

# MEDICARE

## Quick Reference Guide

Reimbursement Guidelines  
for Referral Sources



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COMMODOES / PATIENT LIFTS / LIFT CHAIRS

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## Medicare Documentation Requirements

For Medicare to consider payment on durable medical equipment (DME), the supplier needs to make sure the coverage criteria is met as outlined within the respective medical policies and related policy articles (LCDs) based on medical record documentation provided by the referral source.

The in-person visit may be performed by a nurse practitioner (NP), physician assistant (PA), clinical nurse specialist (CNS), or physician. To ensure medical necessity, the DME supplier must obtain the standard written order (SWO) prior to submitting the claim for payment.

It's best practice to ensure the coverage criteria is met prior to dispensing the DME item.

The LCDs and related policy articles for DME items may be reviewed in more detail on the DME MAC Medicare websites.

The information in this guide was compiled by VGM Group, Inc., a member service organization.

The information provided herein is our judgment about interpretation of applicable policies and regulations and is believed to be current and substantially accurate as of the time of publication. Policies and regulations are subject to amendment or repeal, and the governing agency may issue official or informal interpretations, rulings or opinions at any time. The opinions and information expressed herein are subject to change based on such factors and should not be taken as legal advice or as binding on the authors. Contents updated January 2023.



## Bedside Commodes

- ▶ **Bedside commodes are only covered if the patient is room-confined or unable to get to toilet facilities.** Commodes are not covered if they are placed over the toilet in the bathroom. Medical need must be documented in patient's medical record.
- ▶ A commode is covered when the patient is physically incapable of utilizing regular toilet facilities. This would occur in one of the following situations:
  - ▶ The patient is confined to a single room, **OR**
  - ▶ The patient is confined to one level of the home environment, and there is no toilet on that level, **OR**
  - ▶ The patient is confined to the home, and there are no toilet facilities in the home.
- ▶ Heavy-duty commodes: Width equal to or greater than 23 inches and a weight capacity of 300 pounds or more.
- ▶ Detachable arms are covered when used to facilitate transfers or if the patient has a body configuration that requires extra width. This applies to any commode.
- ▶ Supplier must have documentation on file detailing why patient is room-confined or unable to access toilet facilities.

## Patient Lifts

- ▶ Patient lifts (hydraulic or power) are covered if transfer between bed and a chair, a wheelchair, or commode requires the assistance of more than one person and, without the use of a lift, the patient would be bed-confined.

## Lift Chairs

All of the following criteria must be met in order to consider coverage:

- ▶ Patient must be able to ambulate once standing [cannot be used in conjunction with a wheelchair or power operated vehicle (POV)].
- ▶ Has severe arthritis of hip or knee, or severe neuromuscular disease. Diagnosis required.
- ▶ Must be a part of the physician's course of treatment and be prescribed to effect improvement, or arrest or retard deterioration of the patient's condition.
- ▶ Patient must be completely incapable of standing up from any chair in their home. The fact that a patient has difficulty or is even incapable of getting up from a chair, particularly a low chair, is not sufficient justification for a seat-lift mechanism. Almost all patients who are capable of ambulating can get out of an ordinary chair if the seat height is appropriate and the chair has arms.
- ▶ Once standing, the patient must have the ability to ambulate.

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## Support Surfaces

GROUP 1 (overlays)

GROUP 2 (pressure reducing)

GROUP 3 (air-fluidized bed)

**GROUP 1** (mostly overlays) Patient must meet criteria 1, 2, or 3.

1. Completely immobile – Patient cannot make changes in body position without assistance, **OR**
2. Limited mobility – Patient cannot independently make changes in body position significant enough to alleviate pressure, **OR**
3. Any stage pressure ulcer on the trunk or pelvis.

If the patient meets criteria 2 or 3 above they must also have at least one of the following conditions:

- A. Impaired nutritional status
- B. Fecal or urinary incontinence
- C. Altered sensory perception
- D. Compromised circulatory status

**GROUP 2** (pressure-reducing)

**Prior authorization is REQUIRED for all types of Group 2 Support Surfaces prior to delivery. Decision takes a minimum of 5 days.**

Patient must meet criteria 1 **AND** 2, **OR** criteria 3, **OR** criteria 4 below.

1. Multiple stage 2 pressure ulcers located on trunk or pelvis that have failed to improve over the last month **AND**
2. Patient has been on a comprehensive ulcer treatment program for at least the past month, which has included: the use of an appropriate Group 1 support surface; regular assessment; appropriate turning, positioning, and wound care; moisture and incontinence management; and nutritional assessment and intervention.
3. Large or multiple stage 3 or 4 pressure ulcer(s) on the trunk or pelvis, **OR**
4. Recent myocutaneous flap or skin graft for a pressure ulcer on the trunk or pelvis (surgery within the past 60 days), and patient has been on a Group 2 or 3 support surface immediately prior to discharge from the hospital or nursing facility (discharge within the past 30 days).

**GROUP 3** (air-fluidized bed) Patient must meet ALL of the following.

1. Stage 3 (full-thickness tissue loss) or stage 4 (deep tissue destruction) pressure sore.
2. Bedridden or chair bound as a result of severely limited mobility.
3. In absence of an air-fluidized bed, the patient would require institutionalization.
4. The air-fluidized bed is ordered in writing by the patient's attending physician based upon a comprehensive assessment and evaluation of the patient after conservative treatment has been tried without success. Conservative treatment should generally include: frequent repositioning; use of Group 2 wound management; nutritional optimization; education of patient and caregiver on the prevention and/or management of pressure ulcers; and assessment by physician, nurse, or other licensed health care practitioner at least weekly.

- ▶ A trained adult caregiver is available to assist the beneficiary with activities of daily living, fluid balance, dry skin care, repositioning, recognition and management of altered mental status, dietary needs, prescribed treatments, and management and support of the air-fluidized bed system and its problems such as leakage.
- ▶ A treating practitioner directs the home treatment regimen, and reevaluates and recertifies the need for the air-fluidized bed on a monthly basis.
- ▶ All other alternative equipment has been considered and ruled out.

## Beds

Coverage is considered for a fixed-height hospital bed when at least one of the following are met:

- ▶ Patient has a medical condition which requires positioning of the body in ways not feasible with an ordinary bed.
- ▶ Patient requires positioning of the body in ways not feasible with an ordinary bed in order to alleviate pain.
- ▶ Patient requires the head of the bed to be elevated more than 30 degrees most of the time because of congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), or problems with aspiration.
- ▶ Patient requires traction equipment that can only be attached to a hospital bed.
- ▶ **Semi-electric beds are considered for coverage if one of the above criteria is met AND**
  - ▶ If the patient requires frequent changes in body position to alleviate pain, prevent aspiration, or a respiratory issue.
  - ▶ If a heavy-duty-type bed is medically necessary, the weight must be at least 350 pounds and must be documented.

Medicare does not cover full electric beds.

### Standard written order requirements:

- ▶ Beneficiary's name
- ▶ Date of order
- ▶ Detailed description of the item being ordered (be specific to the type of bed, for example: fixed height, semi-electric, high/low semi-electric bed, etc.)
- ▶ Any other items being billed
- ▶ Treating practitioner's printed name or national provider identifier (NPI)
- ▶ Treating practitioner's signature



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## Mobility Equipment

Medicare pays for the least costly alternative, which means a cane and walker need to be considered and ruled out before ordering a manual wheelchair. This information all needs to be clearly documented in the medical record.

### ITEM REQUIRED

- **Cane** – Beneficiary has a mobility limitation that impairs the ability to participate in at least one mobility-related activity of daily living (MRADL) in the home.
- **Walker** – Beneficiary has a mobility limitation that cannot be corrected with a cane and impairs the ability to participate in at least one MRADL in the home. Heavy duty (HD) would need weight greater than 300 pounds.
- **Specialty walker** (HD – multiple braking system, variable wheel resistance walker) – Patient meets criteria for a walker but cannot use standard due to severe neurologic disorder or other condition causing restricted use of one hand (obesity alone is not a sufficient reason).
- **Manual wheelchairs**

All the coverage criteria below must be met for a standard manual wheelchair:

- The beneficiary has a mobility limitation that significantly impairs their ability to participate in one or more MRADL such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home.
- The beneficiary's mobility limitation cannot be sufficiently resolved by the use of an appropriately fitted cane or walker.
- Use of a manual wheelchair will significantly improve the beneficiary's ability to participate in MRADLs and the beneficiary will use it on a regular basis in the home.
- Beneficiary's home provides adequate access between rooms for use of the manual wheelchair. The beneficiary has not expressed an unwillingness to use the manual wheelchair. In addition to the above, one of the following: The beneficiary has sufficient upper extremity function and other physical and mental capabilities needed to safely self-propel the wheelchair during a typical day, OR the beneficiary has a caregiver who is available and willing to provide assistance with wheelchair.
  - a. **Hemi-height** – Needs manual wheelchair; needs lower seat to floor height for transfers and/or to assist with self-propelling with feet.
  - b. **Lightweight** – Rule out cane/walker and standard weight manual wheelchair. MUST be independent in self-propelling with the lightweight wheelchair (cannot be needed solely for caregiver convenience).
  - c. **High-strength lightweight** – Rule out standard, hemi-height and lightweight. Needs a seat width, seat depth, seat-to-floor height not available in ANY lower level base and/or patient is up in chair greater than 2 hours per day and highly active. Does not have to be self-propelled. Needs could relate to activity level or size of patient (i.e., extremely tall or very short and requires ultra-hemi seat height).
  - d. **Ultra lightweight** – Requires assistive technology professional (ATP) and physical/occupational therapist (PT/OT) evaluation as well as face-to-face exam by physician and must have past history of use of same type base and activity both inside and outside the home. Patient must be a full-time, independent, manual wheelchair user and must require individualized fitting and adjustments such as, but not limited to, axle configuration, wheel chamber, or seat and back angles that are not available on a lower-level wheelchair. Need to be very specific as to what is needed on this base that is NOT available on a high-strength lightweight base (K0005).
  - e. Heavy-duty base is covered if patient needs a manual wheelchair and weight is greater than 250 pounds.
  - f. Extra heavy duty is covered if patient needs a manual wheelchair and weight is greater than 300 pounds.
  - g. A transport chair (E1037, E1038, or E1039) is covered in lieu of a standard manual wheelchair for use within the home.

With all manual wheelchairs, the first rule to remember is that the need is for IN THE HOME and must rule out each lower-level item before a higher-level item is covered.

### Standard written order requirements:

- ▶ Beneficiary's name
- ▶ Date of order
- ▶ Detailed description of the item being ordered (be specific to the type of mobility equipment, for example: walker with wheels, lightweight manual wheelchair, hemi-height manual wheelchair, heavy-duty manual wheelchair, etc.)
- ▶ Any other items being billed
- ▶ Treating practitioner's printed name or NPI
- ▶ Treating practitioner's signature

## Non-Invasive Ventilators

Non-invasive ventilator (NIV) treatment is generally covered if treatment is needed for:

- ▶ Neuromuscular disorder
- ▶ Thoracic disorder diseases
- ▶ Chronic respiratory failure associated with a respiratory illness such as chronic obstructive pulmonary disease (COPD)

If patient has had repeated hospital admissions due to respiratory failure, make sure that information is documented because it will help meet coverage requirements.

**Remember, Medicare pays for the least costly alternative, which means a bilevel positive airway pressure (bilevel PAP) or bilevel PAP spontaneous/timed (S/T) machine needs to be considered, or tried and ruled out. Clinical documentation must be specific to the individual patient's needs.**

If a ventilator is used, make sure follow-up visits are documented in the medical record by the treating practitioner to show there was a decrease in admissions.

Make sure the documentation is very clear and thorough as to why the patient needs a ventilator versus a respiratory assist device such as a bilevel PAP or bilevel PAP S/T. **The medical record needs to include documentation that supports the severity of the disease and why the ventilator is the appropriate piece of equipment for the patient.**

The key component is painting the picture, which means tell the story of the patient's medical condition that warrants a NIV versus a bilevel PAP. Supporting documentation can include arterial blood gas (ABG), pulmonary function tests (PFTs), assessments by respiratory therapists (RTs) or physical therapists (PTs), nurses' notes, etc.

Monthly rental payments include the payment for supplies and accessories.

### Standard written order requirements:

- ▶ Beneficiary's name
- ▶ Date of order
- ▶ Detailed description of the item being ordered and any other items being billed
- ▶ Ventilator settings
- ▶ Frequency of use
- ▶ Treating practitioner's printed name or NPI
- ▶ Treating practitioner's signature

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## Oxygen and Oxygen Equipment

A new home oxygen equipment medical policy (LCD) is effective for dates of service on or after January 1, 2023. The key is making sure the medical record from the patient's chart is clearly documenting the initial need and ongoing need for home oxygen. The medical record does not include the prescription/order.

Oxygen coverage is divided into 4 groups. The blood gas study result begins the process for determining which group the beneficiary qualifies under. Keeping in mind Group 1 is the most common group for coverage.

Blood gas study refers to either a pulse oximetry test or an ABG test.

### GROUP 1

Coverage includes acute (short term) or chronic (long term) conditions. Documentation of the medical need is vital for any medical condition.

1. The treating practitioner has ordered and evaluated the results of the qualifying blood gas study performed at the time of need.
2. The beneficiary's blood gas study meets the criteria for Group 1.
3. The provision of oxygen therapy and equipment in the home setting will improve the beneficiary's condition.
4. The blood gas study must meet 1 of the 3 testing methods along with the additional criteria indicated below.
  - ▶ Performed by a physician, qualified provider, or laboratory service that can bill Medicare such as an independent diagnostic testing facility (IDTF), **AND**
  - ▶ Study must have been performed at time of need:
    - A. Time of need is defined as during the patient's illness when presumption is that the provision of oxygen will improve the patient's condition in the home setting.
    - B. For an inpatient hospital patient anticipated to require oxygen upon going home, the time of need would be within 2 days of discharge.

**Method 1:** At rest while awake, oxygen saturation equal to or less than 88% or ABG equal to or less than 55 mm Hg. This can be done on room air or with oxygen. Be sure it's documented how it was performed.

**Method 2:** If during exercise, must have the following 3 tests documented:

1. Oxygen saturation on room air at rest – should be above 88%.
  2. Oxygen saturation on room air with exercise – needs to be equal to or less than 88%.
  3. Oxygen saturation on oxygen with exercise – shows improvement with oxygen.
- NOTE: If patient qualifies with Method 2, then WHOEVER does the testing must document and provide all 3 test results described above; otherwise the oxygen will not be covered. All 3 tests must be performed at the same time.

**Method 3:** During sleep on room air oxygen saturation equal to or less than 88%. Test must be a minimum of 2 hours of recording time.

For Group 1, all items listed above need to be met.

### Continued Coverage for Group 1.

Once initial need has been met, ongoing medical need is just as important for continued coverage.

Ongoing need may be documentation in the medical record and/or a standard written order (SWO). Timely documentation is within the preceding 12 months.

### GROUP 2

▶ ABG with partial pressure of oxygen (PO<sub>2</sub>) of 56-59 mm Hg or oxygen saturation of 89% at rest, while awake, during sleep for 5 minutes, or during exercise as described under Group 1, **AND**

1. Dependent edema suggesting CHF, **OR**
2. Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, echocardiogram, or "P" pulmonale on EKG, **OR**
3. Erythrocythemia with hematocrit greater than 56%.

**GROUP 2:** A re-evaluation and a repeat qualifying blood gas test by the treating

practitioner between the 61st and 90th days after initiation of therapy and a new SWO by the treating practitioner.

### GROUP 3:

#### Group 3 criteria:

Initial coverage of home oxygen therapy and oxygen equipment is reasonable and necessary for Group 3 if all of the following conditions are met:

- ▶ Absence of hypoxemia defined in Group 1 and Group 2 above; **AND**,
- ▶ A medical condition with distinct physiologic, cognitive, and/or functional symptoms documented in high-quality, peer-reviewed literature to be improved by oxygen therapy, such as cluster headaches (not all inclusive).

\*Group 3 coverage is currently for cluster headaches only.

### GROUP 4:

#### Group 4 criteria – Non-Covered Group:

Oxygen therapy and oxygen equipment will be denied as not reasonable and necessary if any of the following conditions are present:

- ▶ Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood and there are other preferred treatments; **OR**,
- ▶ Dyspnea without cor pulmonale or evidence of hypoxemia; **OR**,
- ▶ Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities but in the absence of systemic hypoxemia. There is no evidence that increased PO<sub>2</sub> will improve the oxygenation of tissues with impaired circulation; **OR**,
- ▶ Terminal illnesses that do not affect the ability to breathe.

#### Helpful notes:

- ▶ Beneficiaries do not change group classification when going from initial coverage to continued coverage based upon changes in blood oxygen testing results.
- ▶ Portable oxygen is considered when the blood gas study is performed while patient is awake or with exercise. At-night use only does not qualify for a portable unit.
- ▶ A frequency of use must be indicated, e.g., 2 liters per minute (lpm) continuous or 3 lpm at night. PRN or as needed basis is not covered by Medicare.
- ▶ DMEPOS suppliers are not considered as qualified to perform blood gas studies.
- ▶ If the patient is under a Part A covered stay payment such as hospital, nursing facility, home health, or hospice that meets the qualified provider standard, need to be sure that patient is under a Part A covered payment; if not, then the requirements are not met and qualification would be invalid.

#### Standard written order must contain the following:

1. Beneficiary's name
2. Date of order
3. Detailed description of the item being ordered
4. Route of administration
5. Frequency of use
6. Length of need
7. Treating practitioner's printed name or NPI
8. Treating practitioner's signature

#### Obstructive sleep apnea (OSA) with use of home oxygen therapy:

For patients requiring the use of home oxygen with PAP device, both the PAP and oxygen policies must be met. **The qualifying blood gas study must be performed during a titration study at a sleep lab facility making sure the pressure is at an optimal setting. Once the optimal pressure is determined, then the testing for the oxygen begins.** The titration study needs to be minimum of 2 hours of recording time. There has to be a reduction in apnea-hypopnea index/respiratory disturbance index (AHI/RDI) reduced to less than or equal to an average of 10 events/hour, or if the initial AHI/RDI was less than an average of 10 events per hour, then the titration demonstrates further reduction in AHI/RDI. If the beneficiary qualifies during the titration study, the use of home oxygen cannot be prescribed for the diagnosis of OSA. **There needs to be another medical condition that is being unmasked that is documented in the patient's medical record.**

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## Respiratory Assist Devices (RADs)

There are 4 different clinical groups characterized as:

GROUP 1: Restrictive Thoracic Disorders

GROUP 2: Severe Chronic Obstructive Pulmonary Disease (COPD)

GROUP 3: Central Sleep Apnea (CSA) or Complex Sleep Apnea (CompSA)

GROUP 4: Hypoventilation Syndrome

### FOR INITIAL COVERAGE:

#### GROUP 1: Restrictive Thoracic Disorders

1. Neuromuscular disease or severe thoracic cage abnormality **AND**
2. One of the following:
  - a. Arterial blood gas (ABG) PaCO<sub>2</sub>, while awake and breathing patient's prescribed FiO<sub>2</sub> is greater than 45 mm Hg, **OR**
  - b. Sleep oximetry demonstrates oxygen saturation less than 88% for more than 5 minutes nocturnal, while breathing prescribed FiO<sub>2</sub>, **OR**
  - c. For neuromuscular disease (only)
    - i. Maximal inspiratory pressure less than 60 cm H<sub>2</sub>O **OR**
    - ii. Forced vital capacity less than 50% predicted.
3. COPD does not contribute significantly to patient's pulmonary function.

#### GROUP 2: Severe COPD

##### Standard bilevel PAP without backup (E0470):

1. ABG PaCO<sub>2</sub>, while awake and breathing patient's prescribed FiO<sub>2</sub> greater than 52 mm Hg; **AND**
2. Sleep oximetry demonstrates oxygen saturation of less than or equal to 88% for at least 5 minutes nocturnal, done while breathing at 2 lpm or the patient's prescribed FiO<sub>2</sub> (whichever is higher); **AND**
3. Prior to initiating therapy, sleep apnea and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out. (Note: Formal sleep testing is not required if there is sufficient information in the medical record to demonstrate that the beneficiary does not suffer from some form of sleep apnea, including obstructive sleep apnea or OSA, CSA, or CompSA, as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation.)

##### Bilevel PAP with backup (E0471):

##### Covered for COPD in the following 2 situations:

**Situation 1** – Bilevel PAP with backup started any time after a period of initial use of bilevel PAP without backup if both A and B are met:

- A. ABG PaCO<sub>2</sub>, while awake and breathing beneficiary's prescribed FiO<sub>2</sub>, shows that the beneficiary's PaCO<sub>2</sub> worsens greater than or equal to 7 mm Hg compared to original result from #1 above.
- B. Facility-based polysomnogram (PSG) demonstrates oxygen saturation less than or equal to 88% for at least 5 minutes nocturnal (minimum recording 2 hours) while using bilevel PAP without backup that is not caused by obstructive upper airway event.

**Situation 2** – Bilevel PAP with backup no sooner than 61 days after initial issue of bilevel PAP without backup if both A and B are met:

- A. ABG PaCO<sub>2</sub> done while awake and breathing beneficiary's prescribed FiO<sub>2</sub>, still remains greater than or equal to 52 mm Hg **AND**
- B. Sleep oximetry, while breathing with bilevel PAP without backup, demonstrates oxygen saturation less than or equal to 88% for at least 5 minutes nocturnal, (minimum recording time of 2 hours) while breathing oxygen at 2 lpm or prescribed FiO<sub>2</sub>, whichever is higher.

#### GROUP 3: Central Sleep Apnea or Complex Sleep Apnea

Prior to initiating therapy, a complete, facility-based, attended polysomnogram must be performed documenting both A and B.

- A. Diagnosis of central sleep apnea (CSA) or complex sleep apnea (CompSA), **AND**
- B. Significant improvement of the sleep-associated hypoventilation with the bilevel PAP with or without backup while breathing prescribed FiO<sub>2</sub>.
  - ▶ For either CSA or CompSA, the sleep study must identify the central apnea entral hypopnea index (CAHI) defined below.

##### Central sleep apnea (CSA) is defined as:

1. An AHI greater than or equal to 5, **AND**
2. The sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas, **AND**
3. A CAHI is greater than or equal to 5 per hour, **AND**
4. Presence of at least one of the following:
  - ▶ Sleepiness
  - ▶ Difficulty initiating or maintaining sleep, frequent awakenings, or nonrestorative sleep
  - ▶ Awakening short of breath
  - ▶ Snoring
  - ▶ Witnessed apneas
5. There is no evidence of daytime or nocturnal hypoventilation
  - ▶ For diagnosis of CSA, the central CAHI is defined as the average number of episodes of central apnea and central hypopnea per hour of sleep without the use of a positive airway pressure device.

##### Complex sleep apnea (CompSA) is a form of central apnea specifically identified by all of the following:

1. With use of a positive airway pressure device without a backup rate (E0601 or E0470), the PSG shows a pattern of apneas and hypopneas that demonstrates the persistence or emergence of central apneas or central hypopneas upon exposure to CPAP (E0601), or a bilevel device without backup rate (E0470) device when titrated to the point where obstructive events have been effectively treated (obstructive AHI less than 5 per hour).
2. After resolution of the obstructive events, the sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; and
3. After resolution of the obstructive events, a CAHI greater than or equal to 5 per hour.
  - ▶ For CompSA, the CAHI is determined during the use of a positive airway pressure device after obstructive events have disappeared.
  - ▶ If the AHI or CAHI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events used to calculate the AHI or CAHI must be at least the number of events that would have been required in a 2-hour period (i.e., greater than or equal to 10 events).

#### GROUP 4: Hypoventilation Syndrome

##### Bilevel PAP without backup covered if 1, 2, and either 3 or 4 are met:

1. ABG PaCO<sub>2</sub>, done while awake breathing prescribed FiO<sub>2</sub> is greater than or equal to 45 mm Hg.
2. Spirometry shows FEV1/FVC greater than or equal to 70%.
3. ABG PaCO<sub>2</sub>, done during sleep or immediately upon awaking breathing prescribed FiO<sub>2</sub> shows the beneficiary's PaCO<sub>2</sub> worsened greater than or equal to 7mm Hg compared to result in criteria 1 above.
4. PSG demonstrates oxygen saturation less than or equal to 88% for at least 5 minutes nocturnal (minimum recording time of 2 hours) not caused by obstructive upper airway events.

### Bilevel PAP with backup covered if 1, 2, and either 3 or 4 are met:

1. Bilevel PAP without backup is being used.
2. Spirometry shows FEV1/FVC greater than or equal to 70%.
3. ABG PaCO<sub>2</sub> done while awake breathing prescribed FIO<sub>2</sub> shows the beneficiary's PaCO<sub>2</sub> worsens greater than or equal to 7 mm Hg compared to ABG performed to qualify for bilevel PAP without backup.
4. PSG demonstrates oxygen saturation less than or equal to 88% for at least 5 minutes nocturnal (minimum recording time of 2 hours) that is not caused by obstructive upper airway events.

### Standard written order requirements:

- ▶ Beneficiary's name
- ▶ Date of order
- ▶ Detailed description of item(s) being ordered such as device, humidity, type of mask, headgear, filters or tubing, or brand name/model number
- ▶ Pressure settings
- ▶ Frequency of use or duration
- ▶ Treating practitioner's printed name or NPI
- ▶ Treating practitioner's signature

### Continued coverage beyond the first 3 months:

Must be re-evaluated by the treating practitioner no sooner than 61st day after initial therapy.

- ▶ Documenting that the patient is compliant with the device. Compliance is consistently using the machine for at least 4 hours per a 24-hour period.
- ▶ Documentation that the patient is benefiting from use of the therapy.
- ▶ Make sure it's signed and dated by the treating practitioner.

## Positive Airway Pressure (PAP) Devices

For positive airway pressure or bilevel PAP **without** backup—the only diagnosis that is covered is obstructive sleep apnea (OSA), G47.33.

### For initial coverage, all 3 of the following have been met:

1. Evidence of a face-to-face evaluation by the treating practitioner prior to the sleep test to assess the patient for OSA.
2. Sleep test that meets the following:
  - a. The AHI or RDI is greater than or equal to 15 events per hour with minimum of 30 events, **OR**
  - b. The AHI or RDI is greater than or equal to 5 and less than 14 events per hour with a minimum of 10 events and documentation of:
    1. Excessive daytime sleepiness, impaired cognition, mood disorders, insomnia **OR**
    2. Hypertension, ischemic heart disease, or history of stroke.
3. The patient and/or caregiver has received instruction from the supplier on the proper use and care of the equipment.

Please note that Medicare FFS defines hypopnea as an abnormal 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.** (Cannot be scored using the 3% when it's Medicare FFS.)

### Coverage with the Diagnosis of OSA Includes:

A sleep test (Type I, II, III, IV) that meets the Medicare requirements for a valid sleep tests as outlined in the NCD 240.4.1.

The sleep test is ordered by the beneficiary's treating practitioner.

The sleep test is conducted by an entity that qualifies as a Medicare provider of sleep tests and is compliance with all applicable state regulatory requirements.

### Standard written order requirements:

- ▶ Beneficiary's name
- ▶ Date of order
- ▶ Detailed description of item(s) being ordered such as device, humidity, type of mask, headgear, filters or tubing, or brand name/model number
- ▶ Pressure settings
- ▶ Frequency of use or duration
- ▶ Treating practitioner's printed name or NPI
- ▶ Treating practitioner's signature

### Continued coverage beyond the first 3 months:

Between 31 and 91 days of therapy, the following must occur:

1. Face-to-face clinical re-evaluation with treating practitioner documenting that symptoms of OSA are improved and the patient is benefiting from therapy.
2. Objective evidence of adherence to therapy, reviewed by the treating practitioner. Adherence to therapy is using the PAP at a minimum of 4 hours per night on 70% of nights during a consecutive 30-day period anytime during the trial period.

If patient fails the initial 3-month trial period, then they need to re-qualify for a PAP device and then follow the initial coverage criteria. The medical equipment supplier does not receive reimbursement when the trial period is considered failed.

If PAP device is tried and found ineffective, whether it's during the facility testing or in the home, substitution of a bilevel PAP without backup may occur according to the following:

- ▶ If more than 30 days remaining in trial period, the length of the trial period does not change.
- ▶ If less than 30 days remaining in trial period, the length of the trial, the clinical re-evaluation and adherence to therapy must occur before the 120th day.
- ▶ If PAP device was used more than 3 months, then switched, the clinical re-evaluation must occur between the 31st-91st day following the initiation of the bilevel PAP without backup.

### Concurrent use of oxygen with PAP therapy

If a patient requires simultaneous use of home oxygen therapy and a PAP device, documentation by the treating practitioner in the medical record must clearly demonstrate that the requirements for coverage outlined in both the PAP and oxygen policy have been met. Refer to the oxygen section for coverage criteria of home oxygen therapy.



## Small Volume Nebulizer Machines

Nebulizers are covered only in the following situations indicated below by the charts. The medical record needs documentation to support the medical necessity to administer one of the following inhalation drugs for one of the listed conditions:

| Drug  | HCPCS Code   | Covered Condition  | ICD-10 Codes **  |
|---|--|--|--|
| Albuterol<br>Arformoterol<br>Budesonide<br>Cromolyn<br>Formoterol<br>Ipratropium<br>Levalbuterol<br>Metaproterenol<br>DuoNeb<br>Revefenacin | J7611, J7613<br>J7605<br>J7626<br>J7631<br>J7606<br>J7644<br>J7612, J7614<br>J7669<br>J7620<br>J7677 | Obstructive pulmonary disease                              | J41.0, J41.1, J41.8, J42, J43.0, J43.1, J43.2, J43.8, J43.9, J44.0, J44.1, J44.9, J45.20, J45.21, J45.22, J45.30, J45.31, J45.32, J45.40, J45.41, J45.42, J45.50, J45.51, J45.52, J45.901, J45.902, J45.909, J45.990, J45.991, J45.998, J47.0, J47.1, J47.9, J60, J62.0, J61, J62.8, J63.0-J63.6, J64, J65, J66.0, J66.1, J66.2, J66.8, J67.0-J67.9, J68.0-J68.4, J68.8, J68.9, J69.0, J69.1, J69.8, J70.0-J70.5, J70.8, J70.9   |
| Dornase alfa  | J7639  | Cystic fibrosis  | E84.0  |
| Tobramycin  | J7682  | Cystic fibrosis<br>Bronchiectasis                          | A15.0, J47.0, J47.1, Q33.4, A15.0, E84.0, J47.0, J47.1, J47.9, Q33.4   |
| Pentamidine   | J2545  | HIV<br>Pneumocystosis<br>Complications of organ transplant | B20, B59, T86.00-T86.03, T86.09-T86.15, T86.19 - T86.23, T86.30-T86.33, T86.810-T86.812  |
| Acetylcysteine  | J7608  | Persistent thick or tenacious pulmonary secretions         | A22.1, A37.01, A37.11, A37.81, A37.91, A48.1, B25.0, B44.0, B77.81, E84.0, J09.X1, J09.X2, J09.X3, J09.X9, J10.00, J10.01, J10.08, J10.1, J10.2, J10.81, J10.82, J10.83, J10.89, J11.00, J11.08, J11.1, J11.2, J11.81, J11.82, J11.83, J11.89, J12.0, J12.1, J12.2, J12.3, J12.81, J12.89, J12.9, J13, J14, J15.0, J15.1, J15.20, J15.21, J15.212, J15.29, J15.3, J15.4, J15.5, J15.6, J15.7, J15.8, J15.9, J16.0, J16.8, J18, J18.1, J18.8, J18.9, J40, J41.0, J41.1, J41.8, J42, J43.0, J43.1, J43.2, J43.8, J43.9, J44.0, J44.1, J44.9, J45.20, J45.21, J45.22, J45.30, J45.31, J45.32, J45.40, J45.41, J45.42, J45.50, J45.51, J45.52, J45.901, J45.902, J45.909, J45.990, J45.991, J45.998, J47.0, J47.1, J47.9, J60, J61, J62.0, J62.8, J63.0, J63.1, J63.2, J63.3-J63.6, J64, J65, J66.0-J66.2, J66.8, J67.0-J67.9, J68.0-J68.4, J68.8, J68.9, J69.0, J69.1, J69.8, J70.0-J70.5, J70.8, J70.9 |

### Other Types of Nebulizers:

| Equipment   | Covered Condition and ICD-10 Codes  |
|---|---|
| Large Volume Nebulizer = A7007<br>Related Compressor = E0565, E0572<br>Water or Saline = A4217, A7018 | Cystic Fibrosis = E84.0<br>Bronchiectasis = J47.9, J47.1, J47.0, Q33.4<br>Tracheostomy = Z43.0, Z93.0<br>Tracheobronchial stent = J39.8, J98.09 |
| Filtered Nebulizer = A7006<br>Compressor = E0565, E0572   | HIV = B20<br>Pneumocystosis = B59<br>Complications of organ transplant = T86.89, T86.891, T86.899   |

\*\*Frequently additional codes are required for documentation. Please refer to policy for other covered diagnoses.

### Ultrasonic Nebulizer (E0574) with Treprostinil (J7686) or Controlled Dose Inhalation Drug Delivery System (K0730) and Iloprost (Q4074), the following criteria need to be met:

- Patient has diagnosis of pulmonary artery hypertension (I27.0 or I27.20, I27.21, I27.24, I27.83), **AND**
- Pulmonary hypertension is not secondary to pulmonary venous hypertension or disorders of the respiratory system, **AND**
- Patient has primary pulmonary hypertension or pulmonary hypertension which is secondary to one of the following conditions:
  - ▶ Connective tissue disease, **OR**
  - ▶ Thromboembolic disease of the pulmonary arteries, **OR**
  - ▶ HIV infection, **OR**
  - ▶ Cirrhosis, **OR**
  - ▶ Anorexigens (diet drugs), **OR**
  - ▶ Congenital left to right shunts, etc.

### Nebulizer machines

- If one of the above conditions is present, the following criteria must also be met:
  - Pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition, **AND**
  - Mean pulmonary artery pressure is greater than 25 mm Hg at rest or greater than 30 mm Hg with exertion, **AND**
  - Patient has significant symptoms from the pulmonary hypertension (such as severe dyspnea on exertion, fatigue, angina, syncope), **AND**
  - Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out.

If none of the drugs used with a nebulizer are covered, the compressor, nebulizer, and other related accessories/supplies will be denied as not reasonable and necessary.

### Standard written order requirements:

- ▶ Beneficiary's name
- ▶ Date of order
- ▶ Detailed description of the DME item being ordered or brand name/model number
- ▶ Name, dosage, and concentration of drug(s) being dispensed
- ▶ Specific frequency and duration of administration
- ▶ Quantity to be dispensed
- ▶ Number of refills
- ▶ Treating practitioner's printed name or NPI
- ▶ Treating practitioner's signature

| INHALATION DRUGS AND SOLUTIONS  | MAXIMUM PER MONTH  |
|---|--|
| Acetylcysteine  | 74 grams/month   |
| Albuterol   | 465 mg/month (See below for exception)                     |
| Albuterol/Ipratropium combination   | 186 units/month  |
| Arformoterol  | 930 micrograms/month – 62 units/month                      |
| Budesonide  | 62 units/month   |
| Cromolyn sodium   | 2480 mg/month – 248 units/month                            |
| Dornase alfa  | 78 mg/month  |
| Formoterol  | 1240 micrograms/month – 62 units/month                     |
| Ipratropium bromide   | 93 mg/month  |
| Levalbuterol  | 232.5 mg/month – 465 units/month (See below for exception) |
| Metaproterenol  | 2800 mg/month – 280 units/month (See below for exception)  |
| Pentamidine   | 300 mg/month   |
| Revefenacin   | 5250 mcg/month   |
| Treprostinil  | 31 units/month   |
| Sterile saline or water, 10ml/unit (A4216, A4218)                           | 56 units/month   |
| Distilled water, sterile water, or sterile saline in large volume nebulizer | 18 liters/month  |

When albuterol, levalbuterol, or metaproterenol are prescribed as rescue/supplemental medication for beneficiaries who are taking formoterol or arformoterol, the maximum milligrams/month that are reasonably billed are:

| DRUG                              | MAXIMUM MILLIGRAMS/MONTH      |
|-----------------------------------|-------------------------------|
| Albuterol                         | 78 mg/month                   |
| Albuterol/Ipratropium combination | 31 units/month                |
| Levalbuterol                      | 39 mg/month – 78 units/month  |
| Metaproterenol                    | 470 mg/month – 47 units/month |

Claims for more than these amounts of drugs will be denied as not reasonable and necessary.