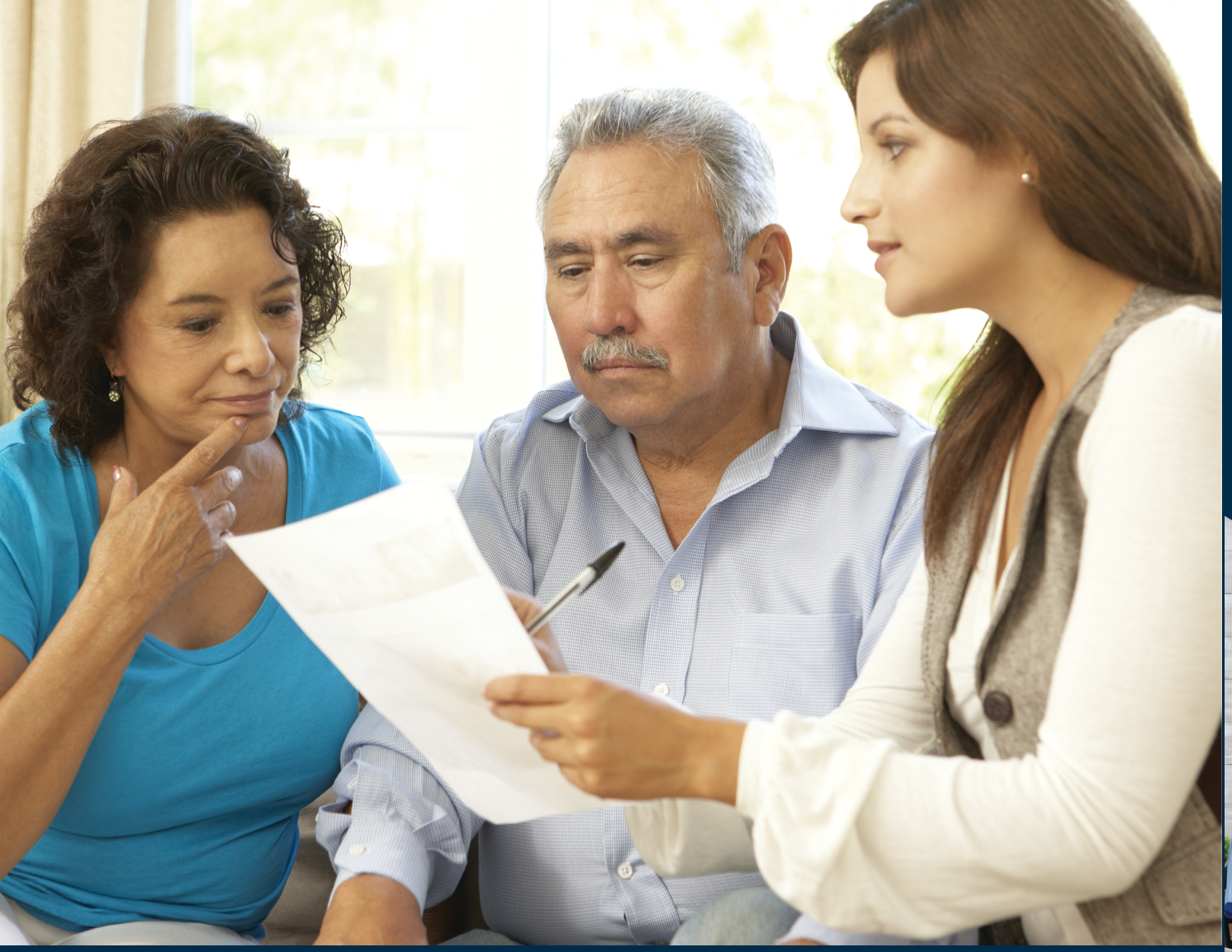


We are happy to provide the equipment needed by your Medicare patients. For your convenience, we've provided this quick reference guide, which contains reimbursement guidelines. Together we can continue to ensure patients get the highest quality care and the equipment they need in the most timely manner possible.

(888) 606-8778
hartmedical.org

MEDICARE

Quick Reference Guide

Reimbursement Guidelines for Referral Sources

- Patient Lifts
- Lift Chairs
- Commodes
- Support Surfaces
- Beds
- Mobility
- NIVs
- Home Oxygen
- RADs
- PAPs
- Nebulizers

Hart Medical Equipment

Medicare Documentation Requirements

These items require that the Durable Medical Equipment (DME) supplier obtain the standard written order and the medical record prior to delivery of the item. The face-to-face evaluation must have occurred within 6 months of the order date on the standard written order. The face-to-face evaluation may be performed by a nurse practitioner (NP), physician assistant (PA), clinical nurse specialist (CNS), or physician.

For any item to be considered for coverage by Medicare, the patient must meet the guidelines as outlined in the medical policies and associated articles as described on the Medicare websites, and the clinical records must prove the medical necessity.

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 September 2020.

Nebulizer Machines

a) If one of the above conditions is present, the following criteria must also be met:
   1. Pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition, **AND**
   2. Mean pulmonary artery pressure is greater than 25 mm Hg at rest or greater than 30 mm Hg with exertion, **AND**
   3. Patient has significant symptoms from the pulmonary hypertension (such as severe dyspnea on exertion, fatigue, angina, syncope) **AND**
   4. 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, the 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/Ipratroprium 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.

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 Arformoterol Budesonide Cromolyn Formoterol Ipratropium Levalbuterol Metaproterenol	J7611, J7613 J7605 J7626 J7631 J7606 J7644 J7612, J7614 J7669 J7620	Obstructive pulmonary disease	J41.0, J41.1, J41.8, J42, J43.0, 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, 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 Bronchiectasis	A15.0, J47, 7.9,Q33.4, A15.0, E84.0, J47.0, J47.1, J47.9, Q33.4
Pentamidine	J2545	HIV Pneumocystosis Complications of organ transplant	B20, B59, T86.00-T86.03,T86.09-T86.13, 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, 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

Other Types of Nebulizers:

Equipment	Covered Condition and ICD-10 Codes
Large Volume Nebulizer = A7007 Related Compressor = E0565, E0572 Water or Saline = A4217, A7018	Cystic Fibrosis = E84.0 Bronchiectasis = J47.9, J47.1, J47.0, Q33.4 Tracheostomy = Z43.0, Z93.0 Tracheobronchial stent = J39.8, J98.09
Filtered Nebulizer = A7006 Compressor = E0565, E0572	HIV = B20 Pneumocystosis = B59 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:

1. Patient has diagnosis of pulmonary artery hypertension (I27.0 or I27.20, I27.21, I27.24, I27.83), **AND**
2. Pulmonary hypertension is not secondary to pulmonary venous hypertension or disorders of the respiratory system, **AND**
3. 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.

Bedside Commodes, Patient Lifts, and Lift Chairs

- **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.

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. 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.

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:

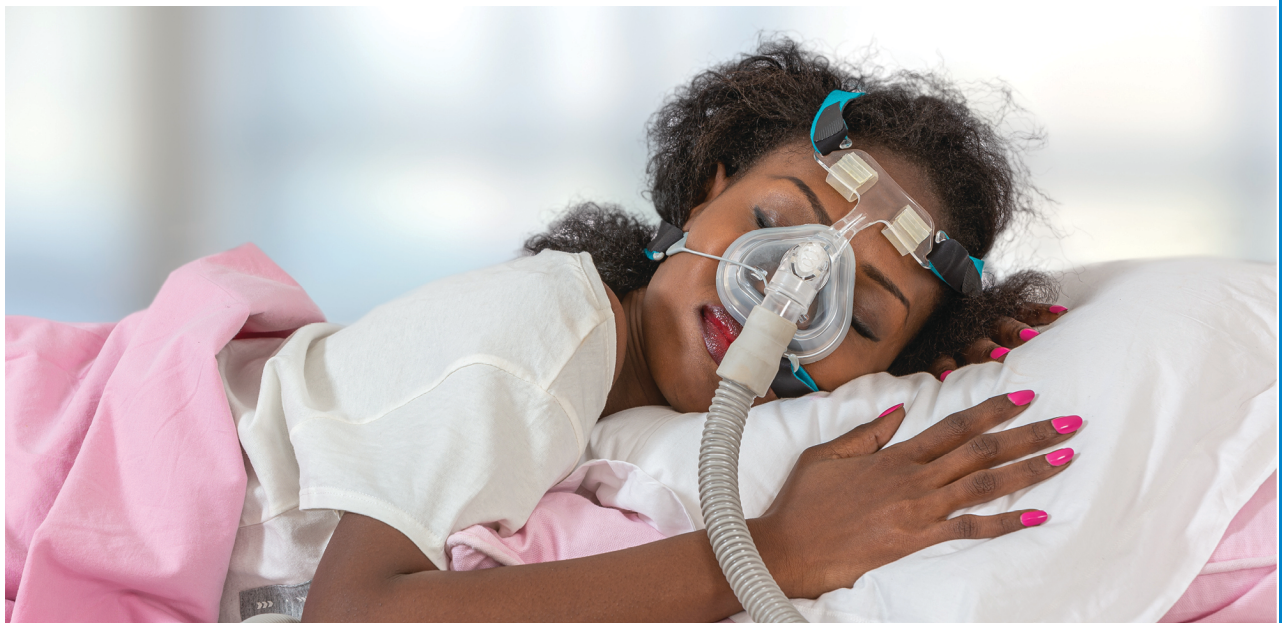
1. Face-to-face clinical re-evaluation with treating practitioner documenting that symptoms of OSA are improved and the patient is benefiting from therapy.
2. Objective evidence of adherence to therapy, reviewed by the treating practitioner. Adherence to therapy is using the PAP at a minimum of 4 hours 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.

If PAP device is tried and found ineffective, whether it's during the facility testing or in the home, substitution of a BiPAP 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 BiPAP 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.



RADs continued

BiPAP with backup covered if 1, 2, and either 3 or 4 are met:

1. BiPAP without backup is being used.
2. Spirometry shows FEV1/FVC greater than or equal to 70%.
3. ABG $PaCO_2$ done while awake breathing prescribed FiO_2 shows the beneficiary's $PaCO_2$ worsens greater than or equal to 7 mm Hg compared to ABG performed to qualify for BiPAP 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 BiPAP **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.)

   For PAP devices with initial date of service on or after 01.01.2010, all sleep tests must be interpreted by a physician who holds either:

1. Current certification in Sleep Medicine by the ABSM; or,
2. Current subspecialty certification in Sleep Medicine by a member board of the ABSM; or,
3. Completed residency or fellowship training by ABSM with all requirements for subspecialty certification, until next eligible exam is offered.

4. Active staff membership of a sleep center or laboratory accredited by AASM, ACHC, or JCAHO.

Beds

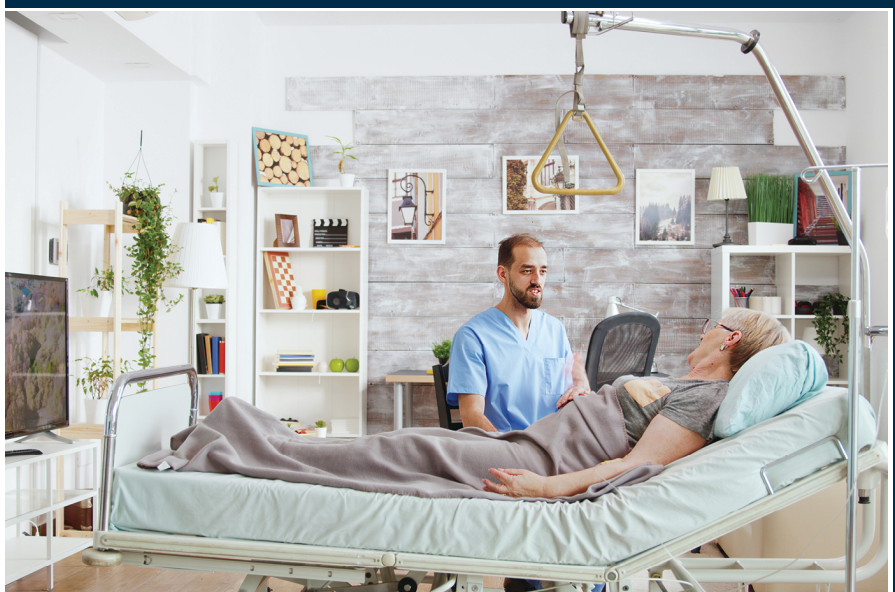
Coverage is considered for a fixed-height hospital bed when **at least one** of the following are met:

- 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
- Length of need
- Treating practitioner's printed name or national provider identifier (NPI)
- Treating practitioner's signature



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

1. **Cane** – Written order and there is a mobility impairment but potential for ambulation.
2. **Walker** – Written order and there is mobility impairment that cannot be corrected with a cane but potential for ambulation. Heavy duty (HD) would need weight greater than 300 pounds.
3. **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).
4. **Manual wheelchairs** – The beneficiary has a mobility limitation that significantly impairs their ability to participate in one or more mobility-related activities of daily living (MRADLs) 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.
   a. Standard – Rule out cane and walker; does not have to be able to self-propel, but needs manual wheelchair for use within the home.
   b. Hemi-height – Needs manual wheelchair; needs lower seat to floor height for transfers and/or to assist with self-propelling with feet.
   c. 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).
   d. 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).
   e. 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 (K0004).
   f. Heavy-duty base is covered if patient needs a manual wheelchair and weight is greater than 250 pounds.
   g. Extra heavy duty is covered if patient needs a manual wheelchair and weight is greater than 300 pounds.
   h. 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.

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 BiPAP with or without backup while breathing prescribed FiO2.

- 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 an 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 bi-level 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

BiPAP without backup covered if 1, 2, and either 3 or 4 are met:

1. ABG $PaCO_2$, done while awake breathing prescribed FiO_2 is greater than or equal to 45 mm Hg.
2. Spirometry shows FEV1/FVC greater than or equal to 70%.
3. ABG $PaCO_2$, done during sleep or immediately upon awaking breathing prescribed FiO_2 shows the beneficiary's $PaCO_2$ 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.

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) $PaCO_2$, while awake and breathing patient's prescribed FiO_2 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_2, **OR**
   c. For neuromuscular disease (only)
      i. Maximal inspiratory pressure less than 60 cm H_2O **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 BiPAP without backup (E0470):

1. ABG $PaCO_2$, while awake and breathing patient's prescribed FiO2 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_2 (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.)

BiPAP with backup (E0471):
Covered for COPD in the following 2 situations:

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

A. ABG $PaCO_2$, while awake and breathing beneficiary's prescribed FiO_2, shows that the beneficiary's $PaCO_2$ 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 BiPAP without backup that is not caused by obstructive upper airway event.

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

A. ABG $PaCO_2$ done while awake and breathing beneficiary's prescribed FiO_2, still remains greater than or equal to 52 mm Hg **AND**
B. Sleep oximetry, while breathing with BiPAP 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_2, whichever is higher.

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
- Length of need
- 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 (BiPAP) or bilevel positive airway pressure spontaneous/timed (BiPAP 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 BiPAP or BiPAP 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 BiPAP. 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
- Length of need
- Treating practitioner's printed name or NPI
- Treating practitioner's signature

Oxygen and Oxygen Equipment

The key is to make sure there is documentation in the medical record indicating need for home oxygen therapy. For Group 1 and Group 2, there must be evidence of an in-person visit with the treating practitioner performed within 30 days before the initial certification.

GROUP 1

All of the following must be documented.

1. Patient has a severe lung disease or hypoxia-related symptom that might improve with therapy.
   Examples:
   - ► COPD, diffuse interstitial lung disease, bronchiectasis, cystic fibrosis.
   - ► Hypoxia-related symptoms such as pulmonary hypertension, recurring CHF due to chronic cor pulmonale, erythrocytosis, impairment of cognitive process, nocturnal restlessness, and morning headache.
   - ► Hypoxemia alone will not be covered. There needs to be an underlying condition causing the hypoxemia.
   - ► Non-covered conditions: angina pectoris in absence of hypoxemia, breathlessness without cor pulmonale or hypoxemia, severe peripheral vascular disease, terminal illnesses that do not affect lungs, pneumonia.

2. Alternative treatment measures such as medications, inhalers, nebulizer treatments, etc., have been tried or considered and ruled out. Make sure this is clearly documented in the medical records.

3. 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:
     A. Within 30 days of initial certification while patient is in a chronic stable state, OR
     B. During an inpatient hospital stay and done within 2 days prior to discharge date.

   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 de 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 WHOMEVER 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% for at least 5 minutes and does not have to be continuous.
   - ► If the testing was performed in an emergency room, then it's considered an acute situation and would not be considered as acceptable for coverage.

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

GROUP 2

- ► ABG with partial pressure of oxygen (PO2) 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%.

Helpful notes:

- ► If portable oxygen is being ordered, there needs to be documentation in the medical records indicating the patient is mobile within the home.
- ► 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, i.e. 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.
- ► A completed Oxygen certificate of medical necessity (CMN) is required in order for Medicare to reimburse. The DME supplier is not allowed to complete sections B and D on the CMN. The requirement is that this be completed by the treating practitioner.

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

- ► The CMN can be the Standard Written Order but must contain all the information listed above.

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 oximetry study performed during this titration shows oxygen saturation of 88% or less for 5 total minutes (does not have to be continuous). 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.

Recertification:

The following to be obtained with the recert CMN for either Group 1 or Group 2:

1. Re-evaluation by treating physician documenting patient is benefiting from the oxygen therapy and has shown improvement.
2. Copy of most recent qualifying blood gas study (can be from the initial test, if that is the most recent).

GROUP 1 = Required after 12 months of initial certification, which means the re-evaluation **must occur within 90 days prior to the date of recertification.**
GROUP 2 = Required after 3 months of initial certification, which means the re-evaluation **must occur between the 61st-90th day following the initial date.**