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| CMS Manual System | Department of Health & Human Services (DHHS) |
| Pub 100-03 Medicare National Coverage Determinations | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 13374 | Date: August 21, 2025 |
| | Change Request 14177 |

SUBJECT: Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors that effective June 9, 2025, contractors shall pay claims for Respiratory Assist Device (RADs) with or without a backup rate feature and Home Mechanical Ventilators (HMFVs), in the home, as treatment for patients with Chronic Respiratory Failure (CRF) consequent to Chronic Obstructive Pulmonary Disease (COPD).

EFFECTIVE DATE: June 9, 2025

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: October 22, 2025

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|--------------|---|
| N | 1/240/240.9/Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD) |
| R | 1/280/280.1/Durable Medical Equipment Reference List (Effective May 5, 2005) |

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

Attachment - Business Requirements

| | | | |
|-------------|--------------------|-----------------------|-----------------------|
| Pub. 100-03 | Transmittal: 13374 | Date: August 21, 2025 | Change Request: 14177 |
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I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors that effective June 9, 2025, contractors shall pay claims for Respiratory Assist Device (RADs) with or without a backup rate feature and Home Mechanical Ventilators (HMFVs), in the home, as treatment for patients with Chronic Respiratory Failure (CRF) consequent to Chronic Obstructive Pulmonary Disease (COPD).

II. GENERAL INFORMATION

A. Background: RADs with bi-level capability, with or without a backup rate feature, are devices that use a non-invasive interface (mask) to deliver a higher level of airway pressure when the patient inhales than when the patient exhales. A backup rate feature enables the device to provide a prespecified respiratory rate if the patient's spontaneous respiratory rate decreases below a set number.

A HMFV delivers a predetermined amount of air with each breath and typically has more monitoring, safety, alarm and backup power features (batteries) than a RAD.

B. Policy: Effective for services performed on or after June 9, 2025, the Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to cover RADs, with or without a backup rate feature and HMFVs, in the home, to deliver high intensity Noninvasive Ventilation (NIV) as treatment for patients with CRF consequent to COPD as long as certain patient criteria is met.

Note: This CR does not contain coding and billing instructions for masks.

III. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

| Number | Requirement | Responsibility | | | | | | | | |
|--------------|---|----------------|---|-----|------------|---------------------------|-----|-----|-----|-------|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| 14177 - 03.1 | Effective for claims with dates of service on and after June 9, 2025, contractors shall pay claims for RADs with or without a backup rate feature and HMFVs, in the home, as treatment for patients with CRF consequent to COPD as described in Pub. 100-03, Medicare NCD Manual, | | | | X | | | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|--------|---|----------------|---|-----|------------|---------------------------|-----|-----|-----|-------|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | Chapter 1, Section 240.9. Please also see Pub. 100-03, Medicare NCD Manual, Chapter 1, Section 280.1(DME List). | | | | | | | | | |

IV. PROVIDER EDUCATION

Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.

Impacted Contractors: DME MAC

V. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

| X-Ref Requirement Number | Recommendations or other supporting information: |
|--------------------------------|--|
| | |

Section B: All other recommendations and supporting information: N/A

VI. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VII. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare National Coverage Determinations Manual

Chapter 1, Part 4 (Sections 200 -310.1) Coverage Determinations

Table of Contents
(Rev. 13374; Issued: 08-21-25)

Transmittals for Chapter 1

240.9 – Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD)

240.9 – Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD)

(Rev. 13374; Issued: 08-21-25; Effective:06-09-25; Implementation: 10-22-25)

A. General

Respiratory Assist Devices (RADs) with bi-level capability, with or without a backup rate feature, are devices that use a non-invasive interface (mask) to deliver a higher level of airway pressure when the patient inhales than when the patient exhales. A backup rate feature on certain RADs enables the device to provide a prespecified respiratory rate if the patient's spontaneous respiratory rate decreases below a set number.

Compared with RADs, home mechanical ventilators typically have additional ventilatory modes, monitoring, ventilator control, and safety, alarm, and backup power features (batteries).

B. Nationally Covered Indications

I. Respiratory Assist Devices (RADs)

(a) Initial Coverage Criteria

(i) RAD with Backup Rate Feature

*The Centers for Medicare & Medicaid Services (CMS) will cover in the home a RAD with backup rate feature to deliver high intensity noninvasive ventilation (NIV) as treatment for patients with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD). A RAD with backup rate feature is covered in the home for an initial 6-month period for patients with COPD when **all the following** criteria are met:*

- The patient exhibits persistent hypercapnia as demonstrated by $\text{PaCO}_2 \geq 52$ mmHg by arterial blood gas during awake hours while breathing his/her prescribed FiO_2 ; **and***
- Sleep apnea is not the predominant cause of the hypercapnia (Formal sleep testing is not required if, per the treating clinician, the patient does not experience sleep apnea as the predominant cause of hypercapnia.); **and***
- The patient demonstrates **one of the following** characteristics:*

*Stable COPD, without increase in or new onset of more than one respiratory symptom (cough, sputum production, sputum purulence, wheezing, or dyspnea) lasting 2 or more days and no change of pharmacological treatment during the 2-week period before initiation of NIV, **or***
Hypercapnia present for at least 2 weeks post hospitalization after resolution of an exacerbation of COPD requiring acute NIV.

By the end of the initial 6-month period, a RAD with backup rate feature must be utilized as high intensity therapy, defined as a minimum IPAP ≥ 15 cm H₂O and backup respiratory rate of at least 14 breaths per minute.

(ii) RAD without Backup Rate Feature

*CMS will cover in the home a RAD without backup rate feature for a patient with CRF consequent to COPD who cannot tolerate high intensity NIV **or** for whom the backup rate feature is otherwise*

medically inappropriate. A RAD without backup rate feature is covered in the home for an initial 6-month period for patients with COPD when **all of the following** criteria are met:

- The patient exhibits hypercapnia as demonstrated by $\text{PaCO}_2 \geq 52$ mmHg by arterial blood gas during awake hours while breathing his/her prescribed FiO_2 ; **and**
- Sleep apnea is not the predominant cause of the hypercapnia; (Formal sleep testing is not required if, per the treating clinician, the patient does not experience sleep apnea as the predominant cause of hypercapnia.).

(iii) RAD Upon Hospital Discharge

CMS will cover in the home a RAD with or without backup rate feature immediately upon hospital discharge for an initial 6-month period for patients with acute on chronic respiratory failure due to COPD, if the patient required either a RAD or ventilator within the 24-hour period prior to hospital discharge and the treating clinician determines that the patient is at risk of rapid symptom exacerbation or rise in PaCO_2 after discharge.

(b) Continuing Usage Criteria for a RAD

Patients must be evaluated at least twice within the first year after initially receiving a RAD. Evaluations must occur by the end of the six-month initial coverage period and again during months 7-12.

First evaluation:

By 6 months after receiving initial coverage of a RAD, the treating clinician must establish that usage criteria and clinical outcomes are being met. Specifically, the patient must be determined by a clinician to use the RAD at least 4 hours per 24-hour period, on at least 70% of days in a 30-day period and achieve **at least one** the following clinical outcomes:

- Normalization (< 46 mmHg) of PaCO_2 , **or**
- Stabilization of a rising PaCO_2 , **or**
- 20% reduction in PaCO_2 from baseline value, **or**
- Improvement of **at least one** of the following patient symptoms associated with chronic hypercapnia:
 - headache
 - fatigue
 - shortness of breath
 - confusion
 - sleep quality

Second evaluation:

Between 7-12 months after initially receiving a RAD, the treating clinician must establish the patient is using the device at least 4 hours per 24-hour period on at least 70% of days in each paid rental month.

Post second evaluation:

The patient must be using the device at least 4 hours per 24-hour period on at least 70% of days in each remaining paid rental month and any month in which accessories/supplies are dispensed.

II. Home Mechanical Ventilators

(a) Initial Coverage Criteria

CMS will cover a home mechanical ventilator (HMV) used in a volume targeted mode as treatment for a patient with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD) who exhibits certain clinical characteristics.

*(i) An HMV is covered for an initial 6-month period for patients with COPD when **all of the following** criteria are met:*

- *The patient exhibits hypercapnia as demonstrated by $\text{PaCO}_2 \geq 52$ mmHg by arterial blood gas during awake hours while breathing his/her prescribed FiO_2 ; **and***
- *Sleep apnea is not the predominant cause of the hypercapnia (Formal sleep testing is not required if, per the treating clinician, the patient does not experience sleep apnea as the predominant cause of hypercapnia.); **and***
- *The patient demonstrates **at least one** of the following characteristics:*
- *Requires oxygen therapy at an $\text{FiO}_2 \geq 36\%$ or $\geq 4\text{L}$ nasally, **or***
- *Requires ventilatory support for more than 8 hours per 24-hour period, **or***
- *Requires the alarms and internal battery of a HMV, because the patient is unable to effectively breathe on their own for more than a few hours and the unrecognized interruption of ventilatory support is likely to cause a life-threatening condition if the patient or caregiver cannot be otherwise alerted as determined by the treating clinician, **or***
- *Per the treating clinician, none of the below are likely to be achieved with consistent use of a RAD with backup rate feature for at least 4 hours per 24-hour period on at least 70% of days because the patient's needs exceed the capabilities of a RAD as justified by the patient's medical condition:*
- *Normalization (< 46 mmHg) of PaCO_2 , **or***
- *Stabilization of a rising PaCO_2 , **or***
- *20% reduction in PaCO_2 from baseline value, **or***
- *Improvement of **at least one** of the following patient symptoms associated with chronic hypercapnia:*
 - *headache*
 - *fatigue*
 - *shortness of breath*
 - *confusion*
 - *sleep quality*

(ii) Home Mechanical Ventilator Use Upon Hospital Discharge

CMS will cover in the home an HMV used in a volume targeted mode immediately upon hospital discharge for an initial 6-month period for patients with acute on chronic respiratory failure due to COPD if the patient's needs exceeded the capabilities of a RAD (with or without backup rate feature) and required usage of a ventilator within the 24-hour period prior to hospital discharge and the treating clinician determines that the patient is at risk of rapid symptom exacerbation or rise in PaCO_2 after discharge.

b) Continuing Usage Criteria for an HMV

Patients must be evaluated at least twice within the first year after initially receiving an HMV. Evaluations must occur by the end of the six-month initial coverage period and again during months 7-12.

First evaluation:

By 6 months after receiving initial coverage of an HMV, the treating clinician must establish that usage criteria are being met. The patient must be determined by a clinician to use the HMV at least 4 hours per 24-hour period, on at least 70% of days in a 30-day period.

Second Evaluation:

Between 7-12 months after initially receiving an HMV, the treating clinician must establish the patient is using the device at least 4 hours per 24-hour period on at least 70% of days in each paid rental month.

Post second evaluation:

The patient must be using the device at least 4 hours per 24-hour period on 70% of days in each paid rental month.

(c) Masks for HMVs

For patients who use an HMV in a volume targeted mode: 1) for greater than 8 hours in any 24-hour period; and 2) use an oronasal mask at night, a different interface (e.g., mouthpiece ventilation or nasal mask) is covered for daytime hours. Note, coverage of such supplies does not exclude coverage of additional supplies necessary for the effective use of the HMV.

C. Nationally Non-Covered Indications

N/A

D. Other

Medicare Administrative Contractors (MACs) may make reasonable and necessary determinations under section 1862(a)(1)(A) of the Social Security Act for any patient seeking initial coverage or continued coverage for RADs or HMVs used as treatment of chronic respiratory failure consequent to COPD.

Additionally, CMS will make conforming changes in Section 280.1 (Durable Medical Equipment List) of the National Coverage Determinations (NCD) Manual to add a cross reference to the new NCD section 240.9 (NIPPV in the Home for the Treatment of CRF Consequent to COPD).

(This NCD last reviewed June 2025.)

280.1 - Durable Medical Equipment Reference List (Effective May 5, 2005)

(Rev. 13374; Issued: 08-21-25; Effective:06-09-25; Implementation: 10-22-25)

The durable medical equipment (DME) list that follows is designed to facilitate the A/B MAC (HHH) and DME MACs processing of DME claims. This section is designed as a quick reference tool for determining the coverage status of certain pieces of DME and especially for those items commonly referred to by both brand and generic names. The information contained herein is applicable (where appropriate) to all DME national coverage determinations (NCDs) discussed in the DME portion of this manual. The list is organized into two columns. The first column lists alphabetically various generic categories of equipment on which NCDs have been made by the Centers for Medicare & Medicaid Services (CMS); the second column notes the coverage status.

In the case of equipment categories that have been determined by CMS to be covered under the DME benefit, the list outlines the conditions of coverage that must be met if payment is to be allowed for the rental or purchase of the DME by a particular patient, or cross-refers to another section of the manual where the applicable coverage criteria are described in more detail. With respect to equipment categories that cannot be covered as DME, the list includes a brief explanation of why the equipment is not covered. This

DME list will be updated periodically to reflect any additional NCDs that CMS may make with regard to other categories of equipment.

When the A/B MAC (HHH) or DME MAC receives a claim for an item of equipment which does not appear to fall logically into any of the generic categories listed or has not been addressed in the processes outlined in regulations at 42 CFR §§414.114 and 414.240, the A/B MAC (HHH) or DME MAC has the authority and responsibility for deciding whether those items are covered under the DME benefit.

These decisions must be made by each A/B MAC (HHH) and DME MAC based on the advice of its medical consultants, taking into account:

- The Medicare Claims Processing Manual, Chapter 20, “Durable Medical Equipment Prosthetics and Orthotics, and Supplies (DMEPOS).”
- Whether the item has been approved for marketing by the Food and Drug Administration (FDA) and is otherwise generally considered to be safe and effective for the purpose intended; and
- Whether the item is reasonable and necessary for the individual patient.

The term DME is defined as equipment which, according to 42 CFR §414.202:

- Can withstand repeated use; i.e., could normally be rented and used by successive patients;
- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years;
- Is primarily and customarily used to serve a medical purpose;
- Generally, is not useful to a person in the absence of illness or injury; and,
- Is appropriate for use in a patient’s home.

Durable Medical Equipment Reference List

| Item | Coverage |
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| Air Cleaners | Deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act). |
| Air Conditioners | Deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act). |
| Air-Fluidized Beds | (See Air-Fluidized Beds §280.8 of this manual.) |
| Alternating Pressure Pads, Mattresses and Lamb’s Wool Pads | Covered if patient has, or is highly susceptible to, decubitus ulcers and patient’s physician specifies that he/she will be supervising the course of treatment. |
| Audible/Visible Signal/ Pacemaker Monitors | (See Self-Contained Pacemaker Monitors.) |
| Augmentative Communication Devices | (See Speech-Generating Devices §50.1 of this manual.) |
| Bathtub Lifts | Deny--convenience item; not primarily medical in nature (§1861(n) of the Act). |
| Bathtub Seats | Deny--comfort or convenience item; hygienic equipment; not primarily medical in nature (§1861(n) of the Act). |

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| Bead Beds | (See §280.8.) |
| Bed Baths (home type) | Deny--hygienic equipment; not primarily medical in nature (§1861(n) of the Act). |
| Bed Lifters (bed elevators) | Deny--not primarily medical in nature (§1861(n) of the Act). |
| Bedboards | Deny--not primarily medical in nature (§1861(n) of the Act). |
| Bed Pans (autoclavable hospital type) | Covered if patient is bed-confined. |
| Bed Side Rails | (See Hospital Beds §280.7 of this manual.) |
| Beds-Lounges (power or medical in nature (§1861(n) of the Act). | Deny--not a hospital bed; comfort or convenience item; not primarily manual) |
| Beds (Oscillating) | Deny--institutional equipment; inappropriate for home use. |
| Item | Coverage |
| Bidet Toilet Seats | (See Toilet Seats.) |
| Blood Glucose Analyzers (Reflectance Colorimeter) | Deny--unsuitable for home use (see §40.2 of this manual). |
| Blood Glucose Monitors | Covered if patient meets certain conditions (see §40.2 of this manual). |
| Braille Teaching Texts | Deny--educational equipment; not primarily medical in nature (§1861(n) of the Act). |
| Canes | Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual). |
| Carafes | Deny--convenience item; not primarily medical in nature (§1861(n) of the Act). |
| Catheters | Deny—non-reusable disposable supply (§1861(n) of the Act). (See Medicare Claims Processing Manual, Chapter 20, DMEPOS). |
| Commodes | Covered if patient is confined to bed or room. NOTE: The term “room-confined” means that patient’s condition is such that leaving the room is medically contraindicated. The accessibility of bathroom facilities generally would not be a factor in this determination. However, confinement of a patient to a home in a case where there are no toilet facilities in the home may be equated to room confinement. Moreover, payment may also be made if a patient’s medical condition confines him to a floor of the home and there is no bathroom located on that floor. |
| Communicators | (See §50.1 of this manual, Speech Generating Devices.) |
| Continuous Passive Motion Devices | Continuous passive motion devices are devices covered 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. There is insufficient evidence to justify coverage for longer periods of time or for other applications. |

Continuous Positive Airway

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| Pressure (CPAP) Devices | (See §240.4 of this manual.) |
| Crutches | Covered if patient meets Mobility Assistive Equipment clinical criteria (see section 280.3 of this manual). |
| Cushion Lift Power Seats | (See Seat Lifts.) |

Item

Coverage

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| Dehumidifiers (room or central heating system type) | Deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act). |
| Diathermy Machines (standard pulses wave types) | Deny--inappropriate for home use (see §150.5 of this manual). |
| Digital Electronic Pacemaker Monitors | (See Self-Contained Pacemaker Monitors). |
| Disposable Sheets and Bags | Deny—non-reusable disposable supplies (§1861(n) of the Act). |
| Elastic Stockings | Deny—non-reusable supply; not rental-type items (§1861(n) of the Act.) (See §270.5 of this manual.) |
| Electric Air Cleaners | Deny--(see Air Cleaners.) (§1861(n) of the Act). |
| Electric Hospital Beds | (See Hospital Beds §280.7 of this manual.) |
| Electrical Stimulation for Wounds | Deny--inappropriate for home use. (See §270.1 of this manual.) |
| Electrostatic Machines | Deny--(see Air Cleaners and Air Conditioners.) (§1861(n) of the Act). |
| Elevators | Deny--convenience item; not primarily medical in nature (§1861(n) of the Act). |
| Emesis Basins | Deny--convenience item; not primarily medical in nature (§1861(n) of the Act). |
| Esophageal Dilators | Deny--physician instrument; inappropriate for patient use. |
| Exercise Equipment | Deny--not primarily medical in nature (§1861(n) of the Act). |
| Fabric Supports | Deny—non-reusable supplies; not rental-type items (§1861(n) of the Act). |
| Face Masks (oxygen) | Covered if oxygen is covered. (See §240.2 of this manual.) |
| Face Masks (surgical) | Deny—non-reusable disposable items (§1861(n) of the Act). |
| Flow Meters | (See Medical Oxygen Regulators.) (See §240.2 of this manual.) |
| Fluidic Breathing Assisters | (See Intermittent Positive Pressure Breathing Machines.) |
| Fomentation Devices | (See Heating Pads.) |

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| Gel Flotation Pads and Mattresses | (See Alternating Pressure Pads and Mattresses.) |
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| Item | Coverage |
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| Grab Bars | Deny--self-help device; not primarily medical in nature (§1861(n) of the Act). |
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| Heat and Massage Foam Cushion Pads | Deny--not primarily medical in nature; personal comfort item (§1861(n) and 1862(a)(6) of the Act). |
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| Heating and Cooling Plants | Deny--environmental control equipment not primarily medical in nature (§1861(n) of the Act). |
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| Heating Pads | Covered if A/B MAC (HHH) or DME MAC medical staff determines patient's medical condition is one for which the application of heat in the form of a heating pad is therapeutically effective. |
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| Heat Lamps | Covered if A/B MAC (HHH) or DME MAC medical staff determines patient's medical condition is one for which the application of heat in the form of a heat lamp is therapeutically effective. |
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| Hospital Beds | (See §280.7 of this manual.) |
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| Hot Packs | (See Heating Pads.) |
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| Humidifiers (oxygen) | (See Oxygen Humidifiers.) |
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| Humidifiers (room or central heating system types) | (Deny--environmental control equipment; not medical in nature (§1861(n) of the Act). |
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| Hydraulic Lifts | (See Patient Lifts.) |
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| Incontinent Pads | Deny—non-reusable supply; hygienic item (§1861(n) of the Act). |
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| Infusion Pumps | For external and implantable pumps, see §40.2 of this manual. If pump is used with an enteral or parenteral nutritional therapy system, see §180.2 of this manual for special coverage rules. |
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| Injectors (hypodermic jet) | Deny--not covered self-administered drug supply; pressure- powered devices (§1861(s)(2)(A) of the Act) for injection of insulin. |
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| Intermittent Positive Pressure Breathing Machines | Covered if patient's ability to breathe is severely impaired. |
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| Iron Lungs | (See Ventilators.) |
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| Irrigating Kits | Deny—non-reusable supply; hygienic equipment (§1861(n) of the Act). |
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| Lamb's Wool Pads | (See Alternating Pressure Pads, Mattresses, and Lamb's Wool Pads.) |
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| Item | Coverage |
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| Leotards | Deny--(See Pressure Leotards.) (§1861(n) of the Act). |
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| Lymphedema Pumps | Covered (See Pneumatic Compression Devices §280.6 of this manual.) |
| Massage Devices | Deny--personal comfort items; not primarily medical in nature (§1861(n) and 1862(a)(6) of the Act). |
| Mattresses | Covered only where hospital bed is medically necessary. (Separate Charge for replacement mattress should not be allowed where hospital bed with mattress is rented.) (See §280.7 of this manual.) |
| Medical Oxygen Regulators | Covered if patient's ability to breathe is severely impaired. (See §240.2 of this manual.) |
| Mobile Geriatric Chairs | Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual). (See Rolling Chairs). |
| Motorized Wheelchairs | Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual). |
| Muscle Stimulators | Covered for certain conditions. (See §160.12 of this manual) |
| Nebulizers | Covered if patient's ability to breathe is severely impaired. |
| Oscillating Beds | Deny--institutional equipment; inappropriate for home use. |
| Over-bed Tables | Deny--convenience item; not primarily medical in nature (§1861(n) of the Act). |
| Oxygen | Covered if oxygen has been prescribed for use in connection with medically necessary DME. (See §240.2 of this manual.) |
| Oxygen Humidifiers | Covered if oxygen has been prescribed for use in connection with medically necessary DME for purposes of moisturizing oxygen. (See §240.2 of this manual.) |
| Oxygen Regulators (Medical) | (See Medical Oxygen Regulators.) |
| Oxygen Tents | (See §240.2 of this manual.) |
| Paraffin Bath Units (Portable) | (See Portable Paraffin Bath Units.) |
| Paraffin Bath Units (Standard) | Deny--institutional equipment; inappropriate for home use. |
| Parallel Bars | Deny--support exercise equipment; primarily for institutional use; in the home setting other devices (e.g., walkers) satisfy patient's need. |

Item

Coverage

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| Patient Lifts | Covered if A/B MAC (HHH) or DME MAC medical staff determines patient's condition is such that periodic movement is necessary to effect improvement or to arrest/retard deterioration in condition. |
| Percussors | Covered for mobilizing respiratory tract secretions in patients with chronic obstructive lung disease, chronic bronchitis, or emphysema, when patient/operator of powered percussor receives appropriate training by a |

physician/therapist, and no one competent to administer manual therapy is available.

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| Portable Oxygen Systems | 1. Regulated Covered (adjustable covered under conditions specified in a flow rate). Refer all claims to medical staff for this determination. 2. Preset Deny (flow rate deny emergency, first-aid, or not adjustable) precautionary equipment; essentially not therapeutic in nature. |
| Portable Paraffin Bath Units | Covered when patient has undergone a successful trial period of paraffin therapy ordered by a physician and patient's condition is expected to be relieved by long-term use of this modality. |
| Portable Room Heaters | Deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act). |
| Portable Whirlpool Pumps | Deny--not primarily medical in nature; personal comfort items (§§1861(n) and 1862(a)(6) of the Act). |
| Postural Drainage Boards | Covered if patient has a chronic pulmonary condition. |
| Preset Portable Oxygen Units | Deny--emergency, first-aid, or precautionary equipment; essentially not therapeutic in nature. |
| Pressure Leotards | Deny--non-reusable supply, not rental-type item (§1861(n) of the Act). |
| Pulse Tachometers | Deny--not reasonable or necessary for monitoring pulse of homebound patient with/without a cardiac pacemaker. |
| Quad-Canes | Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual). |
| Raised Toilet Seats | Deny--convenience item; hygienic equipment; not primarily medical in nature (§1861(n) of the Act). |
| Reflectance Colorimeters | (See Blood Glucose Analyzers.) |
| Respirators | (See Ventilators.) |

Item

Coverage

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| Rolling Chairs | Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual). 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. Coverage is denied for the wide range of chairs with smaller casters as are found in general use in homes, offices, and institutions for many purposes not related to the care/treatment of ill/injured persons. This type is not primarily medical in nature. (§1861(n) of the Act.) |
| Safety Rollers | Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual). |
| Sauna Baths | Deny--not primarily medical in nature; personal comfort items (§§1861(n) and 1862(a)(6) of the Act). |
| Seat Elevation Equipment (power-operated) on Medicare Covered Power | |

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| Wheelchairs | DME on Medicare-covered power wheelchairs, and covered under conditions specified in §280.16 of this manual |
| Seat Lifts | Covered under conditions specified in §280.4 of this manual. Refer all to medical staff for this determination. |
| Self-Contained Pacemaker Monitors | Covered when prescribed by a physician for a patient with a cardiac pacemaker. (See §§20.8.1 and 280.2 of this manual.) |
| Sitz Baths | Covered if A/B MAC (HHH) or DME MAC medical staff determines patient has an infection/injury of the perineal area and the item has been prescribed by the patient's physician as part of planned regimen of treatment in patient's home. |
| Spare Tanks of Oxygen | Deny--convenience or precautionary supply. |
| Speech Teaching Machines | Deny--education equipment; not primarily medical in nature (§1861(n) of the Act). |
| Stairway Elevators | Deny--(See Elevators.) (§1861(n) of the Act). |
| Standing Tables | Deny--convenience item; not primarily medical in nature (§1861(n) of the Act). |

Item

Coverage

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| Steam Packs- | These packs are covered under same conditions as heating pads. (See Heating Pads.) |
| Suction Machines | Covered if A/B MAC (HHH) or DME MAC medical staff determines that the machine specified in the claim is medically required and appropriate for home use without technical/professional supervision. |
| Support Hose | Deny (See Fabric Supports.) (§1861(n) of the Act). |
| Surgical Leggings | Deny--non-reusable supply; not rental-type item (§1861(n) of the Act). |
| Telephone Alert Systems | Deny--these are emergency communications systems and do not serve a diagnostic/therapeutic purpose. |
| Toilet Seats | Deny--not medical equipment (§1861(n) of the Act). |
| Traction Equipment | Covered if patient has orthopedic impairment requiring traction equipment that prevents ambulation during period of use. (Consider covering devices usable during ambulation; e.g., cervical traction collar, under brace provision.) |
| Trapeze Bars | Covered if patient is bed-confined and needs a trapeze bar to sit up because of respiratory condition, to change body position for other medical reasons, or to get in/out of bed. |
| Treadmill | Deny--exercise equipment; not primarily medical in nature (§1861(n) of the Act). |
| Ultraviolet Cabinets | Covered for selected patients with generalized intractable psoriasis. Using appropriate consultation, the A/B MAC (HHH) or DME MAC should |

determine whether medical/other factors justify treatment at home rather than at alternative sites, e.g., outpatient department of a hospital.

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| Urinals autoclavable | Covered if patient is bed-confined (hospital type). |
| Vaporizers | Covered if patient has a respiratory illness. |
| Ventilators | Covered for treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease (See §240.9 of this manual). Includes both positive/negative pressure types. (See §240.5 of this manual.) |
| Walkers | Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual). |
| Water and Pressure Pads and Mattresses | (See Alternating Pressure Pads, Mattresses, and Lamb's Wool Pads.) |
| Wheelchairs (manual) | Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual). |
| Wheelchairs (power-operated) | Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual). |
| Wheelchairs (scooter/POV) | Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual). |
| Wheelchairs (specially-sized) | Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual). |
| Whirlpool Bath Equipment | Covered if patient is homebound and has a (standard) condition for which the whirlpool bath can be expected to provide substantial therapeutic benefit justifying its cost. Where patient is not homebound but has such a condition, payment is restricted to the cost of providing the services elsewhere; e.g., an outpatient department of a participating hospital, if that alternative is less costly. In all cases, refer claim to medical staff for determination. |
| Whirlpool Pumps | (See Portable Whirlpool Pumps.) (§1861(n) of the Act). |
| White Canes | Deny(See §280.2 of this manual.) (Not considered Mobility Assistive Equipment) |

Cross-references: Medicare Benefit Policy Manual, Chapters 13, "Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Services," 15, "Covered Medical and Other Health Services." Medicare Claims Processing Manual, Chapters 12, "Physician/Practitioner Billing," 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," 23, "Fee Schedule Administration and Coding Requirements."