Medicare Coverage Guidelines

(Follow these guidelines for all Insurance unless they have a specific Policy)

	Covered	Non-Covered	DME CMN	Physicians Order/RX	Written Order Prior to Deliver	Face to Face\Eval	
ADJUSTABLE BED		^					not a hospital bed, not primarily medical in nature; considered a comfort or convenience item.
AEROSOL THERAPY							see NEBULIZER.
AIR-FLUIDIZED BED	^			^	^	^	for the treatment of Stage III or IV pressure ulcers. (See Low Air-Loss Bed for definition of pressure ulcer.) An air-fluidized bed is covered only if all of the following criteria are met: 1. The patient has a Stage III (full thickness tissue loss) or stage IV (deep tissue destruction) pressure ulcer. 2. The patient is bedridden or chair bound as a result of severely limited mobility. 3. In the absence of an air-fluidized bed, the patient would require institutionalization. 4. The air fluidized bed is ordered in writing by the patient's attending physician based upon a comprehensive assessment and evaluation of the patient after 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: – Frequent repositioning of the patient with particular attention to relief of pressure over bony prominences (usually every two hours); **and** – Use of a Group 2 support surface to reduce pressure and shear forces on healing ulcers and to prevent new ulcer formation; **and** – Necessary treatment to resolve any wound infection; **and** – Optimization of nutrition status to promote wound healing; **and** – Debridement by any means, including wet-to-dry gauze dressings, to remove devitalized tissue from the wound bed; **and** – 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: – Education of the patient and caregiver on the prevention and management of pressure ulcers; **and** – Assessment by a physician, nurse or other licensed health practitioner at least weekly, **and** – 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 patient 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 patient 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. *(continued)*
AIR-FLUIDIZED BED *(continued)*							7. A physician directs the home treatment regimen, and re-evaluates and re-certifies the need for the air-fluidized bed on a monthly basis. The physician'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 patient has a co-existing pulmonary disease (the lack of firm back support makes coughing ineffective and dry air inhalation thickens pulmonary secretions). • The patient 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 care required if an air-fluidized bed is used. • Structural support is inadequate to support the weight of an air-fluidized bed system (it generally weighs 1600 lbs. or more). • The home electrical system cannot handle the anticipated increase in energy usage, 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 must be documented by the treating physician 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) at http://www.cgsmedicare.com/jc/coverage/lcdinfo.html for associated ICD-10 diagnosis codes. Coverage is limited to the air-fluidized bed itself. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).** A monthly assessment by the physician must be kept on file by the provider.
ALTERNATING PRESSURE PAD WITH PUMP AND MATTRESS (APP) (includes all flotation devices: air, water, gel, etc.)	^			^	^	^	if one of the following three criteria are met: 1. The patient is completely immobile — i.e., patient cannot make changes in body position without assistance, or 2. The patient has limited mobility — i.e., patient 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 patient 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 *(continued)*
ALTERNATING PRESSURE **PAD WITH PUMP AND** **MATTRESS (APP)** *(continued)*							B. Fecal or urinary incontinence C. Altered sensory perception D. Compromised circulatory status **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).**

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							Patients needing pressure reducing support surfaces should have a care plan which has been established by the patient's physician or home care nurse, which is documented in the patient's medical records, and which generally should include the following: • Education of the patient 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)		^					comfort or convenience item, not primarily medical in nature.
BATHTUB LIFT		^					convenience item; not primarily medical in nature.
BATHTUB RAIL (FLOOR BASE)		^					comfort or convenience item, not primarily medical in nature.
BATHTUB SEAT		^					comfort or convenience item; not primarily medical in nature.
BATHTUB STOOL OR BENCH		^					comfort or convenience item, not primarily medical in nature.
BATHTUB WALL RAIL		^					comfort or convenience item, not primarily medical in nature.
BED BATH		^					hygienic item; not primarily medical in nature.
BEDBOARD		^					convenience item; not primarily medical in nature.
BED CRADLE	^			^			when it is necessary to prevent contact with the bed coverings.
BED LIFTER		^					convenience item; not primarily medical in nature.
BED PAN	^			^			if the patient is confined to bed. Only the autoclavable hospital-type bed pan is covered.
BED SIDE RAILS							see HOSPITAL BED.
BIDET TOILET SEAT		^					hygienic item; not primarily medical in nature.
BI-LEVEL POSITIVE AIRWAY PRESSURE							see RESPIRATORY ASSIST DEVICE.
BLOOD PRESSURE MONITOR	^			^			for end-stage renal disease (ESRD) patients as part of a home hemodialysis system when they have chosen to receive supplies and equipment from an independent provider.
BRAILLE TEACHING TEXTS		^					educational equipment; not primarily medical in nature.
BREAST PROSTHESIS	^			^			if patient has had a mastectomy. Coverage for this equipment is diagnosis driven. Please refer to the applicable Local Coverage Determination (LCD) at http://www.cgsmedicare.com/jc/coverage/lcdinfo.html for 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 are not medically necessary.** An 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. A mastectomy bra (L8000) is covered for a patient 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.
CANE OR CRUTCHES	^			^			if all of the following criteria (1–3) are met: 1. The patient 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 patient from accomplishing the MRADL entirely, or places the patient at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL; or prevents the patient from completing the MRADL within a reasonable time frame. 2. The patient is able to safely use the cane or crutch. 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.
COLD THERAPY		^					not medically necessary.

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COLOSTOMY EQUIPMENT AND SUPPLIES							see OSTOMY EQUIPMENT AND SUPPLIES.
COMMODE	^			^			if the patient is confined to a bed or room. "Room confined" means that the patient's condition is such that leaving the room is medically contraindicated. Coverage is also available for a patient confined to a home without a toilet or confined to one floor and there is no bathroom on that floor.
COMMODE (EXTRA WIDE/ HEAVY DUTY)	^			^			if the patient meets the criteria above for a commode **and** weighs 300 pounds or more.
COMMODE WITH REMOVABLE ARMS	^			^			if the patient meets the criteria above for a commode **and** the detachable arms feature is necessary to facilitate transferring the patient, **or** if the patient has a body configuration that requires extra width.
CONCENTRATOR, OXYGEN							see OXYGEN SYSTEM.
CONTINUOUS PASSIVE MOTION DEVICE (CPM)	^			^			for patients who have received a total knee replacement. Also covered following 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 patient's home. Date of surgery, date of application, date of discharge from the hospital and a narrative description of the surgery or ICD-10 diagnosis code are required.
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.
DEHUMIDIFIER		^					environmental control equipment; not primarily medical in nature.
DIAPERS		^					non-reusable disposable supplies; not a prosthetic device nor required for the effective use of a prosthetic device.
DISPOSABLE SHEETS AND BAGS		^					non-reusable disposable supplies.
ELASTIC STOCKINGS		^					non-reusable supplies; not rental-type items.
ELECTRIC HOSPITAL BED							see HOSPITAL BED.
ELEVATOR		^					convenience item; not primarily medical in nature.
EMESIS BASIN		^					convenience item; not primarily medical in nature.
ENTERAL EQUIPMENT AND SUPPLIES	^		10.0^ CMS 10126	^			if the patient has (a) permanent nonfunction or disease of the structures that normally permit food to reach the small bowel **or** (b) a disease of the small bowel which impairs digestion and absorption of an oral diet, either of which requires tube feedings to provide sufficient nutrients to maintain weight and strength commensurate with the patient's overall health status. The patient must have a permanent impairment. Permanence does not require a determination that there is no possibility that the patient's condition may improve sometime in the future. If the judgment of the attending physician, 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 patient'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 patient must require tube feeding to maintain weight and strength commensurate with the patient's overall health status. • Adequate nutrition must not be possible by dietary adjustment and/or oral supplements. • Coverage is possible for patients with partial impairments — e.g., a patient with dysphagia who can swallow small amounts of food or a patient 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 (B9000-B9002) is ordered, there must be documentation in the patient'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 *(continued)*

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ENTERAL EQUIPMENT AND SUPPLIES *(continued)*							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 patient'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 patients requiring enteral nutrition. Special nutrient formulas are produced to meet unique nutrient needs for specific disease conditions. The patient'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–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* *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 proteins, 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*
EXERCISE EQUIPMENT		^					not primarily medical in nature.
FOLEY CATHETER	^			^			if prescribed by a physician for permanent urinary incontinence or permanent urinary retention, the Foley catheter is covered under the prosthetic device benefit. See PROSTHETIC DEVICES. One catheter per month is covered for routine catheter maintenance. Non-routine catheter changes are covered when documentation from the physician substantiates medical necessity. The test of permanence is considered met on a condition that is not expected to be medically or surgically corrected in the patient within three months. See UROLOGICAL SUPPLIES.
FOOD PUMP	^		10.0^ CMS 10126	^			if prescribed by a physician as an integral part of the patient's covered enteral or parenteral therapy. The need for the pump must be justified in each patient. 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, diarrhea, dumping syndrome, etc. See ENTERAL EQUIPMENT AND SUPPLIES.
FOOD SUPPLEMENTS		^					not primarily medical in nature.
GEL FLOTATION PAD/ MATTRESS	^			^	^	^	if one of the following three criteria are met: 1. The patient is completely immobile — i.e., patient cannot make changes in body position without assistance, **or** 2. The patient has limited mobility — i.e., patient cannot independently make changes in body position significant enough to alleviate pressure and at least one of conditions A – D below, **or** 3. The patient 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 patient should be one in which the patient 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 patient's bony prominence (coccyx or lateral trochanter), can readily palpate the bony prominence. This bottoming out criterion should be tested with the patient 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 position. If the patient bottoms out on the support surface in place, then Medicare will deny as not reasonable and necessary. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).** Patients needing pressure reducing support surfaces should have a care plan which has been established by the patient's physician or home care nurse, which is documented in the patient's medical records, and which generally should include the following: • Education of the patient 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		^					self-help device; not primarily medical in nature.
GRABBING/ REACHING DEVICE (any type, any length, each)		^					comfort or convenience item, not primarily medical in nature.
HEATER		^					environmental control equipment; not primarily medical in nature.
HEATING PAD	^			^			if the application of heat in the form of a heating pad is therapeutically effective to relieve certain types of pain, decrease joint and soft tissue stiffness, relax muscles, or reduce inflammation. Not considered reasonable and necessary to treat pain due to peripheral neuropathy, including but not limited to diabetic neuropathy. Moist electric heating pads or water circulating heat pads with pump have not been established as reasonable and necessary and are considered non-covered. A non-electric heating pad or wrap does not meet the definition of durable medical equipment (DME) and will be denied as non-covered.
HEAT LAMP		^					not reasonable and necessary; the safety and effectiveness of using a heat lamp in the home setting is not established.

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HEEL (OR ELBOW) PROTECTOR		^					comfort or convenience item, not primarily medical in nature.
HOSPITAL BED	^ ^ ^ ^ ^ ^	 ^ 		^	^	^	if the patient's medical record establishes medical necessity due to one or more of the following reasons: 1. The patient's condition requires positioning of the body in ways not feasible in an ordinary bed. 2. The patient requires positioning of the body in ways not feasible in an ordinary bed in order to alleviate pain. 3. The patient 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. 4. The patient's condition requires traction equipment that cannot be affixed to or used on an ordinary bed. If the patient's medical condition requires body positioning, the medical record must describe the severity and frequency of the patient's symptoms. If the medical condition requires special bed attachments, the medical record must specify the attachments. If the patient 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** — If hospital bed coverage requirements are met and the medical record establishes the medical necessity for a variable height hospital bed, this variable height feature may be covered when the patient requires a bed height different than a fixed height bed to permit transfers to chair, wheelchair or standing position. **Semi-Electric Beds** — Electric powered adjustments to raise and lower the head and foot may be covered when the patient's condition requires frequent changes in body position and/or the patient may need immediate changes in body position. **Full-Electric Beds** — The full-electric bed height adjustment feature is not covered; it is a convenience feature. Therefore, a full-electric bed is not covered. **Heavy Duty Bed** — If hospital bed coverage requirements are met and the patient's weight is more than 350 pounds, but does not exceed 600 pounds. **Extra Heavy Duty Bed** — If hospital bed coverage requirements are met and the patient's weight exceeds 600 pounds. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).** **Side Rails** — If the patient's condition requires side rails, they can be covered as an integral part of, or an accessory to, a 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	^			^			if the humidifier is necessary to the operation of the patient'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).
HUMIDIFIER (ROOM)		^					environmental control equipment; not primarily medical in nature.
HYDRAULIC LIFT							see PATIENT LIFT.
ILEOSTOMY EQUIPMENT AND SUPPLIES							see OSTOMY EQUIPMENT AND SUPPLIES.
INCONTINENCE PADS		^					non-reusable supply; hygienic item.
INTRAPULMONARY PERCUSSIVE VENTILATION SYSTEM		^					these devices have not been demonstrated to be reasonable and necessary in the home setting.
IPPB MACHINE	^			^			if the patient's ability to breathe is severely impaired.
LAMB'S WOOL PAD	^			^	^	^	if one of the following three criteria are met: 1. The patient is completely immobile — i.e., patient cannot make changes in body position without assistance, **or** 2. The patient has limited mobility — i.e., patient cannot independently make changes in body position significant enough to alleviate pressure and at least one of conditions A – D below, **or** 3. The patient 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 **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).** The provider must obtain information concerning which, if any, of the above criteria the patient meets in a signed and dated statement from the treating physician. Questions pertaining to medical necessity on any form used to collect this information may not be completed by the provider or anyone in a financial relationship with the provider. This statement must be supported by information in the patient's medical record. Patients needing pressure reducing support surfaces should have a care plan which has been established by the patient's physician or home care nurse, which is documented in the patient's medical records, and which generally should include the following: • Education of the patient 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.
LIQUID OXYGEN SYSTEM							see OXYGEN SYSTEM.
LOW AIR-LOSS BED	^			^	^	^	is covered if the patient meets at least one of the following three criteria (1, 2 or 3): 1. The patient 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 patient 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 patient has large or multiple Stage III or IV pressure ulcer(s) on the trunk or pelvis. *(continued)*

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LOW AIR-LOSS BED *(continued)*							3. The patient 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 of 3 support surface immediately prior to discharge from a hospital or nursing facility within the past 30 days. **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) at http://www.cgsmedicare.com/jc/coverage/lcdinfo.html for associated ICD-10 diagnosis codes. If the patient is on a Group 2 support surface, there should be a care plan established by the physician or home care nurse which includes the above elements. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).** **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: Observable pressure related alteration of intact skin whose indicators as compared to the adjacent or opposite area on the body may include changes in one or more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel) and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues. Stage II: Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater. Stage III: Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue. Stage IV: Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers. The provider must obtain information concerning which, if any, of the above criteria the patient meets in a signed and dated statement from the treating physician. Questions pertaining to medical necessity on any form used to collect this information may not be completed by the provider or anyone in a financial relationship with the provider. This statement must be supported by information in the patient'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)		^					nonreusable disposable item.
MASSAGE DEVICE		^					comfort item; not primarily medical in nature.
MATTRESS	^			^			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 patient's condition requires a replacement innerspring mattress (E0271) or foam rubber mattress (E0272) it will be covered for a patient-owned hospital bed.
MECHANICAL IN-EXSUFFLATION DEVICE (Cough-Stimulating Device)	^			^	^	^	is covered for patients who meet all of the following criteria**:** 1. The patient 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. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).** Coverage for this equipment is diagnosis driven. Please refer to the applicable Local Coverage Determination (LCD) at http://www.cgsmedicare.com/jc/coverage/lcdinfo.html for associated ICD-10 diagnosis codes.
NASAL PAP							see POSITIVE AIRWAY PRESSURE (PAP).
NEBULIZER AND NEBULIZER SUPPLIES	^			^	^*	^*	when the following conditions have been met: 1. It is reasonable and necessary to administer albuterol, arformoterol, budesonide, cromolyn, formoterol, ipratropium, levalbuterol, or metaproterenol for the management of obstructive pulmonary disease, **or** 2. It is reasonable and necessary to administer dornase alpha to a patient with cystic fibrosis, **or** 3. It is reasonable and necessary to administer tobramycin to a patient with cystic fibrosis or bronchiectasis, **or** 4. It is reasonable and necessary to administer pentamidine to patients 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) at http://www.cgsmedicare.com/jc/coverage/lcdinfo.html 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. A large volume nebulizer, related compressor, and water or saline are covered when it is reasonable and necessary to deliver humidity to a patient with thick, tenacious secretions, who has cystic fibrosis, bronchiectasis, a tracheostomy, or a tracheobronchial stent. A compressor and filtered nebulizer are also covered when it is reasonable and necessary to administer pentamidine to patients with HIV, pneumocystosis, or complications of organ transplants. A small volume ultrasonic nebulizer and related accessories are reasonable and necessary to administer treprostinil inhalation solution only. Claims used with other inhalation solutions will be denied as not reasonable and necessary. A controlled dose inhalation drug delivery system is covered when it is reasonable and necessary to deliver iloprost to patients 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 covered when all of the following criteria 1 – 3 are met: 1. The patient 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 patient 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** ***NOTE: Only** NEBULIZERS require WOPD/F2F documentation. *(continued)*

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NEBULIZER AND NEBULIZER SUPPLIES *(continued)*							c. The patient 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	^			^			when administered via a prescribed nebulizer: • Acetylcysteine (up to 74 grams/month) • Albuterol (up to 465 mg/month) — see below for exception • Albuterol/Ipratropium combination (up to 186 units/month) • Arformoterol (Brovana) (up to 930 mcg or 62 units/month) • 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) — see below for exception • Metaproterenol (up to 2800 mg/month or 280 units/month) — see below for exception • Pentamidine (up to 300 mg/month) • Sterile saline or water, 10 ml/unit (up to 56 units/month) • Tobramycin • Treprostinil (up to 31 units/month) **Special Drug Coverage** A short-acting beta-adrenergic agonist (SABA) drug is 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)
NEBULIZER MEDICATIONS *(continued)*							• 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 patient 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. **Documentation and Prescription Requirements** There must be clear documentation in the patient'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 patient is actually using and assure that the patient has nearly exhausted the supply on hand prior to dispensing any additional items. Suppliers must not deliver refills without a request from a patient, and must not exceed a patient's expected utilization.

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NEGATIVE PRESSURE WOUND THERAPY	^			^	^	^	when either criterion A or B is met: **Initial Coverage Requirements:** A. Ulcers and wounds **in the home setting**: The patient has a chronic Stage III or 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 should have been tried **or** considered and ruled out prior to application of NPWT. Complete wound therapy **must** include criterion 1 **and** criteria 2, 3 **or** 4, as applicable, depending on the type of wound. 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 patient'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 IV pressure ulcers: (a) The patient has been appropriately turned and positioned, **and** (b) The patient has used a Group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis, **and** (c) The patient's moisture and incontinence have been appropriately managed. 3. For neuropathic (for example, diabetic) ulcers: (a) The patient 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 inpatient** 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 provider cannot bill Medicare Part B for the time the treatment is used in an inpatient setting. 1. An ulcer or wound, described under A above, is encountered in the inpatient 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 physician, **or** 2. The patient has complications of a surgically created wound (for example, dehiscence) or a traumatic wound *(continued)*
NEGATIVE PRESSURE WOUND THERAPY *(continued)*							(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 patient that will not allow for healing times achievable with other topical wound treatments). **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).** 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. 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. If the licensed medical professional does not conduct a direct assessment of the wound(s) being treated, does not supervise or perform the NPWT dressing changes and does not document the changes in the ulcer's dimensions and characteristics on a **monthly** basis, the NPWT pump and supplies will be denied as not reasonable and necessary. 2. In the judgment of the treating physician, 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 inpatient 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 patient, whether or not by the physician's order. Documentation of the history, previous treatment regimens, and current wound management for which an NPWT pump is being billed must be present in the patient'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 physician describing the initial condition of the wound (including measurements) and the efforts to address all aspects of wound care (listed in A1
NEGATIVE PRESSURE WOUND THERAPY *(continued)*							Coverage is provided up to a maximum of 10 canister sets per month unless there is documentation evidencing a large volume of drainage and the patient is using a stationary pump with the largest capacity canister. Suppliers are required to have contact with the patient or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a request from a patient, and must not exceed a patient's expected utilization. Regardless of utilization, a supplier must not dispense more than a one (1)-month quantity at a time.

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NEUROMUSCULAR STIMULATOR	^			^	^	^	**Disuse Atrophy** If limited to the treatment of disuse atrophy where the brain, spinal cord and peripheral nerve supply are intact and other non- neurological reasons for the patient's disuse are causing the atrophy, e.g., in cases involving casting or splinting of a limb, contracture involving scarring of soft tissue (as in burn lesions) or hip replacement (until orthotic training begins). Solitary diagnosis of "disuse atrophy" is not sufficient. The patient's medical record must contain evidence that the device is being used for disuse atrophy in the setting of an intact nerve supply. A diagnosis of disuse atrophy resulting from conditions with non-intact nerves such as CVA, Bell's palsy, or neuritis will be denied as not medically necessary. **Spinal Cord Injury** For Neuromuscular Stimulator use with walking for patients with spinal cord injury, coverage is limited to patients 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 patient 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** 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. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).**
NON-INVASIVE VENTILATOR (NIV)							see VENTILATOR — NON-INVASIVE AND INVASIVE
OSTEOGENESIS STIMULATOR (NON-SPINAL)	^			^	^	^	if any of the following criteria are met: 1. Nonunion 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) at http://www.cgsmedicare.com/jc/coverage/lcdinfo.html for associated ICD-10 diagnosis codes. Nonunion 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 *(continued)*
OSTEOGENESIS STIMULATOR (NON-SPINAL)							fracture site, and with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).**
OSTEOGENESIS STIMULATOR (SPINAL)	^			^	^	^	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. Coverage for this equipment is diagnosis driven. Please refer to the applicable Local Coverage Determination (LCD) at http://www.cgsmedicare.com/jc/coverage/lcdinfo.html for associated ICD-10 diagnosis codes. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).**
OSTOMY EQUIPMENT AND SUPPLIES	^			^			if patient 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 Local Coverage Determination (LCD) at http://www.cgsmedicare.com/jc/coverage/lcdinfo.html for associated ICD-10 diagnosis codes. The quantity of ostomy supplies needed by a patient is determined by the type of ostomy, its location, its construction and the condition of the skin surface surrounding the stoma. Provision of ostomy supplies should be limited to a three-month supply for a patient at home. **Note:** Ostomy supplies are not separately payable when a patient is in a covered home health episode. When the patient 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.
OVERBED TABLE		^					convenience item; not primarily medical in nature.
OXYGEN — HIGH LITER FLOW	^		484.0^ CMS 484			^	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 patient is on 4 or more LPM meets Group I or II criteria. If Medicare pays a stationary unit at the high liter flow allowable, a portable system is not separately payable. 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	^		484.0^ CMS 484		^*	^*	for patients with a severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy. The patient's physician must have tried or considered alternative treatment measures and deemed them clinically ineffective. The above information should be documented in the patient's medical record. ***NOTE:** CONCENTRATORS do **not** require WOPD; however, t is required within 30 days of the setup. Patients with the following conditions may require home oxygen therapy: • Asthma. • Chronic Obstructive Pulmonary Disease (COPD). – Chronic bronchitis. – Emphysema. • Pulmonary fibrosis. • Congestive heart failure. • Occupational lung disease *(continued)*

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OXYGEN SYSTEM *(continued)*	■		■		■		• Lung cancer. • Cystic fibrosis. Provided the following conditions are met: 1. The treating physician has determined that the patient has a severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy, **and** 2. The patient's blood gas study meets the criteria stated below, **and** 3. The qualifying blood gas study was performed by a physician or by a qualified provider of laboratory services or Independent Diagnostic Testing Facility (IDTF), **and** 4. The qualifying blood gas study was obtained under the following conditions: – If the qualifying blood gas study is performed during an inpatient hospital stay, the reported test must be the one obtained closest to, but no earlier than, two days prior to the hospital discharge date, **or** – If the qualifying blood gas study is not performed during an inpatient hospital stay, the reported test must be performed while the patient is in a chronic stable state, i.e., not during a period of acute illness or an exacerbation of their underlying disease, **and** 5. Alternative treatment measures have been tried or considered and deemed clinically ineffective. A physician's written Certificate of Medical Necessity (CMN) is required and the CMN must specify: • Diagnosis of the disease requiring oxygen therapy (see above). • The oxygen flow rate (e.g., 2 liters per minute). • The frequency and duration of oxygen use (e.g., 10 minutes per hour, 12 hours per day). • The duration of oxygen need (e.g., 4 – 12 months or lifetime). There are three 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%, for at least 5 minutes taken during sleep for a patient 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%, for at least five minutes taken during sleep 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 patient 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 exercise when the patient was breathing room air. **Group II** Criteria include the presence of (a) an arterial PO_2 of 56 – 59 mm Hg or an arterial blood oxygen saturation of 89% at rest (awake), during sleep for at least five minutes, or during exercise (as described under Group I criteria) and (b) any of the following:
OXYGEN SYSTEM *(continued)*	■		■		■		<u>Qualifying test during exercise:</u> In instances where a patient qualifies for oxygen based on a test conducted during exercise, the following tests must be obtained in order for coverage criteria to be met: • A test taken while the patient is at rest breathing room air, **and** • During exercise, while the patient continues to breathe room air, **and** • A test taken with the patient receiving supplemental oxygen, which shows an improvement in the hypoxemia that was demonstrated during exercise when the patient was breathing room air. All three tests must be performed within the same testing session. Exercise testing must be performed in-person by a physician 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. <u>Qualifying test conducted during sleep:</u> In instances where a patient qualifies for oxygen based on a test conducted during sleep, the following tests must be obtained in order for coverage criteria to be met: • Home sleep oximetry is limited solely to stand-alone overnight pulse oximetry performed in the patient'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. • During sleep, the patient's arterial PO_2 is <55 mm Hg or the O_2 SAT <88% for at least five minutes; **or** • 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% for at least five minutes and the patient 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. Patients who meet coverage criteria during sleep do not qualify for payment of portable oxygen equipment. **Polysomnography and Home Sleep Tests** Coverage of home oxygen therapy requires that the patient be tested in the "chronic stable state." Chronic stable state is a requirement of the National Coverage Determination (CMS Internet-only Manual, Pub. 100-3, Section 240.2) and is one of the key criteria when determining coverage of home oxygen therapy. The NCD defines chronic stable state as "…not during a period of an acute illness or an exacerbation of their underlying disease." Based on this NCD definition, all co-existing diseases or conditions that can cause hypoxia must be treated and the patient be in a chronic stable state before oxygen therapy is considered eligible for payment. In the case of OSA, it is required that the OSA be appropriately and sufficiently treated such that the patient is in the chronic stable state before oxygen saturation results obtained during sleep testing are considered qualifying for oxygen therapy. **Concurrent Use of Oxygen with PAP Therapy** For patients with OSA, this means that the OSA must be sufficiently treated such that the underlying severe lung disease 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: 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 patient is using the PAP device at

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OXYGEN SYSTEM *(continued)*							If all of the above criteria are met, for the purposes of a qualifying oxygen saturation test, the patient is considered to be in the "chronic stable state." To be eligible for Medicare coverage and payment for home oxygen therapy for concurrent use with PAP therapy, in addition to being in the chronic stable state, the patient must meet all other coverage requirements for oxygen therapy. Patients 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 Certification: Group I and II patients must be tested while in a chronic stable state, within 2 days prior to an inpatient hospital discharge or within 30 days prior to the Initial Certification date if conducted as an outpatient. Recertification: For patients initially meeting Group I criteria, the most recent qualifying blood gas study prior to the thirteenth month of therapy must be reported on the Recertification CMN. Group II patients must be tested between the 61st and 90th day after the date of initial certification. **Cluster Headaches** Only a stationary gaseous oxygen system (E0424) and related contents (E0441) are covered for the treatment of cluster headaches (please refer to the applicable Local Coverage Determination (LCD) at http://www.cgsmedicare.com/jc/coverage/lcdinfo.html for associated ICD-10 diagnosis codes) for patients who are enrolled in a clinical trial approved by CMS and are in compliance with the requirements at InterOM 100-3 §240.2.2 for dates of service on or after 01/04/2011. This section states, in part: Only those patients diagnosed with the condition of cluster headache are eligible for participation in a clinical study. CMS adopts the diagnostic criteria used by the International Headache Society to form a definitive diagnosis of CH. Therefore, the home use of oxygen to treat CH is covered by Medicare only when furnished to Medicare patients who have had at least five severe to very severe unilateral headache attacks lasting 15 – 180 minutes when untreated. (Intensity of pain: Degree of pain usually expressed in terms of its functional consequence and scored on a verbal 5-point scale: 0 = no pain; 1 = mild pain, does not interfere with usual activities; 2 = moderate pain, inhibits but does not wholly prevent usual activities; 3 = severe pain, prevents all activities; 4 = very severe pain. It may also be expressed on a visual analogue scale.) The headaches must be accompanied by at least one of the following findings: 1. Ipsilateral conjunctival injection and/or lacrimation; **or** 2. Ipsilateral nasal congestion and/or rhinorrhea; **or** 3. Ipsilateral eyelid edema; **or** 4. Ipsilateral forehead and facial sweating; **or** 5. Ipsilateral miosis and/or ptosis; **or** 6. A sense of restlessness or agitation. Claims for oxygen equipment not meeting the criteria above will be denied as not reasonable and necessary. Claims for stationary oxygen equipment other than E0424 and all portable oxygen equipment used for cluster headaches will be denied as not reasonable and necessary. Claims for E0424 and E0441 used to treat cluster headaches follow the same payment rules as for all other covered oxygen equipment. Refer to the related Policy Article for information on statutory payment rules and coding guidelines to be used for these claims. **Physician Evaluation**
OXYGEN SYSTEM *(continued)*							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 patient. 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.
OXYGEN SYSTEM — OXIMETERS AND REPLACEMENT PROBES		^					will be denied as non-covered because they are monitoring devices that provide information to physicians to assist in managing the patient's treatment.
OXYGEN SYSTEM (PORTABLE)	^		484.0^ CMS 484		^*	^*	if the patient 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 except in instances where the patient qualifies for higher liter flow (> 4 LPM). ***NOTE:** HOMEFILL systems do **not** require WOPD; however, a F2F is required within 30 days of the setup. If a portable oxygen system is covered, the provider must provide whatever quantity of oxygen the patient uses; Medicare's reimbursement is the same, regardless of the quantity of oxygen dispensed. Portable gaseous oxygen system home compressor used to fill portable oxygen cylinders (also known as a home fill system) describes a feature of an oxygen concentrator that allows the patient to fill portable gaseous oxygen cylinders from a stationary concentrator. This feature may be integrated into the stationary concentrator or be a separate component. When this system is billed, the standard portable gaseous oxygen system must not be used. As a result of the Deficit Reduction Act (DRA) and the Medicare Improvements for Patients and Providers Act (MIPPA), payment for portable gaseous or liquid contents begins when the 36-month rental cap for the stationary equipment is met.
OXYGEN TRAVELING PATIENTS							**Relocation and Travel** Months 1 through 36 If the patient 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 patient is outside the service area, the home supplier is encouraged to either provide the equipment and related items/services or assist the patient 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 patient 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 patient are non-covered. Payment for oxygen furnished by an airline is the responsibility of the patient 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.
PACEMAKER MONITOR	^			^			**if prescribed by a physician for a patient with a cardiac pacemaker.**
PARAFFIN BATH (PORTABLE)	^			^			if the patient has undergone a successful trial period of paraffin therapy and long-term use will relieve the patient's condition. Institutional paraffin bath units are not covered.
PARALLEL BARS		^					primarily for institutional use. In the home setting, other devices (e.g., a walker) satisfy the patient's need.
PATIENT LIFT	^			^	^*	^*	if transfer between bed and a chair, wheelchair, or commode is required and, without the use of a lift, the patient would be bed confined. A multi-positional patient transfer system is covered if the patient meets this criteria and requires supine positioning for transfers. ***NOTE:** Multi-positional PATIENT LIFTS require WOPD/F2F documentation.
PEAK FLOWMETERS	^			^	^	^	for the self-monitoring of patients with pure asthma when they are used as part of a comprehensive asthma management program. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).**

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	Covered	Non-Covered	DME CMN	Physicians Order/RX	Written Order Prior to Delivery	Face to Face\Eval	
PERCUSSOR	^			^	^	^	for mobilizing respiratory tract secretions caused by COPD, chronic bronchitis or emphysema when the patient or operator of the device has been trained by a physician or therapist and no one is available to administer manual therapy to the patient. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).**
PNEUMATIC COMPRESSION DEVICE	^		04.04B CMS 846		^	^	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 physician of the medical necessity of a pneumatic compression device must include: 1. The patient's diagnosis and prognosis; **and** 2. Symptoms and objective findings, including measurements which establish the severity of the condition; **and** 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 patient (or caregiver) to apply the device for continued use in the home. **Lymphedema coverage:** The patient must undergo a four-week trial of conservative therapy that, when concluded, the physician 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. **Chronic venous insufficiency (CVI) with venous status ulcers coverage:** The patient 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 physician. Conservative therapy includes: • Use of an appropriate compression bandage system or compression garment; **and** • Appropriate dressings for the wound; **and** • Exercise; **and** • Elevation of the limb. A signed and dated Certificate of Medical Necessity (CMN) is required in all instances. In addition, for patients with a diagnosis of CVI with venous stasis ulcers, the patient's medical record must also document: *(continued)*
PNEUMATIC COMPRESSION DEVICE *(continued)*							• 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 physician for the conservative treatment period (six months). If a segmental, calibrated gradient pressure pneumatic compression device is ordered, the physician 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. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).**
PORTABLE OXYGEN SYSTEM							see OXYGEN SYSTEM (PORTABLE).
POSITIVE AIRWAY PRESSURE (PAP) DEVICE	^			^	^	^	if the patient is diagnosed with obstructive sleep apnea (OSA). Coverage for this equipment is diagnosis driven. Please refer to the applicable Local Coverage Determination (LCD) at http://www.cgsmedicare.com/jc/coverage/lcdinfo.html 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 patient's diagnosis is other than OSA. The diagnosis of OSA must be documented by either an attended, facility-based polysomnogram (sleep study) or an inpatient hospital-based or home-based sleep test (HST). The sleep study must be signed by the interpreting physician who must be certified in sleep medicine under one of the following criteria: • Current certification in Sleep Medicine by the American Board of Sleep Medicine; **or** • Current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties; **or** • Completed residency or fellowship training by an AMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the physician is eligible; **or** • Is an active staff member of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM) or The Joint Commission. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).** **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 patient has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the patient for obstructive sleep apnea. The initial evaluation should document pertinent information about the patient'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 *(continued)*

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POSITIVE AIRWAY PRESSURE (PAP) DEVICE *(continued)*							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 patient has a Medicare-covered 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). C. The patient and/or his/her caregiver has/have received instruction from the provider of the PAP device and accessories in the proper use and care of the equipment. <u>Bi-Level Device</u> A bi-level device without backup rate is covered for those patients 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 physician must document that an appropriate interface has been properly fit and the patient uses it without difficulty, the CPAP pressure setting prevented the patient from tolerating the therapy and lower pressure settings of the CPAP tried but failed to: • Adequately control the symptoms of OSA, **or** • Improve sleep quality, **or** • 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 physician must conduct a face-to-face clinical re-evaluation and document that the patient is benefiting from PAP therapy. Documentation of clinical benefit is demonstrated by: 1. Face-to-face clinical re-evaluation by the treating physician (between the 31st and 91st day) with documentation that symptoms of obstructive sleep apnea are improved and the patient is benefiting from PAP therapy; **and**
POSITIVE AIRWAY PRESSURE (PAP) DEVICE *(continued)*							1. Face-to-face clinical re-evaluation by the treating physician 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. Patients who switch from a CPAP to a bi-level device after the first 3 months require a new face-to-face evaluation but a new sleep study is not required. **Replacement PAP** If Medicare covered a PAP device for the patient more than 5 years ago, a replacement PAP device may be provided under the following circumstances: 1. Patient must have had a qualifying sleep study and have a face-to-face evaluation with the treating physician indicating the patient continues to use the PAP device. A new physician's order 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 prescription 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 patient or caregiver (lost). **Patient Entering Medicare** If the patient 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 patient had a sleep test, prior to FFS Medicare enrollment, that meets the Medicare AHI/RDI coverage criteria in effect at the time that the patient seeks Medicare coverage of a replacement PAP device and/or accessories. 2. Face-to-face patient evaluation with the treating physician <u>after</u> the Medicare effective date that indicates the patient's diagnosis of OSA and the patient continues to use the PAP device. 3. A new physician's order is needed to reaffirm the medical necessity of the replacement PAP. There is no trial period for patients qualified under the Patient Entering Medicare or Replacement PAP requirements. However, if the patient had a CPAP unit previously and switches to a bi-level or vice versa, the patient must qualify for the new device following the new set-up guidelines. **Concurrent Use of Oxygen with PAP Therapy** Some patients 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
POSITIVE AIRWAY PRESSURE **(PAP) DEVICE** *(continued)*							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

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							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 physician 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.
POSTURAL DRAINAGE BOARD (POV)	^			^			if the patient has a chronic pulmonary condition.
PRESSURE LEOTARDS		^					non-reusable supply.
QUAD CANE							see CANES/CRUTCHES.
RAISED TOILET SEAT		^					hygienic convenience item; not primarily medical in nature.
RECLINER WITH ELEVATING SEAT							see SEAT LIFT MECHANISM.
REGULATOR (OXYGEN)							see OXYGEN SYSTEM.
REPAIRS	^			^			for patient-owned equipment if the equipment is medically necessary. A new prescription for repairs is not required. However, the DME MAC should have a prescription on file to recognize that this is a repair of patient-owned equipment. 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 physician order and/or new CMN (if required) is needed to reaffirm the medical necessity of the item.
RESPIRATORY ASSIST DEVICE (RAD)	^			^	^	^	is covered for the first three months of therapy under the following conditions: 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 physician must fully document in the patient's medical record symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).** *(continued)*
RESPIRATORY ASSIST DEVICE (RAD) *(continued)*							A RAD (E0470, E0471) is covered for those patients 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 patient'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: a. An arterial blood gas $PaCO_2$, done while awake and breathing the patient's prescribed FIO_2 is □ 45 mm Hg; **or** b. Sleep oximetry demonstrates oxygen saturation □ 88% for □ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the patient's prescribed recommended FIO_2; **or** c. For a neuromuscular disease (only), either i or ii: i. Maximal inspiratory pressure is < 60 cm H_20; **or** ii. Forced vital capacity is < 50% predicted. C. Chronic obstructive pulmonary disease does not contribute significantly to the patient'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 physician) will be covered for the first three months of therapy. II. Severe COPD An <u>E0470 device</u> is covered if criteria A – C are met: A. An arterial blood gas $PaCO_2$, done while awake and breathing the patient's prescribed FIO_2, 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 patient's prescribed FIO_2 (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 patient 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 patients with COPD are met, an E0470 device will be covered for the first three months of therapy. An <u>E0471 device</u> will be covered for a patient with COPD in either of the two situations below, depending on the testing performed to demonstrate the need. <u>Situation 1:</u> For Group II patients (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. a. An arterial blood gas $PaCO_2$, done while awake and breathing the patient's prescribed FIO_2, shows that the patient's $PaCO_2$ worsens □ 7 mm Hg compared to the original result from criterion A,(above). b. 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)

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RESPIRATORY ASSIST DEVICE (RAD) *(continued)*							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 patient'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 physician) will be covered for patients 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. A. An initial arterial blood gas $PaCO_2$, done while awake and breathing the patient's prescribed FIO_2, is **≥** 45 mm Hg; **and** B. Spirometry shows an FEV1/FVC **≥** 70%. (Refer to II. SEVERE COPD (above) for information about device coverage for patients with FEV1/FVC < 70%.) C. An arterial blood gas $PaCO_2$, done during sleep or immediately upon awakening, and breathing the patient's prescribed FIO_2, shows the patient'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 patient 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 FEV1/FVC **≥** 70%. (Refer to II. SEVERE COPD (above) for information about device coverage for patients with FEV1/FVC < 70%.) C. An arterial blood gas $PaCO_2$, done while awake and breathing the patient's prescribed FIO_2, shows that the patient's $PaCO_2$ worsens **≥** 7 mm Hg compared to the ABG result performed to qualify the patient 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.) **Note: Ventilator with Noninvasive Interfaces** The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations Manual stipulates that ventilators (E0450, E0460 – E0464) are covered for the following conditions: neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. Each of these disease categories are comprised of conditions that can vary from severe and life-threatening to less serious forms. These disease groups may appear to overlap conditions described in the Respiratory Assist Devices (RAD) LCD but they are not overlapping. Choice of an appropriate device i.e., a ventilator versus a bi-level PAP device is made based upon the severity of the condition. CMS distinguished RAD from ventilation "in a patient for whom interruption or failure of respiratory support leads to death."
RESPIRATORY ASSIST DEVICE (RAD) *(continued)*							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 physician. There must be documentation in the patient's medical record about the progress of relevant symptoms and patient usage of the device up to that time. Failure of the patient 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 **A DME provider is NOT considered a qualified provider of any testing referenced above.**
RESTRAINTS, ANY TYPE (Body, Chest, Wrist or Ankle)		^					comfort or convenience item, not primarily medical in nature.
ROLLABOUT/ROLLING CHAIR	^			^	^	^	if patient 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. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).**
SAFETY ROLLERS	^			^			if patient meets Mobility Assistive Equipment clinical criteria.
SAUNA BATH		^					not primarily medical in nature; personal comfort item.
SEAT LIFT MECHANISM	^		07.0^A CMS 849	^	^	^	if prescribed by a physician for patients with severe arthritis of the hip or knee, muscular dystrophy or some other neuromuscular disease, and use of the device benefits the patient therapeutically. Coverage is limited to the seat lift mechanism only. Coverage is limited to seat lifts that operate smoothly, can be controlled by the patient, and can help the patient 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 patient 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 patient 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 physician's course of treatment and be prescribed to affect improvement or arrest or retard deterioration in the patient's condition. 3. The patient must be completely incapable of standing up from a regular armchair or any chair in their home. (The fact that a patient has difficulty or is even incapable of getting up from a chair, is not sufficient justification for a seat lift mechanism. Almost all patients who are capable of ambulating can get out of an ordinary chair if the seat height is appropriate and the chair has arms.) 4. Once standing, the patient must have the ability to ambulate. The physician ordering the seat lift mechanism must be the treating physician or a consulting physician for the disease or condition resulting in the need for a seat lift. The physician's record must document that all appropriate therapeutic modalities (e.g., medication, physical therapy) have been tried and failed to enable the patient to transfer from a chair to a standing position. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).**
SITZ BATH	^			^			if the patient has been diagnosed with an infection or injury of the perineal area and the physician 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		^					convenience item; not primarily medical in nature.
STANDING TABLE		^					convenience item; not primarily medical in nature.

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STETHOSCOPE	^			^			if prescribed by a physician as part of a home hemodialysis system and all coverage criteria for home dialysis has been met. Supplies for home dialysis related to the treatment of End Stage Renal Disease (ESRD) must be provided by the ESRD facility.
SUCTION CATHETERS	^			^			when a suction pump is supplied to the patient. 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, unless additional documentation is provided. 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. In this situation, the medical necessity for more than three catheters per week would require additional documentation.
SUCTION MACHINE	^			^			if patient has difficulty raising and clearing secretions secondary to any of the following conditions: • Cancer or surgery of the throat or mouth. • Dysfunction of the swallowing muscles. • Unconsciousness or obtunded state. • Tracheostomy
SURGICAL DRESSINGS	^			^			when medically necessary for the treatment following a surgical procedure or when debridement of a wound is medically necessary.
SURGICAL LEGGINGS		^					not covered.
TELEPHONE ALERT SYSTEM		^					not covered.
TELEPHONE ARM		^					not covered.
TOILET RAIL		^					comfort or convenience item, not primarily medical in nature.
TOILET SEAT		^					not covered.
TRACHEOSTOMY CARE KITS	^			^			for patients 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) at http://www.cgsmedicare.com/jc/coverage/lcdinfo.html for associated ICD-10 diagnosis codes. A detailed written order is required which includes the duration of need, frequency and utilization for all supplies ordered. 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. A 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. *(continued)*
TRACHEOSTOMY CARE KITS *(continued)*							Tracheostomy/laryngectomy tube plug/stop (A7527) is used as an alternative to a tracheostomy/laryngectomy tube and therefore for a patient 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 patient's medical record. If adequate documentation is not provided when requested, the excess quantities will be denied as not reasonable and necessary.
TRACTION EQUIPMENT	^			^	^	^	if both of the following criteria are met: 1. The patient 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 patient and the patient tolerated the selected device. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).**
TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR (TENS) AND SUPPLIES	^		06.0^B CMS	^	^	^	for the treatment of patients with chronic, intractable pain or acute post-operative pain when one of the following coverage criteria are met. Coverage for this equipment is diagnosis driven. Please refer to the applicable Local Coverage Determination (LCD) at http://www.cgsmedicare.com/jc/coverage/lcdinfo.html for associated ICD-10 diagnosis codes. The physician ordering the TENS unit and related supplies must be the treating physician 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: • 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. • The pain must have been present for at least three months. • 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. III. Chronic Low Back Pain (CLBP) TENS therapy for CLBP is only covered when all of the following criteria are met: • The patient has a diagnosis that supports medical necessity. • The patient must be enrolled in an approved clinical study. TENS used for CLBP in an approved clinical trial does not require a trial rental period or an assessment of effectiveness by the treating physician. Upon the patient's enrollment into an approved study, the TENS is eligible for purchase. TENS therapy for CLBP that does not meet these criteria 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 patient 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 physician to determine the effectiveness of the TENS unit in modulating the pain. For coverage of *(continued)*

Medicare Coverage Guidelines

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	Covered	Non-Covered	DME CMN	Physicians Order/RX	Written Order Prior to Delivery	Face to Face\Eval	
TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR (TENS) AND SUPPLIES *(continued)*							a purchase, the physician must determine that the patient 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 patient's pain. If it is ordered for use with 4 leads, the medical record must document why 2 leads are insufficient to meet the patient'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: • It has been prescribed by the treating physician for use in delivering covered TENS treatment and one of the following medical indications is met: – The patient 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** – The patient 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** – The patient has a documented medical condition, such as skin problems, that preclude the application of conventional electrodes, adhesive tapes, and lead wires, **or** – The patient 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 patient has a documented skin problem prior to the start of the trial period. **A physician's written prescription/order must be furnished to the provider prior to the delivery (WOPD).** For a purchased TENS unit, a Certificate of Medical Necessity (CMN), which has been completed, signed and dated by the treating physician. The CMN may act as a substitute for a written order if it contains all the required elements of an order. A CMN is not needed for a TENS rental.
TRANSFER TUB RAIL ATTACHMENT		^					comfort or convenience item, not primarily medical in nature.
TRAPEZE BAR	^			^			if the patient 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 — If the patient 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 equipment is covered if the patient meets the criteria for regular trapeze equipment and the patient's weight is more than 250 pounds.
TREADMILL		^					exercise equipment; not primarily medical in nature.
TUB CHAIR		^					comfort or convenience item; not primarily medical in nature.
ULTRAVIOLET LIGHT CABINET	^			^	^	^	for selected patients with generalized intractable psoriasis, if medical and other factors justify treatment at home, rather than at an alternative site, such as the outpatient department of a hospital. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).**
URINALS	^			^			if patient is bed confined.
UROLOGICAL SUPPLIES i.e., Indwelling Catheters, Drainage Bags, Urinary Catheters, etc.	^			^			if prescribed by the physician for a patient 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 patient 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 patient 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 patient'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. A 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 patient'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. A 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: Covered when the associated catheter is reasonable and necessary. Leg bags are indicated for patients who are ambulatory or are chair or wheelchair bound. The use of leg bags for bedridden patients would be denied as not reasonable and necessary. **Intermittent Catheterization** For each episode of covered catheterization (up to 200 per month): • One catheter and an individual packet of lubricant, **or** *(continued)*

Medicare Coverage Guidelines

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	Covered	Non-Covered	DME CMN	Physicians Order/RX	Written Order Prior to Delivery	Face to Face\Eval	
UROLOGICAL SUPPLIES *(continued)*							• 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 patient's medical record: – The patient resides in a nursing facility. – The patient is immunosuppressed. – The patient has radiologically documented vesico-ureteral reflux while using intermittent catheterization. – The patient is a spinal-cord injured female with neurogenic bladder who is pregnant. – The patient 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 patients 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 patients 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. The supplier must monitor the amount of supplies and accessories a patient is actually using and assure that the patient has nearly exhausted the supply on hand prior to dispensing any additional items.
VAPORIZER	^			^			if the patient has a respiratory illness.
VENTILATOR — NON-INVASIVE AND INVASIVE	^			^	^	^	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. Used to treat chronic respiratory failure when life support is needed (> 12 hours per day and/or patient cannot breathe independently) for a patient for whom interruption or failure of respiratory support could lead to death. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).** Medicare will cover a second ventilator if it is required to serve a different purpose that is determined by the patient's medical needs. Two examples of this are: – A patient 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. – A patient who is confined to a wheelchair requires a ventilator mounted on the wheelchair for use during the day and needs another ventilator of the same type for use while in bed. Without two pieces of equipment, the patient 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.
WALKER	^			^			If all of the following criteria are met: 1. A patient who has a personal mobility deficit sufficient to impair his/her participation in mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home, **and** 2. The patient must be able to safely use the walker, **and** 3. The functional mobility deficit must be sufficiently resolved by use of a walker. A Heavy Duty Walker is covered for patients 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 patients who meet 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. Enhancement accessories of walkers will be denied as non-covered. 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	^			^	^	^	if the patient has a mobility limitation that significantly impairs his/her ability to participate in one or more Mobility Related Activities of Daily Living (MRADLs) in the home. MRADLs are toileting, feeding, dressing, grooming, and bathing performed in customary locations in the home. A mobility limitation is one that: • Prevents the patient from accomplishing the MRADLs entirely, **or** • Places the patient at a reasonably determined heightened risk of illness, injury, or death secondary to the attempts to participate in MRADLs, **or** • Prevents the patient from completing the MRADLs within a reasonable time frame, **or** • There are other conditions that limit the patient's ability to participate in MRADLs at home, i.e., impaired cognition or vision, and the other conditions can be compensated so that the patient can use the wheelchair for MRADLs, **and** • The patient's mobility limitation cannot be resolved with the use of a cane or walker, **and** • The patient's home environment can safely support the use of the equipment and provides adequate access between rooms, maneuvering space, and surfaces for use of the wheelchair provided, **and** • Use of a wheelchair will significantly improve the patient's ability to participate in MRADLs and the patient will use it on a regular basis in the home, **and** • The patient has not expressed an unwillingness to use the wheelchair in the home, **and** • The patient has sufficient upper extremity function and other physical and mental capabilities needed to safely self-propel the manual wheelchair during a typical day, **or** • The patient has a caregiver who is available, willing, and able to provide assistance with the wheelchair. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).** Documentation of the patient's medical history, use of other equipment, mobility limitations, and ability to use the wheelchair safely must be obtained from the physician's office for a manual wheelchair and accessories. Special sizes (e.g., narrow, extra-wide, lightweight) are covered if the provider can determine from the information on file or other sources, that a special size is medically necessary to accommodate the physical size of the patient or any size restrictions imposed by the patient's home (e.g., narrow doorways) based on the below requirements. **Hemi wheelchairs** (K0002) are covered if medical documentation establishes that the patient is unable to use a standard wheelchair because the patient requires a lower seat height (17" to 18") due to short stature or to enable a patient to place his/her feet on the ground for propulsion. *(continued)*