FIFTEENTH EDITION

Medicare *Screening List*

A Reference Tool for Healthcare Professionals

Therapies and products for home respiratory care, sleep apnea, home enteral nutrition, negative pressure wound care, and home medical equipment services and supplies **for homecare patients**

APRIA®
Part of the Owens & Minor Family

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COMPLEX REIMBURSEMENT MADE EASIER

Aptria has been among the nation's leading home healthcare providers for nearly three decades. Our comprehensive range of services is designed to offer quality homecare as a cost-effective option for patients who are suitable homecare candidates.

In today's healthcare environment, the decision to administer treatment at home is often dependent upon reimbursement. Who will pay? Does the patient have insurance? If so, which healthcare provider is contracted with their insurance company? Does the patient qualify for treatment under Medicare?

This guide provides a summary of Medicare's coverage guidelines. For detailed guidelines, please refer to the applicable Local Coverage Determination (LCD) or National Coverage Determination (NCD).

Documentation Requirements

The guide includes an "SWO" column indicating when a Standard Written Order is required and a "F2F/Eval" column indicating when a Face-to-Face (F2F) evaluation with an authorized prescriber is required. **Note:** Standard Written Order Prior to Delivery (SWOPD) requirements are currently pending Centers for Medicare and Medicaid Services (CMS) guidance.

Under the Affordable Care Act, a treating practitioner (physician, physician assistant [PA], nurse practitioner [NP] or clinical nurse specialist [CNS]) is required to document that they have had a face-to-face (F2F) encounter examination with the beneficiary in the six (6) months prior to the written order for certain Durable Medical Equipment (DME) items. The record of the face-to-face encounter must document that the beneficiary was evaluated and/or treated for a condition that supports the item ordered. (**Note:** Medicare Local Coverage Determination [LCD] for some products may provide different timeframes in which a face-to-face evaluation must be conducted. If there is a variance between the timeframes defined in the Affordable Care Act and the LCD, the LCD timeframe should always be used.)

The date of the standard written order (SWO) must not be prior to the date of the face-to-face encounter. The SWO must include: the beneficiary's name or Medicare Beneficiary Identifier, order date, a description of the item ordered, the quantity to be dispensed (if applicable), the treating practitioner's name or National Provider Identifier (NPI), the treating practitioner's signature.

Apria is contracted with most insurance companies and managed care organizations to provide home oxygen services, ventilation therapy (non-invasive and invasive), PAP, respiratory medications, continuous glucose monitors, and negative pressure wound therapy. You will find that Apria can serve nearly every patient. Call your nearest Apria location for more information.

CMS requires the use of ICD-10 coding for all claims billed to Medicare by physicians, hospitals, and durable medical and respiratory equipment providers like Apria. Certain items are covered by Medicare only when the beneficiary's condition falls under specific ICD-10 coding guidelines and those products have been identified throughout this Medicare Screening List.

Apria is committed to maintaining close ties with the medical community and remains an ongoing source of information for the treating practitioner, case manager, discharge planner, clinician and office personnel. We are continually striving to be the first choice for all your home healthcare needs.

Comprehensive Homecare Services

Apria provides a broad range of products and associated services that give maximum functionality and independence to the patient. From complex negative pressure wound therapy to home oxygen delivery designed to make patients' lives more comfortable and convenient, Apria is the only name you need to know.

- Respiratory therapy services and products
- Supplemental oxygen systems
- Home-delivered respiratory medications
- Ventilation therapy (non-invasive and invasive)
- Positive airway pressure (PAP)
- Respiratory assist devices (RADs)
- Negative pressure wound therapy (NPWT)
- Continuous glucose monitors (CGMs)

Work with the Leader: Experience, Resources, Clinical Expertise

We offer years of homecare experience and clinical excellence and work with our referral sources to ensure that the patient receives the prescribed therapy and benefits from our combined expertise.

As of the release of this publication, the United States is under the COVID-19 Public Health Emergency (PHE) and some of the guidelines in this document may be subject to PHE-related waivers. Please see CMS Coronavirus Waivers and Flexibilities for additional information and updates related to COVID-19 waivers.

Clinicians directly employed by Apria Because we employ so many of the clinicians providing care to our patients, such as respiratory therapists and pharmacists, we are better able to control quality.

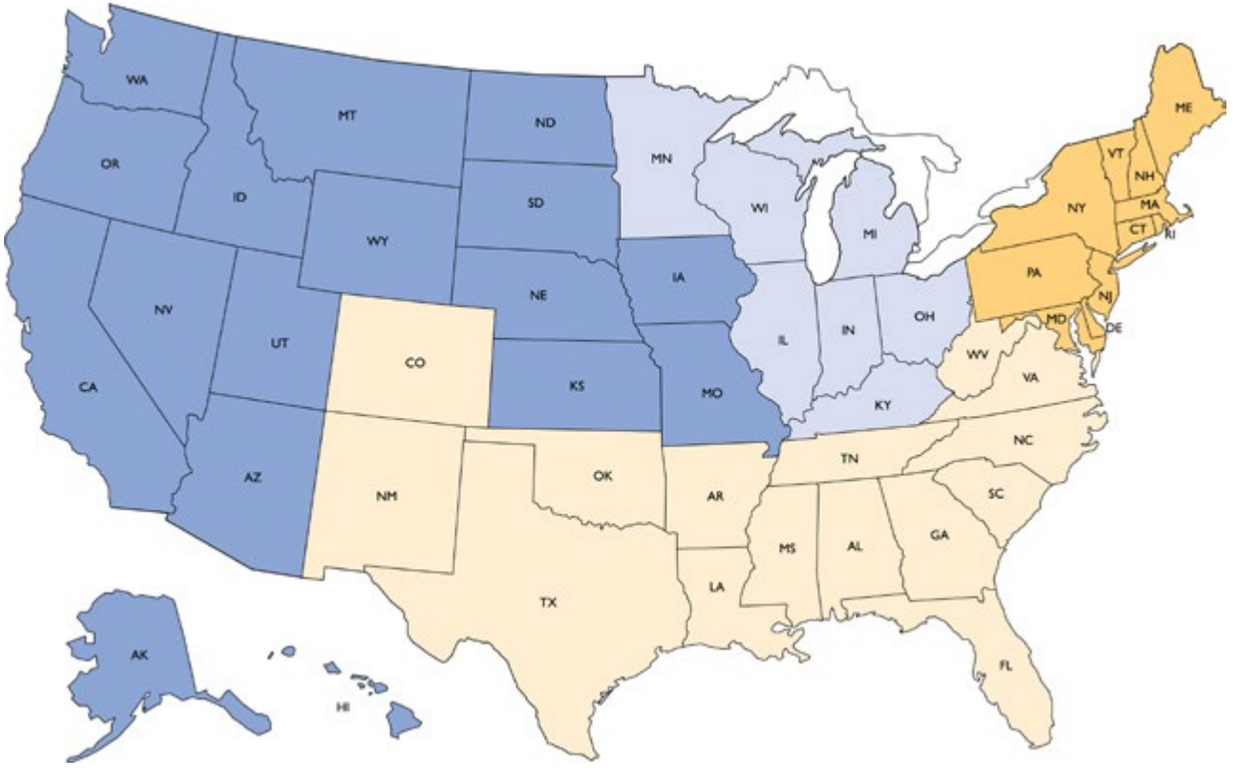
Geographic reach We are here to help, with over 6,000 employees serving almost 2 million patients nationwide. With more than 275 service locations nationwide, Apria's service area ensures consistent, quality care when patients travel or move within the United States.

Patient satisfaction Apria measures patient satisfaction via an independent third party and uses trend data to continually improve our service.

Call Apria today to refer a patient or to ask for more information about Medicare's coverage requirements.

For more information call
1.888.492.7742
or visit us at
Apria.com

CONTRACTOR MEDICAL DIRECTORS



MEDICARE ADMINISTRATIVE CONTRACTORS (MACs)

The Contractor Medical Directors (CMDs) are responsible for developing medical policy for respiratory care products and services, Negative Pressure Wound Therapy (NPWT), home medical equipment, orthotics, prosthetics and supplies (DMEPOS), and home infusion therapies. The Durable Medical Equipment Medicare Administrative Contractors (DME MACs) are responsible for processing claims and providing education to providers.

Jurisdiction A

Smitha M. Ballyamanda, MD
Contractor Medical Director

DME MAC
Noridian Healthcare Solutions, LLC
noridianmedicare.com

- Connecticut
- Delaware
- District of Columbia
- Maine
- Maryland
- Massachusetts
- New Hampshire
- New Jersey
- New York
- Pennsylvania
- Rhode Island
- Vermont

Jurisdiction B

Sunil V. Lalla, MD
Contractor Medical Director

DME MAC
CGS
CGSMedicare.com

- Illinois
- Indiana
- Kentucky
- Michigan
- Minnesota
- Ohio
- Wisconsin

Jurisdiction C

Robert Hoover, MD
Contractor Medical Director

DME MAC
CGS
CGSMedicare.com

- Alabama
- Arkansas
- Colorado
- Florida
- Georgia
- Louisiana
- Mississippi
- New Mexico
- North Carolina
- Oklahoma
- Puerto Rico
- South Carolina
- Tennessee
- Texas
- Virgin Islands
- Virginia
- West Virginia

Jurisdiction D

Peter J. Gurk, MD
Contractor Medical Director

DME MAC
Noridian Healthcare Solutions, LLC
noridianmedicare.com

- Alaska
- American Samoa
- Arizona
- California
- Guam
- Hawaii
- Idaho
- Iowa
- Kansas
- Missouri
- Montana
- Nebraska
- Nevada
- North Dakota
- Northern Marianas
- Oregon
- South Dakota
- Utah
- Washington
- Wyoming

ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
ADJUSTABLE BED		✓				not covered; not a hospital bed, not primarily medical in nature; considered a comfort or convenience item.
✳ **AEROSOL THERAPY**						see NEBULIZER.
AIR-FLUIDIZED BED	✓		✓		✓	covered only if all of the following criteria are met: 1. The beneficiary has a Stage III (full thickness tissue loss) or Stage IV (deep tissue destruction) pressure ulcer. (See LOW AIR-LOSS BED for definition of pressure ulcer.) 2. The beneficiary is bedridden or chair bound as a result of severely limited mobility. 3. In the absence of an air-fluidized bed, the beneficiary would require institutionalization. 4. The air fluidized bed is ordered by the beneficiary's treating practitioner based upon a comprehensive assessment and evaluation of the beneficiary after completion of a course of conservative treatment designed to optimize conditions that promote wound healing. The evaluation generally must be performed within one month prior to initiation of therapy with the air-fluidized bed. 5. The course of conservative treatment must have been at least one month in duration without progression toward wound healing. This month of prerequisite conservative treatment may include some period in an institution as long as there is documentation available to verify that the necessary conservative treatment was rendered. Conservative treatment must include: a. Frequent repositioning of the beneficiary with particular attention to relief of pressure over bony prominences (usually every two hours); **and** b. Use of a Group 2 support surface to reduce pressure and shear forces on healing ulcers and to prevent new ulcer formation; **and** c. Necessary treatment to resolve any wound infection; **and** d. Optimization of nutrition status to promote wound healing; **and** e. Debridement by any means, including wet-to-dry gauze dressings, to remove devitalized tissue from the wound bed; **and** f. Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings protected by an occlusive covering, while the wound heals. In addition, conservative treatment should generally include: g. Education of the beneficiary and caregiver on the prevention and management of pressure ulcers; **and** h. Assessment by a physician, nurse or other licensed healthcare practitioner at least weekly; **and** i. Appropriate management of moisture/incontinence. An occlusive barrier is required, when necessary, to maintain a moist wound-healing environment that may otherwise be compromised by the drying action of airflow generated by air-fluidized therapy. If moist dressings are NOT required because of the wound characteristics (e.g., heavily exudative wound, etc.), the occlusive barrier is not required as a condition for reimbursement. Wet-to-dry dressings when used for debridement do not require an occlusive dressing. Use of wet-to-dry dressings for wound debridement, begun during the period of conservative treatment and which continue beyond 30 days will not preclude coverage of an air-fluidized bed. Should additional debridement again become necessary while a beneficiary is using an air-fluidized bed (after the first 30-day course of conservative treatment) that will not cause the air-fluidized bed to be denied. 6. 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. 7. A treating practitioner directs the home treatment regimen, and re-evaluates and re-certifies the need for the air-fluidized bed on a monthly basis. *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
AIR-FLUIDIZED BED *(continued)*						The treating practitioner's monthly assessment must document the need for the equipment with a written statement specifying: • The size of the ulcer(s); • If the ulcer is not healing, what other aspects of the care plan are being modified to promote healing; • Continued use of the bed is reasonable and necessary for wound management. 8. All other alternative equipment has been considered and ruled out. An air-fluidized bed will be denied as not reasonable and necessary under any of the following circumstances: • The beneficiary has a co-existing pulmonary disease (the lack of firm back support makes coughing ineffective and dry air inhalation thickens pulmonary secretions). • The beneficiary requires treatment with wet soaks or moist wound dressings that are not protected with an impervious covering, such as plastic wrap or other occlusive material. • The caregiver is unwilling or unable to provide the type of care required by the beneficiary on an air-fluidized bed. • Structural support is inadequate to support the weight of an air-fluidized bed system (it generally weighs 1600 lbs. or more). • Electrical system is insufficient for the anticipated increase in energy consumption, **or** • Other known contraindications exist. Payment is not included for the caregiver or for architectural adjustments such as electrical or structural improvement. The continued coverage of an air-fluidized bed as reasonable and necessary must be documented by the treating practitioner every month. Continued use of an air fluidized bed is covered until the ulcer is healed or, if healing does not continue, there is documentation to show that: 1. Other aspects of the care plan are being modified to promote healing, **or** 2. The use of the bed is reasonable and necessary for wound management. Coverage for this equipment is diagnosis driven. Please refer to the applicable Local Coverage Determination (LCD) for associated ICD-10 diagnosis codes. Coverage is limited to the air-fluidized bed itself. A monthly assessment by the treating practitioner must be kept on file by the supplier.
ALTERNATING PRESSURE MATTRESS (POWERED PRESSURE REDUCING MATTRESS)						see LOW AIR-LOSS BED.
ALTERNATING PRESSURE PAD WITH PUMP AND MATTRESS (APP) (Includes all flotation devices: air, water, gel, etc.)	✓		✓		✓	covered if one of the following three criteria are met: 1. The beneficiary is completely immobile (i.e., beneficiary cannot make changes in body position without assistance), **or** 2. The beneficiary has limited mobility (i.e., beneficiary cannot independently make changes in body position significant enough to alleviate pressure), and has at least one of conditions a – d below, **or** 3. The beneficiary has any stage pressure ulcer on the trunk or pelvis and at least one of conditions a – d below. Conditions for criteria 2 and 3 (in each case the medical record must document the severity of the condition sufficiently to demonstrate the medical necessity for a pressure reducing support surface): a. Impaired nutritional status b. Fecal or urinary incontinence c. Altered sensory perception d. Compromised circulatory status

(continued)

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
ALTERNATING PRESSURE PAD WITH PUMP AND MATTRESS (APP) *(continued)*						Beneficiaries needing pressure reducing support surfaces should have a care plan which has been established by the beneficiary's treating practitioner or home care nurse, which is documented in the beneficiary's medical records, and which generally should include the following: • Education of the beneficiary and caregiver on the prevention and/or management of pressure ulcers. • Regular assessment by a nurse, physician, or other licensed healthcare practitioner. • Appropriate turning and positioning. • Appropriate wound care (for a Stage II, III, or IV ulcer). • Appropriate management of moisture/incontinence. • Nutritional assessment and intervention consistent with the overall plan of care.
APNEA MONITOR (INFANT)		✓				not covered.
AQUA K-PAD		✓				not covered; not reasonable and necessary.
ARTERIOSONDE						see BLOOD PRESSURE MONITOR.
BATH/SHOWER CHAIR (with or without wheels, any size)		✓				not covered; comfort or convenience item, not primarily medical in nature.
BATHTUB LIFT		✓				not covered; comfort or convenience item, not primarily medical in nature.
BATHTUB RAIL (FLOOR BASE)		✓				not covered; comfort or convenience item, not primarily medical in nature.
BATHTUB SEAT		✓				not covered; comfort or convenience item; not primarily medical in nature.
BATHTUB STOOL OR BENCH		✓				not covered; comfort or convenience item, not primarily medical in nature.
BATHTUB WALL RAIL		✓				not covered; comfort or convenience item, not primarily medical in nature.
BED BATH		✓				not covered; comfort or convenience item, not primarily medical in nature.
BED CRADLE	✓		✓			covered when it is necessary to prevent contact with the bed coverings.
BED PAN	✓		✓			covered for beneficiaries who are bed-confined.
BED SIDE RAILS						see HOSPITAL BED.
✶ **BI-LEVEL POSITIVE AIRWAY PRESSURE**						see RESPIRATORY ASSIST DEVICE.
BLOOD PRESSURE MONITOR	✓		✓			covered for beneficiaries with end-stage renal disease (ESRD) as part of a home hemodialysis system when they have chosen to receive supplies and equipment from an independent supplier.
BREAST PROSTHESIS	✓		✓			covered for beneficiaries who have had a mastectomy. Coverage for this equipment is diagnosis driven. Please refer to the applicable Local Coverage Determination (LCD) associated ICD-10 diagnosis codes. The Medicare program will pay for one breast prosthesis per side for the useful lifetime of the prosthesis. Two prostheses, one per side, are allowed for those persons who have had bilateral mastectomies. Custom prostheses (L8035) are not medically necessary. *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
BREAST PROSTHESIS *(continued)*						**External Breast Prosthesis Garment, with Mastectomy Form** (L8015) is covered for use in the postoperative period prior to a permanent breast prosthesis or as an alternative to a mastectomy bra and breast prosthesis. **Mastectomy Bra** (L8000) is covered for a beneficiary who has a covered mastectomy form (L8020) or silicone (or equal) breast prosthesis (L8030) when the pocket of the bra is used to hold the form/prosthesis. **Breast Prostheses, Silicone or Equal, with Integral Adhesive** (L8031) are not medically necessary as medical necessity has not been established.
CANE OR CRUTCHES	✓		✓			covered if all of the following criteria (1–3) are met: 1. The beneficiary has a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living (MRADL) in the home such as toileting, feeding, dressing, grooming, and bathing performed in customary locations in the home. A mobility limitation is one that prevents the beneficiary from accomplishing the MRADL entirely, or places the beneficiary at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL; or prevents the beneficiary from completing the MRADL within a reasonable time frame, **and** 2. The beneficiary is able to safely use the cane or crutch, **and** 3. The functional mobility deficit can be sufficiently resolved by use of a cane or crutch. An underarm, articulating, spring-assisted crutch will be denied as not reasonable and necessary as medical necessity has not been established.
COLOSTOMY EQUIPMENT AND SUPPLIES						see OSTOMY EQUIPMENT AND SUPPLIES.
COMMODE	✓		✓			covered when the beneficiary is physically incapable of utilizing regular toilet facilities. This would occur in the following situations: 1. The beneficiary is confined to a single room, **or** 2. The beneficiary is confined to one level of the home environment and there is no toilet on that level, **or** 3. The beneficiary is confined to the home and there are no toilet facilities in the home.
COMMODE (EXTRA WIDE/ HEAVY DUTY)	✓		✓			covered if the beneficiary meets the criteria above for a commode **and** weighs 300 pounds or more. see COMMODE.
COMMODE WITH REMOVABLE ARMS	✓		✓			covered if the beneficiary meets the criteria above for a commode **and** the detachable arms feature is necessary to facilitate transferring the beneficiary, **or** if the beneficiary has a body configuration that requires extra width. A commode with seat lift mechanism is covered if the beneficiary meets the criteria above for a commode **and** meets the coverage criteria for a seat lift mechanism (see Local Coverage Determination [LCD] and Policy Article on Seat Lift Mechanisms). see COMMODE.
COMPRESSION STOCKINGS	✓		✓			covered when it is used as a primary or secondary dressing over wounds that meet the statutory requirements for a qualifying wound (surgically created or modified, or debrided). See NEGATIVE PRESSURE WOUND THERAPY.
✶ **CONCENTRATOR, OXYGEN**						see OXYGEN SYSTEM.

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
CONTINUOUS BLOOD GLUCOSE MONITOR (CGM)	✓		✓		✓	To be eligible for coverage of a CGM and related supplies, the beneficiary must meet all of the following initial coverage criteria 1–5: 1. The beneficiary has diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); **and** 2. The beneficiary's treating practitioner has concluded that the beneficiary (or beneficiary's caregiver) has sufficient training using the CGM prescribed as evidenced by providing a prescription; **and** 3. The CGM is prescribed in accordance with its FDA indications for use; **and** 4. The beneficiary for whom a CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below: a. The beneficiary is insulin-treated; **or** b. The beneficiary has a history of problematic hypoglycemia with documentation of at least one of the following (see the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section of the LCD-related Policy Article [A52464]): • Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL [3.0mmol/L]) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; **or** • A history of one level 3 hypoglycemic event (glucose <54mg/dL [3.0mmol/L]) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia. 5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person or Medicare-approved telehealth visit with the beneficiary to evaluate their diabetes control and determined that criteria 1–4 above are met. **CGM Continued Coverage** Every six (6) months following the initial prescription of the CGM, the treating practitioner conducts an in-person or Medicare-approved telehealth visit with the beneficiary to document adherence to their CGM regimen and diabetes treatment plan. When a CGM (code E2102 or E2103) is covered, the related supply allowance (code A4238 or A4239) is also covered. Supplies (code A4238) for an adjunctive CGM integrated into an external insulin infusion pump are covered when the beneficiary meets both the CGM coverage criteria and the coverage criteria for an external insulin infusion pump. Refer to the External Infusion Pumps LCD (L33794) for additional information regarding billing a CGM receiver incorporated into an insulin infusion pump. If any of the initial coverage criteria 1–5, or the continued coverage criterion are not met, the CGM and related supply allowance will be denied as not reasonable and necessary.
CONTINUOUS PASSIVE MOTION DEVICE (CPM)	✓		✓			covered for beneficiaries who have received a total knee replacement or have undergone the revision of a major component of a previous total knee replacement (i.e., tibial components or femoral component). To qualify for coverage, use of the device must commence within 2 days following surgery. In addition, coverage is limited to that portion of the 3-week period following surgery during which the device is used in the beneficiary's home. When billing for a CPM, all of the following documentation must be included with the claim: Date of surgery, date of application of CPM, date of discharge from the hospital and a narrative description of the surgery or ICD-10 diagnosis code.
✳ **CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE (CPAP)**						see POSITIVE AIRWAY PRESSURE (PAP) DEVICE.
COUGH STIMULATOR						see MECHANICAL IN-EXSUFFLATION DEVICE.
CRUTCHES						see CANE OR CRUTCHES.
CUSHION LIFT POWER SEAT						see SEAT LIFT MECHANISM.
DIAPERS		✓				not covered; non-reusable disposable supplies; not a prosthetic device nor required for the effective use of a prosthetic device.

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
ELASTIC STOCKINGS		✓				not covered; non-reusable supplies; not rental-type items.
ELECTRIC HOSPITAL BED						see HOSPITAL BED.
ENTERAL EQUIPMENT AND SUPPLIES	✓		✓			covered if the beneficiary has: 1. Permanent nonfunction or disease of the structures that normally permit food to reach the small bowel, **or** 2. A disease of the small bowel which impairs digestion and absorption of an oral diet, either of which requires tube feedingsto provide sufficient nutrients to maintain weight and strength commensurate with the beneficiary's overall health status. The beneficiary must have a permanent impairment. Permanence does not require a determination that there is no possibility that the beneficiary's condition may improve sometime in the future. If the judgment of the treating practitioner, substantiated in the medical record, is that the condition is of long and indefinite duration (ordinarily at least three months), the test of permanence is considered met. Enteral nutrition will be denied as non-covered in situations involving temporary impairments. **Indications for Home Enteral Therapy** The beneficiary's condition could be either anatomic (e.g., obstruction due to head and neck cancer or reconstructive surgery, etc.) or due to a motility disorder (e.g., severe dysphagia following a stroke, etc.). • The beneficiary must require tube feeding to maintain weight and strength commensurate with the beneficiary's overall health status. • Adequate nutrition must not be possible by dietary adjustment and/or oral supplements. • Coverage is possible for beneficiaries with partial impairments — e.g., a beneficiary with dysphagia who can swallow small amounts of food or a beneficiary with Crohn's disease who requires prolonged infusion of enteral nutrients to overcome a problem with absorption. Enteral nutrition products that are administered orally and related supplies are **not covered**. If the coverage requirements are met, all related supplies, equipment and nutrients are also covered, including IV poles. No more than one-month's supply of enteral nutrients, equipment or supplies are allowed for one-month's prospective billing. If a pump (B9002) is ordered, there must be documentation in the beneficiary's medical record to justify its use (e.g., that gravity feeding is not satisfactory due to reflux and/or aspiration, diarrhea, dumping syndrome, administration rate less than 100 ml/hr., blood glucose fluctuations or circulatory overloads, gastrostomy/jejunostomy tube used for feeding). If the medical necessity of the pump is not documented, the pump will be denied as not medically necessary. Special nutrients (B4149, B4153–B4155, B4157, B4161 and B4162) also require additional documentation in the beneficiary's medical record to justify its use. A standard formula (B4150 – enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit; or B4152 — enteral formula, nutritionally complete, calorically dense [equal to or greater than 1.5 Kcal/ml] with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit) is appropriate for the majority of beneficiaries requiring enteral nutrition. Special nutrient formulas are produced to meet unique nutrient needs for specific disease conditions. The beneficiary's medical record must adequately document the specific condition and the need for the special nutrient. More than 3 nasogastric tubes (B4081–B4083), or 1 gastrostomy or jejunostomy tube (B4087 or B4088) every 3 months is not reasonable and necessary. **Detailed description of billing codes:** B4149 Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube . . . . . 100 calories – 1 unit B4153 Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube . . . . . 100 calories – 1 unit *(continued)*

ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
ENTERAL EQUIPMENT AND SUPPLIES *(continued)*						B4154 Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube ..... 100 calories – 1 unit B4155 Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube ..... 100 calories – 1 unit B4157 Enteral formula nutritionally complete, for special metabolic needs for inherited disease of metabolism, includes 0proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube ..... 100 calories – 1 unit B4161 Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube ..... 100 calories – 1 unit B4162 Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube ..... 100 calories – 1 unit
FOLEY CATHETER	✓		✓			covered under the prosthetic device benefit if prescribed by a treating practitioner for permanent urinary incontinence or permanent urinary retention. See PROSTHETIC DEVICES. One catheter per month is covered for routine catheter maintenance. Non-routine catheter changes are covered when documentation from the treating practitioner substantiates medical necessity such as for the following indications: 1. Catheter is accidentally removed (e.g., pulled out by beneficiary) 2. Malfunction of catheter (e.g., balloon does not stay inflated, hole in catheter) 3. Catheter is obstructed by encrustation, mucous plug, or blood clot 4. History of recurrent obstruction or urinary tract infection for which it has been established that an acute event is prevented by a scheduled change frequency of more than once per month The test of permanent urinary retention is defined as retention that is not expected to be medically or surgically corrected in the beneficiary within three months. If the medical record, including the judgment of the treating practitioner, indicates the condition is of long and indefinite duration (ordinarily at least three months), the test of permanence is considered met. See UROLOGICAL SUPPLIES.
FOOD PUMP	✓		✓			covered if prescribed by a treating practitioner as an integral part of the beneficiary's covered enteral or parenteral therapy. There must be sufficient medical documentation to establish that the food pump is medically necessary, i.e., that gravity feeding is not satisfactory due to reflux and/or aspiration, severe diarrhea, dumping syndrome, administration rate less than 100 ml/hr, blood glucose fluctuations, circulatory overload, gastrostomy/jejunostomy tube used for feed). See ENTERAL EQUIPMENT AND SUPPLIES.
FOOD SUPPLEMENTS		✓				not covered; not primarily medical in nature.
FOOT BRACES	✓		✓		✓	covered under the Medicare Braces Benefit (Social Security Act §1861(s)(9)). For coverage under this benefit, the orthosis must be a rigid or semi-rigid device, which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Items that are not sufficiently rigid to be capable of providing the necessary immobilization or support to the body part for which it is designed do not meet the statutory definition of the Braces Benefit. Items that do not meet the definition of a brace are statutorily noncovered, no benefit. *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
FOOT BRACES *(continued)*						**Ankle-Foot Orthoses (AFOs) Not Used During Ambulation** An AFO is covered if either all of criteria 1– 4 or criterion 5 is met: 1. Plantar flexion contracture of the ankle (refer to the Group 1 Codes in the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses) with dorsiflexion on passive range of motion testing of at least 10 degrees (i.e., a nonfixed contracture); **and** 2. Reasonable expectation of the ability to correct the contracture; **and** 3. Contracture is interfering or expected to interfere significantly with the beneficiary's functional abilities; **and** 4. Used as a component of a therapy program which includes active stretching of the involved muscles and/or tendons, **or** 5. The beneficiary has plantar fasciitis (refer to the Group 1 Codes in the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses). If a static or dynamic positioning AFO is used for the treatment of a plantar flexion contracture, the pre-treatment passive range of motion must be measured with a goniometer and documented in the medical record. There must be documentation of an appropriate stretching program carried out by professional staff (in a nursing facility) or caregiver (at home). **AFOs and Knee-Ankle-Foot Orthoses (KAFOs) Not Used During Ambulation** An AFO used during ambulation is covered for ambulatory beneficiaries with weakness or deformity of the foot and ankle who: 1. Require stabilization for medical reasons, **and** 2. Have the potential to benefit functionally. KAFOs are covered for ambulatory beneficiaries for whom an AFO is covered and for whom additional knee stability is required. AFOs and KAFOs that are custom-fabricated are covered for ambulatory beneficiaries when the basic coverage criteria listed above and one of the following criteria are met: 1. The beneficiary could not be fit with a prefabricated AFO; **or** 2. The condition necessitating the orthosis is expected to be permanent or of long-standing duration (more than 6 months); **or** 3. There is a need to control the knee, ankle or foot in more than one plane; **or** 4. The beneficiary has a documented neurological, circulatory, or orthopedic status that requires custom fabricating over a model to prevent tissue injury; **or** 5. The beneficiary has a healing fracture which lacks normal anatomical integrity or anthropometric proportions. Coverage for this equipment may be limited based on HCPCS. Please refer to the applicable Local Coverage Determination (LCD)for associated HCPCS requirements.
GEL FLOTATION PAD/ MATTRESS	✓		✓		✓	covered if one of the following three criteria are met: 1. The beneficiary is completely immobile (i.e., beneficiary cannot make changes in body position without assistance), **or** 2. The beneficiary has limited mobility (i.e., beneficiary cannot independently make changes in body position significant enough to alleviate pressure and at least one of conditions a–d below), **or** 3. The beneficiary has any stage pressure ulcer on the trunk or pelvis and at least one of conditions a–d below. Conditions for criteria 2 and 3 (in each case the medical record must document the severity of the condition sufficiently to demonstrate the medical necessity for a pressure reducing support surface): a. Impaired nutritional status b. Fecal or urinary incontinence c. Altered sensory perception d. Compromised circulatory status The support surface provided for the beneficiary should be one in which the beneficiary does not "bottom out." Bottoming out is when an outstretched hand, placed palm up between the undersurface of the mattress overlay or mattress and the beneficiary's bony prominence (coccyx or lateral trochanter), can readily palpate the bony prominence. This bottoming out criterion should be tested with the beneficiary in the supine position with their head flat, in the supine position with their head slightly elevated (no more than 30 degrees), and in the side-lying *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
GEL FLOTATION PAD/ MATTRESS *(continued)*						position. If the beneficiary bottoms out on the support surface in place, then Medicare will deny as not reasonable and necessary. Beneficiaries needing pressure reducing support surfaces should have a care plan which has been established by the beneficiary's treating practitioner or home care nurse, which is documented in the beneficiary's medical records, and which generally should include the following: • Education of the beneficiary and caregiver on the prevention and/or management of pressure ulcers. • Regular assessment by a nurse, physician, or other licensed healthcare practitioner. • Appropriate turning and positioning. • Appropriate wound care (for a stage II, III, or IV ulcer). • Appropriate management of moisture/incontinence. • Nutritional assessment and intervention consistent with the overall plan of care.
GERI-CHAIR/GLIDEABOUT CHAIR						see ROLLABOUT/ROLLING CHAIR.
GRAB BARS		✓				not covered; self-help device; not primarily medical in nature.
GRABBING/REACHING DEVICE (any type, any length, each)		✓				not covered; comfort or convenience item, not primarily medical in nature.
✶ **HIGH FREQUENCY CHEST WALL OSCILLATION DEVICE (HFCWO)**	✓		✓		✓	covered for beneficiaries who meet Criterion 1, 2, or 3, and Criterion 4 below: 1. There is a diagnosis of cystic fibrosis; **or** 2. There is a diagnosis of bronchiectasis which has been confirmed by a high resolution, spiral, or standard CT scan and which is characterized by: • Daily productive cough for at least 6 continuous months; **or** • Frequent (i.e., more than 2/year) exacerbations requiring antibiotic therapy. **Note:** Chronic bronchitis and chronic obstructive pulmonary disease (COPD) in the absence of a confirmed diagnosis of bronchiectasis does not meet this criterion. **Or** 3. The beneficiary has one of the following neuromuscular disease diagnoses. • Post-polio • Anterior horn cell diseases • Acid maltase deficiency • Quadriplegia • Paralysis of the diaphragm • Myotonic disorders • Multiple sclerosis • Hereditary muscular dystrophy • Other myopathies **Note:** Reference Medicare HFCWO Policy Article A52494 for additional diagnoses. **And** 4. There must be well-documented failure of standard treatments to adequately mobilize retained secretions. **Note:** There must be information in the beneficiary's medical record that describes in detail the underlying medical condition(s) that cause the accumulation of pulmonary secretions, the treatment interventions (for example, chest physiotherapy, postural drainage, medications used, mechanical modalities such as in-exsufflation devices (not all inclusive)) and the effectiveness of the treatment. It is not reasonable and necessary for a beneficiary to use both a HFCWO device (E0483) and a mechanical in-exsufflation device (E0482). **Supplies** • Supplies used in conjunction with an HFCWO are included in Medicare's monthly reimbursement for the rental of the HFCWO and are not separately billable. • Replacement supplies (A7025 and A7026), used with beneficiary owned equipment, are covered if the beneficiary meets the criteria listed for the base device.

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
HOSPITAL BED	✓		✓		✓	covered if the beneficiary's medical record establishes medical necessity due to one or more of the following reasons: 1. The beneficiary's medical condition requires positioning of the body in ways not feasible in an ordinary bed. Elevation of the head/upper body less than 30 degrees does not usually require the use of a hospital bed, **or** 2. The beneficiary requires positioning of the body in ways not feasible in an ordinary bed in order to alleviate pain, **or** 3. The beneficiary requires the head of the bed to be elevated more than 30 degrees most of the time due to congestive heart failure, chronic pulmonary disease, or problems with aspiration, **or** 4. The beneficiary requires traction equipment, that cannot be affixed to or used on an ordinary bed. If the beneficiary's medical condition requires body positioning, the medical record must describe the severity and frequency of the beneficiary's symptoms. If the medical condition requires special bed attachments, the medical record must specify the attachments. If the beneficiary needs a hospital bed other than fixed height, the medical record must support the additional coverage requirements below for the specific bed type.
	✓					**Variable Height Feature** may be covered when the beneficiary requires a bed height different than a fixed height bed to permit transfers to chair, wheelchair or standing position if hospital bed coverage requirements are met and the medical record establishes the medical necessity for a variable height hospital bed.
	✓					**Semi-Electric Bed** (electric powered adjustments to raise and lower the head and foot) may be covered when the beneficiary's condition requires frequent changes in body position and/or the beneficiary may need immediate changes in body position.
		✓				**Full-Electric Bed** is not covered (the full-electric bed height adjustment feature is a non-covered convenience feature; therefore, a full-electric bed is not covered).
	✓					**Heavy Duty Bed** is covered if hospital bed coverage requirements are met and the beneficiary's weight is more than 350 pounds, but does not exceed 600 pounds.
	✓					**Extra Heavy Duty Bed** is covered if hospital bed coverage requirements are met and the beneficiary's weight exceeds 600 pounds.
	✓					**Side Rails** are covered if the beneficiary's condition requires side rails; they can be covered as an integral part of, or an accessory to, a covered hospital bed. Side rails are not covered when used on a bed other than a hospital bed. They are included in the rental of a bed.
HOYER LIFT						see PATIENT LIFT.
HUMIDIFIER	✓		✓			covered if it is necessary to the operation of the beneficiary's covered oxygen or positive airway pressure (PAP) equipment or Respiratory Assist Device (RAD). See POSITIVE AIRWAY PRESSURE (PAP), OXYGEN SYSTEM and RESPIRATORY ASSIST DEVICE (RAD).
HYDRAULIC LIFT						see PATIENT LIFT.
ILEOSTOMY EQUIPMENT AND SUPPLIES						see OSTOMY EQUIPMENT AND SUPPLIES.
INCONTINENCE PADS		✓				not covered; non-reusable supply; hygienic item.
INSULIN, INSULIN PUMP AND SUPPLIES	✓		✓		✓	covered as medically reasonable and necessary in the home setting for the treatment of diabetic beneficiaries who meet either A **or** B **AND** either C **or** D: A. C-peptide testing requirement — must meet criterion 1 or 2 and criterion 3: 1. C-peptide level is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
INSULIN, INSULIN PUMP AND SUPPLIES *(continued)*						2. For beneficiaries with renal insufficiency and a creatinine clearance (actual or calculated from age, weight, and serum creatinine) less than or equal to 50 ml/minute, a fasting C-peptide level is less than or equal to 200 percent of the lower limit of normal of the laboratory's measurement method 3. A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/d B. Beta cell autoantibody test is positive. C. The beneficiary has completed a comprehensive diabetes education program, and has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day), with frequent self-adjustments of insulin doses for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria while on the multiple daily injection regimen: 1. Glycosylated hemoglobin level (HbAlc) > 7.0%, 2. History of recurring hypoglycemia, 3. Wide fluctuations in blood glucose before mealtime, 4. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl, **or** 5. History of severe glycemic excursions. D. The beneficiary has been on an external insulin infusion pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment. **Continued Coverage of the Insulin Pump** requires that the beneficiary be seen and evaluated by the treating practitioner at least every 3 months. The pump must be ordered by and follow-up care of the beneficiary must be managed by a treating practitioner who manages multiple beneficiaries with CSII and who works closely with a team including nurses, diabetes educators, and dietitians who are knowledgeable in the use of CSII. See GLUCOSE MONITORS/CONTINUOUS GLUCOSE MONITORS.
INTRAPULMONARY PERCUSSIVE VENTILATION SYSTEM		✓				not covered; these devices have not been demonstrated to be reasonable and necessary in the home setting.
IPPB MACHINE	✓		✓			covered if the beneficiary's ability to breathe is severely impacted.
LIQUID OXYGEN SYSTEM						see OXYGEN SYSTEM.
LOW AIR-LOSS BED	✓		✓		✓	covered if the beneficiary meets at least one of the following three criteria (1, 2 or 3): 1. The beneficiary has multiple Stage II pressure ulcers located on the trunk or pelvis which have failed to improve over the past month, during which time the beneficiary has been on a comprehensive ulcer treatment program including each of the following: a. Use of an appropriate Group 1 support surface, **and** b. Regular assessment by a nurse, physician, or other licensed healthcare practitioner, **and** c. Appropriate turning and positioning, **and** d. Appropriate wound care, **and** e. Appropriate management of moisture/incontinence, **and** f. Nutritional assessment and intervention consistent with the overall plan of care 2. The beneficiary has large or multiple Stage III or IV pressure ulcer(s) on the trunk or pelvis. 3. The beneficiary had a myocutaneous flap or skin graft for a pressure ulcer on the trunk or pelvis within the past 60 days, and has been on a Group 2 or 3 support surface immediately prior to discharge from a hospital or nursing facility within the past 30 days. *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
LOW AIR-LOSS BED *(continued)*						

Note: When a Group 2 support surface is covered following a myocutaneous flap or skin graft, coverage generally is limited to 60 days from the date of surgery.

Coverage for this equipment is diagnosis driven. Please refer to the applicable Local Coverage Determination (LCD) for associated ICD-10 diagnosis codes.

If the beneficiary is on a Group 2 support surface, there should be a care plan established by the treating practitioner or home care nurse which includes the above elements. The support surface provided for the beneficiary should be one in which the beneficiary does not "bottom out."

Ongoing Coverage

Continued use of a Group 2 support surface is covered until the ulcer is healed or, if healing does not continue, there is documentation in the medical record to show that:

1. Other aspects of the care plan are being modified to promote healing, **or**
2. The use of the Group 2 support surface is medically necessary for wound management.

Pressure Ulcer Stages

Stage I: Intact skin with a localized area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature, or firmness may precede visual changes. Color changes do not include purple or maroon discoloration; these may indicate deep tissue pressure injury.

Stage II: Partial-thickness skin loss involving exposed dermis. The wound bed is viable, pink or red, moist, and may also present as an intact or ruptured serum-filled blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. This stage should not be used to describe moisture associated skin damage (MASD) including incontinence associated dermatitis (IAD), intertriginous dermatitis (ITD), medical adhesive related skin injury (MARSI), or traumatic wounds (skin tears, burns, abrasions).

Stage III: Full-thickness skin loss in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the extent of tissue loss this is an unstageable pressure injury.

Stage IV: Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edged), undermining and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss, this is an unstageable pressure injury.

Unstageable Pressure Injury

Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) on the heel or ischemic limb should not be softened or removed.

Deep Tissue Pressure Injury (DTPI)

Persistent non-blanchable deep red, maroon or purple discoloration Intact or non-intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood filled blister. Discoloration may appear differently in darkly pigmented skin. Pain and temperature change often precede skin color changes. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure injury (Unstageable, Stage 3 or Stage 4). DTPI should not be used to describe a vascular, traumatic, neuropathic, or dermatologic conditions.

The supplier must obtain information concerning which, if any, of the above criteria the beneficiary meets in a signed and dated statement from the

(continued)

ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
LOW AIR-LOSS BED *(continued)*						treating practitioner. Questions pertaining to medical necessity on any form used to collect this information may not be completed by the supplier or anyone in a financial relationship with the supplier. This statement must be supported by information in the beneficiary's medical record. Coverage is limited to the low-air loss bed itself.
LYMPHEDEMA PUMP						see PNEUMATIC COMPRESSION DEVICE.
✳ **MASK (OXYGEN OR PAP)**						see POSITIVE AIRWAY PRESSURE (PAP) or OXYGEN SYSTEM.
MASK (SURGICAL)		✓				not covered; nonreusable disposable item.
MATTRESS	✓		✓			covered if a hospital bed is medically necessary and coverage requirements for the hospital bed have been met, a mattress for the hospital bed is also covered. See HOSPITAL BED. If a beneficiary's condition requires a replacement innerspring mattress (E0271) or foam rubber mattress (E0272) it will be covered for a beneficiary-owned hospital bed.
MECHANICAL IN-EXSUFFLATION DEVICE (COUGH-STIMULATING DEVICE)	✓		✓		✓	covered for beneficiaries who meet all of the following criteria**:** 1. The beneficiary has a neuromuscular disease, **and** 2. The condition causes a significant impairment of the chest wall and/or diaphragmatic movement, such that it results in an inability to clear retained secretions. Coverage for this equipment is diagnosis driven. Please refer to the applicable Local Coverage Determination (LCD) for associated ICD-10 diagnosis codes.
✳ **NASAL PAP**						see POSITIVE AIRWAY PRESSURE (PAP).
✳ **NEBULIZER AND NEBULIZER SUPPLIES**	✓		✓		✓*	covered when it is reasonable and necessary to administer the following FDA-approved inhalation solutions listed below: 1. It is reasonable and necessary to administer albuterol, arformoterol, budesonide, cromolyn, formoterol, ipratropium, levalbuterol, metaproterenol, or revefenacin for the management of obstructive pulmonary disease, **or** 2. It is reasonable and necessary to administer dornase alpha to a beneficiary with cystic fibrosis, **or** 3. It is reasonable and necessary to administer tobramycin to a beneficiary with cystic fibrosis or bronchiectasis, **or** 4. It is reasonable and necessary to administer pentamidine to a beneficiary with HIV, pneumocystosis, or complications of organ transplants, **or** 5. It is reasonable and necessary to administer acetylcysteine for persistent thick or tenacious pulmonary secretions. Coverage for this equipment is diagnosis driven. Please refer to the applicable Local Coverage Determination (LCD) for associated ICD-10 diagnosis codes. Use of compounded inhalation solutions will be denied as not reasonable and necessary. If none of the drugs used with a nebulizer are covered, the nebulizer, compressor and its accessories/supplies will be denied as not reasonable and necessary. **Large Volume Nebulizer, Related Compressor, and Water or Saline** are considered for coverage when it is reasonable and necessary to deliver humidity to a beneficiary with thick, tenacious secretions, who has cystic fibrosis, bronchiectasis, a tracheostomy, or a tracheobronchial stent. **Compressor and Filtered Nebulizer** are also covered when it is reasonable and necessary to administer pentamidine to beneficiaries with HIV, pneumocystosis, or complications of organ transplants. *(continued)*

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***Note:** Only NEBULIZERS require F2F documentation.

ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
NEBULIZER AND NEBULIZER SUPPLIES *(continued)*						**Small Volume Ultrasonic Nebulizer and Related Accessories** are considered for coverage when it is reasonable and necessary to administer treprostinil inhalation solution to beneficiaries with pulmonary hypertension only. Claims for use with other inhalation solutions will be denied as not reasonable and necessary. **Controlled Dose Inhalation Drug Delivery System** is considered for coverage when it is reasonable and necessary to deliver iloprost to beneficiaries with pulmonary hypertension only. Claims for use with other inhalation solutions will be denied as not reasonable and necessary. **Treprostinil Inhalation Solution and Iloprost** are considered for coverage when all of the following criteria 1–3 are met: 1. The beneficiary has a diagnosis of pulmonary artery hypertension; **and** 2. The pulmonary hypertension is not secondary to pulmonary venous hypertension or disorders of the respiratory system; **and** 3. The beneficiary has primary pulmonary hypertension or pulmonary hypertension which is secondary to one of the following conditions: connective tissue disease, thromboembolic disease of the pulmonary arteries, human immunodeficiency virus (HIV) infection, cirrhosis, anorexigens or congenital left to right shunts. If these conditions are present, the following criteria (a–d) must be met: a. The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition, **and** b. The mean pulmonary artery pressure is > 25 mm Hg at rest or > 30 mm Hg with exertion, **and** c. The beneficiary has significant symptoms from the pulmonary hypertension, **and** d. Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out. **Nebulizer Supplies** Separately payable if the related aerosol compressor and individual accessories are reasonable and necessary. A4619 Face tent ..... 1/1 month A7003 Administration set, with small volume non-filtered pneumatic nebulizer, disposable ..... 2/1 month A7004 Small volume non-filtered pneumatic nebulizer, disposable ..... 2/1 month (in addition to A7003) A7005 Administration set, with controlled dose inhalation drug delivery system, non-disposable ... 1/6 months A7005 Administration set, with controlled dose inhalation drug delivery system, non-disposable ... 1/3 months (only with K0730) A7006 Administration set, with small volume filtered pneumatic nebulizer ..... 1/1 month A7007 Large volume nebulizer, disposable, unfilled, used with aerosol compressor ..... 2/1 month A7010 Corrugated tubing, disposable, used with large volume nebulizer, 1 unit (100 feet) ..... 1/2 months A7011 Corrugated tubing, non-disposable, used with large volume nebulizer, 1 unit (10 feet) ..... 1/1 year A7012 Water collection device, used with large volume nebulizer ..... 2/1 month A7013 Filter, disposable, used with aerosol compressor ..... 2/1 month A7014 Filter, non-disposable, used with aerosol compressor or ultrasonic generator ..... 1/3 months A7015 Aerosol mask ..... 1/1 month A7016 Dome and mouthpiece, used with small volume ultrasonic nebulizer ..... 2/1 year A7017 Nebulizer, durable, glass or autoclavable plastic, bottle type ..... 1/3 years A7525 Tracheostomy mask ..... 1/1 month E1372 Immersion external heater for nebulizer ..... 1/3 years
NEBULIZER MEDICATIONS	✓		✓			covered when administered via a prescribed nebulizer: Acetylcysteine ..... up to 74 grams/month) Albuterol ..... up to 465 mg/month* Albuterol/Ipratropium combination ..... up to 186 units/month) Arformoterol (Brovana) ..... up to 930 mcg or 62 units/month *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
✳ **NEBULIZER MEDICATIONS** *(continued)*						Budesonide .....up to 31 mg/month or 62 units/month Cromolyn sodium ..... up to 2,480 mg/month or 248 units/month Distilled water, sterile water, or sterile saline in large volume nebulizer .....up to 18 liters/month Dornase alpha .....up to 78 mg/month Formoterol (Perforomist) .....up to 1240 mcg or 62 units/month Ipratropium bromide .....up to 93 mg/month Levalbuterol .....up to 232.5 mg/month or 465 units/month* Metaproterenol.....up to 2800 mg/month or 280 units/month* Pentamidine .....up to 300 mg/month Revefenacin.....up to 5250 mcg/month Sterile saline or water, 10 ml/unit .....up to 56 units/month Tobramycin Treprostinil .....up to 31 units/month *See Special Drug Coverage below. **Special Drug Coverage** The following are short-acting bronchodilators with beta-adrenergic agonist stimulatory effect (SABA) drugs that are covered if it is used as a rescue/supplemental medication in addition to the long-acting beta-adrenergic agonist drug, Formoterol or Arformoterol. (See criterion (a) in the NEBULIZER section.) Albuterol .....up to 78 mg/month Albuterol/Ipratropium combination .....up to 31 units/month Levalbuterol .....up to 39 mg/month or 78 units/month Metaproterenol.....up to 470 mg/month or 47 units/month Claims for more than these amounts of drugs will be denied as not reasonable and necessary. It is not reasonable and necessary for a beneficiary to use more than one of these at a time. The use of more than one of these drugs at the same time will be denied as not reasonable and necessary. Revefenacin is a long-acting muscarinic antagonist. Concurrent use of long-acting and short-acting muscarinic antagonists, such as ipratropium is not reasonable and necessary. Therefore, if a long-acting muscarinic antagonist is used, the short-acting muscarinic antagonist will be denied as not reasonable and necessary. **Documentation Requirements** There must be clear documentation in the beneficiary's medical records, within 12 months prior to the date of service, corroborating the medical necessity of the current use. The supplier must monitor the amount of supplies and accessories a beneficiary is actually using and assure that the beneficiary has nearly exhausted the supply on hand prior to dispensing any additional items. Suppliers must not deliver refills without a request from a beneficiary, and must not exceed a beneficiary's expected utilization.
✳ **NEGATIVE PRESSURE WOUND THERAPY**	✓		✓		✓	covered when either criterion A or B is met: **Initial Coverage Requirements** A. Ulcers and wounds **<u>in the home setting</u>:** The beneficiary has a chronic Stage III or Stage IV pressure ulcer, neuropathic (for example, diabetic) ulcer, venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology. A complete wound therapy program described by criterion 1 and criteria 2, 3 **or** 4, as applicable depending on the type of wound, must have been tried or considered and ruled out prior to the application of NPWT. *(continued)*

ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
✳ **NEGATIVE PRESSURE WOUND THERAPY** *(continued)*						1. For all ulcers or wounds, the following components of a wound therapy program must include a minimum of all of the following general measures, which should **either** be addressed, applied, **or** considered and ruled out prior to application of NPWT: a. Documentation in the beneficiary's medical record of evaluation, care, and wound measurements by a licensed medical professional, **and** b. Application of dressings to maintain a moist wound environment, **and** c. Debridement of necrotic tissue if present, **and** d. Evaluation of and provision for adequate nutritional status. 2. For Stage III or Stage IV pressure ulcers: a. The beneficiary has been appropriately turned and positioned, **and** b. The beneficiary has used a Group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis, **and** c. The beneficiary moisture and incontinence have been appropriately managed. 3. For neuropathic (for example, diabetic) ulcers: a. The beneficiary has been on a comprehensive diabetic management program, **and** b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities. 4. For venous insufficiency ulcers: a. Compression bandages and/or garments have been consistently applied, **and** b. Leg elevation and ambulation have been encouraged. B. Ulcers and wounds encountered in **an in-patient** setting: In either situations B-1 or B-2, NPWT will be covered when treatment continuation is ordered beyond discharge to the home setting. A DMEPOS supplier cannot bill Medicare Part B for the time the treatment is used in an in-patient setting. 1. An ulcer or wound, described under A above, is encountered in the in-patient setting and, after wound treatments described under A-1 through A-4 have been tried or considered and ruled out, NPWT is initiated because it is considered to be the best available treatment option in the judgment of the treating practitioner, **or** 2. The beneficiary has complications of a surgically created wound (for example, dehiscence) or a traumatic wound (for example, pre-operative flap or graft) where there is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (for example, other conditions of the beneficiary that will not allow for healing times achievable with other topical wound treatments). If criterion A or B is not met, the NPWT pump and supplies will be denied as not reasonable and necessary. Additionally, an NPWT pump and supplies will be denied at any time as not reasonable and necessary if one or more of the following are present: • The presence in the wound of necrotic tissue with eschar, if debridement is not attempted • Untreated osteomyelitis within the vicinity of the wound • Cancer present in the wound • The presence of a fistula to an organ or body cavity within the vicinity of the wound **Continued Coverage Criteria** C. For wounds and ulcers described under criterion A **or** B, once placed on an NPWT pump and supplies, in order for coverage to continue, a licensed medical professional must do the following: 1. On a regular basis, a. Directly assess the wound(s) being treated with the NPWT pump, **and** b. Supervise or directly perform the NPWT dressing changes, **and** 2. On at least a monthly basis, document changes in the ulcer's dimensions and characteristics.

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
✶ **NEGATIVE PRESSURE WOUND THERAPY** *(continued)*						If criteria C-1 and C-2 are not fulfilled, continued coverage of the NPWT pump and supplies will be denied as not reasonable and necessary. For wounds and ulcers described under criterion A or B, an NPWT pump and supplies will be denied as not reasonable and necessary with any of the following, whichever occurs earliest: 1. Criteria C-1 and C-2 cease to occur. 2. In the judgment of the treating practitioner, adequate wound healing has occurred to the degree that NPWT may be discontinued. 3. Any measurable degree of wound healing has failed to occur over the prior month. Wound healing is defined as improvement occurring in either surface area (length times width) or depth of the wound. 4. Four months (including the time NPWT was applied in an in-patient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of the most recent wound. 5. Once equipment or supplies are no longer being used for the beneficiary. Documentation of the history, previous treatment regimens, and current wound management for which an NPWT pump is being billed must be present in the beneficiary's medical record. This documentation must include such elements as length of sessions of use, dressing types and frequency of change, and changes in wound conditions, including precise measurements (length, width, and depth), quantity of exudates, presence of granulation and necrotic tissue and concurrent measures being addressed relevant to wound therapy (debridement, nutritional concerns, support surfaces in use, positioning, incontinence control, etc.). The medical record must include a statement from the treating practitioner describing the initial condition of the wound (including measurements) and the efforts to address all aspects of wound care (listed in A-1 through A-4). For each subsequent month, the medical record must include updated wound measurements and what changes are being applied to effect wound healing. **Supplies for the NPWT** A maximum of 15 dressing kits per wound per month are covered when used with a covered Negative Pressure Wound Therapy pump. Coverage is provided up to a maximum of 10 canister sets per month unless there is documentation evidencing a drainage greater than 90 ml of exudate per day and the beneficiary is using a stationary pump with the largest capacity canister. Suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a request from a beneficiary, and must not exceed a beneficiary's expected utilization. Regardless of utilization, a supplier must not dispense more than a one (1)-month quantity at a time.
NEUROMUSCULAR ELECTRICAL STIMULATOR (NMES)	✓		✓		✓	coverage is limited to the treatment of disuse atrophy where nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and other non-neurological reasons for disuse atrophy, e.g., in cases involving casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions or hip replacement until orthotic training begins. For Neuromuscular Electrical Stimulator use with walking for beneficiaries with spinal cord injury, coverage is limited to beneficiaries who have completed a training program which consists of at least 32 physical therapy sessions with the device over a period of three months, and meet ALL of the following criteria. The beneficiary must: 1. Have intact lower motor units (L1 and below) (both muscle and peripheral nerve); **and** 2. Have muscle and joint stability for weight bearing at upper and lower extremities and be able to demonstrate balance and control to maintain an upright support posture independently; **and** 3. Demonstrate brisk muscle contraction to NMES and have sensory perception electrical stimulation sufficient for muscle contraction; **and** 4. Possess high motivation, commitment and cognitive ability to use such devices for walking; **and** 5. Be able to transfer independently and demonstrate independent standing tolerance for at least 3 minutes; **and** 6. Be able to demonstrate hand and finger function to manipulate controls; **and** *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
NEUROMUSCULAR ELECTRICAL STIMULATOR (NMES) *(continued)*						7. Be at least 6 months post recovery spinal cord injury and restorative surgery; **and** 8. Be without hip and knee degenerative disease and have no history of long bone fracture secondary to osteoporosis; **and** 9. Demonstrate a willingness to use the device long-term. NMES for walking will not be covered in SCI beneficiary with any of the following: 1. Persons with cardiac pacemakers 2. Severe scoliosis or severe osteoporosis 3. Skin disease or cancer at area of stimulation 4. Irreversible contracture; **or** 5. Autonomic dysflexia
✶ **NON-INVASIVE VENTILATOR (NIV)**						see VENTILATOR (NON-INVASIVE AND INVASIVE).
OSTEOGENESIS STIMULATOR (NON-SPINAL)	✓		✓		✓	covered if any of the following criteria are met: 1. Non-union of a long bone fracture defined as radiographic evidence that fracture healing has ceased for three or more months prior to starting treatment with the osteogenesis stimulator, **or** 2. Failed fusion of a joint other than in the spine where a minimum of nine months has elapsed since the last surgery, **or** 3. Congenital pseudarthrosis. Coverage for this equipment is diagnosis driven. Please refer to the applicable Local Coverage Determination (LCD) for associated ICD-10 diagnosis codes. Non-union of a long bone fracture must be documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days, each including multiple views of the fracture site, and with a written interpretation by a treating practitioner stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.
OSTEOGENESIS STIMULATOR (SPINAL)	✓			✓	✓	covered if any of the following criteria are met: 1. Failed spinal fusion where a minimum of nine months has elapsed since the last surgery, **or** 2. Following a multilevel spinal fusion surgery, **or** 3. Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site. Coverage for this equipment is diagnosis driven. Please refer to the applicable Local Coverage Determination (LCD) for associated ICD-10 diagnosis codes.
OSTOMY EQUIPMENT AND SUPPLIES	✓		✓			covered if beneficiary is diagnosed with an ostomy (a surgically created opening [stoma] to divert urine, feces or ileal contents outside the body). Ostomy supplies are appropriately used for colostomies; ileostomies; or urinary ostomies. Use for other conditions will be denied as non-covered. Coverage for this equipment is diagnosis driven. Please refer to the applicable Policy Article (A52487) at this link. The quantity of ostomy supplies needed by a beneficiary is determined by the type of ostomy, its location, its construction and the condition of the skin surface surrounding the stoma. The Local Coverage Determination (LCD) provides the usual maximum quantity of supplies for the various ostomy supplies. Provision of ostomy supplies should be limited to a three-month supply for a beneficiary at home. **Note:** Ostomy supplies are not separately payable when a beneficiary is in a covered home health episode. When the beneficiary is in a covered home health episode, ostomy supplies must be provided by the home health agency and payment is included in the home health agency's Medicare payment rate.

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OVERBED TABLE		✓				not covered; convenience item; not primarily medical in nature.
OXYGEN (HIGH LITER FLOW)	✓				✓	covered if basic oxygen coverage criteria have been met, a higher allowance for a stationary system for a flow rate of greater than 4 liters per minute (LPM) will be paid only if a blood gas study performed while the beneficiary is on 4 or more LPM meets Group I or II criteria. If a flow rate greater than 4 LPM is billed and the coverage criterion for the higher allowance is not met, payment will be made at the standard fee schedule rate.
✶ **OXYGEN SYSTEM**	✓				✓	covered if the treating practitioner has ordered and evaluated the results of a qualifying blood gas study performed at the time of need and the beneficiary's blood gas studies meet one of the criteria below; and the qualifying blood gas study was performed by a treating practitioner or by a qualified provider or supplier of laboratory services; and the provision of oxygen and oxygen equipment in the home setting will improve the beneficiary's condition. Time of need is defined as during the patient's illness when the presumption is that the provision of oxygen will improve the patient's condition in the home setting. For an inpatient hospital patient anticipated to require oxygen upon going home, the time of need would be within 2 days of discharge. Documentation for initial coverage requires information in the medical record showing: • Evidence of qualifying test results at the time of need; **and** • Evidence of an evaluation of the qualifying test results by a treating practitioner The above information should be documented in the beneficiary's medical record. Beneficiaries with the following conditions may require home oxygen therapy: • Asthma • Chronic Obstructive Pulmonary Disease (COPD) – Chronic bronchitis – Emphysema • Pulmonary fibrosis • Congestive heart failure due to cor pulmonale, right heart failure or diastolic heart failure • Occupational lung disease • Lung cancer • Cystic fibrosis There are four basic groups of values for ABGs and O_2 saturation that will determine coverage. **Group I** Criteria include any of the following: 1. An arterial PO_2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88% taken at rest (awake), **or** 2. An arterial PO_2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken during sleep for a beneficiary who demonstrates an arterial PO_2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89% while awake, **or** 3. A decrease in arterial PO_2 more than 10 mm Hg, or a decrease in arterial oxygen saturation more than 5% from baseline saturation, taken during sleep and associated with symptoms or signs reasonably attributable to hypoxemia (e.g., cor pulmonale, "P" pulmonale on EKG, documented pulmonary hypertension and erythrocytosis), **or** 4. An arterial PO_2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88%, taken during exercise for a beneficiary who demonstrates an arterial PO_2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89% during the day while at rest. In this case, oxygen is provided for during exercise if it is documented that the use of oxygen improves the hypoxemia that was demonstrated during

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
OXYGEN SYSTEM *(continued)*						exercise when the beneficiary was breathing room air. **Note:** Coverage for beneficiaries meeting Group I criteria is limited to 12 months or the treating practitioner specified length of need, whichever is shorter. **Group II** Criteria include the presence of: 1. An arterial PO_2 of 56 – 59 mm Hg or an arterial blood oxygen saturation of 89% at rest (awake), during sleep, or during exercise (as described under Group I criteria), **and** 2. Any of the following: a. Dependent edema suggesting congestive heart failure, **or** b. Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF), **or** c. Erythrocythemia with a hematocrit greater than 56%. **Note:** Coverage for beneficiaries meeting Group II criteria is limited to 3 months or the treating practitioner specified length of need, whichever is shorter. **Group III** Criteria: 1. Absence of hypoxemia defined in Group I and Group II above; **and** 2. 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 IV** Criteria: Oxygen therapy and oxygen equipment will also be denied as not reasonable and necessary if any of the following conditions are present: 1. 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** 2. Dyspnea without cor pulmonale or evidence of hypoxemia; **or** 3. 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_2 will improve the oxygenation of tissues with impaired circulation; **or** 4. Terminal illnesses that do not affect the ability to breathe. Qualifying test during exercise: In instances where a beneficiary qualifies for oxygen based on a test conducted during exercise, the following tests must be obtained in order for coverage criteria to be met: 1. Testing at rest without oxygen: A test taken while the beneficiary is at rest breathing room air, **and** 2. Testing during exercise without oxygen: During exercise, while the beneficiary continues to breathe room air, **and** 3. Testing during exercise with oxygen applied (to demonstrate the improvement of the hypoxemia) is required: A test taken with the beneficiary receiving supplemental oxygen, which shows an improvement in the hypoxemia that was demonstrated during exercise when the beneficiary was breathing room air. All three tests must be performed within the same testing session. Exercise testing must be performed in-person by a treating practitioner or other medical professional qualified to conduct exercise oximetry testing. Unsupervised or remotely supervised home exercise testing does not qualify as a valid test for purposes of Medicare reimbursement of home oxygen and oxygen equipment. **Note:** Oximetry obtained after exercise while resting, sometimes referred to as "recovery" testing, is not part of the three required test elements and is not valid for determining eligibility for oxygen coverage. Qualifying test conducted during sleep: In instances where a beneficiary qualifies for oxygen based on a test conducted during sleep, the following tests must be obtained in order for coverage criteria to be met: *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
OXYGEN SYSTEM *(continued)*						1. During sleep, the beneficiary's arterial PO_2 is <55 mm Hg or the O_2 SAT <88%, **or** 2. During sleep, there is a decrease in the arterial PO_2 of more than 10 mm Hg or a decrease in the O_2 SAT of more than 5% and the beneficiary suffers with symptoms (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia) or signs (cor pulmonale, "P" pulmonale on EKG, pulmonary hypertension, erythrocytosis) reasonably attributable to hypoxemia. Overnight sleep oximetry may be performed in a facility or at home. For home overnight oximetry studies, the oximeter provided to the beneficiary must be tamper-proof and must have the capability to download data that allows documentation of the duration of oxygen desaturation below a specified value. • Baseline saturation is defined as the mean saturation level during the duration of the test. For purposes of meeting criterion 3 described in Group I above there must be a minimum of 2 hours test time recorded for sleep oximetry. The result must reach a qualifying test value. • Home overnight sleep oximetry is limited solely to stand-alone overnight pulse oximetry performed in the beneficiary's home. Overnight oximetry performed as part of home sleep testing or part of any other home testing is not considered to be eligible under this provision to be used for qualification for home oxygen. • Beneficiaries may self-administer home based overnight oximetry tests under the direction of a Medicare-enrolled Diagnostic Testing Facility (IDTF). • A DME supplier or another shipping entity may deliver a pulse oximetry test unit and related technology to a beneficiary's home under the following circumstances: – The beneficiary's treating practitioner has contacted the IDTF to order an overnight pulse oximetry test before the test is performed. – The test is performed under the direction and/or instruction of a Medicare-approved IDTF. Because it is the beneficiary who self-administers this test, the IDTF must provide clear written instructions to the beneficiary on proper operation of the test equipment and must include access to the IDTF in order to address other concerns that may arise. The DME supplier may not create this written instruction, provide verbal instructions, answer questions from the beneficiary, apply or demonstrate the application of the testing equipment to the beneficiary, or otherwise participate in the conduct of the test. – The test unit is sealed and tamper-proof such that test results cannot be accessed by anyone other than the IDTF which is responsible for transmitting the test report to the treating practitioner. The DME supplier may use related technology to download test results from the testing unit and transmit those results to the IDTF. In no case may the DME supplier access or manipulate the test results in any form. **Note:** Overnight oximetry does not include oximetry obtained during polysomnography or other sleep testing for sleep apnea, regardless of the location the testing was performed. Beneficiaries who meet coverage criteria during sleep do not qualify for payment of portable oxygen equipment. **Concurrent Use of Oxygen with PAP Therapy** Some beneficiaries may require the simultaneous use of home oxygen therapy and oxygen equipment with a PAP device. To be considered for simultaneous coverage, all requirements in both the Oxygen and Oxygen Equipment and Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea LCDs must be met. For beneficiaries with Obstructive Sleep Apnea (OSA), this means that the OSA must be sufficiently treated such that the underlying condition resulting in hypoxemia is unmasked. This must be demonstrated before oxygen saturation results obtained during polysomnography are considered qualifying for oxygen therapy. A qualifying oxygen saturation test may only occur during a titration polysomnographic study (either split night or stand-alone) if all of the following criteria are met: 1. The titration is conducted over a minimum of two (2) hours; **and** 2. During titration: *(continued)*

ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
✳ **OXYGEN SYSTEM** *(continued)*						a. The AHI/RDI is reduced to less than or equal to an average of ten (10) events per hour; **or** b. If the initial AHI/RDI was less than an average of ten (10) events per hour, the titration demonstrates further reduction in the AHI/RDI; **and** 3. Nocturnal oximetry conducted for the purpose for oxygen reimbursement qualification may only be performed after optimal PAP settings have been determined and the beneficiary is using the PAP device at those settings; **and** 4. The nocturnal oximetry conducted during the PSG demonstrates an oxygen saturation ≤ 88%. Beneficiaries who qualify for oxygen therapy based on testing conducted only during the course of a sleep test are eligible only for reimbursement of stationary equipment. **Initial SWO and Visit Requirements** An initial SWO is required in the following situations: 1. With the first claim for home oxygen billed to Medicare Fee-for-Service. 2. During the first 36 months of the rental period, when there has been a change in the beneficiary's condition that has caused a break in medical necessity of at least 60 days plus whatever days remain in the rental month during which the need for oxygen ended. 3. When the equipment is replaced because the reasonable useful lifetime of prior equipment has been reached. 4. When the equipment is replaced because of irreparable damage, theft, or loss of the originally dispensed equipment. In situations 3 and 4 (replacement equipment), repeat blood gas testing is not required and the most recent qualifying test may be used. **Recertification and Visit Requirements** • For beneficiaries initially meeting Group I criteria, there is no formal requirement for a re-evaluation but practitioners should ensure the oxygen remains reasonable and necessary. • Beneficiaries initially meeting Group II criteria must be seen and re-evaluated by the treating practitioner and retested between the 61st and 90th day after the initiation of therapy. A new SWO is required at that time. • Beneficiaries initially meeting Group III criteria must be seen and re-evaluated by the treating practitioner and retested between the 61st and 90th after initiation of therapy. A new SWO is required. **Note:** If oxygen coverage is approved, any equipment and supplies necessary to the beneficiary's use of covered home oxygen therapy, such as regulators (flowmeters), humidifiers and face masks, are also covered. Back-up oxygen tanks are not covered. Supplies are not separately reimbursable unless the equipment is owned by the beneficiary. **Reasonable Useful Lifetime (RUL)** The RUL for oxygen equipment is 5 years. The RUL is not based on the chronological age of the equipment. It starts on the initial date of service and runs for 5 years from that date. As a result of the Deficit Reduction Act (DRA) and the Medicare Improvements for Patients and Providers Act (MIPPA), Medicare will pay for stationary gaseous or liquid oxygen equipment rental for 36 months, at which time it is considered capped. After the equipment has reached cap, Medicare will pay for stationary contents until the RUL has been met. At any time after the end of the 5 year reasonable useful lifetime for oxygen equipment, the beneficiary may elect to receive new equipment, thus beginning a new 36-month rental period.
OXYGEN SYSTEM (OXIMETERS AND REPLACEMENT PROBES)		✓				not covered; monitoring devices that provide information to treating practitioners to assist in managing the beneficiary's treatment.
✳ **OXYGEN SYSTEM (PORTABLE)**	✓				✓	covered if the beneficiary is mobile within the home **and** the qualifying blood gas study was performed while at rest (awake) or during exercise. If the only qualifying blood gas study was performed during sleep, portable oxygen will be denied as not medically necessary. If coverage criteria are met, a portable oxygen system is usually separately payable in addition to the stationary system. If a portable oxygen system is *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
✶ **OXYGEN SYSTEM (PORTABLE)** *(continued)*						covered, the supplier must provide whatever quantity of oxygen the beneficiary uses; Medicare's reimbursement is the same, regardless of the quantity of oxygen dispensed. Oxygen Portable systems include: E0431 (Portable Gaseous Oxygen System), E0433 and E0434 (Portable Liquid Oxygen System), E1392 (Portable Oxygen Concentrator) and K0738 (Portable Gaseous Oxygen System-home compressor used to fill portable oxygen cylinders).
✶ **OXYGEN TRAVELING BENEFICIARIES**						**Relocation and Travel** Months 1 through 36 If the beneficiary relocates outside the supplier's service area (for either short-term travel, extended temporary relocation, or permanent relocation), then for the remainder of the rental month for which it billed, the home supplier is required to provide the equipment and related items/service or make arrangements with a different supplier to provide the equipment, items, and services. For subsequent rental months that the beneficiary is outside the service area, the home supplier is encouraged to either provide the equipment and related items/services or assist the beneficiary in finding another supplier in the new location. The home supplier may not bill for or be reimbursed by Medicare if it is not providing oxygen equipment or has not made arrangements with a different supplier to provide the equipment on the anniversary billing date. Medicare will pay only one supplier to provide oxygen during any one-rental month. Months 37 through 60 Medicare law requires that the supplier that furnishes the oxygen and oxygen equipment during the 36th month of continuous use must continue to furnish the oxygen and oxygen equipment after the cap for any period of medical need for the remainder of the reasonable useful lifetime of the equipment. Therefore, if the beneficiary relocates outside the supplier's service area (for either short-term travel, extended temporary relocation, or permanent relocation), the home supplier is required to either provide the equipment and related items/services or make arrangements with a different supplier to provide the equipment and related items/services. Miscellaneous Oxygen services furnished by an airline to a beneficiary are non-covered. Payment for oxygen furnished by an airline is the responsibility of the beneficiary and not the responsibility of the supplier. Medicare does not cover items or services provided/used outside the United States and its territories. The supplier is not required to provide or arrange for oxygen use in those situations.
PATIENT LIFT	✓		✓		✓	covered if transfer between bed and a chair, wheelchair, or commode is required and, without the use of a lift, the beneficiary would be bed confined. A multi-positional patient transfer system is covered if the beneficiary meets this criteria **and** requires supine positioning for transfers.
PEAK FLOWMETERS	✓		✓		✓	covered for the self-monitoring of beneficiaries with pure asthma when they are used as part of a comprehensive asthma management program.
PERCUSSOR	✓		✓		✓	covered for mobilizing respiratory tract secretions caused by COPD, chronic bronchitis or emphysema when the beneficiary or operator of the device has been trained by a practitioner and no one is available to administer manual therapy to the beneficiary.
PNEUMATIC COMPRESSION DEVICE	✓				✓	covered when criteria for lymphedema coverage or chronic venous insufficiency (CVI) with venous stasis ulcers coverage is met in addition to the general coverage criteria. **General Coverage Criteria** Determination by the treating practitioner of the medical necessity of a pneumatic compression device must include: 1. The beneficiary's diagnosis and prognosis; **and** 2. Symptoms and objective findings, including measurements which establish the severity of the condition; **and** *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
✳ **PNEUMATIC COMPRESSION DEVICE** *(continued)*						3. The reason the device is required, including the treatments which have been tried and failed; **and** 4. The clinical response to an initial treatment with the device. Clinical response includes the change in pretreatment measurements, ability to tolerate the treatment session and parameters, and ability of the beneficiary (or caregiver) to apply the device for continued use in the home. A signed and dated Standard Written Order (SWO) is required in all instances. **Lymphedema Coverage** The beneficiary must undergo a four-week trial of conservative therapy that, when concluded, the treating practitioner determines that there has been no significant improvement. Conservative therapy includes: • Use of an appropriate compression bandage system or compression garment (the garment may be prefabricated or custom fabricated, but must provide adequate graduated compression); **and** • Exercise; **and** • Elevation of the limb **Lymphedema Extending onto the Chest, Trunk and/or Abdomen** The beneficiary must undergo a four-week trial of conservative therapy that, when concluded, the treating practitioner determines that there has been no significant improvement. Conservative therapy includes: • At least four weeks of daily, multi-hour home use after fitting, training and supervision by skilled technician; **and** • Use of an appropriate compression bandage system or compression garment; **and** • Exercise; **and** • Elevation (where appropriate); **and** • Manual and self-manual lymphatic drainage at least 30 minutes per day; **and** • Evaluation of diet; **and** • Medications as appropriate; **and** • Correction of anemia and/or hypoprotenemia **Chronic Venous Insufficiency (CVI) with Venous Status Ulcers Coverage** The beneficiary must have one or more venous stasis ulcer(s) of the lower extremities that have failed to heal after six months of conservative therapy which has been directed by the treating practitioner. Conservative therapy includes: • Use of an appropriate compression bandage system or compression garment; **and** • Appropriate dressings for the wound; **and** • Medications as appropriate; **and** • Exercise; **and** • Elevation of the limb; **and** • Appropriate wound care for the ulcer In addition, the beneficiary's medical record must also document: • Location and size of venous stasis ulcer(s); **and** • Length of time ulcer has been continuously present; **and** • Conservative treatment methods (as listed above) have been tried; **and** • History of regular visits with the treating practitioner for the conservative treatment period (six months).

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PNEUMATIC COMPRESSION DEVICE *(continued)*						If a segmental, calibrated gradient pressure pneumatic compression device is ordered, the treating practitioner must indicate the following: • The treatment plan including the pressure in each chamber, and the frequency and duration of each treatment; **and** • Whether a segmented compressor without calibrated gradient pressure or a non-segmented compressor with a segmented appliance has been tried and the results of the trial; **and** • Why additional features are needed; **and** • The name, model number and manufacturer of the device.
PORTABLE OXYGEN SYSTEM						see OXYGEN SYSTEM (PORTABLE).
POSITIVE AIRWAY PRESSURE (PAP) DEVICE	✓		✓		✓	covered if the beneficiary is diagnosed with obstructive sleep apnea (OSA). Coverage for this equipment is diagnosis driven. Please refer to the applicable Local Coverage Determination (LCD) for associated ICD-10 diagnosis code. The PAP policy applies to both a Continuous Positive Airway Pressure (CPAP) device as well as a bi-level device when used to treat OSA. Please refer to Respiratory Assist Device (RAD) for bi-level coverage criteria when the beneficiary's diagnosis is other than OSA. The diagnosis of OSA must be documented by either an attended, facility-based polysomnogram (sleep study) or an in-patient hospital-based or home-based sleep test (HST). The sleep study must be signed by the interpreting practitioner. **Initial Coverage for New Set-Up (First 3 Months)** <u>Continuous Positive Airway Pressure (CPAP)</u> A single level continuous positive airway pressure (CPAP) device is covered for the treatment of obstructive sleep apnea (OSA) if criteria A – C are met. A. The beneficiary has a in-person clinical evaluation by the treating practitioner prior to the sleep test to assess the beneficiary for obstructive sleep apnea. The initial evaluation should document pertinent information about the beneficiary's history of sleep-related issues and should address the following elements, but may include other details. Each element would not have to be addressed in every evaluation. **History** 1. Signs and symptoms of sleep disordered breathing including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches 2. Duration of symptoms 3. Validated sleep hygiene inventory such as the Epworth Sleepiness Scale **Physical Exam** 1. Focused cardiopulmonary and upper airway system evaluation 2. Neck circumference 3. Body mass index (BMI) B. The beneficiary has a sleep test that meets either of the following criteria (1 or 2): 1. The Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) ≥ 15 events per hour with a minimum of 30 events; **or** 2. AHI or RDI ≥ 5 and ≤ 14 events per hour with a minimum of 10 events and documentation of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, or history of stroke. If the AHI or RDI is calculated based on less than 2 hours of sleep or recording time, the total number of recorded events used to calculate the AHI or RDI, respectively, must be at least the number of events that would have been required in a 2 hour period (i.e., must reach greater than or equal to 30 events without symptoms or greater than or equal to 10 events with symptoms). *(continued)*

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✳ **POSITIVE AIRWAY PRESSURE (PAP) DEVICE** *(continued)*						C. The beneficiary and/or his/her caregiver has/have received instruction from the supplier of the PAP device and accessories in the proper use and care of the equipment. Bi-Level Device A bi-level device without backup rate is covered for those beneficiaries with OSA who meet criteria A – C above, in addition to criterion D: D. A single level positive airway pressure device has been tried and proven ineffective, based on a therapeutic trial conducted in either a facility or in a home setting. Ineffective is defined as documented failure to meet therapeutic goals using a PAP device during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings). The treating practitioner must document that an appropriate interface has been properly fit and the beneficiary uses it without difficulty, the CPAP pressure setting prevented the beneficiary from tolerating the therapy and lower pressure settings of the CPAP tried but failed to: 1. Adequately control the symptoms of OSA, **or** 2. Improve sleep quality, **or** 3. Reduce the AHI/RDI to acceptable levels. **Continued Coverage Beyond the First 3 Months of Therapy** No sooner than the 31st day but no later than the 91st day after initiating therapy, the treating practitioner must conduct a face-to-face clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy. Documentation of clinical benefit is demonstrated by: 1. Face-to-face clinical re-evaluation by the treating practitioner (between the 31st and 91st day) with documentation that symptoms of obstructive sleep apnea are improved and the beneficiary is benefiting from PAP therapy; **and** 2. Objective evidence of adherence to use of the PAP device. Adherence to therapy is defined as use of PAP at least 4 hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage. This can be accomplished either through direct download or visual inspection of adherence information. If the above criteria are not met, continued coverage of a PAP device and related accessories will be denied as not medically necessary. Beneficiaries who fail the initial 12 week trial are eligible to re-qualify for a PAP device but must have both: 1. In-person clinical re-evaluation by the treating practitioner to determine the etiology of the failure to respond to PAP therapy; **and** 2. Repeat sleep test in a facility-based setting (Type 1 study).This may be a repeat diagnostic, titration or split-night study. Beneficiaries who switch from a CPAP to a bi-level device after the first 3 months require a new in-person evaluation but a new sleep study is not required. **Replacement PAP** If Medicare covered a PAP device for the beneficiary more than 5 years ago, a replacement PAP device may be provided under the following circumstances: 1. Beneficiary must have had a qualifying sleep study and have an in-person evaluation with the treating practitioner indicating the beneficiary continues to use the PAP device. A new practitioner's signed standard written order (SWO) is needed to reaffirm the medical necessity of the replacement PAP. 2. If the original unit was not covered more than 5 years ago but the unit was stolen, lost, or damaged beyond repair due to a specific incident, a new SWO as well as additional documentation is required: a. A police report (stolen); **or** b. Copy of the insurance claim (damaged); **or** c. Written statement from the beneficiary or caregiver (lost). *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
✳ **POSITIVE AIRWAY PRESSURE (PAP) DEVICE** *(continued)*						**Beneficiary Entering Medicare** If the beneficiary had a PAP device that was originally covered by another insurance company and now requires a new device or supplies under Medicare, the following are required prior to billing: 1. There must be documentation that the beneficiary had a sleep test, prior to FFS Medicare enrollment, that meets the Medicare AHI/RDI coverage criteria in effect at the time that the beneficiary seeks Medicare coverage of a replacement PAP device and/or accessories. 2. In-person beneficiary evaluation with the treating practitioner after the Medicare effective date that indicates the beneficiary's diagnosis of OSA and the beneficiary continues to use the PAP device. 3. A new treating practitioner's SWO is needed to reaffirm the medical necessity of the replacement PAP. There is no trial period for beneficiaries qualified under the Patient Entering Medicare or Replacement PAP requirements. However, if the beneficiary had a CPAP unit previously and switches to a bi-level or vice versa, the beneficiary must qualify for the new device following the new set-up guidelines. **Concurrent Use of Oxygen with PAP Therapy** Some beneficiaries may require the simultaneous use of home oxygen therapy with a PAP device. To be considered for simultaneous coverage, all requirements in the Indications and Limitations of Coverage and/or Medical Necessity for both Oxygen and Oxygen Equipment and Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea LCDs must be met. Please refer to the Oxygen Policy for additional coverage criteria. **PAP Accessories** A4604 Tubing with integrated heating element ..... 1/3 months A7027 Combination oral/nasal mask ..... 1/3 months A7028 Oral cushion for combination oral/nasal mask ..... 2/1 month A7029 Nasal pillows for combination oral/nasal mask ..... 2/1 month A7030 Full face mask ..... 1/3 months A7031 Replacement face mask interface for full face mask ..... 1/1 month A7032 Replacement cushion for nasal mask interface ..... 2/1 month A7033 Replacement pillows for nasal cannula type interface ..... 2/1 month A7034 Nasal interface (mask or cannula type) ..... 1/3 months A7035 Headgear ..... 1/6 months A7036 Chinstrap ..... 1/6 months A7037 Tubing ..... 1/3 months A7038 Disposable filter ..... 2/1 month A7039 Non-disposable filter ..... 1/6 months A7046 Replacement water chamber for humidifier ..... 1/6 months Accessories in excess of these time frames are rarely considered medically necessary. **Humidifiers** Either a non-heated or heated humidifier is covered when ordered by the treating practitioner for use with a covered PAP. E0561 Humidifier, non-heated, used with positive airway pressure device E0562 Humidifier, heated, used with positive airway pressure device
POSITIVE PRESSURE VENTILATOR						see VENTILATOR (NON-INVASIVE AND INVASIVE).

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
QUAD CANE						see CANES/CRUTCHES.
RAISED TOILET SEAT		✓				not covered; hygienic convenience item; not primarily medical in nature.
RECLINER WITH ELEVATING SEAT						see SEAT LIFT MECHANISM.
✶ **REGULATOR (OXYGEN)**						see OXYGEN SYSTEM.
REPAIRS	✓		✓			covered for beneficiary-owned equipment if the equipment is medically necessary. A new standard written order (SWO) for repairs is not required. If Medicare paid for the base item initially, medical necessity has been established. With respect to reimbursement for the repair, there are two documentation requirements: 1. Treating practitioner must document that the DMEPOS item being repaired continues to be reasonable and necessary. 2. Treating practitioner or supplier must document that the repair itself is reasonable and necessary. The supplier must maintain detailed records describing the need for and nature of all repairs including a detailed explanation of the justification for any component or part replaced as well as the labor time to restore the item to its functionality. **Repair HCPC Codes:** • K0739 Repair or non-routine service for DME other than oxygen requiring the skill of a technician, labor component, per 15 minutes • K0740 Repair or non-routine service for oxygen equipment requiring the skill of a technician, labor component, per 15 minutes **Note:** Parts and labor covered under manufacturer or supplier warranty are not considered reasonable and necessary. Repairs of rented equipment are not covered. This includes items in the frequent and substantial servicing, oxygen equipment, capped rental and inexpensive or routinely purchased payment categories which are being rented. Repairs are not allowed if coverage criteria is not met, or the equipment is under warranty, or Medicare previously denied the equipment. For a replacement to be covered, a new SWO is required to reaffirm the medical necessity of the item.
✶ **RESPIRATORY ASSIST DEVICE (RAD)**	✓		✓		✓	covered for the first three months of therapy under the following conditions: A RAD (E0470, E0471) is covered for those beneficiaries with one of the following clinical disorders: 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 (Comp SA); or IV. Hypoventilation syndrome; and who also meet the following criteria: I. Restrictive Thoracic Disorders An E0470 or E0471 device is covered when criteria A – C are met: A. There is documentation in the beneficiary's medical record of a neuromuscular disease (for example, amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (for example, post-thoracoplasty for TB). B. One of the following: 1. An arterial blood gas $PaCO_2$, done while awake and breathing the beneficiary's prescribed FIO_2 is ≥ 45 mm Hg; **or** 2. Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the beneficiary's prescribed recommended FIO_2; **or** 3. For a neuromuscular disease (only), either i or ii: a. Maximal inspiratory pressure is < 60 cm H_2O; **or** b. Forced vital capacity is < 50% predicted.

(continued)

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
✳ **RESPIRATORY ASSIST DEVICE (RAD)** *(continued)*						C. Chronic obstructive pulmonary disease does not contribute significantly to the beneficiary's pulmonary limitation. If all of the above criteria are met, either an E0470 or an E0471 device (based upon the judgment of the treating practitioner) will be covered for the first three months of therapy. II. Severe COPD An E0470 device is covered if criteria A – C are met: A. An arterial blood gas $PaCO_2$, done while awake and breathing the beneficiary's prescribed FIO2, is ≥ 52 mm Hg. B. Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the beneficiary's prescribed FIO2 (whichever is higher). C. 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 (Obstructive Sleep Apnea [OSA], CSA and/or Comp SA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation). If all of the above criteria for beneficiaries with COPD are met, an E0470 device will be covered for the first three months of therapy. An E0471 device will be covered for a beneficiary with COPD in either of the two situations below, depending on the testing performed to demonstrate the need. Situation 1: For Group II beneficiaries (COPD) who qualified for an E0470 device, an E0471 started any time after a period of initial use of an E0470 device is covered if **both** criteria a and b are met. 1. An arterial blood gas $PaCO_2$, done while awake and breathing the beneficiary's prescribed FIO2, shows that the beneficiary's $PaCO_2$ worsens ≥ 7 mm Hg compared to the original result from criterion A,(above). 2. A facility-based PSG demonstrates oxygen saturation ≤ 88% for ≥ a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours) while using an E0470 device that is not caused by obstructive upper airway events — i.e., AHI < 5. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea). Situation 2: For Group II beneficiaries (COPD) who qualified for an E0470 device, an E0471 device will be covered if, at a time no sooner than 61 days after initial issue of the E0470 device, **both** of the following criteria A and B are met: 1. An arterial blood gas $PaCO_2$ is done while awake and breathing the beneficiary's prescribed FIO2, still remains ≥ 52 mm Hg. 2. Sleep oximetry while breathing with the E0470 device, demonstrates oxygen saturation ≤ 88% for ≥ a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the beneficiary's prescribed FIO_2 (whichever is higher). III. Central Sleep Apnea or Complex Sleep Apnea An E0470 or E0471 device is covered when, prior to initiating therapy, a complete facility-based, attended PSG is performed documenting the following: (A **and** B) A. The diagnosis of central sleep apnea (CSA) or complex sleep apnea (Comp SA); **and** B. Significant improvement of the sleep-associated hypoventilation with the use of an E0470 or E0471 device on the settings that will be prescribed for initial use at home, while breathing the beneficiary's prescribed FIO_2. If all of the above criteria are met, either an E0470 or an E0471 device (based upon the judgment of the treating practitioner) will be covered for beneficiaries with documented CSA or Comp SA for the first three months of therapy. IV. Hypoventilation Syndrome An E0470 device is covered if both criteria A and B and either criterion C or D are met. *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
✳ **RESPIRATORY ASSIST DEVICE (RAD)** *(continued)*						A. An initial arterial blood gas $PaCO_2$, done while awake and breathing the beneficiary's prescribed FIO_2, is ≥ 45 mm Hg; **and** B. Spirometry shows an $FEV_1/FVC \geq 70\%$. (Refer to II. SEVERE COPD (above) for information about device coverage for beneficiaries with $FEV_1/FVC < 70\%$.) C. An arterial blood gas $PaCO_2$, done during sleep or immediately upon awakening, and breathing the beneficiary's prescribed FIO_2, shows the beneficiary's $PaCO_2$ worsened ≥ 7 mm Hg compared to the original result in criterion 1 (above); **or** D. A facility-based PSG or HST demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events — i.e., AHI < 5. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea.) An E0471 device is covered for a beneficiary with hypoventilation syndrome if both criteria A, B, and either criterion C or D are met: A. A covered E0470 device is being used; **and** B. Spirometry shows an $FEV_1/FVC \geq 70\%$. (Refer to II. SEVERE COPD (above) for information about device coverage for beneficiaries with $FEV_1/FVC < 70\%$.) C. An arterial blood gas $PaCO_2$, done while awake and breathing the beneficiary's prescribed FIO_2, shows that the beneficiary's $PaCO_2$ worsens ≥ 7 mm Hg compared to the ABG result performed to qualify the beneficiary for the E0470 device; **or** D. A facility-based PSG or HST demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events — i.e., AHI < 5 while using an E0470 device. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea.) **Medical Record Documentation Requirements** For an E0470 (Respiratory Assist Device, Bi-Level Pressure Capability, Without Backup Rate Feature, Used with Noninvasive Interface) or an E0471 (Respiratory Assist Device, Bi-Level Pressure Capability, with Backup Rate Feature, Used with Noninvasive Interface) RAD to be covered, the treating practitioner must fully document in the beneficiary's medical record symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc. Beneficiaries covered for the first three months of an E0470 or an E0471 device must be re-evaluated to establish the medical necessity of continued coverage by Medicare beyond the first three months. While the beneficiary may certainly need to be evaluated at earlier intervals after this therapy is initiated, the re-evaluation upon which Medicare will base a decision to continue coverage beyond this time must occur no sooner than 61 days after initiating therapy by the treating practitioner. There must be documentation in the beneficiary's medical record about the progress of relevant symptoms and beneficiary usage of the device up to that time. Failure of the beneficiary to be consistently using the E0470 or E0471 device for an average of 4 hours per 24 hour period by the time of the re-evaluation (on or after 61 days after initiation of therapy) would represent non-compliant utilization for the intended purposes and expectations of benefit of this therapy. **Note: A DME supplier is NOT considered a qualified supplier of any testing referenced above.**
RESUSCITATORS		✓				not covered.
ROLLABOUT/ROLLING CHAIR	✓		✓		✓	covered if beneficiary meets Mobility Assistive Equipment clinical criteria (see Wheelchairs). Coverage is limited to those roll-about chairs having casters of at least 5 inches in diameter and specifically designed to meet the needs of ill, injured, or otherwise impaired individuals.
SAFETY ROLLERS	✓		✓			covered if beneficiary meets Mobility Assistive Equipment clinical criteria.
SEAT LIFT MECHANISM	✓		✓		✓	covered if prescribed by the treating practitioner for beneficiaries with severe arthritis of the hip or knee, muscular dystrophy or some other neuromuscular disease, and use of the device benefits the beneficiary therapeutically. *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
SEAT LIFT MECHANISM *(continued)*						Coverage is limited to the seat lift mechanism only. Coverage is limited to seat lifts that operate smoothly, can be controlled by the beneficiary, and can help the beneficiary stand and sit without other assistance. Coverage will not be provided for seat lifts that operate using a spring-release mechanism with a sudden, catapult-like motion that jolts the beneficiary from a seated to a standing position. Also, if the seat lift uses a recliner feature, this feature will not be covered. The seat lift mechanism is covered if all of the following criteria are met: 1. The beneficiary must have severe arthritis of the hip or knee or have a severe neuromuscular disease. 2. The seat lift mechanism must be a part of the practitioner's course of treatment and be prescribed to affect improvement or arrest or retard deterioration in the beneficiary's condition. 3. The beneficiary must be completely incapable of standing up from a regular armchair or any chair in their home. (The fact that a beneficiary has difficulty or is even incapable of getting up from a chair is not sufficient justification for a seat lift mechanism. Almost all beneficiaries who are capable of ambulating can get out of an ordinary chair if the seat height is appropriate and the chair has arms.) 4. Once standing, the beneficiary must have the ability to ambulate. The practitioner ordering the seat lift mechanism must be the treating practitioner or a consulting practitioner for the disease or condition resulting in the need for a seat lift. The practitioner's record must document that all appropriate therapeutic modalities (e.g., medication, physical therapy) have been tried and failed to enable the beneficiary to transfer from a chair to a standing position.
SITZ BATH	✓		✓			covered if the beneficiary has been diagnosed with an infection or injury of the perineal area and the practitioner has prescribed the sitz bath as part of a planned regimen of home care treatment.
SPHYGMOMANOMETER WITH CUFF						see BLOOD PRESSURE MONITOR.
SPHYGMOSTAT						see BLOOD PRESSURE MONITOR.
STAIRGLIDE		✓				not covered; convenience item; not primarily medical in nature.
STETHOSCOPE	✓		✓			see BLOOD PRESSURE MONITOR.
SUCTION CATHETERS	✓		✓			covered when a suction pump is supplied to the beneficiary. Tracheal suction catheters are separately payable supplies. In most cases, in the home setting, sterile catheters are medically necessary only for tracheostomy suctioning. No more than three suction catheters per day are covered for medically necessary tracheostomy suctioning. When a tracheal suction catheter is used in the oropharynx, which is not sterile, the catheter can be reused if properly cleansed and/or disinfected. More than three catheters per week will be denied as not reasonable and necessary for oropharyngeal suctioning.
SUCTION MACHINE	✓		✓			covered if medically required and appropriate for home use without technical or professional supervision and the beneficiary has difficulty raising and clearing secretions secondary to any of the following conditions: 1. Cancer or surgery of the throat or mouth 2. Dysfunction of the swallowing muscles 3. Unconsciousness or obtunded state 4. Tracheostomy
SURGICAL DRESSINGS	✓		✓			covered when medically necessary for the treatment following a surgical procedure or when debridement of a wound is medically necessary.

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
TELEPHONE ALERT SYSTEM		✓				not covered.
TOILET RAIL		✓				not covered; comfort or convenience item, not primarily medical in nature.
TOILET SEAT		✓				not covered.
TRACHEOSTOMY CARE KITS	✓		✓			covered for beneficiaries following an open surgical tracheostomy which has been or is expected to be open for at least three months. Coverage for this equipment is diagnosis driven. Please refer to the applicable Local Coverage Determination (LCD) for associated ICD-10 diagnosis codes. The quantities of supplies included in a tracheostomy care kit are expected to provide all necessary quantities for the care of the tracheostomy site and there must not be any additional quantity billed of these codes for this purpose. **Tracheostomy Care or Cleaning Starter Kit** (A4625) is covered following an open surgical tracheostomy. Beginning two weeks post-operatively, code A4625 is no longer considered by Medicare to be medically necessary and, if that code is billed, will be denied as not reasonable and necessary. Alternatively, tracheostomy care kits provided after the first two postoperative weeks are considered for coverage and should be coded as A4629. **Tracheostomy/Laryngectomy Tube Plug/Stop** (A7527) is used as an alternative to a tracheostomy/laryngectomy tube and therefore for a beneficiary receiving A7527 claims for A7520, A7521 and A7522 will be denied as not reasonable or necessary. **Heat/Moisture Exchangers (HME)** are a type of stoma cover which help laryngectomees partially restore functions previously performed by the nose and upper airway. An HME may be used by itself or in addition to a tracheostoma valve (A7501). An explanation for use of a greater quantity of supplies than are covered by Medicare must be clearly documented in the beneficiary's medical record. If adequate documentation is not provided when requested, the excess quantities will be denied as not reasonable and necessary.
TRACTION EQUIPMENT	✓		✓		✓	covered if both of the following criteria are met: 1. The beneficiary has a musculoskeletal or neurologic impairment requiring traction equipment, **and** 2. The appropriate use of a home cervical traction device has been demonstrated to the beneficiary and the beneficiary tolerated the selected device.
TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR (TENS) AND SUPPLIES	✓		✓		✓	covered for the treatment of beneficiaries with chronic, intractable pain or acute post-operative pain when one of thefollowing coverage criteria are met. Coverage for this equipment is diagnosis driven. Please refer to the applicable Local Coverage Determination (LCD) for associated ICD-10 diagnosis codes. The practitioner ordering the TENS unit and related supplies must be the treating practitioner for the disease or condition justifying the need for the TENS unit. I. Acute Post-operative Pain TENS is covered for acute post-operative pain. Coverage is limited to 30 days (one month's rental) from the day of surgery. Payment will be made only as a rental. A TENS unit will be denied as not reasonable and necessary for acute pain (less than three months duration) other than for post-operative pain. II. Chronic Pain Other than Low Back Pain TENS is covered for chronic, intractable pain other than chronic low back pain when **all** of the following criteria are met: A. The presumed etiology of the pain must be a type that is accepted as responding to TENS therapy. Examples of conditions for which TENS therapy is not considered to be reasonable and necessary are (not all-inclusive): headache, visceral abdominal pain, pelvic pain, temporomandibular joint (TMJ) pain. B. The pain must have been present for at least three months. *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR (TENS) AND SUPPLIES *(continued)*						C. Other appropriate treatment modalities must have been tried and failed. TENS therapy for chronic pain that does not meet these criteria will be denied as not reasonable and necessary. <u>Chronic Low Back Pain (CLBP)</u> TENS therapy for CLBP will be denied as not reasonable and necessary. When used for the treatment of chronic, intractable pain, the TENS unit must be used by the beneficiary on a trial basis for a minimum of one month (30 days), but not to exceed two months. The trial period will be paid as a rental. The trial period must be monitored by the treating practitioner to determine the effectiveness of the TENS unit in modulating the pain. For coverage of a purchase, the treating practitioner must determine that the beneficiary is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time. A 4-lead TENS unit may be used with either 2 leads or 4 leads, depending on the characteristics of the beneficiary's pain. If it is ordered for use with 4 leads, the medical record must document why 2 leads are insufficient to meet the beneficiary's needs. Replacement supplies are covered when they are medically necessary and are used with a TENS unit that has been purchased. Replacement of lead wires more often than every 12 months would rarely be medically necessary. A conductive garment used with a TENS unit is rarely reasonable and necessary, but is covered only if: 1. It has been prescribed by the treating practitioner for use in delivering covered TENS treatment **and** 2. One of the following medical indications is met: a. The beneficiary cannot manage without the conductive garment because there is such a large area or so many sites to be stimulated and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes, and lead wires, **or** b. The beneficiary cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes, and lead wires, **or** c. The beneficiary has a documented medical condition, such as skin problems, that preclude the application of conventional electrodes, adhesive tapes, and lead wires, **or** d. The beneficiary requires electrical stimulation beneath a cast to treat chronic intractable pain. A conductive garment is not covered for use with a TENS device during the trial period unless the beneficiary has a documented skin problem prior to the start of the trial period and the TENS is reasonable and necessary for the beneficiary.
TRANSFER TUB RAIL ATTACHMENT		✓				not covered; comfort or convenience item, not primarily medical in nature.
TRAPEZE BAR	✓		✓			covered if the beneficiary has a covered hospital bed and the trapeze is being attached to the bed, and needs to sit up because of a respiratory condition, to change body position for other medical reasons, or to get in and out of bed. **Free Standing Trapeze** is covered if the beneficiary does not have a covered bed and needs to sit up because of a respiratory condition, to change body position for other medical reasons, or to get in and out of bed. **Heavy Duty Trapeze** is covered if the beneficiary meets the criteria for regular trapeze equipment and the beneficiary's weight is more than 250 pounds.
TUB CHAIR		✓				not covered; comfort or convenience item; not primarily medical in nature.
ULTRAVIOLET LIGHT CABINET	✓		✓		✓	covered for selected beneficiaries with generalized intractable psoriasis, if medical and other factors justify treatment at home, rather than at an alternative site, such as the out-patient department of a hospital.
URINALS (AUTOCLAVABLE)	✓		✓			covered if beneficiary is bed confined (hospital type).

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
UROLOGICAL SUPPLIES i.e., Indwelling Catheters, Drainage Bags, Urinary Catheters, etc.	✓		✓			covered if prescribed by the treating practitioner for a beneficiary who has permanent urinary incontinence or permanent urinary retention. Permanence is defined as the condition is not expected to be medically or surgically corrected in that beneficiary within three months. If the catheter or the external urinary collection device meets the coverage criteria, then the related supplies that are necessary for their effective use are also covered. Urological supplies that are used for purposes not related to the covered use of catheters or external urinary collection devices will be denied as noncovered. The beneficiary must have a permanent impairment of urination. The use of a urological supply for the treatment of chronic urinary tract infection or other bladder condition in the absence of permanent urinary incontinence or retention is noncovered. The written order must include the type of supplies ordered and the approximate quantity to be used per unit of time. The medical necessity for use of a greater quantity of supplies than the amounts specified in the policy must be well documented in the beneficiary's medical record and must be available upon request. **Indwelling Catheter** One catheter per month is covered for routine catheter maintenance. Non-routine catheter changes are covered when documentation substantiates medical necessity, i.e., catheter is accidently removed, malfunction of catheter, catheter obstruction, history of recurrent obstruction or urinary tract infection for which it has been established that an acute event is prevented by a scheduled change frequency of more than once per month, etc. **Specialty Indwelling Catheter or an All-Silicone Catheter** is covered when the criteria for an indwelling catheter (above) are met and there is documentation in the beneficiary's medical record to justify the medical need for that catheter, i.e., recurrent encrustation, inability to pass a straight catheter, or sensitivity to latex, etc. If documentation does not substantiate medical necessity, it will be denied as not reasonable and necessary. **Three-Way Indwelling Catheter** (either alone or with other components) will be covered only if continuous catheter irrigation is reasonable and necessary. **Continuous Irrigation of Indwelling Catheters** Supplies for continuous irrigation of a catheter are covered if there is a history of obstruction of the catheter and the patency of the catheter cannot be maintained by intermittent irrigation in conjunction with reasonable and necessary catheter changes. Continuous irrigation as a primary preventative measure will be denied as not reasonable and necessary. Documentation must substantiate the medical necessity of catheter irrigation and in particular continuous irrigation as opposed to intermittent irrigation. The records must also indicate the rate of solution administration and the duration of need. **Intermittent Irrigation of Indwelling Catheters** Supplies for the intermittent irrigation of an indwelling catheter are covered when they are used on an as needed (non-routine) basis in the presence of acute obstruction of the catheter. Routine intermittent irrigations of a catheter will be denied as not reasonable and necessary. Routine irrigations are defined as those performed at predetermined intervals. **Catheter Insertion Tray** One insertion tray will be covered per episode of indwelling catheter insertion. More than one tray per episode will be denied as not reasonable and necessary. SEE FOLEY CATHETER. One intermittent catheter with insertion supplies will be covered per episode of reasonable and necessary sterile intermittent catheterization. See guidelines below. **Urinary Drainage Collection System** is covered when the associated catheter is reasonable and necessary. **Leg Bags** are indicated for beneficiaries who are ambulatory or are chair or wheelchair bound. The use of leg bags for bedridden beneficiaries would be denied as not reasonable and necessary.

(continued)

ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
UROLOGICAL SUPPLIES i.e., Indwelling Catheters, Drainage Bags, Urinary Catheters, etc. *(continued)*						**Intermittent Catheterization** For each episode of covered catheterization (up to 200 per month): 1. One catheter and an individual packet of lubricant, **or** 2. One sterile intermittent catheter kit will be covered if one of the following criteria is met. Documentation supporting the need for the intermittent catheter kit must be contained in the beneficiary's medical record: a. The beneficiary resides in a nursing facility. b. The beneficiary is immunosuppressed. c. The beneficiary has radiologically documented vesico-ureteral reflux while using intermittent catheterization. d. The beneficiary is a spinal-cord injured female with neurogenic bladder who is pregnant. e. The beneficiary has had distinct, recurrent urinary tract infections while on a program of sterile intermittent catheterization with A4351/A4352 and sterile lubricant A4332, twice within the 12 months prior to the initiation of sterile intermittent catheter kits. A sterile intermittent urinary catheter kit includes a catheter, lubricant, gloves, antiseptic, solution, applicators, drape and a tray or bag in a sterile package intended for single use. **External Catheter/Urinary Collection Device** Male external catheters (condom-type) or female external urinary collection devices are covered for beneficiaries who have permanent urinary incontinence when used as an alternative to an indwelling catheter. An external catheter or urinary collection device will be denied as not medically necessary for beneficiaries who use an indwelling catheter. Utilization of male external catheters should not exceed 35 per month. Greater utilization must be accompanied by documentation of medical necessity. For female external urinary collection devices, more than one metal cup per week or more than one pouch per day will be denied as not medically necessary. **InFlow™ Device** (A4335) is considered to be reasonable and necessary as an alternative to intermittent catheterization for beneficiaries with Permanent Urinary Retention (PUR) due to Impaired Detrusor Contractility (IDC). One (1) inFlow device may be covered no more than once every 29 days. Claims for the inFlow device billed more than once every 29 days will be denied as not reasonable and necessary. The supplier must monitor the amount of supplies and accessories a beneficiary is actually using and assure that the beneficiary has nearly exhausted the supply on hand prior to dispensing any additional items.
✳ **VENTILATOR (NON-INVASIVE AND INVASIVE)**	✓		✓		✓	covered for treatment of neuromuscular diseases, restrictive thoracic diseases and chronic respiratory failure consequent to chronic obstructive pulmonary disease. Coverage includes positive pressure non-invasive (NIV) and invasive (via tracheostomy) ventilators. Each of these disease categories are conditions where the specific presentation of the disease can vary from patient to patient. For conditions such as these, the specific treatment plan for any individual patient will vary as well. Choice of an appropriate treatment plan, including the determination to use a ventilator vs. a bi-level PAP device, is made based upon the specifics of each individual beneficiary's medical condition. In the event of a claim review, there must be sufficiently detailed information in the medical record to support the treatment selected. Medicare will cover a second ventilator if it is required to serve a different purpose that is determined by the beneficiary's medical needs. Two examples of this are: 1. A beneficiary requires one type of ventilator (e.g., a negative pressure ventilator with a chest shell) for part of the day and needs a different type of ventilator (e.g., positive pressure ventilator with a nasal mask) during the rest of the day. 2. A beneficiary who is confined to a wheelchair requires a ventilator mounted on the wheelchair for use during the day and needs another *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
✳ **VENTILATOR (NON-INVASIVE AND INVASIVE)** *(continued)*						ventilator of the same type for use while in bed. Without two pieces of equipment, the beneficiary may be prone to certain medical complications, may not be able to achieve certain appropriate medical outcomes, or may not be able to use the medical equipment effectively. Supplies, maintenance, servicing and repairs are all included in the monthly rental of the ventilator. A ventilator would not be considered reasonable and necessary for the treatment of Obstructive Sleep Apnea (OSA). Claims for ventilators used for the treatment of conditions described under Positive Airway Pressure (PAP) Device or Respiratory Assist Device (RAD) will be denied as not reasonable and necessary.
VOICE PROSTHESIS AND SUPPLIES						covered for beneficiaries who have had a laryngectomy. Trachea-esophageal voice prostheses identified by HCPCS code L8507 are changed by the beneficiary/caregiver in the home setting. HCPCS code L8509 describes a tracheo-esophageal voice prosthesis, inserted by a practitioner or other health care provider. This type of prosthesis is inserted in a practitioner's office or other out-patient setting. Medicare does not cover the item if it is shipped or dispensed to the beneficiary, who then takes the item to their practitioner's office for insertion.
WALKER	✓		✓			covered If all of the following criteria (1–3) are met: 1. A beneficiary who has a mobility limitation that significantly impairs his/her participation in one or more mobility-related activities of daily living (MRADLs) in the home. A mobility limitation is one that prevents the beneficiary from accomplishing MRADLs entirely, or places the beneficiary at a reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform the MRADL or prevents the beneficiary from completing the MRADL within a reasonable time frame; **and** 2. The beneficiary must be able to safely use the walker; **and** 3. The functional mobility deficit must be sufficiently resolved by use of a walker. **Heavy Duty Walker** is covered for beneficiaries who meet the coverage criteria for a standard walker and who weigh more than 300 pounds. A heavy duty, multiple braking system, variable wheel resistance walker is covered for beneficiaries who meet the coverage criteria for a standard walker and who are unable to use a standard walker due to a severe neurologic disorder or other condition causing the restricted use of one hand. **Walker with Trunk Support** is covered for beneficiaries who meet the coverage criteria for a standard walker and who have documentation in the medical record justifying the medical necessity for the special features. **Leg Extensions** are covered only for beneficiaries who are at least 6 feet tall.
WATER PRESSURE PAD AND MATTRESS						see ALTERNATING PRESSURE PAD WITH PUMP AND MATTRESS.
WHEELCHAIR	✓		✓		✓	covered if Criteria A, B, C, D, and E are met **and** Criterion F **or** G is met. A. The beneficiary has a mobility limitation that significantly impairs his/her 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. A mobility limitation is one that: 1. Prevents the beneficiary from accomplishing an MRADL entirely, **or** 2. Places the beneficiary at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL, **or** 3. Prevents the beneficiary from completing an MRADL within a reasonable time frame. B. The beneficiary's mobility limitation cannot be sufficiently resolved by the use of an appropriately fitted cane or walker. C. The beneficiary's home provides adequate access between rooms, maneuvering space, and surfaces for use of the manual wheelchair that is provided. *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
WHEELCHAIR *(continued)*						D. 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. E. The beneficiary has not expressed an unwillingness to use the manual wheelchair that is provided in the home. F. The beneficiary has sufficient upper extremity function and other physical and mental capabilities needed to safely self-propel the manual wheelchair that is provided in the home during a typical day. Limitations of strength, endurance, range of motion, or coordination, presence of pain, or deformity or absence of one or both upper extremities are relevant to the assessment of upper extremity function. G. The beneficiary has a caregiver who is available, willing, and able to provide assistance with the wheelchair. Documentation of the beneficiary's medical history, use of other equipment, mobility limitations, and ability to use the wheelchair safely must be obtained from the practitioner's office for a manual wheelchair and accessories. **Transport Chair** (E1037, E1038 or E1039) is covered as an alternative to a standard manual wheelchair if the basic coverage criteria are met. **Standard Hemi Wheelchairs** (K0002) are covered if medical documentation establishes that the beneficiary is unable to use a standard wheelchair because the beneficiary requires a lower seat height (17" to 18") due to short stature or to enable a beneficiary to place his/her feet on the ground for propulsion. **Lightweight Wheelchairs** (K0003) are covered when a beneficiary cannot propel himself or herself in a standard wheelchair in the home and the beneficiary is actually able to self-propel in a lightweight chair. **High Strength Lightweight Wheelchairs** (K0004) are covered when the beneficiary needs the wheelchair while engaging in frequent activities in the home that cannot be performed in a standard or lightweight wheelchair or the beneficiary requires a seat width, depth or height that cannot be accommodated in a standard, lightweight or hemi-wheelchair and spends at least two hours per day in the wheelchair. This type of wheelchair would rarely be medically necessary if the expected duration of need is less than three months. **Ultra-Lightweight Manual Wheelchair** (K0005) is covered when the beneficiary is a full-time manual wheelchair user and individualized fitting and adjustments for one or more features such as, but not limited to, axle configuration, wheel camber, or seat and back angles which cannot be accommodated by a K0001–K0004 manual wheelchair and a specialty evaluation was performed by a licensed/certified medical professional such as a PT, OT or practitioner who is trained and experienced in rehabilitation wheelchair evaluations and that documents the medical necessity for the wheelchair and its special features. And the wheelchair is provided by a Rehabilitative Technology Supplier that employees RESNA-certified Assistive Technology Professional who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the beneficiary. **Heavy Duty Wheelchairs** (K0006) are covered for beneficiaries weighing more than 250 pounds or having severe spasticity. **Extra Heavy Duty Wheelchairs** (K0007) are covered for beneficiaries weighing more than 300 pounds. **Manual Wheelchair with Tilt in Space** (E1161) is covered if the beneficiary meets the general coverage for a manual wheelchair and if a specialty evaluation was performed by a licensed/certified medical professional such as a PT, OT or practitioner who is trained and experienced in rehabilitation wheelchair evaluations and that documents the medical necessity for the wheelchair and its special features And the wheelchair is provided by a Rehabilitative Technology Supplier that employees RESNA-certified Assistive Technology Professional who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the beneficiary. **Custom Manual Wheelchair Base** (K0008) is covered if, the general coverage criteria for a wheel base is met and the specific configuration required cannot be met using one of the standard manual wheelchair bases plus an appropriate combination of wheelchair seating systems, cushions, options or accessories such that the individual construction of a unique individual manual wheelchair base is required. A custom manual wheelchair is not reasonable and necessary if the expected duration of need is less than 3 months.

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
WHEELCHAIR ACCESSORIES	✓		✓		✓*	covered if all of the criteria in the wheelchair section have been met and the option/accessory itself is medically necessary. ***Note:** Some WHEELCHAIR ACCESSORIES require SWO/F2F documentation. **Arm of Chair** (E0973, K0017, K0018, K0020) is covered if beneficiary requires an arm height that is different than that available using non-adjustable arms and the beneficiary spends at least two hours per day in the wheelchair. **Arm Trough** (E2209) is covered if beneficiary has quadriplegia, hemiplegia, or uncontrolled arm movements. **Footrest/Legrest** (E0990, K0046, K0047, K0053, K0195) is covered if beneficiary has a musculoskeletal condition or the presence of a cast or brace which prevents 90 degree flexion at the knee. Also covered if beneficiary has significant edema of the lower extremities that requires elevation or the beneficiary meets the criteria for and has a reclining back on the wheelchair. **Non-standard Seat Frame** (E2201 – E2204) is covered only if the beneficiary's dimensions justify the need. **Gear Reduction Drive Wheel** (E2227) is covered if the following are met: The beneficiary has been self-propelling in a manual wheelchair for at least one year, and the beneficiary has had a specialty evaluation that was performed by a licensed/certified medical professional, such as an PT, OT or practitioner who has specific training and experience in rehabilitation wheelchair evaluations and that documents the need for the device in the beneficiary's home. The wheelchair is provided by a supplier that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheel chair selection for the beneficiary. **Batteries and Chargers**: up to 2 batteries (E2359, E2361, E2363, E2365 E2371, K0733) at any one time are allowed for a power wheelchair. **Single Mode Battery Charge** (E2366) is appropriate for charging a sealed lead battery. The usual maximum frequency of replacement for a lithium-based battery (E2397) is one every 3 years. Only one battery is allowed at any one time. **Power Seating System** tilt only, recline only or combination tilt and recline with or without power elevating legrests will be covered if criteria 1, 2, and 3 are met and if criterion 4, 5, or 6 is met: 1. The beneficiary meets all the coverage criteria for a power wheelchair described in the Power Mobility Devices LCD; **and** 2. A specialty evaluation that was performed by a licensed/certified medical professional, such as a physical therapist (PT) or occupational therapist (OT) or practitioner who has specific training and experience in rehabilitation wheelchair evaluations of the beneficiary's seating and positioning needs. The PT, OT, or practitioner may have no financial relationship with the supplier; **and** 3. The wheelchair is provided by a supplier that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the beneficiary. 4. The beneficiary is at high risk for development of a pressure ulcer and is unable to perform a functional weight shift; **or** 5. The beneficiary utilizes intermittent catheterization for bladder management and is unable to independently transfer from the wheelchair to bed; **or** 6. The power seating system is needed to manage increased tone or spasticity.
WHEELCHAIR SEATING AND BACK CUSHIONS	✓		✓		✓*	covered for beneficiaries who have a Medicare-qualified wheelchair. Coverage for this equipment is diagnosis driven. Please refer to the applicable Local Coverage Determination (LCD) for associated ICD-10 diagnosis codes. ***Note:** Some WHEELCHAIR SEATING AND BACK CUSHIONS require SWO/F2F documentation. **General Use Seat Cushions** (E2601, E2602) **and Back Cushions** (E2611, E2612) are covered for a beneficiary who has a manual wheelchair or power wheelchair with a sling/solid seat/back which meets Medicare coverage criteria. Cushions for POVs (power operated vehicles) and PWCs (power wheelchairs) with a captain's chair seat will be denied as not medically necessary. If a general use cushion is provided with a power wheelchair with a sling/solid seat/back instead of Captain's Chair, the wheelchair and the cushion(s) will be covered if either criterion 1 or criterion 2 is met: *(continued)*

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ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
WHEELCHAIR SEATING AND BACK CUSHIONS *(continued)*						1. The cushion is provided with a covered power wheelchair base that is not available in a Captain's Chair model — i.e., codes K0839, K0840, K0843, K0860, K0861, K0862, K0863, K0864, K0890, K0891; **or** 2. A skin protection and/or positioning seat or back cushion that meets coverage criteria is provided. **Skin Protection Seat Cushion** (E2603, E2604, E2622, E2623): 1. Covered for a beneficiary who has a manual wheelchair or PWC with a sling/solid seat/back and the beneficiary meets Medicare criteria for it, **and** 2. The beneficiary has **either** of the following (a or b): a. A current pressure ulcer or past history of a pressure ulcer on the area of contact with the seating surface, as reflected in a diagnosis code listed in Group 1 of the ICD-10 code list in the LCD-related Policy Article, **or** b. Absent or impaired sensation in the area of contact with the seating surface or inability to carry out a functional weight shift as reflected in a diagnosis code listed in Group 2 of the ICD-10 code list in the LCD-related Policy Article. **Positioning Seat Cushion** (E2605, E2606) **or Positioning Back Cushion** (E2613 – E2616, E2620, E2621), **and Positioning Accessory** (E0953, E0955 – E0957, E0960) are covered for a beneficiary who meets both of the following criteria: 1. The beneficiary has a manual wheelchair or a power wheelchair with a sling/solid seat/back and the beneficiary meets Medicare coverage criteria for it, **and** 2. The beneficiary has any significant postural asymmetries that are due to one of the following (a or b): a. A diagnosis code listed in Group 2 of the ICD-10 code list in the LCD-related Policy Article; **or** b. A diagnosis code listed in Group 3 of the ICD-10 code list in the LCD-related Policy Article. The appearance of a code in this section does not necessarily indicate coverage. **Headrest** (E0955) is also covered when the beneficiary has a covered manual tilt-in-space wheelchair, manual semi or fully reclining back on a manual wheelchair, a manual fully reclining back on a power wheelchair, or power tilt and/or recline power seating system. **Combination Skin Protection and Positioning Seat Cushions** (E2607, E2608, E2624, E2625) are covered for a beneficiary who meets the criteria for **both** a skin protection seat cushion and a positioning seat cushion. (Note special instructions for a combination skin protection and positioning cushion in the ICD-10 code list in the LCD-related Policy Article.) **Custom Fabricated Seat Cushion** (E2609) is covered if criteria 1 **and** 3 below are met. A custom fabricated back cushion (E2617) is covered if criteria 2 **and** 3 below are met: 1. Beneficiary meets all of the criteria for a prefabricated skin protection seat cushion or positioning seat cushion, 2. Beneficiary meets all of the criteria for a prefabricated positioning back cushion, 3. There is a comprehensive **written evaluation** by a licensed/certified medical professional, such as a physical therapist (PT) or occupational therapist (OT), which clearly explains why a prefabricated seating system is not sufficient to meet the beneficiary's seating and positioning needs. The PT or OT may have no financial relationship with the supplier. **Detailed description of billing codes:** **(The appearance of a code in this section does not necessarily indicate coverage)** Group 1 Codes: E2601 General use wheelchair seat cushion ..... Width less than 22 inches, any depth E2602 General use wheelchair seat cushion ..... Width 22 inches or greater, any depth E2603 Skin protection wheelchair seat cushion ..... Width less than 22 inches, any depth E2604 Skin protection wheelchair seat cushion ..... Width 22 inches or greater, any depth

(continued)

ITEM	Covered	Non-Covered	SWO	SWOPD	F2F	COVERAGE CRITERIA
WHEELCHAIR SEATING AND BACK CUSHIONS *(continued)*						E2605 Positioning wheelchair seat cushion . . . . . Width less than 22 inches, any depth E2606 Positioning wheelchair seat cushion . . . . . Width 22 inches or greater, any depth E2607 Skin protection and positioning wheelchair seat cushion. . . . . Width less than 22 inches, any depth E2608 Skin protection and positioning wheelchair seat cushion. . . . . Width 22 inches or greater, any depth E2609 Custom fabricated wheelchair seat cushion . . . . . Any size E2613 Positioning wheelchair back cushion, posterior . . . . . Width less than 22 inches, any height, including any type mounting hardware E2614 Positioning wheelchair back cushion, posterior . . . . . Width 22 inches or greater, any height, including any type mounting hardware E2615 Positioning wheelchair back cushion, posterior-lateral . . . . . Width less than 22 inches, any height, including any type mounting hardware E2616 Positioning wheelchair back cushion, posterior-lateral . . . . . Width 22 inches or greater, any height, including any type mounting hardware E2617 Custom fabricated wheelchair back cushion. . . . . Any size, including any type mounting hardware E2620 Positioning wheelchair back cushion, planar back with lateral supports . . . . . Width less than 22 inches, any height, including any type mounting hardware E2621 Positioning wheelchair back cushion, planar back with lateral supports . . . . . Width 22 inches or greater, any height, including any type mounting hardware E2622 Skin protection wheelchair seat cushion, adjustable. . . . . Width less than 22 inches, any depth E2623 Skin protection wheelchair seat cushion, adjustable. . . . . Width 22 inches or greater, any depth E2624 Skin protection and positioning, wheelchair seat cushion, adjustable . . . . . Width less than 22 inches, any depth E2625 Skin protection and positioning wheelchair seat cushion, adjustable. . . . . Width 22 inches or greater, any depth

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