that the beneficiary met new adherence to therapy
• New trial period begins at month four
Coverage for RAD Without Backup

Criteria D

- E0470 is covered for patients with OSA if:
  - Patient meets initial coverage criteria A-C and
  - Patient has had CPAP tried and proven ineffective in a facility or a home setting
Ineffective Scenario’s

• Based on a therapeutic trial conducted in either:
  – Facility
    • Failure may occur during the titration portion of the qualifying split night study
  – Home setting
    • Failure may occur after the beneficiary has been using their PAP device at home
      – Despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings)
CPAP Failure Documentation

• Interface fit and comfort
  – Appropriate interface properly fit
  – Beneficiary using without difficulty
  – Is CPAP effective with properly fit interface?
  – If moving to BiPAP will this properly fit interface be used?

• CPAP pressure settings
  – Prevented beneficiary from tolerating therapy and;
  – Lower settings of CPAP were tried but failed to:
    • Control symptoms of OSA, or
    • Improve sleep quality; or
    • Reduce AHI/RDI to acceptable levels
Evaluation, Trial, Adherence

During initial three month trial of the CPAP
  – More than 30 days remain:
    • Trial length remains same
    • Re-evaluation between 31\textsuperscript{st} and 91\textsuperscript{st} day
    • Adherence to therapy on the RAD prior to 91\textsuperscript{st} day
  – Less than 30 days remain:
    • Re-evaluation must occur before the 120\textsuperscript{th} day
    • Adherence to therapy on the RAD before the 120\textsuperscript{th} day

After the initial three month trial of the CPAP
  – New evaluation
  – New three month trial with the RAD
    • Clinical re-evaluation between 31\textsuperscript{st} and 91\textsuperscript{st} day with RAD
    • Adherence to therapy with RAD
Beneficiaries Entering Medicare

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

  1. Sleep test prior to FFS Medicare that meets AHI/RDI criteria in effect at the time a replacement PAP and/or accessories are needed, and

  2. FTF evaluation following enrollment in FFS Medicare by treating physician that documents
     a) Diagnosis of OSA; and
     b) Beneficiary continues to use the PAP device

• If above not met, claim denies as not reasonable and necessary
Respiratory Assist Devices (RAD)
RAD Initial Coverage Criteria

• Beneficiary’s medical record fully documents symptoms characteristic of
  – Sleep-associated hypoventilation
    • Such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc.
RAD Coverage Groups

I. Restrictive thoracic disorders (i.e., neuromuscular diseases or severe thoracic cage abnormalities)

II. Severe chronic obstructive pulmonary disease (COPD)

III. Central sleep apnea (CSA) or complex sleep apnea (CompSA)

IV. Hypoventilation syndrome
Restrictive Thoracic Disorders

Beneficiary must meet A-C:

A. Neuromuscular disease or severe thoracic cage abnormality AND

B. One of the following
   a. Arterial blood gas PaCO2, while awake and breathing patient’s prescribed FIO2 is > 45 mm Hg, or
   b. Sleep oximetry demonstrates oxygen saturation < 88% for > 5 minutes nocturnal, while breathing prescribed FIO2, or
   c. For neuromuscular disease (only)
      i. maximal inspiratory pressure < 60 cm H2O or
      ii. Forced vital capacity < 50% predicted

C. COPD does not contribute significantly to patient’s pulmonary limitation
Severe COPD E0470

Beneficiary must meet A-C:

A. ABG PaCO2, while awake and breathing patient’s prescribed FIO2, ≥ 52 mm Hg; and

B. Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes nocturnal, done while breathing at 2 LPM or the patient’s prescribed FIO2 (whichever is higher); and

C. Prior to initiating therapy, sleep apnea and treatment with CPAP has been considered and ruled out
  • Formal sleep testing may not be required (LCD revision effective 12/1/2014)
  • Medical records must eliminate sleep apnea as a prominent cause of symptoms
Severe COPD E0471

E0471 covered for COPD in following 2 situations:

• Situation 1 – E0471 started anytime after a period of initial use of E0470 if both A and B are met
  
  A. ABG PaCO2, while awake and breathing beneficiary’s prescribed FIO2, shows that the beneficiary’s PaCO2 worsens ≥ 7 mm Hg compared to original result criterion A
  
  B. Facility-based PSG demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes nocturnal (minimum recording 2 hours) while using E0470 that is not caused by obstructive upper airway event
Severe COPD E0471

- Situation 2 – E0471 no sooner than 61 days after initial issue of E0470 both A and B met:
  
  A. ABG PaC02 done while awake and breathing beneficiary’s prescribed FI02, still remains ≥ to 52 mm Hg AND

  B. Sleep oximetry, while breathing with E0470, demonstrates oxygen saturation ≤ 88% for ≥ 5 cumulative minutes nocturnal, (minimum recording time of 2 hours) while breathing oxygen at 2 LPM or prescribed FI02, whichever is higher
CSA or CompSA

• Prior to initiating therapy, a PSG must be performed documenting A and B
  A. Diagnosis of CSA or CompSA, and
  B. Significant improvement of the sleep-associated hypoventilation with the E0470 or E0471
Q: What if the sleep lab does not separate central from obstructive on the hypopneas?

A: The supplier would need to have in their possession or request the raw data from the polysomnogram that separates the central hypopneas from the obstructive hypopneas.

If a beneficiary is going to qualify per the current RAD LCD:

• the Central apneas and hypopneas would need to be differentiated from the Obstructive apneas and hypopneas.
• If the Polysomnogram doesn’t differentiate Medical Review would not be able to determine if the beneficiary meets criteria and qualifies for the RAD device.
FAQ on CAHI (2)

Q: Is it required to have the specific abbreviation (CAHI Index) listed, or is it acceptable to make the calculation to determine that the counts meet the requirements?

A: In cases where the sleep study hadn't specifically listed the central apnea-central hypopnea index (CAHI measurement), but the calculation can and has been made based on the data in the report (before submitting data to the contractor) this documentation would be acceptable in most cases thru the Physician interpretation.

– This definition is based upon polysomnographic scoring recommendations by the American Academy of Sleep Medicine.
Hypoventilation Syndrome (1)

- E0470 covered if both criteria A and B and either criterion C or D are met.
  
  A. ABG PaCO2, done awake breathing prescribed FIO2 is $\geq 45$mm Hg
  
  B. Spirometry shows FEV1/FVC $\geq 70$
  
  C. ABG PaCO2, done during sleep or immediately upon waking breathing prescribed FIO2 shows the beneficiary’s PaCO2 worsened $\geq 7$mm Hg compared to result in criterion A above
  
  D. PSG or HST demonstrates oxygen sat $\leq 88\%$ for $\geq 5$ minutes nocturnal (minimum recording time of 2 hours) not caused by obstructive upper airway events
Hypoventilation Syndrome (2)

- E0471 covered if criteria A, B and either C or D
  
  A. E0470 is being used
  B. Spirometry shows FEV1/FVC ≥ 70%
  C. ABG PaCO2 done awake breathing prescribed FIO2 shows the beneficiary’s PaCO2 worsens ≥ 7 mm Hg compared to ABG performed to qualify for E0470
  D. PSG or HST demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes nocturnal (minimum recording time of 2 hours) that is not caused by obstructive upper airway events
Continued Coverage Beyond First Three Months for RAD

• Must be re-evaluated by treating physician
  – Signed and dated statement
    • No sooner than 61st day after initiating therapy
    • Declaring compliant (consistent) use of device
      – Average of 4 hours per 24 hour period by re-evaluation
    • Beneficiary benefiting from use
Non-Invasive Ventilators
Ventilator with Noninvasive Interfaces Coverage

• NCD Manual (Internet-Only Manual, Publ. 100-3, Chapter 1, Part 4, Section 280.1 stipulates ventilator coverage for
  – Neuromuscular diseases
  – Thoracic restrictive diseases
  – Chronic respiratory failure consequent to chronic obstructive pulmonary disease
Q: Can you clarify what suppliers should be documenting for respiratory assist device (RAD) patients with ALS, COPD or other conditions where the beneficiary is prescribed a ventilator?

A: A ventilator is considered for coverage for the treatment of neuromuscular diseases, thoracic restrictive diseases, or chronic respiratory failure consequent to chronic obstructive pulmonary disease. The medical record documentation would need to fully support that the beneficiary needs to be on the ventilator as the treatment for these disease categories.
Oxygen and PAP
Nocturnal Oxygen Testing Requirements
Overnight Oximetry, OSA AND PSG (1)

- Testing must be done in Chronic Stable State
- Both oxygen LCD and PAP LCD must be followed
- OSA sufficiently treated and lung disease unmasked
Overnight Oximetry, OSA AND PSG

- Overnight oximetry during home sleep test not eligible to be used for oxygen qualification.
- Testing may only occur during a Titration Study and
  1. Minimum 2 hours
  2. During titration specific reduction in AHI/RDI criteria met
  3. Only performed after optimal PAP settings determined
  4. Nocturnal oximetry conducted during PSG shows ≤88% for 5 minutes.
Affordable Care Act Section 6407
Face-to-Face and WOPD
Face-to-Face Evaluation for ACA Section 6407

- Must take place within 6 months prior to WOPD
- May be performed by MD, DO, NP, PA, or CNS
- Must document beneficiary was seen/treated for condition requiring the DME
- Evaluation and written order must be received by supplier prior to delivery of DME
- Implemented July 1st, 2013
- Applies only to specific equipment listed
Detailed Written Order - Supplies

• Basic Elements
  – Beneficiary’s name
  – Physician’s name
  – Date of the order and the start date, if start date is different from the date of the order
  – Detailed description of the item(s)
  – Physician signature and signature date

• Additional Elements
  – Item(s) to be dispensed
  – Frequency of use
  – Quantity to be dispensed/used per unit of time
  – Number of refills
Acceptable Detailed Written Order

• May be completed by someone other than physician
  – Treating physician must review, sign and date

• Acceptable orders
  – Fax
  – Photocopy
  – Electronic
  – Original pen and ink

• Required for all supplies if not part of WOPD for equipment
FAQ

Q: Does the ordering physician have to be the same physician that conducts the face-to-face evaluation?

A: No. The physician that signs the WOPD does not have to be the same physician that conducts the face-to-face evaluation.

  – Prescriber must have knowledge and documentation that the F2F evaluation was conducted.
Medical Records
Medical Records

Program Integrity Manual (100-08, Chapter 5)

Benefits for DME are dependent on thorough medical records.

*Must be available upon request
Signature Requirements

• CMS “Medicare Program Integrity Manual” (Publication 100-08, Chapter 3, Section 3.3.2.4)

<table>
<thead>
<tr>
<th>What is required for a valid signature?</th>
<th>For a signature to be valid, the following criteria must be met:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Services that are provided or ordered must be authenticated by the ordering practitioner;</td>
</tr>
<tr>
<td></td>
<td>• Signatures are handwritten, electronic, or stamped (stamped signatures are only permitted in the case of an author with a physical disability who can provide proof to a CMS contractor of an inability to sign due to a disability); and</td>
</tr>
<tr>
<td></td>
<td>• Signatures are legible.</td>
</tr>
</tbody>
</table>

Amendments, Corrections and Delayed Entries

- Program Integrity Manual
  - Publication 100-08, Chapter 3, section 3.3.2.5

- Clearly and permanently identify amendment, correction or delayed entry as such, and

- Clearly indicate the date and author, and

- Not delete but instead clearly identify all original content

- Must be for the purpose of clarification

- Cannot be for the sole purpose of reimbursement
Assisting Your Patients by Working with DME Supplier

- Your medical records are critical
- Please assist by documenting each individual “story”
- Key is “why” the ordered item is needed
- Face-to-Face Written Order Prior to Delivery Physician Letter
  - [https://med.noridianmedicare.com/web/jddme/policies/physician-resources/face-to-face-wopd](https://med.noridianmedicare.com/web/jddme/policies/physician-resources/face-to-face-wopd)
Resources
Resources

- Policies
  - LCD/Policy Article
  - Documentation Checklists
  - “Dear Physician” Letters

- Education & Outreach
  - Noridian Supplier Manual
Email Updates

• Tuesday and Friday
• Latest updates and announcements
• Customizable
• Sign-up in the lower right corner of our website
• Click "subscribe"
Beneficiary Contact Information

- Beneficiaries who need assistance can be directed to:
  - 1-800-Medicare (800-633-4227)
    - Question on claims and coverage of equipment
  - Social Security Administration (800-772-1213)
    - Update name/address, questions on premiums, Medicare entitlement
  - Benefits Coordination Recovery Center (855-798-2627)
    - Primary insurance information update
Questions
Thank you!