Medicare Screening List

NINTH EDITION

A reference tool for the healthcare professionals when ordering home respiratory therapies and products, sleep apnea therapies and products and home medical equipment services and supplies for homecare patients.

APRIA HEALTHCARE®

Table of Contents

Table of Contents (Continued)

Apria logo ✶ denotes Apria core services or products

Complex Reimbursement Made Easier

Apria Healthcare has been among the nation's leading home healthcare providers since the 1980s. Our comprehensive range of services is designed to offer quality homecare as a cost-effective option for patients who are suitable homecare candidates.

In today's healthcare environment, part of the decision to administer treatment at home is dependent upon reimbursement issues. Who will pay? Does the patient have insurance? If so, which healthcare provider is contracted with which insurance company? Does the patient qualify for treatment under Medicare? Does the patient reside in a Competitive Bidding Area (CBA), and, if so, which provider is contracted with Medicare in that area? (**Note:** Medicare has implemented competitive bidding in 109 areas of the country. Under this program, beneficiaries residing in or visiting a CBA must obtain competitively bid items, such as oxygen, CPAP/RAD, negative pressure wound therapy, hospital beds, wheelchairs, walkers and support surfaces from a Medicare contract provider.)

New Documentation Requirements in 2013

This version of the guide now includes a "F2F/WOPD" column indicating when a Face-to-Face (F2F) evaluation and Written Order Prior to Delivery (WOPD) are required.

Under the Affordable Care Act, a physician is required to document that the physician, physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS) has had a face-to-face (F2F) encounter examination with a beneficiary in the six (6) months prior to the written order for certain DME items. (**Note:** Medicare Local Coverage Determination (LCD) for some products may provide different timeframes in which a face-to-face evaluation must be conducted. If there is a variance between the timeframes defined in the Affordable Care Act and the LCD, the LCD timeframe should always be used.)

The record of the face-to-face encounter must document that the beneficiary was evaluated and/or treated for a condition that supports the item ordered. If the item was ordered by a PA, NP, or CNS, a physician (MD or DO) must document the occurrence of a face-to-face encounter by signing/co-signing and dating the pertinent portion of the medical record.

The date of the written order must not be prior to the date of the face-to-face encounter. The written order must include: the beneficiary's name, the item of DME ordered, the prescribing practitioner's National Provider Identifier (NPI), the signature of the ordering practitioner and the date of the order.

You should be aware that reimbursement guidelines do change. As new rules or guidelines take effect, count on Apria to be your information resource. As of this printing, the Medicare guidelines herein are accurate and complete. However, if you have any questions, you should call your local Apria Healthcare branch.

Apria Healthcare is contracted with most insurance companies and managed care organizations to provide home oxygen services, PAP, respiratory medications and negative pressure wound therapy. Additionally, Apria is a Medicare contract provider for oxygen and CPAP/RAD in all Medicare Competitive Bidding Areas (CBAs) and is a contract provider for negative pressure wound therapy in most CBAs. You will find that Apria Healthcare can serve nearly every patient. Call your nearest Apria location for more information.

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

Comprehensive Homecare Services

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

- Respiratory therapy services and products
- Supplemental oxygen systems
- Home-delivered respiratory medications
- Positive airway pressure (PAP)
- Respiratory assist devices (RADs)
- Negative pressure wound therapy

Work with the Leader: Experience, Resources, Clinical Expertise

We work with our referral sources to ensure that the patient receives the prescribed therapy and benefits from our combined expertise.

We offer years of homecare experience and clinical excellence. Our Essential Care Model™ ensures continuity of care delivery for all patients nationwide.

Call your local Apria Healthcare branch today to refer a patient.

To locate the Apria Healthcare branch nearest you, visit us at

apria.com

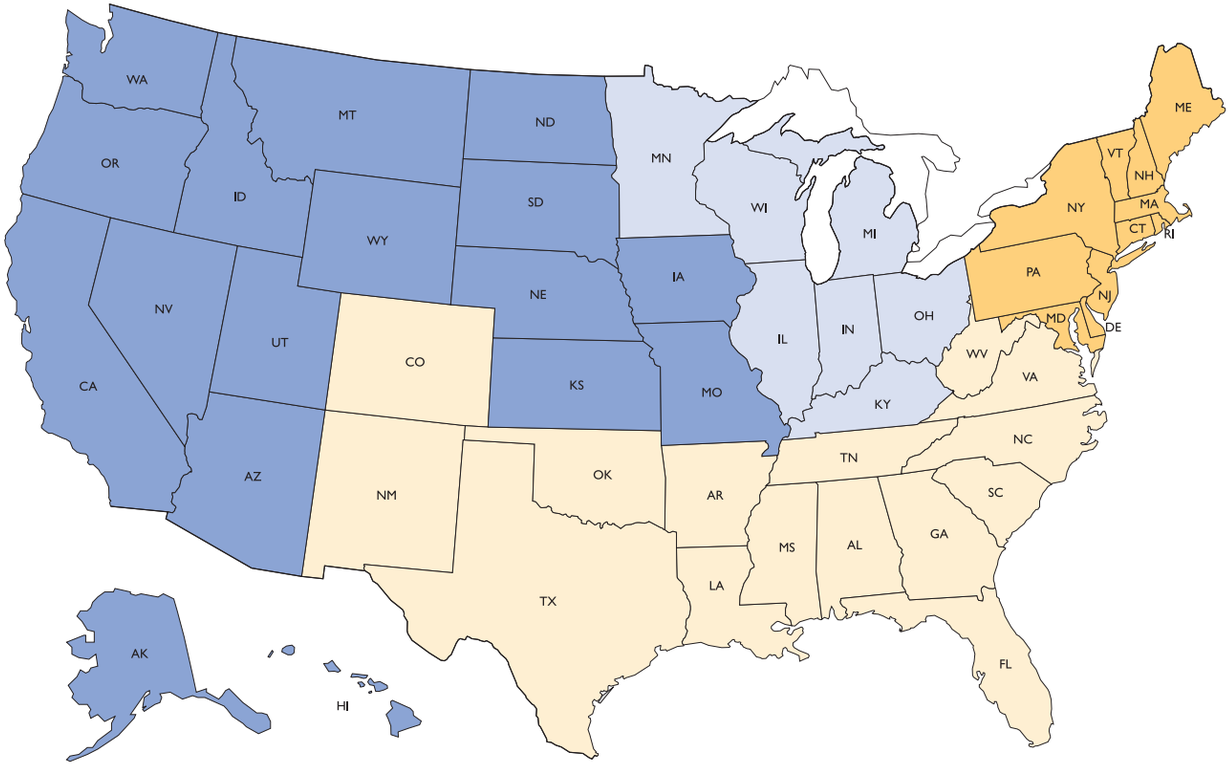
Clinicians directly employed by Apria Healthcare. Because we employ so many of the clinicians providing care to our patients — like respiratory therapists and pharmacists — we are better able to control quality.

Geographic reach. We are here to help, with over 12,000 employees serving patients nationwide. With more than 400 locations nationwide, Apria Healthcare's service area ensures consistent, quality care when patients travel or move within the United States.

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

Contractor Medical Directors

MEDICARE ADMINISTRATIVE CONTRACTORS (MACs)



The Contractor Medical Directors (CMDs) are responsible for developing medical policy for home infusion therapies, respiratory care products and services, home medical equipment, orthotics, prosthetics and supplies (DMEPOS). The CMDs oversee the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) which are responsible for processing claims and providing provider education.

Jurisdiction A

Paul Hughes, M.D.
Contractor Medical Director
DME MAC
National Heritage Insurance Co.
75 Sgt. Wm. Terry Dr.
Hingham, MA 02043
medicarenhic.com

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

Jurisdiction B

Stacey Brennan, M.D.
Contractor Medical Director
DME MAC
National Government Services
8115 Knue Rd.
Indianapolis, IN 46250
ngsmedicare.com

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

Jurisdiction C

Robert Hoover, M.D.
Contractor Medical Director
DME MAC
CGS
PO Box 20010
Nashville, TN 37228
CGSMedicare.com

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

Jurisdiction D

Eileen Moynihan, M.D.
Richard W. Whitten, M.D.
Contractor Medical Directors
DME MAC
Noridian Healthcare Solutions, LLC
PO Box 6727 / 900 42nd St. South
Fargo, ND 58108-6727
noridianmedicare.com

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

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
ADJUSTABLE BED		✓					not a hospital bed, not primarily medical in nature; considered a comfort or convenience item.
ADJUSTABLE CHAIR	✓			✓			for end-stage renal disease (ESRD) beneficiaries as part of a home hemodialysis system when they have chosen to receive supplies and equipment from an independent provider.
✶ **AEROSOL THERAPY**							see NEBULIZER.
AIR CONDITIONER		✓					environmental control equipment; not primarily medical in nature.
AIR-FLUIDIZED BED	✓			✓		✓	for the treatment of Stage III or IV pressure sores. (See Low Air-Loss Bed for definition of pressure sore.) 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 sore. 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. 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. 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. *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
AIR-FLUIDIZED BED *(continued)*							An air-fluidized bed is not covered under any of the following circumstances: • The patient has a co-existing pulmonary disease. • The patient requires moist wound dressings that are not protected with an impervious covering, like plastic wrap. • The caregiver is unwilling or unable to provide the care required if an air-fluidized bed is used. • Structural support in the home cannot accommodate the weight of an air-fluidized bed. • The home electrical system cannot handle the anticipated increase in energy usage, or • Other known contraindications exist. 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. Caregiver services and electrical or structural improvements to the patient's room are not covered.
AIR PURIFIER		✓					environmental control equipment; not primarily medical in nature.
ALARM (OR ALERT) DEVICES (not otherwise classified)		✓					comfort or convenience item, not primarily medical in nature.
ALTERNATING PRESSURE MATTRESS (POWERED PRESSURE REDUCING MATTRESS)							see LOW AIR-LOSS BED.
ALTERNATING PRESSURE PAD WITH PUMP AND MATTRESS (APP) (includes all flotation devices: air, water, gel, etc.)	✓			✓	✓		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 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.

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
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 GLUCOSE ANALYZER (REFLECTANCE COLORIMETER)		✓					unsuitable for home use.
BLOOD GLUCOSE DISPOSABLE MONITOR (includes test strips)		✓					non-reusable supply.
BLOOD GLUCOSE MONITOR AND SUPPLIES*	✓			✓		✓*	for patients who are diabetic and who can better control their blood glucose levels by checking these levels and appropriately contacting their attending physician for advice and treatment. ***NOTE: Only** a BLOOD GLUCOSE MONITOR requires F2F/WOPD documentation. To be eligible for coverage, the patient must meet **both** of the **basic** criteria: 1. The patient has diabetes (ICD-9 Codes 249.00 – 250.93) which is being treated by a physician; **and** 2. The patient's physician has concluded that the patient or caregiver has sufficient training using the particular device prescribed, as evidenced by providing a prescription for the appropriate supplies and frequency of blood glucose testing. *(continued)*

*Provided through our Star Medical Rx pharmacy division

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ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
BLOOD GLUCOSE MONITOR AND SUPPLIES* *(continued)*							**Utilization Limits for Supplies** Normal utilization: • For a patient who is **not** currently being treated with insulin injections, **up to** 100 test strips and 100 lancets every three months are covered if the basic criteria 1 – 2 above are met. • For a patient who **is** currently being treated with insulin injections, 300 test strips and **up to** 300 lancets every three months are covered if the basic criteria 1 – 2 above are met. High utilization requires additional documentation: • For a patient who **is not** currently being treated with insulin injections, **more than** 100 test strips and 100 lancets every three months are covered if criteria (a) – (c) are met; • For a patient who **is** currently being treated with insulin injections, **more than** 300 test strips and **more than** 300 lancets every three months are covered if criteria (a) – (c) below are met: (a) Basic coverage criteria 1 – 2 listed above must be met. (b) The treating physician has seen the patient and has evaluated their diabetes control within 6 months prior to ordering quantities of strips and lancets that exceed the utilization guidelines; **and** (c) If refills of quantities of supplies that exceed the utilization guidelines are dispensed, there must be documentation in the physician's records that the patient is actually testing at the frequency that corroborates the quantity of supplies that have been dispensed. If the patient is regularly using quantities of supplies that exceed the utilization guidelines, new documentation must be present at least every 6 months. The supplier may not directly collect beneficiary testing information (logs), nor may they collect beneficiary testing information (logs) and forward to the treating physician for inclusion in the medical records to demonstrate compliance with this requirement. **A beneficiary or his/her caregiver must specifically request refills of glucose monitor supplies before they are dispensed.** The provider must not automatically dispense a quantity of supplies on a predetermined regular basis, even if the beneficiary has authorized this in advance. A new order is required when there has been a change in the testing frequency. Home glucose blood monitors with integrated voice synthesizers or integrated lancing/blood sample are covered when the patient meets all of the above criteria and the treating physician certifies that the patient has a severe visual impairment (corrected, 20/200 or worse in both eyes) or an impairment of manual dexterity severe enough for a special monitoring system.
BLOOD PRESSURE MONITOR	✓			✓			for end-stage renal disease (ESRD) beneficiaries 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 ICD-9-CM diagnosis codes V10.3, V45.71, 174.0-174.9, 198.81, 233.0, or 457.0. 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.**
CANE OR CRUTCHES	✓			✓			if reasonable and necessary for 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. Coverage is based on an algorithmic approach to determine if a patient will qualify. The patient must be able to safely use the cane or crutches and the functional mobility deficit must be sufficiently resolved by use of the cane or crutch. An underarm, articulating, spring-assisted crutch will be denied as not reasonable and necessary.
COLD THERAPY		✓					not medically necessary.
COLOSTOMY EQUIPMENT AND SUPPLIES							see OSTOMY EQUIPMENT AND SUPPLIES.

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ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
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.
COMMUNICATOR							see SPEECH GENERATING DEVICES.
✶ **CONCENTRATOR, OXYGEN**							see OXYGEN SYSTEM.
CONTINUOUS PASSIVE MOTION DEVICE (CPM)	✓			✓			for patients who have received a total knee replacement. 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-9 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.
DISPOSABLE SHEETS AND BAGS		✓					non-reusable disposable supplies.
ELASTIC STOCKINGS		✓					non-reusable supplies; not rental-type items.
ELECTRIC HOSPITAL BED							see HOSPITAL BED.
ELECTRONIC SPEECH AID	✓			✓			under Part B as prosthetic devices when the patient has had radical neck surgery and/or extensive radiation to the anterior part of the neck, a laryngectomy or the larynx is permanently inoperative. There are two types of speech aids. One operates by placing a vibrating head against the throat; the other amplifies sound waves through a tube which is inserted into the user's mouth.
ELEVATOR		✓					convenience item; not primarily medical in nature.
EMESIS BASIN		✓					convenience item; not primarily medical in nature.

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD
ENTERAL EQUIPMENT AND SUPPLIES	✓		10.03 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 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 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 bet denied as not medically necessary.

Special nutrients (B4149, B4153-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 three nasogastric tubes, or one gastrostomy or jejunostomy tube every three months is rarely medically 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 included 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

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
EPOETIN (EPO/Aranesp)	✓			✓			if all of the following criteria have been met: 1. The patient is on dialysis which is being administered as Method II home dialysis. 2. The EPO/Aranesp is self-administered at home by the patient or caregiver who has been determined by the physician or back-up dialysis facility to be competent to administer the drug and to be capable of understanding and implementing a plan of care. 3. Prior to initiation of therapy, the back-up dialysis facility or the physician responsible for all dialysis-related services furnished to the patient has made a comprehensive assessment that includes: a) Measurement of the patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin and blood pressure, b) Assurance that the patient or a caregiver who assists the patient is: i) trained by the facility to inject EPO/Aranesp and is capable of carrying out the procedure, ii) capable of reading and understanding the drug labeling, **and** iii) trained in, and capable of observing, aseptic techniques, c) Assurance that the EPO/Aranesp can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child having access to the drug and syringes. 4. The patient has anemia and the most recent hematocrit prior to initiating EPO/Aranesp treatment is 30% or less (or hemoglobin level is < 10.1 gm% or less), unless there is medical documentation showing the need for EPO/Aranesp treatment despite a hematocrit of 31% or higher (or hemoglobin is 10.2 gm% or higher). For example, patients with severe angina, severe pulmonary distress, or severe hypotension may require EPO/Aranesp to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels. 5. For patients who are being treated with EPO/Aranesp, the hematocrit is between 30% and 36% (or comparable hemoglobin level). 6. The patient is under the care of a back-up dialysis facility which has a written care plan for monitoring home use of EPO/Aranesp, including the following: a) Review of diet and fluid intake for aberrations as indicated by hyperkalemia and elevated blood pressure secondary to volume overload, b) Review of medications to ensure adequate provision of supplemental iron, c) Ongoing evaluations of hematocrit and iron stores, d) Re-evaluation of the dialysis prescription, taking into account the patient's increased appetite and red blood cell volume, e) A method for the physician and back-up dialysis facility to follow-up on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results, f) Training of the patient to identify the signs and symptoms of hypotension and hypertension, **and** g) The decrease or discontinuance of EPO/Aranesp if hypertension is uncontrollable. 7. The patient is under the care of a physician who is responsible for all dialysis-related services and who orders the EPO/Aranesp and follows the drug labeling instructions when monitoring the EPO/Aranesp home therapy. 8. The patient's physician or back-up dialysis facility develops a protocol that follows the drug label instructions, makes the protocol available to the patient to ensure safe and effective home use of EPO/Aranesp, and maintains adequate records to allow quality assurance for review by Network and State Survey agencies. The patient's dialysis physician or facility must maintain a flow sheet or log recording the dates and results of hematocrit tests, iron studies and the EPO/Aranesp prescription with dates of change. This information must be available upon request. Medical necessity for maintaining the hematocrit higher than 36% must be documented in the patient's medical record and may be requested. If the goal is to maintain the hematocrit between 30 – 36%, a copy of the flow sheet/log for the past three months documenting hematocrit dates and dates of EPO/Aranesp order changes is required. The amount of EPO/Aranesp that the patient has on hand must be limited to a two-month supply.
EXERCISE EQUIPMENT		✓					not primarily medical in nature.

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
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	✓		10.03 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 or PARENTERAL 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 **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.
GERI-CHAIR/GLIDEABOUT CHAIR							see ROLLABOUT/ROLLING CHAIR.
GLUCOMETER							see BLOOD GLUCOSE MONITOR.

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
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. 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.
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 of the following reasons: 1. The patient's condition requires positioning of the body, e.g., to alleviate pain, prevent contractures, or avoid respiratory infections, in ways not feasible in an ordinary bed. 2. The patient's condition requires special attachments that cannot be affixed to or used on an ordinary bed. 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. 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. **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 is covered for the following conditions: • The patient requires a bed height different than a fixed height bed to permit transfers to chair, wheelchair or standing position. • Patients with severe arthritis and other injuries to the lower extremities, e.g., fractured hip. Feature enables the patient to place his/her feet on the floor while sitting on the edge of the bed. • Severe cardiac patients who are able to leave bed, but who must avoid the strain of "jumping" up or down. • Spinal cord injuries, including quadriplegic and paraplegic patients, multiple limb amputees and stroke patients, who are able to transfer from bed to a wheelchair with or without assistance. • Other severely debilitating diseases, if the variable height feature is required to assist the patient in ambulating.
	✓						**Semi-Electric Beds** — Electric powered adjustments to raise and lower the head and foot may be covered if medical necessity is established under the following conditions: • The patient's condition requires frequent changes in body position and/or the patient may need immediate changes in body position (i.e., no delay can be tolerated), **and** • The patient can operate the controls. (Exceptions can be made in cases of spinal cord injury or brain damage.)
		✓					**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. If the patient qualifies, Medicare will reimburse this item at a semi-electric bed allowable.
	✓						**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.
	✓						**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.

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
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.
IMMUNOSUPPRESSIVE DRUGS	✓			✓			when they are medically necessary to prevent or treat rejection of a Medicare-covered organ transplant. Immunosuppressive drugs are covered only after a heart, liver, kidney, bone marrow/stem cell, lung or heart/lung transplant; or a pancreatic islet cell transplant or partial pancreatic tissue transplantation that is part of a NIH-sponsored clinical trial (performed on or after 10/01/04); or a whole organ pancreas transplant performed concurrent with or subsequent to a kidney transplant because of diabetic nephropathy (performed on or after July 1, 1999); or intestinal transplant (performed on or after 04/01/01), or for whole pancreas transplants alone (performed on or after April 26, 2006) that meet the following criteria: 1. The transplant is performed in a facility that is Medicare-approved for kidney transplantation; **and** 2. Patient must have a diagnosis of type I diabetes; **and** (a) Must be beta cell autoantibody positive; **or** (b) Must demonstrate insulinopenia, (fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method). A fasting glucose must be obtained when performing a fasting C-peptide determination. Fasting C-peptide levels are considered valid when a concurrently obtained fasting glucose is < 225 mg/dL; **and** 3. Must have a history of labile (brittle or medically-uncontrollable) insulin-dependent diabetes mellitus resulting in documented recurrent, severe, acutely life-threatening metabolic complications requiring hospitalization(s). Complications may include frequent hypoglycemia where the patient is unaware, recurring severe ketoacidosis, or recurring severe hypoglycemic attacks; **and** 4. Must have been under the care of an endocrinologist and have clinical documentation denoting optimal and intensive management was provided for at least 12 months, having received the most medically-recognized advanced insulin formulations and delivery systems; **and** 5. Must demonstrate being able to emotionally and mentally understand the significant risks associated with surgery and be able to effectively manage the lifelong need for immunosuppression; **and** 6. Must otherwise be a suitable candidate for transplantation. If the transplant met Medicare coverage criteria in effect at the time of the surgery and the patient was enrolled in Medicare Part A at the time of the transplant (whether payment was made by Medicare or another insurer), then immunosuppressive drugs are covered. There is no coverage under this benefit for supplies used in conjunction with the administration of parenteral immunosuppressive drugs. Immunosuppressive drug coverage is limited to 36 months for patients whose Medicare entitlement is based solely on end-stage renal disease (ESRD). Immunosuppressive drugs are not covered when used for the treatment of patients with non-transplant related diagnoses (e.g., rheumatoid arthritis, connective tissue diseases, vasculitis). Parenteral azathioprine or methylprednisolone is limited to those situations in which the medication cannot be tolerated or

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
IMMUNOSUPPRESSIVE DRUGS *(continued)*							absorbed if taken orally and is self-administered by the patient. Issues with oral administration must be documented in the medical record. Parenteral cyclosporine, antithymocyte globulin, muromonab-CD3, tacrolimus and daclizumab are not proven to be safe when administered in the home setting and are non-covered when administered in that setting.
INCONTINENCE PADS		✓					non-reusable supply; hygienic item.
INFUSION PUMP (EXTERNAL)	✓		09.03 CMS 10125	✓		✓	for the following indications: 1. Administration of deferoxamine for the treatment of chronic iron overload. 2. Administration of chemotherapy for the treatment of primary hepatocellular carcinoma or colorectal cancer where this disease is unresectable or where the patient refuses surgical excision of the tumor. 3. Administration of morphine for the treatment of intractable pain caused by cancer. 4. Administration of other drugs if: • Parenteral administration of the medication in the home is reasonable and necessary. • An infusion pump is necessary to safely administer the medication; **and** Criteria A • The drug is administered by a prolonged infusion of at least eight hours because of proven improved clinical efficacy. • The therapeutic regimen is proven or generally accepted to have significant advantages over (a) intermittent bolus administration regimens **or** (b) infusions lasting less than eight hours. **OR** Criteria B • The drug is administered by intermittent infusion (each episode of infusion lasting less than eight hours) which does not require the patient to return to the physician's office prior to the beginning of each infusion. • Systemic toxicity or adverse effects of the drug are unavoidable without infusing it at a strictly controlled rate as indicated in the Physician's Desk Reference or the US Pharmacopoeia Drug Information. The criteria for additional uses of infusion pumps as described in number 4 above are met in the following situations: A. Administration of cladribine, fluorouracil, cytarabine, bleomycin, floxuridine, doxorubicin, vincristine or vinblastine by continuous infusion over at least eight hours when the regimen is proven or generally accepted to have significant advantages over intermittent administration regimens. This does not apply to primary hepatocellular carcinoma or colorectoral cancer. B. Administration of narcotic analgesics (except meperidine) in place of morphine to a patient with intractable pain caused by cancer who has not responded to an adequate oral/transdermal therapeutic regimen and/or cannot tolerate oral/transdermal narcotic analgesics. C. Administration of the following antifungal or antiviral drugs: foscarnet, amphotericin B, acyclovir, and gancyclovir. D. Administration of parenteral inotropic therapy, using the drugs dobutamine, milrinone, and/or dopamine for patients with congestive heart failure and depressed cardiac function if a patient has all of the following conditions: 1. Dyspnea at rest or with minimal exertion despite treatment with maximum or near maximum tolerated doses of digoxin, a loop diuretic, and an angiotensin-converting enzyme inhibitor or another vasodilator (e.g., hydralazine or isosorbide dinitrate), used simultaneously (unless allergic or intolerant), **and** 2. Doses are within the following ranges (lower doses will be covered only if part of a weaning or tapering protocol from higher dose levels): (a) Dobutamine 2.5 to 10 mcg/kg/min. (b) Milrinone 0.375 to 0.750 mcg/kg/min. (c) Dopamine less than or equal to 5 mcg/kg/min., **and** 3. Invasive hemodynamic or thoracic electrical bioimpedence studies performed within six months prior to the initiation of home inotropic therapy show. *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD
INFUSION PUMP (EXTERNAL) *(continued)*						

(a) Cardiac index (CI) is less than or equal to 2.2 liters/min/meter squared and/or pulmonary capillary wedge pressure (PCWP) is greater than or equal to 20 mm Hg before inotrope infusion on maximum medical management, **and**
(b) At least a 20% increase in CI and/or at least a 20% decrease in PCWP during inotrope infusion at the dose initially prescribed for home infusion, **and**

4. An improvement in patient well being (less dyspnea, improved diuresis, improved renal function and/or reduction in weight), with the absence of dyspnea at rest at the time of discharge and the capability of outpatient evaluation by the prescribing physician at least monthly, **and**
5. In the case of continuous infusion, there is documented deterioration in clinical status when the drug(s) is tapered or discontinued under observation in a hospital, or in the case of intermittent infusions, there is documentation of repeated hospitalizations for congestive heart failure despite maximum medical management, **and**
6. Any life threatening arrhythmia is controlled prior to hospital discharge and there is no need for routine electrocardiographic monitoring at home, **and**
7. The patient is maintained on the lowest practical dose and efforts to decrease the dose of the drug(s) or the frequency/duration of infusion are documented during the first three months of therapy, **and**
8. The patient's cardiac symptoms, vital signs, weight; lab values and response to therapy are routinely assessed and documented in the patient's medical record.

E. Administration of epoprostenol (J1325*) or treprostinil (J3285*) for patients with primary pulmonary hypertension (PPH), or pulmonary hypertension secondary to:
- A connective tissue disease, **or**
- Thromboembolic disease of the pulmonary arteries,
- Human immunodeficiency virus (HIV) infection,
- Cirrhosis,
- Diet drugs,
- Congenital left to right shunts, etc.,

And meets all of the following criteria:

1. Pulmonary hypertension is not secondary to pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease, etc.) or disorders of the respiratory system (COPD, interstitial lung disease, OSA or other sleep disorders, alveolar hypoventilation disorders, etc.).
2. Mean pulmonary artery pressure is greater than 25 mm Hg at rest, or greater than 30 mm Hg with exertion, **and**
3. The patient has significant symptoms from the pulmonary hypertension (i.e., severe dyspnea on exertion, and either fatigability, angina or syncope), **and**
4. Treatment with an oral calcium channel blocking agent has been considered and ruled out or tried and failed.
5. The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the condition.

F. Gallium nitrate (J1457*) is covered for the treatment of symptomatic cancer-related hypercalcemia (ICD-9 Code 275.42). In general, patients with a serum calcium (corrected for albumin) less than 12 mg/dl would not be expected to be symptomatic. The recommended usage for gallium nitrate is daily for five consecutive days. Usage beyond five days and/or more than one course of treatment for the same episode of hypercalcemia are considered not medically necessary.

G. Ziconotide (J2278*) is covered for the management of severe chronic pain in patients for whom intrathecal (IT or epidural) therapy is warranted, and who are intolerant of or refractory to other treatment (systemic analgesics, adjunctive therapies, IT morphine).

H. Subcutaneous immune globulin (J1559, J1561, J1562*) is covered if:
- The subcutaneous immune globulin preparation is a pooled plasma derivative which is approved for the treatment of primary immune deficiency disease; **and**
- The patient has a diagnosis of primary immune deficiency disease (ICD-9 codes 279.04, 279.05, 279.06, 279.12, 279.2).

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
INFUSION PUMP (EXTERNAL) *(continued)*							Coverage of subcutaneous immune globulin applies only to those products that are specifically labeled as subcutaneous administration products. Only an E0779 infusion pump is covered for the administration of subcutaneous immune globulin. If a different pump is used, it will be denied as not reasonable and necessary. **Equipment and Supplies:** An external infusion pump, related medication and supplies will be denied as not medically necessary in the home setting for the treatment of thromboembolic disease and/or pulmonary embolism by heparin infusion. When an infusion pump is covered, the medication used in the pump and necessary supplies are also covered. When a pump has been purchased by the Medicare Program, other insurer or the patient, the medication and supplies will continue to be covered as long as the coverage criteria for the pump are met. Supplies for the maintenance of a parenteral drug infusion catheter are covered during the period of covered use of an infusion pump. They are also covered for the weeks in between covered infusion pump use, not to exceed four weeks per episode. Supplies used with an external infusion pump are covered. Allowance is based on the number of cassettes, bags or syringes prepared. For intermittent infusions, no more than 1 cassette or bag is covered for each dose of medication. For continuous infusion, the concentration of the drug and size of the cassette or bag should be maximized to result in the fewest cassettes or bags in keeping with good pharmacologic and medical practice. Medications and supplies that are dispensed but not used for completely unforeseen circumstances (e.g., emergency admission to hospital, drug toxicity, etc.) are covered. Providers are expected to anticipate changing needs for drugs (e.g., planned hospital admissions, drug level testing with possible dosage change, etc.) in their drug and supply preparation and delivery schedule. ***= Detailed description of billing codes:*** *J1325 Injection, epoprostenol . . . . . .0.5 mg.* *J1457 Injection, gallium nitrate . . . . . .1 mg.* *J1559 Injection, immune globulin (hizentra) . . . . . .100 mg.* *J1561 Injection, immune globulin, (gamunex/gamunex-C/gammaked), non-lyophilized (e.g., liquid) . . . .500 mg.* *J1562 Injection, immune globulin (vivaglobin) . . . . . .100 mg.* *J2278 Injection, ziconotide . . . . . .1 microgram* *J3285 Injection, treprostinil . . . . . .1 mg.*
INFUSION PUMP (IMPLANTABLE)	✓			✓		✓	if medically necessary for the intra-arterial infusion of 5-FUdR for the treatment of liver cancer for patients with primary hepatocellular carcinoma or Duke's Class D colorectal cancer, in whom the metastases are limited to the liver, and where (1) the disease is unresectable **or** (2) the patient refuses surgical excision of the tumor. An implantable infusion pump is covered when used to administer anti-spasmodic drugs intrathecally (e.g., baclofen) to treat chronic intractable spasticity in patients who have proven unresponsive to less invasive medical therapy. The patient must have responded favorably to a trial intrathecal dose of the anti-spasmodic drug. To administer opioid drugs, e.g., morphine, intrathecally or epidurally for the treatment of severe chronic intractable pain of malignant or nonmalignant origin in patients who have a life expectancy of at least three months and who have proved unresponsive to less invasive medical therapy. The patient must have responded favorably to administration using a temporary intrathecal/epidural catheter with adequately acceptable pain relief and degree of side effects. If these coverage requirements are met, payment can also be made for drugs used with the infusion pump, so long as the drugs are prescribed as medically necessary. Use of an implantable infusion pump for infusion of heparin for the treatment of thromboembolic disease and/or the infusion of insulin to treat diabetes is NOT covered. The DME MAC will not process claims for implantable infusion pumps or medications and supplies used in conjunction with an implantable infusion pump. Claims for these items should be submitted to the local carrier.

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
INJECTOR (INSULIN)		✓					non-covered; self-administered drug supply.
INSULIN INFUSION PUMP (EXTERNAL)	✓		09.03 CMS 10125	✓			if for the administration of continuous subcutaneous insulin for the treatment of diabetes mellitus (ICD-9 Codes 249.00 – 250.93) if criterion A or B is met and if criterion C or D is met: A. C-peptide testing requirement — must meet criterion 1 or 2 and criterion 3: 1. C-peptide level is ≤ 110% of the lower limit of normal of the laboratory's measurement method, **or** 2. For patients with renal insufficiency and a creatinine clearance (actual or calculated from age, weight, and serum creatinine) ≤ 50 ml/minute, fasting C-peptide level is ≤ 200% of the lower limit of normal of the laboratory's measurement method, **and** 3. A fasting blood sugar obtained at the same time as the C-peptide level ≤ 225 mg/dl, **or** B. Beta cell autoantibody test is positive, **and** C. Completion of a comprehensive diabetes education program; patient has been on a program of multiple daily injections of insulin (at least three injections per day) with frequent self-adjustments of the insulin dose for at least six months prior to the use of the insulin pump, and has documented frequency of glucose self-testing on average of at least four times per day during the two months prior to use of the insulin pump, and meets one or more of the following while on the multiple injection regimen: • Glycosylated hemoglobin level (HbA1C) greater than 7%. • History of recurring hypoglycemia. • Wide fluctuations in blood glucose before mealtime. • Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl. • History of severe glycemic excursions, **or** D. Patient has been on an external insulin infusion pump prior to enrollment in Medicare and: • Has documented frequency of glucose self-testing an average of at least four times per day during the month prior to Medicare enrollment. Patients on an external insulin infusion pump must be seen and evaluated at least every three months by a treating physician who manages multiple patients on continuous subcutaneous insulin infusion therapy and who works closely with a team including nurses, diabetic educators, and dietitians knowledgeable in the use of continuous subcutaneous insulin infusion therapy. Subcutaneous insulin is administered using ambulatory infusion pump E0784. Claims for usage of infusion pumps other than E0784 will be denied as not reasonable and necessary.
INTRAPULMONARY PERCUSSIVE VENTILATION SYSTEM		✓					these devices have not been demonstrated to be reasonable and necessary in the home setting.
INTRAVENOUS IMMUNOGLOBULIN (IVIG) (For Subcutaneous Immune Globulin, see Infusion Pump [External], Item H)	✓			✓			if all of the following criteria are met: 1. It is an approved pooled plasma derivative for the treatment of primary immune deficiency disease; **and** 2. The patient has a diagnosis of primary immune deficiency disease (ICD-9 Codes 279.04, 279.05, 279.06, 279.12, 279.2); **and** 3. The IVIG is administered in the home; **and** 4. The treating physician has determined that administration of the IVIG in the patient's home is medically appropriate. Coverage is limited to the IVIG itself, not to related supplies and services. For coverage of IVIG under this benefit, it is not necessary for the derivative to be administered through a piece of durable medical equipment.
✶ **IPPB MACHINE**	✓			✓			if the patient's ability to breathe is severely impaired.
IRRIGATING KIT	✓			✓			only for patients whose ostomy equipment and supplies are covered under the prosthetic device benefit. See OSTOMY EQUIPMENT AND SUPPLIES and PROSTHETIC DEVICES.

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
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	✓			✓	✓		if the following conditions are met: A. Criteria 1, 2 and 3, **or** B. Criterion 4, **or** C. Criteria 5 and 6. 1. Multiple Stage II pressure ulcers located on the trunk or pelvis (ICD-9 Codes 707.02 – 707.05). 2. Patient has been on a comprehensive ulcer treatment program for at least the past month which has included the use of an appropriate Group 1 Support Surface. 3. The ulcers have worsened or remained the same over the past month. 4. Large or multiple Stage III or IV pressure ulcer(s) (see below) on the trunk or pelvis (ICD-9 Codes 707.02 – 707.05). 5. Recent myocutaneous flap or skin graft for a pressure ulcer on the trunk or pelvis (surgery within the past 60 days). Coverage is generally limited to 60 days from the date of surgery (ICD-9 Codes 707.02 – 707.05). 6. The patient has been on a Group 2 or 3 Support Surface immediately prior to a recent discharge from a hospital or nursing facility (discharge within the past 30 days). The comprehensive ulcer treatment described in #2 above should generally include: i. Education of the patient and caregiver on the prevention and/or management of pressure ulcers. ii. Regular assessment by a nurse, physician, or other licensed healthcare practitioner (usually at least weekly for a patient with a stage III or IV ulcer).

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
LOW AIR-LOSS BED *(continued)*							iii. Appropriate turning and positioning. iv. Appropriate wound care (for a stage II, III, or IV ulcer). v. Appropriate management of moisture/incontinence. vi. Nutritional assessment and intervention consistent with the overall plan of care. If the patient is on a group 2 surface, there should be a care plan established by the physician or home care nurse which includes the above elements. **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. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).** Monthly assessments must be conducted for continued coverage. These assessments can be conducted and documented by a home health agency. Caregiver services and any electrical or structural improvements to the patient's room are **not** covered.
LYMPHEDEMA PUMP							see PNEUMATIC COMPRESSION DEVICE.
✶ **MASK (OXYGEN or PAP)**	✓			✓			if the face mask is necessary to the operation of the patient's covered oxygen or positive airway pressure equipment. 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. A replacement mattress for the hospital bed is covered if the patient owns the hospital bed.
MECHANICAL IN-EXSUFFLATION DEVICE (Cough-Stimulating Device)	✓			✓		✓	if the following conditions are met: 1. The patient has a neuromuscular disease identified by one of these ICD-9 codes: • Late effects of acute poliomyelitis (138). • Anterior horn cell disease (335.0 – 335.9). • Multiple sclerosis (340). • Paralytic syndromes (344.00 – 344.09). *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
MECHANICAL IN-EXSUFFLATION DEVICE (Cough-Stimulating Device) *(continued)*							• Congenital hereditary muscular dystrophy (359.0). • Hereditary progressive muscular dystrophy (359.1). • Myotonic muscular dystrophy (359.21) • Inclusion body myositis (359.71) **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.
MOTORIZED WHEELCHAIR							see POWER MOBILITY DEVICES.
✳ **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 (ICD-9 codes 491.0 – 508.9), **or** 2. It is reasonable and necessary to administer dornase alpha to a patient with cystic fibrosis (ICD-9 277.02), **or** 3. It is reasonable and necessary to administer tobramycin to a patient with cystic fibrosis or bronchiectasis (ICD-9 codes 277.02, 494.0, 494.1, 748.61, 011.50 – 011.56), **or** 4. It is reasonable and necessary to administer pentamidine to patients with HIV (ICD-9 code 042), pneumocystosis (ICD-9 code 136.3), or complications or organ transplants (ICD-9 codes 996.80 – 996.89), **or** 5. It is reasonable and necessary to administer acetylcysteine for persistent thick or tenacious pulmonary secretions (ICD-9 codes 480.0 – 508.9, 786.4). ***NOTE: Only** NEBULIZERS require F2F/WOPD documentation. 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 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 (ICD-9 diagnosis codes 416.0 or 416.8) 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 (ICD-9 diagnosis codes 416.0 or 416.8); **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** 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. *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD
✶ **NEBULIZER AND NEBULIZER SUPPLIES** *(continued)*						
✶ **NEBULIZER MEDICATIONS**	✓			✓		

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	1/3 months
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

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, 10ml/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)
- Albuterol/Ipratropium combination (up to 31 units/month)
- Levalbuterol (up to 39 mg/month or 78 units/month)
- Metaproterenol (up to 470 mg/month or 47 units/month)

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
✳ **NEBULIZER MEDICATIONS** *(continued)*							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 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. The order for any drug must clearly specify the type of solution to be dispensed to the patient and the administration instructions for that solution. A new order is required at least every 12 months, even if the prescription has not changed. A new order is also required whenever there is a change in the type of solution dispensed or the administration instructions. Compounded inhalation solutions are not medically necessary.
NEEDLE-FREE INJECTION DEVICE		✓					comfort or convenience item, not primarily medical in nature.
NEGATIVE PRESSURE VENTILATOR							see VENTILATOR.
✳ **NEGATIVE PRESSURE WOUND THERAPY**	✓			✓	✓		when either criterion A or B is met: **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).** **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. *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD
✶ **NEGATIVE PRESSURE WOUND THERAPY** *(continued)*						

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 (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).

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

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
✳ **NEGATIVE PRESSURE WOUND THERAPY** *(continued)*							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 through A4). For each subsequent month, the medical record must include updated wound measurements and what changes are being applied to effect wound healing. **Supplies for the NPWT:** A maximum of 15 dressing kits per wound per month are covered when used with a covered Negative Pressure Wound Therapy pump. Coverage is provided up to a maximum of 10 canister sets per month unless there is documentation evidencing a large volume of drainage and the patient is using a stationary pump with the largest capacity canister.
NEUROMUSCULAR STIMULATOR	✓			✓		✓	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.
✳ **NONINVASIVE POSITIVE PRESSURE VENTILATOR WITH RATE (Therapeutic Ventilator; 12 hours or less per day)**							see RESPIRATORY ASSIST DEVICE.
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. A fracture nonunion is considered to exist only when a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days and each including multiple views of the fracture site, have been interpreted by a physician in writing as showing that there has been no evidence of fracture healing between the two sets of radiographs.
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.
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 569.62, V44.3, V55.3, ileostomies, V44.2, V55.2 or urinary ostomies V44.6, V55.6. Use for other conditions will be denied as non-covered.

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
OSTOMY EQUIPMENT AND SUPPLIES *(continued)*							If coverage is established, all related equipment and supplies are also covered, including colostomy and other ostomy bags, irrigation and flushing equipment and other items directly related to ostomy care, whether or not the attachment of a bag is required. 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. months, at which time it is considered capped. After the equipment has reached cap, Medicare will pay for stationary contents.
✳ **OXYGEN — HIGH LITER FLOW**	✓		484.03 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 beneficiary 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**	✓		484.03 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 F2F/WOPD documentation, however a F2F is required within 30 days of the set up. 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. • 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** *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD
✳ **OXYGEN SYSTEM** *(continued)*						

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 mg Hg or an arterial oxygen saturation at or below 88% taken at rest (awake), **or**
2. An arterial PO_2 at or below 55mm 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:

1. Dependent edema suggesting congestive heart failure, **or**
2. Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF), **or**
3. Erythrocythemia with a hematocrit greater than 56%.

Group III Includes patients with arterial PO2 levels at or above 60 mm Hg or arterial blood oxygen saturation is at or above 90%. Group III patients are not covered by Medicare.

Qualifying test during exercise: 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.

Qualifying test conducted during sleep: 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 beneficiary's home. Overnight oximetry performed as part of home sleep testing or part of any other home testing is not considered to be eligible under this provision to be used for qualification for home oxygen.

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD
✶ **OXYGEN SYSTEM** *(continued)*						

- 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiaries 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 beneficiary is using the PAP device at those settings; **and**
4. The nocturnal oximetry conducted during the PSG demonstrates an oxygen saturation ≤ 88% for five (5) minutes total (which need not be continuous).

If all of the above criteria are met, for the purposes of a qualifying oxygen saturation test, the beneficiary 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 beneficiary must meet all other coverage requirements for oxygen therapy. Beneficiaries that 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 (ICD-9 339.00, 339.01, 339.02) for beneficiaries who are enrolled in a clinical trial approved by CMS and are in compliance

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
✳ **OXYGEN SYSTEM** *(continued)*							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 beneficiaries 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 beneficiaries 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** Initial Certification: Group I and II patients must be seen and evaluated within 30 days prior to the date of initial certification. Recertification: Group I and II patients must be seen and re-evaluated within 90 days prior to the recertification date. If the physician visit is not obtained within the 90-day window but the patient continues to use oxygen and the evaluation is obtained at a later date, coverage would resume beginning with the date of that evaluation. If oxygen therapy coverage is approved, the coverage applies regardless of delivery system chosen. If coverage is approved, any equipment and supplies necessary to the patient's use of covered home oxygen therapy, such as regulators (flowmeters), humidifiers and face masks, are also covered. Back-up oxygen tanks are not covered. Supplies are not separately reimbursable unless the equipment is owned by the 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)**	✓		484.03 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 F2F/WOPD documentation, however a F2F is required within 30 days of the set up. If a portable oxygen system is covered, the provider must provide whatever quantity of oxygen the patient uses; Medicare's *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
✶ **OXYGEN SYSTEM (PORTABLE)** *(continued)*							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 beneficiary 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 beneficiary relocates outside the supplier's service area (for either short-term travel, extended temporary relocation, or permanent relocation), then for the remainder of the rental month for which it billed, the home supplier is required to provide the equipment and related items/service or make arrangements with a different supplier to provide the equipment, items, and services. For subsequent rental months that the beneficiary is outside the service area, the home supplier is encouraged to either provide the equipment and related items/services or assist the beneficiary in finding another supplier in the new location. The home supplier may not bill for or be reimbursed by Medicare if it is not providing oxygen equipment or has not made arrangements with a different supplier to provide the equipment on the anniversary billing date. Medicare will pay only one supplier to provide oxygen during any one-rental month. Months 37 through 60 Medicare law requires that the supplier that furnishes the oxygen and oxygen equipment during the 36th month of continuous use must continue to furnish the oxygen and oxygen equipment after the cap for any period of medical need for the remainder of the reasonable useful lifetime of the equipment. Therefore, if the beneficiary relocates outside the supplier's service area (for either short-term travel, extended temporary relocation, or permanent relocation), the home supplier is required to either provide the equipment and related items/services or make arrangements with a different supplier to provide the equipment and related items/services. Miscellaneous Oxygen services furnished by an airline to a beneficiary are non-covered. Payment for oxygen furnished by an airline is the responsibility of the beneficiary and not the responsibility of the supplier. Medicare does not cover items or services provided/used outside the United States and its territories. The supplier is not required to provide or arrange for oxygen use in those situations.
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.
PARENTERAL EQUIPMENT AND SUPPLIES	✓		10.03 CMS 10126	✓			for a patient with permanent (expected to last at least three months), severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition. The patient must have: 1. A condition involving the small intestine and/or its exocrine glands which significantly impairs the absorption of nutrients, **or** 2. A disease of the stomach and/or intestine which is a motility disorder and impairs the ability of nutrients to be transported through the GI system. There must be objective evidence supporting the clinical diagnosis. *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD
PARENTERAL EQUIPMENT AND SUPPLIES *(continued)*						

The ordering physician is expected to see the patient within 30 days prior to the initial certification. If the physician does not see the patient within this time frame, he/she must document the reason why and describe what other monitoring methods were used to evaluate the patient's parenteral nutrition needs.

When nutritional support other than the oral route is needed, tube enteral nutrition is usually preferable to parenteral nutrition for the following reasons:

- In a fluid restricted patient, tube enteral nutrition permits delivery of all necessary nutrients in a more concentrated volume than parenteral nutrition, **and**
- Tube enteral nutrition allows for safer home delivery of nutrients.

Parenteral nutrition is **non-covered** for the patient with a functioning gastrointestinal tract whose need for parenteral nutrition is only due to:

- A swallowing disorder.
- A temporary defect in gastric emptying, i.e., a metabolic or electrolyte disorder.
- A psychological disorder impairing food intake, i.e., depression.
- A metabolic disorder inducing anorexia, i.e., cancer.
- A physical disorder impairing food intake, i.e., the dyspnea of severe pulmonary or cardiac disease.
- A side effect of a medication.
- Renal failure and/or dialysis.

Renal failure and/or dialysis: In order to cover intradialytic parenteral nutrition (IDPN — parenteral nutrition delivered during hemodialysis), documentation must be clear and precise to verify that the patient suffers from a permanently impaired gastrointestinal tract and that there is insufficient absorption of nutrients to maintain adequate strength and weight. Records should document that the patient cannot be maintained on oral or enteral feedings and that due to severe pathology of the alimentary tract, the patient must be intravenously infused with nutrients. Infusions must be vital to the nutritional stability of the patient and not supplemental to a deficient diet or deficiencies caused by dialysis. Physical signs, symptoms and test results indicating severe pathology of the alimentary tract must be clearly evident in any documentation submitted. Patients receiving IDPN must meet the parenteral coverage criteria listed below.

Maintenance of weight and strength commensurate with the patient's overall health status must require intravenous nutrition and must not be possible utilizing all of the following approaches:

1. Modifying the nutrient composition of the enteral diet (e.g., lactose free, gluten free, low in long chain triglycerides, substitution with medium chain triglycerides, provision of protein as peptides or amino acids, etc.), **and**
2. Utilizing pharmacologic means to treat the etiology of the malabsorption (e.g., pancreatic enzymes or bile salts, broad-spectrum antibiotics for bacterial overgrowth, prokinetic medication for reduced motility, etc.).

Diagnoses A – F are covered for parenteral nutrition as they are deemed to be severe enough that the patient would not be able to maintain weight and strength on only oral intake or tube enteral nutrition:

A. Massive small bowel resection (within the past three months).
   - Resection must have left ≤ 5 feet of small bowel beyond the ligament of Treitz, **or**

B. Short bowel syndrome.
   - Severe enough that the patient has net gastrointestinal fluid and electrolyte malabsorption such that on an oral intake of 2.5–3 liters/day the enteral losses exceed 50% of the oral/enteral intake.
   - Urine output is < 1 liter/day, **or**

C. Bowel rest.
   - Required for at least three months, **and**
   - Receiving 20–35 cal/kg/day for treatment of symptomatic pancreatitis with or without pancreatic pseudocyst, **or**

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD
PARENTERAL EQUIPMENT AND SUPPLIES *(continued)*						

- Severe exacerbation of regional enteritis, **or**
- Proximal enterocutaneous fistula where tube feeding distal to the fistula is not possible, **or**

D. Complete mechanical small bowel obstruction.
- Surgery is not an option, **or**

E. Significantly malnourished and severe fat malabsorption.
- 10% weight loss over three months or less.
- Serum albumin ≤ 3.4 gm/dl.
- Fecal fat exceeds 50% of oral/enteral intake on a diet of at least 50 gm of fat/day as measured by a standard 72 hour fecal fat test, **or**

F. Significantly malnourished and has severe motility disturbance of small intestine and/or stomach.
- Motility disturbance is unresponsive to prokinetic medication* demonstrated either:
  - Scintigraphically (solid meal gastric emptying study demonstrating that the isotope fails to reach the right colon by six hours post ingestion), **or**
  - Radiographically (barium or radiopaque pellets fail to reach the right colon by six hours following administration).
  - These studies must be performed when the patient is not acutely ill or on any medication which would decrease bowel motility.
- 10% weight loss over three months or less.
- Serum albumin ≤ 3.4 gm/dl.

***Unresponsiveness defined as presence of daily symptoms of nausea and vomiting while taking maximal doses. This should be recorded in the patient's medical record.**

Patients who do not meet the criteria for the diagnoses listed in A–F must meet criteria 1–2 above plus criteria G and H below.

G. 10% weight loss over three months or less and serum albumin ≤ 3.4 gm/dl, **and**

H. A disease and clinical condition has been documented as being present and it has not responded to altering the manner of delivery of appropriate nutrients (e.g., slow infusion through a tube with the tip located in the stomach or jejunum).

EACH OF THE DIAGNOSES OR CONDITIONS LISTED IN A–H HAVE SPECIFIC COVERAGE QUALIFICATIONS THAT MUST BE MET AND REQUIRE EXTENSIVE ADDITIONAL DOCUMENTATION. PLEASE REFER TO THE MEDICAL POLICY FOR MORE DETAIL. THIS DOCUMENTATION COULD INCLUDE, BUT IS NOT LIMITED TO THE FOLLOWING:

Copies of operative reports, discharge summaries, x-ray reports, physician letters, serum albumin tests, nutritional assessments, caloric intake history, weight history, caloric losses, dietary modifications or supplements tried, detailed description of tube trials on enteral nutrition, prokinetic medications used, etc. The tests required are specific to the patient's diagnosis.

The following are moderate abnormalities which would **require** a failed trial of tube enteral nutrition before parenteral nutrition would be covered:

(Documentation of the failed trial of enteral nutrition would need to be available on request.)

- Moderate fat malabsorption — fecal fat exceeds 25% of oral/enteral intake on a diet of at least 50 gm of fat/day as measured by a standard 72 hour fecal fat test.
- Diagnosis of malabsorption with objective confirmation by methods other than 72 hour fecal fat test (e.g., Sudan stain of stool d-xylose test, etc.).
- Gastroparesis which has been demonstrated (a) radiographically or scintigraphically as described in criterion F, above, with the isotope or pellets failing to reach the jejunum in 3–6 hours, or (b) by manometric motility studies with results consistent with an abnormal gastric emptying which is unresponsive to prokinetic medication.
- Small bowel motility disturbance which is unresponsive to prokinetic medication, demonstrated with a gastric to right colon transit time between 3–6 hours.
- Small bowel resection leaving > 5 feet of small bowel beyond the ligament of Treitz.

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD
PARENTERAL EQUIPMENT AND SUPPLIES *(continued)*						

- Short bowel syndrome which is not severe (as defined in B, above).
- Mild to moderate exacerbation of regional enteritis, or an enterocutaneous fistula.
- Partial mechanical small bowel obstruction where surgery is not an option.

Definition of a Tube Trial:

A concerted effort must be made to place a tube. For gastroparesis, tube placement must be post-pylorus, preferably in the jejunum. Use of a double lumen tube should be considered. Placement of the tube in the jejunum must be objectively verified by radiographic studies or fluoroscopy. Placement via endoscopy or open surgical procedure would also verify location of the tube, however, they are not required.

A trial with enteral nutrition must be made, with appropriate attention to dilution, rate, and alternative formulas to address side effects of diarrhea.

Examples of a failed tube trial would be:

- A person who has had a documented placement of a tube in the post-pyloric area and continues to have problems with vomiting and on radiographic recheck the tube has returned to the stomach.
- After an attempt of sufficient time (5 – 6 hours) to get a tube into the jejunum, the tube does not progress and remains in the stomach or duodenum.
- An attempt of enteral tube feeding with a very slow drip was made. It was initially tolerated well, but vomiting occurred when the rate was increased.
- After placement of the tube in the jejunum and one to two days of enteral tube feeding, the person has vomiting and distension.
- A tube is placed appropriately and remains in place. Enteral nutrition is initiated and the concentration and rate are increased gradually. Over the course of 3 – 4 weeks, attempts to increase the rate and/or concentration and/or alter the formula to reach the targeted intake are unsuccessful, with increase in diarrhea, bloating or other limiting symptoms, and the person is unable to meet the needed nutritional goals (stabilize at desired weight or gain weight as needed).

Parenteral nutrition may be covered in a patient with the ability to obtain partial nutrition from oral intake or a combination of oral/enteral (or even oral/enteral/parenteral) intake as long as the following criteria are met:

1a. A permanent condition of the alimentary tract is present which has been deemed to require parenteral therapy because of its severity (criteria A – F), **or**

1b. A permanent condition of the alimentary tract is present which is unresponsive to standard medical management (criterion H), **and**

2. The person is unable to maintain weight and strength (criterion G).

The ordering physician must document the medical necessity for cal/kg/day outside the range of 20 – 35, protein orders outside the range of 0.8 –1.5 gm/kg/day, dextrose concentration less than 10%, or lipid use greater than 1500 grams per month.

Parenteral nutrition solutions containing little or no amino acids and/or carbohydrates would be covered only in situations A, B or D (above).

Special nutrient formulas, HCPCS codes B5000 – B5200, 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. This information shall be available upon request.

The patient's condition must be monitored to confirm that the coverage criteria for parenteral nutrition continues to be met.

Equipment and Supplies:

Infusion pumps are covered for patients covered for parenteral nutrition. Only one pump (stationary or portable) will be covered at any one time. Additional pumps will be denied as not medically necessary.

If the coverage requirements for parenteral nutrition are met, medically necessary nutrients and supply and administration kits (one each kit per day) will also be covered.

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
PARENTERAL EQUIPMENT AND SUPPLIES *(continued)*							***= Detailed description of billing codes:*** *B5000 Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength; renal — amirosyn RF, nephramine, renamine (premix)* *B5100 Hepatic — freamine HBC, hepatamine, premix* *B5200 Stress — branch chain amino acids, premi*
PATIENT LIFT	✓			✓			if transfer between bed and a chair, wheelchair, or commode is required and, without the use of a lift, the beneficiary would be bed confined.
PEAK FLOWMETERS	✓			✓			for the self-monitoring of patients with pure asthma (ICD-9 Codes 493.00 – 493.11) when they are used as part of a comprehensive asthma management program.
✳ **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.
PNEUMATIC COMPRESSION DEVICE (Used for Lymphedema)	✓		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: • Location and size of venous stasis ulcer(s); **and** • Length of time ulcer has been 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: *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
PNEUMATIC COMPRESSION DEVICE (Used for Lymphedema) *(continued)*							• The treatment plan including the pressure in each chamber, and the frequency and duration of each treatment; **and** • Whether a segmented compressor without calibrated gradient pressure or a non-segmented compressor with a segmented appliance has been tried and the results of the trial; **and** • Why additional features are needed; **and** • The name, model number and manufacturer of the device.
✳ **PORTABLE OXYGEN SYSTEM**							see OXYGEN SYSTEM (PORTABLE).
✳ **POSITIVE AIRWAY PRESSURE (PAP) DEVICE**	✓			✓		✓	if the patient is diagnosed with obstructive sleep apnea (OSA). 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. Effective for services performed on or after 01/01/13: **Concurrent Use of Oxygen with PAP Therapy** Some beneficiaries may require the simultaneous use of home oxygen therapy with a PAP device. To be considered for simultaneous coverage, all requirements in the Indications and Limitations of Coverage and/or Medical Necessity for both Oxygen and Oxygen Equipment and Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea LCDs must be met. Please refer to the Oxygen Policy for additional coverage criteria. The diagnosis of OSA must be documented by either an attended, facility-based polysomnogram (sleep study) or an unattended home 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. **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 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) *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD
✶ **POSITIVE AIRWAY PRESSURE (PAP) DEVICE** *(continued)*						

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.

Bi-Level Device

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 beneficiary 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 beneficiary is benefiting from PAP therapy; **and**
2. Objective evidence of adherence to use of the PAP device. Adherence to therapy is defined as use of PAP at least 4 hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage. This can be accomplished either through direct download or visual inspection of adherence information.

If the above criteria are not met, continued coverage of a PAP device and related accessories will be denied as not medically necessary.

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 prescription is required.
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**

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
✳ **POSITIVE AIRWAY PRESSURE (PAP) DEVICE** *(continued)*							B. Copy of the insurance claim (damaged); **or** C. Written statement from the patient or caregiver (lost). **Beneficiary 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. Qualifying sleep study that occurred prior to the Medicare effective date. 2. Face-to-face patient evaluation with the treating physician after the Medicare effective date that indicates the patient's diagnosis of OSA and the patient continues to use the PAP device. 3. A new prescription. There is no trial period for patients qualified under the Beneficiary 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. **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 . . . . . 1/3months A7031 Replacement face mask interface for full face mask . . . . . 1/1 month A7032 Replacement cushion for nasal mask interface . . . . . 2/1 month A7033 Replacement pillows for nasal cannula type interface . . . . . 2/1 month A7034 Nasal interface (mask or cannula type) . . . . . 1/3 months A7035 Headgear . . . . . 1/6 months A7036 Chinstrap . . . . . 1/6 months A7037 Tubing . . . . . 1/3 months A7038 Disposable filter . . . . . 2/1 month A7039 Non-disposable filter . . . . . 1/6 months A7046 Replacement water chamber for humidifier . . . . . 1/6 months Accessories in excess of these time frames are rarely considered medically necessary. **Humidifiers** Either a non-heated or heated humidifier is covered when ordered by the treating 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.
POSTURAL DRAINAGE BOARD	✓			✓			if the patient has a chronic pulmonary condition.
POWER MOBILITY DEVICES (PMDs)	✓			✓	✓		if extensive coverage criteria are met. Power mobility devices (PMDs) include power operated vehicles (POVs) and power wheelchairs (PWCs). Coverage criteria for PMDs are based on a stepwise progression of medical necessity documented by the physician's comprehensive notes and evaluations. Checklists and provider-generated forms are not a sufficient substitute for this documentation. PMDs are not covered for use outside the patient's home. *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD
POWER MOBILITY DEVICES (PMDs) *(continued)*						

Face-to-Face Examination

For a POV or PWC to be covered, the treating physician must conduct a face-to-face examination of the patient **before** writing the order and the provider must receive a written report of this examination **within 45 days** after completion of the face-to-face examination and prior to the delivery of the device (during a hospital or nursing home stay, the 45-day requirement is from date of discharge).

Physicians should document the exam in a detailed narrative note in their charts in the format they use for other entries. The documentation must clearly indicate the reason for the visit is a mobility evaluation. The narrative should not be in checklist form and supporting documentation should include pertinent diagnostics tests.

The physician may refer the patient to a licensed/certified medical professional (LCMP), such as a physical therapist (PT) or occupational therapist (OT), who has experience and training in mobility evaluations to perform part of the face-to-face examination. This person may have no financial relationship with the provider.

If the patient was referred before being seen by the physician, then once the physician has received and reviewed the written report of this examination, **the physician must see the patient and perform any additional examination that is needed.** The report of the physician's visit shall state concurrence or any disagreement with the LCMP examination. The physician must provide the provider with a copy of both examinations **within 45 days** after the face-to-face examination with the physician.

If the physician saw the patient to begin the examination before referring the patient to an LCMP, then if the physician sees the patient again in person after receiving the report of the LCMP examination, the 45-day period begins on the date of that second physician visit. However, it is also acceptable for the physician to review the written report of the LCMP examination, to sign and date that report, and to state concurrence or any disagreement with that examination. In this situation, the physician must send a copy of the note from his/her initial visit to evaluate the patient plus the annotated, signed, and dated copy of the LCMP examination to the provider. The 45-day period begins when the physician signs and dates the LCMP examination.

Physician's Orders

For a POV or PWC to be covered, the provider must receive a written order from the physician containing the following elements within 45 days of the completion of the face-to-face examination:

1. Beneficiary's name.
2. Description of the item that is ordered.
3. Date of the face-to-face examination.
4. Pertinent diagnoses/conditions that relate to the need for the POV or PWC.
5. Length of need.
6. Physician's signature.
7. Date of physician signature.

A detailed product description listing the HCPCS codes, narrative of the HCPCS codes, model, manufacturer's name, model name and number, provider's charge, Medicare fee allowable for the specific base and each option and accessory that will be separately billed.

Basic Coverage Criteria

All of the following basic criteria (A – C) must be met for a power mobility device (K0800 – K0898) or a push-rim activated power assist device (E0986) to be covered. Additional coverage criteria for specific devices are listed below.

A. 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) such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home. A mobility limitation is one that:
   - Prevents the patient from accomplishing an 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 an MRADL within a reasonable time frame.

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD
POWER MOBILITY DEVICES (PMDs) *(continued)*						

B. The patient's mobility limitation cannot be sufficiently and safely resolved by the use of an appropriately fitted cane or walker.
C. The patient does not have sufficient upper extremity function to self-propel an optimally-configured manual wheelchair in the home to perform MRADLs during a typical day.
Limitations of strength, endurance, range of motion, or coordination, presence of pain, or deformity or absence of one or both upper extremities are relevant to the assessment of upper extremity function.

Power Operated Vehicles (K0800 – K0808 and K0812 — Power operated vehicle, not otherwise classified)

A. POV is covered if all of the basic coverage criteria (A – C) have been met and if criteria D – I are also met.
D. The patient is able to:
- Safely transfer to and from a POV, **and**
- Operate the tiller steering system, **and**
- Maintain postural stability and position while operating the POV in the home.

E. The patient's mental capabilities (e.g., cognition, judgment) and physical capabilities (e.g., vision) are sufficient for safe mobility using a POV in the home.
F. The patient's home provides adequate access between rooms, maneuvering space, and surfaces for the operation of the POV that is provided. (Provider may document this.)
G. The patient's weight is less than or equal to the weight capacity of the POV that is provided.
H. Use of a POV will significantly improve the patient's ability to participate in MRADLs and the patient will use it in the home.
I. The patient has not expressed an unwillingness to use a POV in the home.

Power Wheelchairs (K0813 – K0891 and K0898 — Power wheelchair, not otherwise classified)

A power wheelchair (PWC) is covered if:
(a) All of the Basic Coverage Criteria (A – C) are met; **and**
(b) The patient does not meet coverage criterion D, E, or F for a POV; **and**
(c) Criterion J or K is met; **and**
(d) Criterion L, M, N, and O are met; **and**
(e) Any coverage criteria pertaining to the specific wheelchair type (see below) are met.

J. The patient has the mental and physical capabilities to safely operate the power wheelchair that is provided, **or**
K. If the patient is unable to safely operate the power wheelchair, the patient has a caregiver who is unable to adequately propel an optimally configured manual wheelchair, but is available, willing, and able to safely operate the power wheelchair that is provided, **and**
L. The patient's weight is less than or equal to the weight capacity of the power wheelchair that is provided.
M. The patient's home provides adequate access between rooms, maneuvering space, and surfaces for the operation of the power wheelchair that is provided. (Provider may document this.)
N. Use of a power wheelchair will significantly improve the patient's ability to participate in MRADLs and the patient will use it in the home. For patients with severe cognitive and/or physical impairments, participation in MRADLs may require the assistance of a caregiver.
O. The patient has not expressed an unwillingness to use a power wheelchair in the home.

Specific Types of Power Wheelchairs

I. A Group 1 PWC (K0813 – K0816) or a Group 2 (K0820 – K0829) is covered if all of the coverage criteria (a) – (e) for a PWC are met and the wheelchair is appropriate for the patient's weight.
II. A Group 2 Single Power Option PWC (K0835 – K0840) is covered if all of the coverage criteria (a) – (e) for a PWC are met and if:
A. Criterion 1 **or** 2 is met; **and**
B. Criterion 3 **and** 4 are met.
1. The patient requires a drive control interface other than a hand or chin-operated standard proportional joystick (examples include but are not limited to head control, sip and puff, switch control).

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD
POWER MOBILITY DEVICES (PMDs) *(continued)*						

2. The patient meets coverage criteria for a power tilt or a power recline seating system (see Wheelchair Options and Accessories policy for coverage criteria) and the system is being used on the wheelchair.
3. The patient has had a specialty evaluation that was performed by a licensed/certified medical professional, such as a physical therapist (PT) or occupational therapist (OT), or physician who has specific training and experience in rehabilitation wheelchair evaluations and that documents the medical necessity for the wheelchair and its special features (see Documentation Requirements section). The PT, OT, or physician may have no financial relationship with the provider.
4. The wheelchair is provided by a provider that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the patient.

If a Group 2 Single Power Option PWC is provided and if II(A) or II(B) is not met (including but not limited to situations in which it is only provided to accommodate a power seat elevation feature, a power standing feature, or only power elevating legrests) but the coverage criteria for a PWC are met, payment will be based on the allowance for the least costly medically appropriate alternative Group 2 PWC.

III. A Group 2 Multiple Power Option PWC (K0841 – K0843) is covered if all of the coverage criteria (a) – (e) for a PWC are met and if:
   A. Criterion 1 or 2 is met, **and**
   B. Criterion 3 and 4 are met.
      1. The patient meets coverage criteria for a power tilt and recline seating system (see Wheelchair Options and Accessories policy) and the system is being used on the wheelchair.
      2. The patient uses a ventilator which is mounted on the wheelchair.
      3. The patient has had a specialty evaluation that was performed by a licensed/certified medical professional, such as a PT or OT, or physician who has specific training and experience in rehabilitation wheelchair evaluations and that documents the medical necessity for the wheelchair and its special features (see Documentation Requirements section). The PT, OT, or physician may have no financial relationship with the provider.
      4. The wheelchair is provided by a provider that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the patient.

      If a Group 2 Multiple Power Option PWC is provided and if III(A) or III(B) is not met but the criteria for another PWC are met, payment will be based on the allowance for the least costly medically appropriate alternative Group 2 PWC.

IV. A Group 3 PWC with no power options (K0848 – K0855) is covered if:
   A. All of the coverage criteria (a) – (e) for a PWC are met, **and**
   B. The patient's mobility limitation is due to a neurological condition, myopathy or congenital skeletal deformity, **and**
   C. The patient has had a specialty evaluation that was performed by a licensed/certified medical professional, such as a PT or OT, or physician who has specific training and experience in rehabilitation wheelchair evaluations and that documents the medical necessity for the wheelchair and its special features (see Documentation Requirements section). The PT, OT, or physician may have no financial relationship with the provider.
   D. The wheelchair is provided by a provider that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the patient.

   If a Group 3 PWC is provided and criterion A is met but criterion B, C or D is not met, payment will be based on the allowance for the least costly medically appropriate alternative Group 2 PWC.

V. A Group 3 PWC with Single Power Option (K0856 – K0860) or with Multiple Power Options (K0861 – K0864) is covered if:
   A. The Group 3 criteria IV(A) and IV(B) are met, **and**
   B. The Group 2 Single Power Option (criteria II[A] and II[B]) or Multiple Power Options (criteria III[A] and III[B]) (respectively) are met.

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD
POWER MOBILITY DEVICES (PMDs) *(continued)*						

If a Group 3 Single Power Option or Multiple Power Options PWC is provided and Criterion IV(A) is met, but all of the other coverage criteria are not met, payment will be based on the allowance for the least costly medically appropriate alternative Group 2 or Group 3 PWC.

VI. Group 4 PWCs (K0868 – K0886) have added capabilities that are not needed for use in the home. Therefore, if these wheelchairs are provided and coverage criteria for a Group 2 or Group 3 PWC are met, payment will be based on the allowance for the least costly medically appropriate alternative.

VII. A Group 5 (Pediatric) PWC with Single Power Option (K0890) or with Multiple Power Options (K0891) is covered if:
- A. All the coverage criteria (a) – (e) for a PWC are met, **and**
- B. The patient is expected to grow in height, **and**
- C. The Group 2 Single Power Option (criteria II[A] and II[B]) or Multiple Power Options (criteria III[A] and III[B]) (respectively) are met.

If a Group 5 PWC is provided but all the coverage criteria are not met, payment will be based on the allowance for the least costly medically appropriate alternative.

VIII. A push-rim activated power assist device (E0986) for a manual wheelchair is covered if all of the following criteria are met:
- A. All of the criteria for a power mobility device listed in the Basic Coverage Criteria section are met; **and**
- B. The patient has been self-propelling in a manual wheelchair for at least one year; **and**
- C. The patient has had a specialty evaluation that was performed by a licensed/certified medical professional, such as a PT or OT, or physician who has specific training and experience in rehabilitation wheelchair evaluations and that documents the need for the device in the patient's home. The PT, OT or physician may have no financial relationship with the supplier; **and**
- D. The wheelchair is provided by a supplier that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the patient.

Documentation Requirements

Orders: The order that the supplier must receive within 45 days after completion of the face-to-face examination must contain ALL of the following elements:

1. Beneficiary's name
2. Description of the item that is ordered. This may be general — e.g., "power operated vehicle," "power wheelchair," or "power mobility device" — or may be more specific
3. Date of the face-to-face examination
4. Pertinent diagnoses/conditions that relate to the need for the POV or power wheelchair
5. Length of need
6. Physician's signature
7. Date of physician signature

The physician must sign and date the detailed product description and the supplier must receive it prior to delivery of the PWC or POV.

Face-to-Face Examination: The report of the face-to-face examination should provide information relating to the following questions.

- For POVs and PWCs:
  - What is this patient's mobility limitation and how does it interfere with the performance of activities of daily living?
  - Why can't a cane or walker meet this patient's mobility needs in the home?
  - Why can't a manual wheelchair meet this patient's mobility needs in the home?
- For POVs:
  - Does this patient have the physical and mental abilities to transfer into a POV and to operate it safely in the home?
- For PWCs:
  - Why can't a POV (scooter) meet this patient's mobility needs in the home?
  - Does this patient have the physical and mental abilities to operate a power wheelchair safely in the home?

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
POWER MOBILITY DEVICES (PMDs) *(continued)*							The report should provide pertinent information about the following elements: • Symptoms that limit ambulation • Diagnoses that are responsible for these symptoms • Medications or other treatment for these symptoms • Progression of ambulation difficulty over time • Other diagnoses that may relate to ambulatory problems • How far the patient can walk without stopping • Pace of ambulation • What ambulatory assistance (cane, walker, wheelchair, caregiver) is currently used • What has changed to now require use of a power mobility device • Ability to stand up from a seated position without assistance • Description of the home setting and the ability to perform activities of daily living in the home Physical examination that is relevant to mobility needs: • Weight and height • Cardiopulmonary examination • Musculoskeletal examination – Arm and leg strength and range of motion • Neurological examination – Gait – Balance and coordination A date stamp or equivalent must be used to document the date that the supplier receives the report of the face-to-face examination. The written report of this examination must be available upon request. Physicians shall document the examination in a detailed narrative note in their charts in the format that they use for other entries. The note must clearly indicate that a major reason for the visit was a mobility examination. Specialty Evaluation: The specialty evaluation that is required for patients who receive a Group 2 Single Power Option or Multiple Power Options PWC, any Group 3 PWC or a push-rim activated power assist device is in addition to the requirement for the face-to-face examination. The specialty evaluation provides detailed information explaining why each specific option or accessory — i.e., power seating system, alternate drive control interface, or push-rim activated power assist — is needed to address the patient's mobility limitation. There must be a written report of this evaluation available upon request. Home Assessment: Prior to or at the time of delivery of a POV or PWC, the supplier or practitioner must perform an on-site evaluation of the patient's home to verify that the patient can adequately maneuver the device that is provided considering physical layout, doorway width, doorway thresholds, and surfaces. There must be a written report of this evaluation available upon request.
POWER OPERATED VEHICLE (POV)							see POWER MOBILITY DEVICES.
PRESSURE LEOTARDS		✓					non-reusable supply.
PROSTHETIC DEVICES	✓			✓			when ordered by a physician. Prosthetic devices are items which replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. The test of permanence is considered met if the medical record, including the judgment of the attending physician, indicates that the condition is of long and indefinite duration. Coverage under this benefit includes, but is not limited to, artificial arms and legs, breast prostheses, eye prostheses, parenteral and enteral nutrition, ostomy supplies, urological supplies in patients with permanent urinary incontinence, and glasses or contact lenses in patients with aphakia or pseudophakia. *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
PROSTHETIC DEVICES *(continued)*							Medically necessary supplies that are required for the effective use of a medically necessary prosthetic device are covered. Non-reusable supplies that are not integral to the organ replacement system, like chux, diapers, rubber sheets, etc. are not covered. Repairs, adjustments, and replacement of medically necessary prosthetic devices are covered. Dental prostheses, i.e., dentures, are excluded from coverage.
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.
✶ **RESPIRATOR**							see VENTILATORS.
✶ **RESPIRATORY ASSIST DEVICE (RAD)**	✓			✓		✓	**Initial Coverage Criteria for E0470 and E0471 Devices for the First Three Months of Therapy:** For an E0470 or an E0471 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 RAD (E0470, E0471) is covered for those patients with clinical disorder groups characterized as: 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 ≥ 5 minutes of nocturnal recording time (minimum recording *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD
✶ **RESPIRATORY ASSIST DEVICE (RAD)** *(continued)*						

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, Obstructive Sleep Apnea (OSA) and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out.

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 E0471 device will be covered for a patient with COPD in either of the two situations below, depending on the testing performed to demonstrate the need.

Situation 1: 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 beneficiary'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 ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours) while using an E0470 device that is not caused by obstructive upper airway events — i.e., AHI < 5. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea).

Situation 2: For Group II patients (COPD) who qualified for an E0470 device, an E0471 device will be covered if, at a time no sooner than 61 days after initial issue of the E0470 device, **both** of the following criteria A and B are met:

a. An arterial blood gas $PaCO_2$ is done while awake and breathing the patient's prescribed FIO_2, still remains **≥** 52 mm Hg.
b. Sleep oximetry while breathing with the E0470 device, demonstrates oxygen saturation **≤** 88% for **≥** 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).

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 criteria 1, 2, and either 3 or 4 are met.

1. An initial arterial blood gas $PaCO_2$, done while awake and breathing the patient's prescribed FIO_2, is **≥** 45 mm Hg; **and**
2. Spirometry shows an FEV1/FVC **≥** 70% and an FEV1 **≥** 50% of predicted. (Refer to II. SEVERE COPD (above) for information about device coverage for patients with FEV1/FVC < 70% and FEV1 < 50% of predicted).
3. An arterial blood gas $PaCO_2$, done during sleep or immediately upon awakening, and breathing the patient's prescribed FIO_2, shows the beneficiary's $PaCO_2$ worsened **≥** 7 mm Hg compared to the original result in criterion 1 (above); **or**
4. A facility-based PSG 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 criteria 1, 2, and either 3 or 4 are met:

1. A covered E0470 device is being used; **and**
2. Spirometry shows an FEV1/FVC **≥** 70% and an FEV1 **≥** 50% of predicted. (Refer to II. SEVERE COPD (above) for information about device coverage for patients with FEV1/FVC < 70% and FEV1 < 50% of predicted).
3. An arterial blood gas $PaCO_2$, done while awake and breathing the patient's prescribed FIO_2, shows that the beneficiary's $PaCO_2$ worsens **≥** 7 mm Hg compared to the ABG result performed to qualify the patient for the E0470 device; **or**

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
✳ **RESPIRATORY ASSIST DEVICE (RAD)** *(continued)*							4. A facility-based PSG 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.) Patients covered for the first three months of an E0470 or an E0471 device must be re-evaluated to establish the medical necessity of continued coverage by Medicare beyond the first three months. While the patient may certainly need to be evaluated at earlier intervals after this therapy is initiated, the re-evaluation upon which Medicare will base a decision to continue coverage beyond this time must occur no sooner than 61 days after initiating therapy by the treating 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 **Obstructive Sleep Apnea:** Please see POSITIVE AIRWAY PRESSURE (PAP) DEVICE. **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.
SAFETY ROLLERS	✓			✓			if patient meets Mobility Assistive Equipment clinical criteria.
SAUNA BATH		✓					not primarily medical in nature; personal comfort item.
SEAT LIFT MECHANISM	✓		07.03A 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. To establish medical necessity, evidence must show that: 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, after improvement. 3. The patient must be completely incapable of standing up from a regular armchair or any chair in their home. 4. Once standing, the patient must have the ability to ambulate. 5. All appropriate therapeutic modalities to enable the patient to transfer from a chair to a standing position (e.g., medication, physical therapy) must have been tried and failed. **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.
SPEAKING VALVE	✓			✓			for tracheostomy patients under the prosthetic guidelines. See PROSTHETIC DEVICES.

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
SPEECH GENERATING DEVICES	✓			✓		✓	when **all** of the following criteria (1–7) are met: 1. Prior to the delivery of the speech-generating device (SGD), the patient has had a formal evaluation of the cognitive and communication abilities by a speech language pathologist (SLP). The formal, written evaluation must include at a minimum, the following elements: • Current communication impairment, including the type, severity, language skills, cognitive ability, and anticipated course of the impairment; • An assessment of whether the individual's daily communication needs could be met using other natural modes of communication; • A description of the functional communication goals expected to be achieved and treatment options; • Rationale for selection of a specific device and any accessories; • Demonstration that the patient possesses a treatment plan that includes a training schedule for the selected device; • The cognitive and physical abilities to effectively use the selected device and any accessories to communicate; • For a subsequent upgrade to a previously issued speech generating device, information regarding the functional benefit to the patient of the upgrade compared to the initially provided SGD; **and** 2. The patient's medical condition is one resulting in a severe expressive speech impairment; **and** 3. The patient's speaking needs cannot be met by using natural communication methods; **and** 4. Other forms of treatment have been considered and ruled out; **and** 5. The patient's speech impairment will benefit from the device ordered; **and** 6. A copy of the SLP's written evaluation and recommendation have been forwarded to the patient's treating physician prior to ordering the device; **and** 7. The SLP performing the patient evaluation may not be an employee of or have a financial relationship with the provider of the SGD.
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.
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.

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
SURGICAL LEGGINGS		✓					not covered.
TELEPHONE ALERT SYSTEM		✓					not covered.
TELEPHONE ARM		✓					not covered.
✳ THERAPEUTIC VENTILATOR							see NONINVASIVE POSITIVE PRESSURE WITH RATE or VENTILATOR.
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. 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. Tracheostomy/laryngectomy tube plug/stop (A7527) is used as an alternative to a tracheostomy/laryngectomy tube and therefore for a beneficiary receiving A7527 claims for A7520, A7521 and A7522 will be denied as not reasonable or necessary. Heat/Moisture Exchangers (HME) are a type of stoma cover which help laryngectomees partially restore functions previously performed by the nose and upper airway. An HME may be used by itself or in addition to a tracheostoma valve (A7501). An explanation for use of a greater quantity of supplies than are covered by Medicare must be clearly documented in the beneficiary's medical record. If adequate documentation is not provided when requested, the excess quantities will be denied as not reasonable and necessary.
TRACTION EQUIPMENT	✓			✓		✓	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.
TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR (TENS) AND SUPPLIES	✓		06.03B CMS 848	✓		✓	for the treatment of patients with chronic, intractable pain or acute post-operative pain who meet the following: 1. The pain must have been present for at least three months, **and** 2. The presumed etiology of pain must be a type which is accepted as responding to TENS therapy; this excludes headache, visceral abdominal pain, pelvic pain, TMJ pain, etc. Other appropriate treatment modalities must have been tried and failed, and the medical record must document what treatment modalities have been used (including the names and dosage of medication), the length of time that each type of treatment was used, and the results. When a TENS unit is used for acute post-operative pain, the medical necessity is limited to 30 days from the day of surgery. Payment for more than one month is determined by individual consideration based upon supportive documentation provided by the attending physician. Payment will be made only as a rental. A TENS unit will be denied as not medically necessary for acute pain (less than three months duration) other than post-operative pain. A one-month trial evaluation of TENS is recommended to judge its effectiveness in alleviating the patient's pain. Rental of *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR (TENS) AND SUPPLIES *(continued)*							the TENS unit is covered during this one-month trial usage period. Reimbursement during this one-month trial is limited to the amount which would be payable for the total service, including TENS supplies and evaluation, if provided by the physician or therapist. If the initial TENS therapy trial takes longer than one month, documentation of medical necessity must be provided for all services furnished beyond the first month. The trial period is limited to two months. The trial period must be monitored by the physician to determine the effectiveness of the TENS unit in modulating the pain. For coverage of 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. The physician's records must document a reevaluation of the patient at the end of the trial period, must indicate how often the patient used the TENS unit, the typical duration of use each time and the results. After the trial period, purchase of the TENS unit can be covered under the prosthetic devices benefit. See PROSTHETIC DEVICES. A 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. Medicare will only allow coverage of TENS for Chronic Lower Back Pain (CLBP) defined for this decision as pain for 3 months or longer and not a manifestation of a clearly defined and generally recognizable primary disease entity, when the patient is enrolled in an approved clinical study under coverage with evidence development (CED). 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 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 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. Other conditions can be considered for coverage on an individual basis such as parapsoriasis, cutaneous T-cell lymphomas with a diagnosis of mycosis fungoides or Sezary's disease.
URINALS	✓			✓			if patient is bed confined.
URINE TEST OR REAGENT STRIPS OR TABLETS (100 tablets or strips)		✓					non-reusable supply.

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD
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**
- 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:

(continued)

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
UROLOGICAL SUPPLIES i.e., Indwelling Catheters, Drainage Bags, Urinary Catheters, etc. *(continued)*							– 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 meatal 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	✓			✓		✓	for treatment of neuromuscular diseases, restrictive thoracic diseases and chronic respiratory failure consequent to chronic obstructive pulmonary disease. Coverage includes both positive and negative pressure ventilators. Used to treat chronic respiratory failure when life support is needed (> 12 hours per day and/or patient cannot breathe independently). Patient must have a qualifying diagnosis in addition to a tracheostomy.
WALKER	✓			✓			if reasonable and necessary for 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. Coverage is based on an algorithmic approach to determine if a patient will qualify. The patient must be able to safely use the walker and 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.
WATER PRESSURE PAD AND MATTRESS							See ALTERNATING PRESSURE PAD WITH PUMP AND MATTRESS.
WHEELCHAIR	✓			✓		✓	if the beneficiary has a mobility limitation that significantly impairs his/her ability to participate in one or more Mobility Related Activities of Daily Living (MRADLs) 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 beneficiary from accomplishing the MRADLs entirely, **or** *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
WHEELCHAIR *(continued)*							• Places the beneficiary at a reasonably determined heightened risk of illness, injury, or death secondary to the attempts to participate in MRADLs, **or** • Prevents the beneficiary from completing the MRADLs within a reasonable time frame, **or** • There are other conditions that limit the beneficiary's ability to participate in MRADLs at home, i.e., impaired cognition or vision, and the other conditions can be compensated so that the beneficiary can use the wheelchair for MRADLs, **and** • The beneficiary or caregiver is capable and willing to operate the equipment safely, **and** • The beneficiary's mobility limitation cannot be resolved with the use of a cane or walker, **and** • The beneficiary's home environment can safely support the use of the equipment. Documentation of the beneficiary's medical history, use of other equipment, mobility limitations, and ability to use the wheelchair safely must be obtained from the 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 necessary to accommodate the physical size of the patient or any size restrictions imposed by the patient's home (e.g., narrow doorways). **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 due to short stature or to enable a patient to place his/her feet on the ground for propulsion. **Lightweight wheelchairs** (K0003) are covered when a patient cannot propel himself or herself in a standard wheelchair and the patient is actually able to propel in a lightweight chair. **High strength lightweight wheelchairs** (K0004) are covered when the patient needs the wheelchair while engaging in frequent activities that cannot be performed in a less expensive wheelchair or the patient requires a seat width, depth or height that cannot be accommodated in a standard, lightweight or hemi-wheelchair and spends at least two hours per day in the wheelchair. This type of wheelchair would rarely be medically necessary if the expected duration of need is less than three months. **Heavy duty wheelchairs** (K0006) are covered for patients weighing more than 250 pounds or having severe spasticity. **Extra heavy duty wheelchairs** (K0007) are covered for patients weighing more than 300 pounds. **Please see POWER MOBILITY DEVICES section for information regarding power wheelchairs.**
WHEELCHAIR ACCESSORIES	✓			✓		✓*	if all of the criteria in the wheelchair section have been met. ***NOTE:** Some WHEELCHAIR ACCESSORIES **may** require WOPD/F2F documentation. Examples of accessories/coverage criteria: **Arm of chair** (E0973, K0017, K0018, K0020) — covered if patient requires an arm height that is different than that available using non-adjustable arms and the patient spends at least two hours per day in the wheelchair. **Arm trough** (E2209) — covered if patient has quadriplegia, hemiplegia, or uncontrolled arm movements. **Footrest/legrest** (E0990, K0046, K0047, K0053, K0195) — covered if patient has a musculoskeletal condition or the presence of a cast or brace which prevents 90 degree flexion at the knee. Also covered if patient has significant edema of the lower extremities that requires elevation or the patient meets the criteria for and has a reclining back on the wheelchair. **Non-standard seat frame** (E2201 – E2204) — covered only if the patient's dimensions justify the need. **Anti-rollback device** (E0974) — covered if patient propels on their own and needs the device because of ramps. **Safety belt** (E0978) — covered if patient has weak upper body muscles, upper body instability or muscle spasticity which requires use of this for proper positioning. **Fully reclining back** (E1226) — covered if the patient has one or more of the following conditions: *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
WHEELCHAIR ACCESSORIES *(continued)*							1. The patient is at high risk for development of a pressure ulcer and is unable to perform a functional weight shift; **or** 2. The patient utilizes intermittent catheterization for bladder management and is unable to independently transfer from the wheelchair to the bed. **Check with your local Apria Healthcare customer service representative on all wheelchair accessories and reimbursement.** **Please see POWER MOBILITY DEVICES section for information about accessories for power wheelchairs.**
WHEELCHAIR SEATING AND BACK CUSHIONS	✓			✓			for patients who have a Medicare-qualified wheelchair and are susceptible to, or have decubitus ulcers or have impaired or missing sensation of the area that comes into contact with a wheelchair cushion. There are five different categories of seat and back cushions, presented in least costly to most costly options. To be covered, some seat or back cushions require the patient to meet and exceed all requirements of less-costly categories before being considered eligible for more costly options. **A physician's written prescription/order must be furnished to the provider prior to delivery (WOPD).** **General use** seat cushions (E2601, E2602*) and back cushions (E2611, E2612*) are covered for a patient who has a manual wheelchair or power wheelchair with a sling/solid seat/back which meets Medicare coverage criteria. Cushions for POVs (power operated vehicles) and PWCs (power wheelchairs) with a captain's chair seat will be denied as not medically necessary. **Skin protection** seat cushion (E2603, E2604, K0734, K0735*): 1. Covered for a patient who has a manual wheelchair or PWC with a sling/solid seat/back and the patient meets Medicare criteria for it, **and** 2. The patient has **either** of the following: (a) A current pressure ulcer or past history of a pressure ulcer (707.03 – 707.05) on the area of contact with the seating surface, **or** (b) Absent or impaired sensation in the area of contact with the seating surface or inability to carry out a functional weight shift due to one of the following diagnoses: spinal cord injury resulting in quadriplegia or paraplegia (344.00 – 344.1), other spinal cord disease (336.0 – 336.3), multiple sclerosis (340), other demyelinating disease (341.0 – 341.9), cerebral palsy (343.0 – 343.9), anterior horn cell diseases including amyotrophic lateral sclerosis (335.0 – 335.21, 335.23 – 335.9), post polio paralysis (138), traumatic brain injury resulting in quadriplegia (344.09), spina bifida (741.00 – 741.93), childhood cerebral degeneration (330.0 – 330.9), Alzheimer's disease (331.0), Parkinson's disease (332.0), muscular dystrophy (359.0, 395.1), hemiplegia (342.00 – 342.92, 438.20 – 438.22), Huntington's chorea (333.4), idiopathic torsion dystonia (333.6), athetoid cerebral palsy (333.71). **Positioning** seat cushion (E2605, E2606*) or back cushion (E2613 – E2616, E2620, E2621*), and positioning accessory (E0955 – E0957, E0960*) is covered for a patient who meets both of the following criteria: 1. The patient has a manual wheelchair or a power wheelchair with a sling/solid seat/back and the patient meets Medicare coverage criteria for it, **and** 2. The patient has any significant postural asymmetries that are due to one of the diagnoses listed in criterion 2(b) above or to **one of the following** diagnoses: monoplegia of the lower limb (344.30 – 344.32, 438.40 – 438.42) due to stroke, traumatic brain injury, or other etiology, spinocerebellar disease (334.0 – 334.9), above knee leg amputation (897.2 – 897.7), osteogenesis imperfecta (756.51), transverse myelitis (323.82). **Headrest** (E0955*) is also covered when the patient has a covered manual tilt-in-space wheelchair, manual semi or fully reclining back on a manual wheelchair, a manual fully reclining back on a power wheelchair, or power tilt and/or recline power seating system. Headrests are not medically necessary on POVs or PWCs with captain's seats. **Combination skin protection and positioning** seat cushions (E2607, E2608, K0736, K0737*) are covered for a patient who meets the criteria for **both** a skin protection seat cushion and a positioning seat cushion. *(continued)*

ITEM	Covered	Non-Covered	DME MAC CMN or DIF #	Physician's Order/Rx	WOPD	F2F/WOPD	
WHEELCHAIR SEATING AND BACK CUSHIONS *(continued)*							**Custom fabricated** seat cushion (E2609*) is covered if criteria 1 **and** 3 below are met. A custom fabricated back cushion (E2617*) is covered if criteria 2 **and** 3 below are met: 1. Patient meets all of the criteria for a prefabricated skin protection seat cushion or positioning seat cushion, 2. Patient meets all of the criteria for a prefabricated positioning back cushion, 3. There is a comprehensive **written evaluation** by a licensed/certified medical professional, such as a physical therapist (PT) or occupational therapist (OT), which clearly explains why a prefabricated seating system is not sufficient to meet the patient's seating and positioning needs. The PT or OT may have no financial relationship with the provider. **** = Detailed description of billing codes:*** *E0955 Wheelchair accessory, headrest, cushioned, any type, including fixed mounting hardware, each* *E0956 Wheelchair accessory, lateral trunk or hip support, any type, including fixed mounting hardware, each* *E0957 Wheelchair accessory, medial thigh support, any type, including fixed mounting hardware, each* *E0960 Wheelchair accessory, shoulder harness/straps or chest strap, including any type mounting hardware* *E2601 General use wheelchair seat cushion, width less than 22 inches, any depth* *E2602 General use wheelchair seat cushion, width 22 inches or greater, any depth* *E2603 Skin protection wheelchair seat cushion, width less than 22 inches, any depth* *E2604 Skin protection wheelchair seat cushion, width 22 inches or greater, any depth* *E2605 Positioning wheelchair seat cushion, width less than 22 inches, any depth* *E2606 Positioning wheelchair seat cushion, width 22 inches or greater, any depth* *E2607 Skin protection and positioning wheelchair seat cushion, width less than 22 inches, any depth* *E2608 Skin protection and positioning wheelchair seat cushion, width 22 inches or greater, any depth* *E2609 Custom fabricated wheelchair seat cushion, any size* *E2611 General use wheelchair back cushion, width less than 22 inches, any height, including any type mounting hardware* *E2612 General use wheelchair back cushion, width 22 inches or greater, any height, including any type mounting hardware* *E2613 Positioning wheelchair back cushion, posterior, width less than 22 inches, any height, including any type mounting hardware* *E2614 Positioning wheelchair back cushion, posterior, width 22 inches or greater, any height, including any type mounting hardware* *E2615 Positioning wheelchair back cushion, posterior-lateral, width less than 22 inches, any height, including any type mounting hardware* *E2616 Positioning wheelchair back cushion, posterior-lateral, width 22 inches or greater, any height, including any type mounting hardware* *E2617 Custom fabricated wheelchair back cushion, any size, including any type mounting hardware* *E2620 Positioning wheelchair back cushion, planar back with lateral supports, width less than 22 inches, any height, including any type mounting hardware* *E2621 Positioning wheelchair back cushion, planar back with lateral supports, width 22 inches or greater, any height, including any type mounting hardware* *K0734 Skin protection wheelchair seat cushion, adjustable, width less than 22 inches, any depth* *K0735 Skin protection wheelchair seat cushion, adjustable, width 22 inches or greater, any depth* *K0736 Skin protection and positioning, wheelchair seat cushion, adjustable, width less than 22 inches, any depth* *K0737 Skin protection and positioning wheelchair seat cushion, adjustable, width 22 inches or greater, any depth*
WHIRLPOOL BATH	✓			✓		✓	if the patient is homebound and the whirlpool bath provides substantial medical benefit. If the patient is not homebound, but the patient's condition warrants whirlpool bath therapy, payment is restricted to the cost of providing the service elsewhere, i.e., the outpatient department of a hospital.
WHIRLPOOL, PORTABLE		✓					comfort or convenience item, not primarily medical in nature.
WHIRLPOOL PUMP		✓					comfort or convenience item; not primarily medical in nature.
WHITE CANE		✓					used to identify the patient as blind — not considered Mobility Assistive Equipment.

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