Positive Airway Pressure (PAP) Devices

Face-to-Face Documentation Requirements

For Any New Order On Or After July 1, 2013

- The patient’s medical record must contain sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of the items ordered.
- A Practitioner must have a Face-to-Face evaluation with the beneficiary prior to the written DME order and document the Face-to-Face evaluation in the patient’s medical record. A Practitioner is:
  - Medical Doctor
  - Doctor of Osteopathic Medicine
  - Doctor of Podiatric Medicine
  - Physician Assistant
  - Nurse Practitioner
  - Clinical Nurse Specialist
- Every item subject to Face-to-Face requirements is also subject to mandatory Specific Written Orders prior to delivery. A complete Specific Written Order must be received before the item may be delivered to the patient.
- The Face-to-Face Evaluation must be signed by the Prescribing Practitioner.
- Medicare beneficiaries discharged from a hospital do not need to receive a separate Face-to-Face Evaluation, so long as the Prescribing Practitioner who performed the Face-to-Face encounter in the hospital issues the DME order within six months after the patient’s discharge from the hospital.
- The Face-to-Face Evaluation must occur during the six months prior to the written order for each item.
- Every item subject to Face-to-Face requirements is also subject to mandatory Specific Written Orders prior to delivery. A complete Specific Written Order must be received before the item may be delivered to the patient.

A Written Order for the item must be received before the delivery of the item can take place. A Written Order prior to delivery has five (5) mandatory elements, also referred to as a Five Element Order (5EO).

1. Beneficiary’s name
2. Item of DME ordered - this may be general – e.g., “hospital bed” – or may be more specific.
3. Signature of the prescribing practitioner and date signed
4. Prescribing practitioner’s National Practitioner Identifier (NPI)
5. The date of the order

A date stamp or equivalent must be used to document the date that the order was received.

A Written Order for the item must be received before the delivery of the item can take place. A Written Order prior to delivery has five (5) mandatory elements, also referred to as a Five Element Order (5EO).

- Dosage or concentration
- Route of administration
- Frequency of use
- Duration of infusion
- Quantity to be dispensed
- Number of refills

Additional requirements, if applicable:

- Why does the patient require the item?
- Do the physical examination findings support the need for the item?
- Signs and symptoms that indicate the need for the item
- Diagnoses that are responsible for these signs and symptoms
- Other diagnoses that may relate to the need for the item

Documentation in Medical Records Required by CMS

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<th>Documentation Requirements</th>
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<th>Key Items to Address</th>
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Positive Airway Pressure (PAP) Devices

Face-to-Face Documentation Requirements

HCPCS Codes included:
E0470, E0471, E0472, E0601

Coverage Criteria
The physician must document the Face-to-Face Clinical Evaluations and re-evaluations in a detailed narrative note in their charts in the format that is used for other entries. For the Initial Evaluation, the report would commonly document pertinent information about the following elements, but may include other details:

- **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 the Epworth Sleepiness Scale

- **Physical Exam**
  - Focused cardiopulmonary and upper airway system evaluation
  - Neck circumference
  - Body mass index

Specific Coverage Criteria
An E0601 device is covered for the treatment of obstructive sleep apnea (OSA) if the following criteria are met:

- The patient has a Face-to-Face Clinical Evaluation by the treating physician prior to the sleep test to assess the patient for obstructive sleep apnea.

- The patient has a sleep test that meets one of the following criteria:
  - The Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) is greater or equal to 15 events per hour with a minimum of 30 events; or
  - Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or
  - Hypertension, ischemic heart disease, or history of stroke.

- Patients who fail CPAP may be moved to a bi-level device if an E0601 has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or home setting.

Ineffective is defined as documented failure to meet therapeutic goals using an E601 during the titration portion of a facility-based study or during home use despite optimal therapy (e.g., proper mask selection and fitting and appropriate pressure settings.)

If an E0601 device is tried and found ineffective during the facility-based titration or home trial, substitution of an bi-level device does not require a new initial Face-to-Face Clinical Evaluation or a new sleep test.

If an E0601 device has been used for more than 3 months and the patient is switched to an E0470 or E0471, a new initial Face-to-Face Clinical Evaluation is required, but a new sleep test is not required. A new 3-month trial would begin for use of the bi-level device.