

Chapter 3 Contents

1. General Information
2. Definition of Physician
3. Prescription (Order) Requirements
4. Documentation in the Beneficiary's Medical Record
5. Signature Requirements
6. Refills of DMEPOS Items Provided on a Recurring Basis
7. Beneficiary Authorization
8. Proof of Delivery (POD)
9. Advance Beneficiary Notice (ABN)
10. Miscellaneous Documentation Issues
11. Evidence of Medical Necessity: Power Mobility Devices (PMD)
12. Comprehensive Error Rate Testing (CERT)

1. General Information

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.8

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. The criteria "reasonable and necessary" is based on Social Security Act §1862(a)(1)(A) provisions.

Before submitting a claim to the DME MAC, you must have on file a dispensing order, the written order, the Certificate of Medical Necessity (CMN) (if applicable), the DME MAC Information Form (DIF) (if applicable), information from the treating practitioner concerning the **beneficiary's** diagnosis¹, and any information required for the use of specific modifiers or attestation statements as defined in certain Local Coverage Determinations (LCDs) (see Chapter 9 of this manual for information about LCDs). You should also obtain as much documentation from the **beneficiary's** medical record as you determine you need to assure that coverage criteria for an item has been met. If the information in the beneficiary's medical record does not adequately support the medical necessity for the item, you are liable for the dollar amount involved unless a properly executed advance beneficiary notice (ABN) (see Section 9 below) of possible denial has been obtained.

All documentation must be maintained in the supplier's files for seven (7) years from the date of service (DOS), and be available upon request.

If the Medicare qualifying supplier documentation is older than seven years, proof of continued medical necessity of the item or necessity of the repair can be used as the supporting Medicare qualifying documentation.

Please see Chapter 4 of this manual for information regarding CMNs and DIFs.

¹ Diagnosis codes are required on all claims

2. Definition of Physician

CMS Manual System, Pub. 100-02, *Medicare Benefit Policy Manual*, Chapter 15, §40.4

Physician means any of the following entities legally authorized to practice by a state in which he/she performs this function. The services performed by a physician within these definitions are subject to any limitations posed by the State on the scope of practice.

- Doctor of medicine
- Doctor of osteopathy (including osteopathic practitioner) - must be licensed to practice medicine and surgery
- Doctor of dental surgery or dental medicine
- Chiropractor (see below)
- Doctor of podiatry (see below) or surgical chiropody
- Doctor of optometry

The following practitioners may document the medical necessity of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) items, including completing orders and Certificates of Medical Necessity (CMNs), in place of a physician provided that they meet the practitioner requirements defined in Chapter 15 of the Benefit Policy Manual (Publication 100-02), the services performed are within their scope of practice as defined by their state, and they are treating the beneficiary for the condition for which the item is needed.

- Physician Assistant
- Nurse Practitioner
- Clinical Nurse Specialist

The term physician does not include such practitioners as Christian Science practitioner or naturopath. There is no Medicare benefit for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items ordered by these entities.

Medicare coverage for all items and services furnished or ordered by chiropractors is statutorily excluded, with the exception of treatment by means of manual manipulation of the spine to correct a subluxation. Therefore, all DMEPOS items ordered by chiropractors are denied.

Medicare coverage for all items and services furnished or ordered by podiatrists is limited by state statutes governing the scope of practice for podiatry. You should be familiar with the limitations imposed by the statutes of the state(s) in which you operate and dispense DMEPOS items. Claims submitted to the DME MAC, when furnished or ordered by podiatrists practicing outside the limits of their licensure, will be denied as statutorily non-covered. Podiatrists are excluded by statute from ordering a power operated vehicle (POV) or power wheelchair.

3. Prescription (Order) Requirements

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.2.1 - §5.2.7

All items billed to Medicare require a prescription. For each item billed, you must have a signed and dated order from the treating practitioner. You must keep the order on file and make available upon

request. Items dispensed and/or billed that do not meet these prescription requirements and those below must be submitted with an EY modifier added to each affected HCPCS code.

DISPENSING ORDERS

Equipment and supplies that are NOT on the ACA 6407 list or that require a written order prior to delivery (WOPD) may be delivered upon receipt of a dispensing order (prescription). A dispensing order may be verbal or written. You must keep a record of the dispensing order on file. It must contain:

- The description of the item
- The beneficiary's name
- The prescribing physician/practitioner's name
- The date of the order
- The prescribing physician/practitioner's signature (if a written order) or your signature (if verbal order)

For the "Date of the order" described above, use the date you were contacted by the prescribing physician/practitioner (for verbal orders) or the date entered by the prescribing practitioner (for written dispensing orders).

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The dispensing order must be available upon request.

For items that are provided based on a dispensing order, you must obtain a detailed written order before submitting a claim.

DETAILED WRITTEN ORDERS

A detailed written order (DWO) is required before billing. Someone other than the prescribing physician/practitioner may produce the DWO of the item unless statute, manual instructions, the contractor's LCD or policy articles specify otherwise. However, the prescribing practitioner must review the content and sign and date the document. It must contain:

- The beneficiary's name.
- The date of the order.
- A description of all items, options, accessories or additional features that are separately billed or require an upgraded code. The description can be either a narrative description (e.g., wheelchair or hospital bed), a HCPCS code, a HCPCS code narrative, or a brand name/model number.
- For supplies – list all supplies that are separately billable, and for each include the frequency of use (if applicable), and the quantity dispensed.
- The prescribing physician/practitioner's signature (and date if applicable—see above).

For drugs used as a supply for a DME item, the written order must include:

- The beneficiary's name
- The name of the drug
- The dosage or concentration, if applicable
- The frequency of administration, if applicable
- The duration of infusion, if applicable
- The quantity to be dispensed
- The number of refills
- The date of the order
- The physician/practitioner's signature

For the "date of the order" described above, use the dispensing order date i.e., the date you were contacted by the prescribing practitioner (for verbal orders) or the date entered by the prescribing practitioner (for written dispensing orders).

Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state "PRN" or "as needed" utilization estimates for replacement frequency, use, or consumption are not acceptable (CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.9).

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements. Refer to the "Signature Requirements" section in this chapter.

The DWO must be available upon request.

An exception to the requirement for a written order applies in those limited instances in which the prescribing practitioner is also the supplier and is permitted to furnish specific items of DMEPOS and fulfill the role of the supplier in accordance with any applicable laws and policies. In such cases, a separate order is not required, but the medical record must still contain all of the required order elements.

A prescription is not considered as part of the medical record. Medical information intended to demonstrate compliance with coverage criteria may be included on the prescription but must be corroborated by information contained in the medical record. (PIM 5.7)

NEW ORDER REQUIREMENTS

A new prescription is required:

- For all claims for purchases or initial rentals;
- There is a change in the order for the accessory, supply, drug, etc.;
- On a regular basis (even if there is no change in the order) only if it so specified in the documentation section of a particular medical policy;
- When an item is replaced (see explanation below); or

- There is a change in the supplier, and the new supplier is unable to obtain a copy of a valid order and documentation from the original supplier.

A new order is required when an item is being replaced because the item is worn or the **beneficiary's** condition has changed. Your records should also include beneficiary-specific information regarding the need for the replacement item. This information should be maintained in your files and be available to the DME MACs or UPICs upon request. Failure to provide the appropriate documentation or providing documentation that contains broad, nonspecific explanations will result in claim(s) denial.

A new order is required before replacing lost, stolen, or irreparably damaged items to reaffirm the medical necessity of the item. Proof of loss or damage through documentation such as a police report, picture, or corroborating statement should be submitted with the claim.

WRITTEN ORDERS PRIOR TO DELIVERY (WOPD)

GENERAL

As a condition of payment pursuant to 42 CFR §§ 410.38(c)(1) and (2), 410.38(d) 410.38(e), 410.38(f) and 42 CFR 410.38(g), certain specified covered items of DME require a written order prior to delivery of the item. Someone other than the prescribing physician/practitioner may complete the WOPD of the item unless statute, manual instructions, the contractor's LCD or policy articles specify otherwise. However, the WOPD must be both signed and dated by the prescribing physician/practitioner before the item is dispensed. The supplier must have received the WOPD before dispensing the item. The date of the written order shall be on or before the date of delivery. The DMEPOS supplier shall have on file the completed written order prior to the delivery of these items.

There are two categories of DMEPOS items that require element-specific WOPD:

- As a condition of payment pursuant to 42 CFR 410.38(c), Power Mobility Devices (PMDs) require a 7 Element Order (7EO). A separate Detailed Product Description (DPD) is also required for any associated options and accessories. Please review the PMD policy for additional information.
- As a condition of payment pursuant to 42 CFR 410.38(g), certain specified covered items of DME require a written order prior to delivery of the item (5 Element Order or 5EO).

POWER MOBILITY DEVICES WOPD (7 ELEMENT ORDER)

42 CFR 410.38(c) requires a specific WOPD of PMDs for the HCPCS codes specified in the table contained in the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section of the LCD related Policy Article. The required prescription has seven (7) mandatory elements. For the purposes of this document, the 42 CFR 410.38(c) required order is referred to as a 7EO.

The 7EO must be received by the supplier within 45 days after the completion of the face-to-face examination.

The 7EO must meet all of the requirements below:

- Beneficiary's name
- 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.

- Date of the face-to-face examination
- Pertinent diagnoses/conditions that relate to the need for the PMD
- Length of need
- Prescribing physician/practitioner's signature
- Date the prescription was written

The supplier may provide a template order listing the seven required elements but is prohibited from completing any part of it. The treating physician/practitioner completing the face-to-face requirements must write the 7EO. The 7EO may only be written after the completion of the face-to-face exam requirements.

The DMEPOS supplier shall have on file the 7EO prior to the delivery of these items. A date stamp or equivalent must be used by the supplier to document receipt date.

AFFORDABLE CARE ACT (ACA 6407) 5-ELEMENT ORDER (5EO)

Affordable Care Act Section 6407 (ACA 6407) requirements are found in the Social Security Act Section 1843(a)(11)(B) and its implementing regulation at 42 CFR 410.38(g). The CMS regulation contains the details for the face-to-face examination, written order prior to delivery and the list of items subject to these requirements.

42 CFR 410.38(g) requires a specific written order prior to delivery for specified HCPCS codes. The required prescription has five (5) mandatory elements. For the purposes of this document, the 42 CFR 410.38(g) required order is referred to as a 5EO. The 5EO must meet all of the requirements below.

1. The 5EO must include all of the following elements:
 - The beneficiary's name
 - The description of the item of DME ordered - the description can be either a general description (e.g., wheelchair or hospital bed), a HCPCS code, a HCPCS code narrative, or a brand name/model number
 - The signature of the prescribing physician/practitioner
 - The prescribing physician/practitioner's National Practitioner Identifier (NPI)
 - The date of the order
2. The 5EO must be completed within six (6) months after the required ACA 6407 face-to-face examination; and,
3. The date of the written order shall be on or before the date of delivery or date shipped if the shipping date is used as the DOS.

The DMEPOS supplier shall have on file the 5EO prior to the delivery of these items.

Note that 5EO for these specified DME items require the NPI to be included on the prescription. Prescriptions for other DME items do not have this NPI requirement. You should pay particular attention to orders that include a mix of items, some of which are subject to these order

requirements. For example, oxygen concentrators (E1390) are often ordered in conjunction with portable oxygen (E0431). Orders for code E0431 require inclusion of the NPI while orders for E1390 do not.

Refer to the Standard Documentation Requirements for All Claims Submitted to DME MACs Policy Article (PA) (A55426) for information associated with a 5EO and statutory requirements.

For the "Date of the order" described above, use the date you were contacted by the prescribing practitioner (for verbal orders) or the date entered by the prescribing practitioner (for written dispensing orders).

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

For items that are provided based on a 5EO, you must obtain a detailed written order (see the Detailed Written Order section) before submitting a claim for any associated options, accessories and/or supplies that are separately billed.

The 5EO must be available upon request.

If you deliver an item without first receiving the completed order, the item will be denied.

HCPSC Codes Subject to Written Order Prior to Delivery

Power Mobility Devices

- E0983 Manual wheelchair accessory, power add-on to convert manual wheelchair to motorized wheelchair, joystick control
- E0984 Manual wheelchair accessory, power add-on to convert manual wheelchair to motorized wheelchair, tiller control
- E0986 Manual wheelchair accessory, push activated power assist, each
- E1239 Power wheelchair, pediatric size, NOC
- K0013 Custom motorized/power wheelchair base
- K0800 Power operated vehicle, group 1 standard, patient weight capacity up to and including 300 pounds
- K0801 Power operated vehicle, group 1 heavy duty, patient weight capacity, 301 to 450 pounds
- K0802 Power operated vehicle, group 1 very heavy duty, patient weight capacity 451 to 600 pounds
- K0806 Power operated vehicle, group 2 standard, patient weight capacity up to and including 300 pounds
- K0807 Power operated vehicle, group 2 heavy duty, patient weight capacity 301 to 450 pounds
- K0808 Power operated vehicle, group 2 very heavy duty, patient weight capacity 451 to 600 pounds

- K0812 Power operated vehicle, not otherwise classified
- K0813 Power wheelchair, group 1 standard, portable, sling/solid seat and back, patient weight capacity up to and including 300 pounds
- K0814 Power wheelchair, group 1 standard, portable, captains chair, patient weight capacity up to and including 300 pounds
- K0815 Power wheelchair, group 1 standard, sling/solid seat and back, patient weight capacity up to and including 300 pounds
- K0816 Power wheelchair, group 1 standard, captains chair, patient weight capacity up to and including 300 pounds
- K0820 Power wheelchair, group 2 standard, portable, sling/solid seat/back, patient weight capacity up to and including 300 pounds
- K0821 Power wheelchair, group 2 standard, portable, captains chair, patient weight capacity up to and including 300 pounds
- K0822 Power wheelchair, group 2 standard, sling/solid seat/back, patient weight capacity up to and including 300 pounds
- K0823 Power wheelchair, group 2 standard, captains chair, patient weight capacity up to and including 300 pounds
- K0824 Power wheelchair, group 2 heavy duty, sling/solid seat/back, patient weight capacity 301 to 450 pounds
- K0825 Power wheelchair, group 2 heavy duty, captains chair, patient weight capacity 301 to 450 pounds
- K0826 Power wheelchair, group 2 very heavy duty, sling/solid seat/back, patient weight capacity 451 to 600 pounds
- K0827 Power wheelchair, group 2 very heavy duty, captains chair, patient weight capacity 451 to 600 pounds
- K0828 Power wheelchair, group 2 extra heavy duty, sling/solid seat/back, patient weight capacity 601 pounds or more
- K0829 Power wheelchair, group 2 extra heavy duty, captains chair, patient weight capacity 601 pounds or more
- K0830 Power wheelchair, group 2 standard, seat elevator, sling/solid seat/back, patient weight capacity up to and including 300 pounds
- K0831 Power wheelchair, group 2 standard, seat elevator, captain's chair, patient weight capacity up to and including 300 pounds
- K0835 Power wheelchair, group 2 standard, single power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
- K0836 Power wheelchair, group 2 standard, single power option, captains chair, patient weight capacity up to and including 300 pounds

- K0837 Power wheelchair, group 2 heavy duty, single power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds
- K0838 Power wheelchair, group 2 heavy duty, single power option, captains chair, patient weight capacity 301 to 450 pounds
- K0839 Power wheelchair, group 2 very heavy duty, single power option, sling/solid seat/back, patient weight capacity 451 to 600 pounds
- K0840 Power wheelchair, group 2 extra heavy duty, single power option, sling/solid seat/back, patient weight capacity 601 pounds or more
- K0841 Power wheelchair, group 2 standard, multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
- K0842 Power wheelchair, group 2 standard, multiple power option, captains chair, patient weight capacity up to and including 300 pounds
- K0843 Power wheelchair, group 2 heavy duty, multiple power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds
- K0848 Power wheelchair, group 3 standard, sling/solid seat/back, patient weight capacity up to and including 300 pounds
- K0849 Power wheelchair, group 3 standard, captains chair, patient weight capacity up to and including 300 pounds
- K0850 Power wheelchair, group 3 heavy duty, sling/solid seat/back, patient weight capacity 301 to 450 pounds
- K0851 Power wheelchair, group 3 heavy duty, captains chair, patient weight capacity 301 to 450 pounds
- K0852 Power wheelchair, group 3 very heavy duty, sling/solid seat/back, patient weight capacity 451 to 600 pounds
- K0853 Power wheelchair, group 3 very heavy duty, captains chair, patient weight capacity, 451 to 600 pounds
- K0854 Power wheelchair, group 3 extra heavy duty, sling/solid seat/back, patient weight capacity 601 pounds or more
- K0855 Power wheelchair, group 3 extra heavy duty, captains chair, patient weight capacity 601 pounds or more
- K0856 Power wheelchair, group 3 standard, single power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
- K0857 Power wheelchair, group 3 standard, single power option, captains chair, patient weight capacity up to and including 300 pounds
- K0858 Power wheelchair, group 3 heavy duty, single power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds
- K0859 Power wheelchair, group 3 heavy duty, single power option, captains chair, patient weight capacity 301 to 450 pounds

- K0860 Power wheelchair, group 3 very heavy duty, single power option, sling/solid seat/back, patient weight capacity 451 to 600 pounds
- K0861 Power wheelchair, group 3 standard, multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
- K0862 Power wheelchair, group 3 heavy duty, multiple power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds
- K0863 Power wheelchair, group 3 very heavy duty, multiple power option, sling/solid seat/back, patient weight capacity 451 to 600 pounds
- K0864 Power wheelchair, group 3 extra heavy duty, multiple power option, sling/solid seat/back, patient weight capacity 601 pounds or more
- K0868 Power wheelchair, group 4 standard, sling/solid seat/back, patient weight capacity up to and including 300 pounds
- K0869 Power wheelchair, group 4 standard, captains chair, patient weight capacity up to and including 300 pounds
- K0870 Power wheelchair, group 4 heavy duty, sling/solid seat/back, patient weight capacity 301 to 450 pounds
- K0871 Power wheelchair, group 4 very heavy duty, sling/solid seat/back, patient weight capacity 451 to 600 pounds
- K0877 Power wheelchair, group 4 standard, single power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
- K0878 Power wheelchair, group 4 standard, single power option, captains chair, patient weight capacity up to and including 300 pounds
- K0879 Power wheelchair, group 4 heavy duty, single power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds
- K0880 Power wheelchair, group 4 very heavy duty, single power option, sling/solid seat/back, patient weight 451 to 600 pounds
- K0884 Power wheelchair, group 4 standard, multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
- K0885 Power wheelchair, group 4 standard, multiple power option, captain's chair, weight capacity up to and including 300 pounds
- K0886 Power wheelchair, group 4 heavy duty, multiple power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds
- K0890 Power wheelchair, group 5 pediatric, single power option, sling/solid seat/back, patient weight capacity up to and including 125 pounds
- K0891 Power wheelchair, group 5 pediatric, multiple power option, sling/solid seat/back, patient weight capacity up to and including 125 pounds
- K0898 Power wheelchair, not otherwise classified

K0899 Power mobility device, not coded by DME PDAC or does not meet criteria

ACA 6407 Specified Items

- E0185 Gel or gel-like pressure mattress pad
- E0188 Synthetic sheepskin pad
- E0189 Lamb's wool sheepskin pad
- E0194 Air fluidized bed
- E0197 Air pressure pad for mattress standard length and width
- E0198 Water pressure pad for mattress standard length and width
- E0199 Dry pressure pad for mattress standard length and width
- E0250 Hospital bed fixed height with any type of side rails, mattress
- E0251 Hospital bed fixed height with any type side rails without mattress
- E0255 Hospital bed variable height with any type side rails with mattress
- E0256 Hospital bed variable height with any type side rails without mattress
- E0260 Hospital bed semi-electric (Head and foot adjustment) with any type side rails with mattress
- E0261 Hospital bed semi-electric (head and foot adjustment) with any type side rails without mattress
- E0265 Hospital bed total electric (head, foot and height adjustments) with any type side rails with mattress
- E0266 Hospital bed total electric (head, foot and height adjustments) with any type side rails without mattress
- E0290 Hospital bed fixed height without rails with mattress
- E0291 Hospital bed fixed height without rail without mattress
- E0292 Hospital bed variable height without rail without mattress
- E0293 Hospital bed variable height without rail with mattress
- E0294 Hospital bed semi-electric (head and foot adjustment) without rail with mattress
- E0295 Hospital bed semi-electric (head and foot adjustment) without rail without mattress
- E0296 Hospital bed total electric (head, foot and height adjustments) without rail with mattress
- E0297 Hospital bed total electric (head, foot and height adjustments) without rail without mattress
- E0300 Pediatric crib, hospital grade, fully enclosed

- E0301 Hospital bed Heavy Duty extra wide, with weight capacity 350-600 lbs with any type of rail, without mattress
- E0302 Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, without mattress
- E0303 Hospital bed Heavy Duty extra wide, with weight capacity 350-600 lbs with any type of rail, with mattress
- E0304 Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, with mattress
- E0424 Stationary compressed gas Oxygen System rental; includes contents, regulator, nebulizer, cannula or mask and tubing
- E0431 Portable gaseous oxygen system rental includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
- E0433 Portable liquid oxygen system
- E0434 Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, content gauge, cannula or mask, and tubing
- E0439 Stationary liquid oxygen system rental, includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
- E0441 Oxygen contents, gaseous (1 months supply)
- E0442 Oxygen contents, liquid (1 months supply)
- E0443 Portable Oxygen contents, gas (1 months supply)
- E0444 Portable oxygen contents, liquid (1 months supply)
- E0450 Volume control ventilator without pressure support used with invasive interface
- E0460 Negative pressure ventilator portable or stationary
- E0461 Volume control ventilator without pressure support node for a noninvasive interface
- E0462 Rocking bed with or without side rail
- E0463 Pressure support ventilator with volume control mode used for invasive surfaces
- E0464 Pressure support vent with volume control mode used for noninvasive surfaces
- E0470 Respiratory Assist Device, bi-level pressure capability, without backup rate used non-invasive interface
- E0471 Respiratory Assist Device, bi-level pressure capability, with backup rate for a non-invasive interface
- E0472 Respiratory Assist Device, bi-level pressure capability, with backup rate for invasive interface
- E0480 Percussor electric/pneumatic home model

- E0482 Cough stimulating device, alternating positive and negative airway pressure
- E0483 High Frequency chest wall oscillation air pulse generator system
- E0484 Oscillatory positive expiratory device, non-electric
- E0570 Nebulizer with compressor
- E0575 Nebulizer, ultrasonic, large volume
- E0580 Nebulizer, durable, glass or autoclavable plastic, bottle type for use with regulator or flowmeter
- E0585 Nebulizer with compressor & heater
- E0601 Continuous airway pressure device
- E0607 Home blood glucose monitor
- E0627 Seat lift mechanism incorporated lift-chair
- E0628 Separate Seat lift mechanism for patient owned furniture electric
- E0629 Separate seat lift mechanism for patient owned furniture non-electric
- E0636 Multi positional patient support system, with integrated lift, patient accessible controls
- E0650 Pneumatic compressor non-segmental home model
- E0651 Pneumatic compressor segmental home model without calibrated gradient pressure
- E0652 Pneumatic compressor segmental home model with calibrated gradient pressure
- E0655 Non- segmental pneumatic appliance for use with pneumatic compressor on half arm
- E0656 Non- segmental pneumatic appliance for use with pneumatic compressor on trunk
- E0657 Non- segmental pneumatic appliance for use with pneumatic compressor chest
- E0660 Non- segmental pneumatic appliance for use with pneumatic compressor on full leg
- E0665 Non- segmental pneumatic appliance for use with pneumatic compressor on full arm
- E0666 Non- segmental pneumatic appliance for use with pneumatic compressor on half leg
- E0667 Segmental pneumatic appliance for use with pneumatic compressor on full-leg
- E0668 Segmental pneumatic appliance for use with pneumatic compressor on full arm
- E0669 Segmental pneumatic appliance for use with pneumatic compressor on half leg
- E0671 Segmental gradient pressure pneumatic appliance full leg
- E0672 Segmental gradient pressure pneumatic appliance full arm
- E0673 Segmental gradient pressure pneumatic appliance half leg

- E0675 Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency
- E0692 Ultraviolet light therapy system panel treatment 4 foot panel
- E0693 Ultraviolet light therapy system panel treatment 6 foot panel
- E0694 Ultraviolet multidirectional light therapy system in 6 foot cabinet
- E0720 Transcutaneous electrical nerve stimulation, two lead, local stimulation
- E0730 Transcutaneous electrical nerve stimulation, four or more leads, for multiple nerve stimulation
- E0731 Form fitting conductive garment for delivery of TENS or NMES
- E0740 Incontinence treatment system, Pelvic floor stimulator, monitor, sensor, and/or trainer
- E0744 Neuromuscular stimulator for scoliosis
- E0745 Neuromuscular stimulator electric shock unit
- E0747 Osteogenesis stimulator, electrical, non-invasive, other than spine application
- E0748 Osteogenesis stimulator, electrical, non-invasive, spinal application
- E0749 Osteogenesis stimulator, electrical, surgically implanted
- E0760 Osteogenesis stimulator, low intensity ultrasound, non-invasive
- E0762 Transcutaneous electrical joint stimulation system including all accessories
- E0764 Functional neuromuscular stimulator, transcutaneous stimulations of muscles of ambulation with computer controls
- E0765 FDA approved nerve stimulator for treatment of nausea & vomiting
- E0782 Infusion pumps, implantable, Non-programmable
- E0783 Infusion pump, implantable, Programmable
- E0784 External ambulatory infusion pump
- E0786 Implantable programmable infusion pump, replacement
- E0840 Tract frame attach to headboard, cervical traction
- E0849 Traction equipment cervical, free-standing stand/frame, pneumatic, applying traction force to other than mandible
- E0850 Traction stand, free standing, cervical traction
- E0855 Cervical traction equipment not requiring additional stand or frame
- E0856 Cervical traction device, cervical collar with inflatable air bladder
- E0958 Manual wheelchair accessory, one-arm drive attachment

- E0959 Manual wheelchair accessory-adapter for Amputee
- E0960 Manual wheelchair accessory, shoulder harness/strap
- E0961 Manual wheelchair accessory wheel lock brake extension handle
- E0966 Manual wheelchair accessory, headrest extension
- E0967 Manual wheelchair accessory, hand rim with projections
- E0968 Commode seat, wheelchair
- E0969 Narrowing device wheelchair
- E0971 Manual wheelchair accessory anti-tipping device
- E0973 Manual wheelchair accessory, adjustable height, detachable armrest
- E0974 Manual wheelchair accessory anti-rollback device
- E0978 Manual wheelchair accessory positioning belt/safety belt/ pelvic strap
- E0980 Manual wheelchair accessory safety vest
- E0981 Manual wheelchair accessory Seat upholstery, replacement only
- E0982 Manual wheelchair accessory, back upholstery, replacement only
- E0983 Manual wheelchair accessory power add on to convert manual wheelchair to motorized wheelchair, joystick control
- E0984 Manual wheelchair accessory power add on to convert manual wheelchair to motorized wheelchair, Tiller control
- E0985 Wheelchair accessory, seat lift mechanism
- E0986 Manual wheelchair accessory, push activated power assist
- E0990 Manual wheelchair accessory, elevating leg rest
- E0992 Manual wheelchair accessory, elevating leg rest solid seat insert
- E0994 Arm rest
- E1014 Reclining back, addition to pediatric size wheelchair
- E1015 Shock absorber for manual wheelchair
- E1020 Residual limb support system for wheelchair
- E1028 Wheelchair accessory, manual swing away, retractable or removable mounting hardware for joystick, other control interface or positioning accessory
- E1029 Wheelchair accessory, ventilator tray
- E1030 Wheelchair accessory, ventilator tray, gimbaled

- E1031 Rollabout chair, any and all types with castors 5" or greater
- E1035 Multi-positional patient transfer system with integrated seat operated by care giver
- E1036 Patient transfer system
- E1037 Transport chair, pediatric size
- E1038 Transport chair, adult size up to 300lb
- E1039 Transport chair, adult size heavy duty >300lb
- E1161 Manual Adult size wheelchair includes tilt in space
- E1227 Special height arm for wheelchair
- E1228 Special back height for wheelchair
- E1232 Wheelchair, pediatric size, tilt-in-space, folding, adjustable with seating system
- E1233 Wheelchair, pediatric size, tilt-in-space, folding, adjustable without seating system
- E1234 Wheelchair, pediatric size, tilt-in-space, folding, adjustable without seating system
- E1235 Wheelchair, pediatric size, rigid, adjustable, with seating system
- E1236 Wheelchair, pediatric size, folding, adjustable, with seating system
- E1237 Wheelchair, pediatric size, rigid, adjustable, without seating system
- E1238 Wheelchair, pediatric size, folding, adjustable, without seating system
- E1296 Special sized wheelchair seat height
- E1297 Special sized wheelchair seat depth by upholstery
- E1298 Special sized wheelchair seat depth and/or width by construction
- E1310 Whirlpool non-portable
- E2502 Speech Generating Devices prerecord messages between 8 and 20 Minutes
- E2506 Speech Generating Devices prerecord messages over 40 minutes
- E2508 Speech Generating Devices message through spelling, manual type
- E2510 Speech Generating Devices synthesized with multiple message methods
- E2227 Rigid pediatric wheelchair adjustable
- K0001 Standard wheelchair
- K0002 Standard hemi (low seat) wheelchair
- K0003 Lightweight wheelchair
- K0004 High strength ltwt wheelchair

K0005	Ultra Lightweight wheelchair
K0006	Heavy duty wheelchair
K0007	Extra heavy duty wheelchair
K0009	Other manual wheelchair/base
K0606	AED garment with electronic analysis
K0730	Controlled dose inhalation drug delivery system

Nurse Practitioner or Clinical Nurse Specialist Rules Concerning Orders and CMNs

CMS Manual System, Pub. 100-08, Medicare Program Integrity Manual, Chapter 5, §5.5

A nurse practitioner or clinical nurse specialist may give the dispensing order and sign the detailed written order in the following situations:

- They are treating the beneficiary for the condition for which the item is needed;
- They are practicing independently of a physician;
- They bill Medicare for other covered services using their own provider number; and
- They are permitted to do all of the above in the State in which the services are rendered.

A nurse practitioner or clinical nurse specialist may complete Section B and sign Section D of a CMN if they meet all the criteria described above for signing orders. See Chapter 4 of the manual for information regarding CMNs.

Signatures must comply with CMS signature requirements. Refer to the “Signature Requirements” section in this chapter.

Physician Assistant Rules Concerning Orders and CMNs

CMS Manual System, Pub. 100-08, Medicare Program Integrity Manual, Chapter 5, §§5.3.1 & 5.6

Physician assistants may provide the dispensing order and write and sign the detailed written order if they satisfy all the following requirements:

- They meet the definition of physician assistant found in §1861(aa)(5)(A) of the Act;
- They are treating the beneficiary for the condition for which the item is needed;
- They are practicing under the supervision of a Doctor of Medicine or Doctor of Osteopathy;
- They have their own NPI; and
- They are permitted to perform services in accordance with State law.

Physician assistants may complete Section B and sign Section D of a CMN if they meet all the criteria described above for signing orders.

Signatures must comply with CMS signature requirements. Refer to the “Signature Requirements” section in this chapter.

Supply Replacement/Utilization – Evidence of Medical Necessity

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.9

If replacement supplies are needed for the therapeutic use of purchased DMEPOS, the treating practitioner must specify on the prescription, or on the CMN, the type of supplies needed and the frequency with which they must be replaced, used, or consumed. DME MACs and UPICs evaluate supply utilization information as part of the medical necessity determination for DMEPOS. "PRN" or "as needed" utilization estimates for supply replacement, use, or consumption are not acceptable.

The DME MACs and/or UPICs have procedures in place to monitor utilization of replacement supplies. You must submit updated medical information of the **beneficiary's** condition resulting in changes of the equipment device, or supply utilization. Claims submitted with unexpected increases in supply utilization without supportive documentation will be denied. You must provide this information with the claim where indicated in published policy or make it available to the DME MACs or UPICs on request.

Acceptability of Faxed Orders and Facsimile or Electronic CMNs or DIFs

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.3

When reviewing claims and orders, or auditing CMNs or DIFs for DMEPOS, DME MACs and UPICs may encounter faxed, copied, or electronic orders, CMNs, and DIFs in supplier files. The DME MACs and UPICs will accept these documents as fulfilling the documentation requirements.

The DME MACs and UPICs retain the authority to request additional documentation to support the claim. If a DME MAC finds indications of potential fraud or misrepresentation of these documents or the claims submitted, they will refer the matter to the UPIC for development.

4. Documentation in the **Beneficiary's Medical Record**

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.7; Pub. 100-02, *Medicare Benefit Policy Manual*, Chapter 15; Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 12

Medicare does not automatically assume payment for a DMEPOS item that was covered prior to a beneficiary becoming eligible for the Medicare Fee-for-Service (FFS) program. When a beneficiary receiving a DMEPOS item from another payer (including Medicare Advantage plans) becomes eligible for the Medicare FFS program, Medicare will pay for continued use of the DMEPOS item only if all Medicare coverage, coding, and documentation requirements are met. Additional documentation to support that the item is reasonable and necessary may be required upon request of the DME MAC.

For any DMEPOS item to be covered by Medicare, the **beneficiary's** medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the **beneficiary's** diagnosis and other pertinent information including, but not limited to, duration of the **beneficiary's** condition, clinical course (worsening or improving), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc. If the information in the **beneficiary's** medical record does not adequately support the medical necessity for the item, you are liable for the dollar amount involved unless a properly executed ABN of possible denial has been obtained. See the Advanced Beneficiary Notice section below for information about ABNs.

If an item requires a CMN or DIF, it is recommended that a copy of the completed CMN or DIF be kept in the **beneficiary's** record; however, neither a practitioner's order, nor a CMN nor a DIF nor a supplier-prepared statement nor practitioner's attestation by itself provides sufficient

documentation of medical necessity, even though it is signed by the treating physician or you. There must be information in the beneficiary's medical record that supports the medical necessity for the item and substantiates the answers on the CMN (if applicable) or DIF (if applicable) or information on a supplier-prepared statement or practitioner's attestation (if applicable). See Chapter 4 of this manual for information regarding CMNs and DIFs.

Supplier-produced records, even if signed by the prescribing physician/prescribing practitioner, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes. Templates and forms, including CMS Certificates of Medical Necessity, are subject to corroboration with information in the medical record.

The **beneficiary's** medical record is not limited to the treating physician/practitioner's office records. It may include hospital, nursing home, or home health agency records and records from other professionals. Records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that an item is reasonable and necessary.

The documentation in the **beneficiary's** medical record does not need to be routinely sent to you or to the DME MACs or UPICs; however, the DME MAC or UPIC may request this information in selected cases. If the DME MAC or UPIC does not receive the information when requested, or if the information in the **beneficiary's** medical record does not adequately support the medical necessity for the item, then for assigned claims you are liable for the dollar amount involved unless a properly executed advance beneficiary notice (ABN) of possible denial has been obtained. See the Advanced Beneficiary Notice section below for information about ABNs.

FACE-TO-FACE EXAMINATION

CMS Manual System, Pub. 100-08, Medicare Program Integrity Manual, Chapter 5, §5.2.5

Note: This section does not apply to Power Mobility Devices, as they are covered under a different statutory requirement. Refer to the Power Mobility Devices LCD.

These Affordable Care Act requirements are effective for claims for all of the specified items that require a new order (prescription) on or after July 1, 2013. A delay in enforcement has been made by DME MACs. Other auditing entities may enforce these requirements. This delay in enforcement does not apply to the prescription requirements for a Written Order Prior to Delivery or to the requirement to include the prescriber's NPI on the prescription.

As a condition for payment, Section 6407 of the Affordable Care Act (ACA) requires that a practitioner (Medical Doctor (MD), Doctor of Osteopathic Medicine (DO) or Doctor of Podiatric Medicine (DPM), physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS)) has had a face-to-face examination with a beneficiary within the six (6) months prior to the date of the written order for certain items of DME.

This face-to-face requirement includes examinations conducted via the Centers for Medicare & Medicaid Services (CMS)-approved use of telehealth examinations (as described in Chapter 15 of the Medicare Benefit Policy Manual and Chapter 12 of the Medicare Claims Processing Manual - CMS Internet-Only Manuals, Pub. 100-02 and 100-04, respectively).

For the treating physician/practitioner prescribing a specified DME item:

- The face-to-face examination with the beneficiary must be conducted within the six (6) months prior to the date of the prescription.
- The face-to-face examination must document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered.

All Medicare coverage and documentation requirements for DMEPOS also apply. There must be sufficient medical information included in the medical record to demonstrate that the applicable coverage criteria are met. Refer to the applicable LCD for information about the medical necessity criteria for the item(s) being ordered.

The treating practitioner that conducted the face-to-face examination does not need to be the prescriber for the DME item; however, the prescriber must:

- Verify that the qualifying in-person visit occurred within the 6-months prior to the date of their prescription; and,
- Have documentation of the qualifying face-to-face examination that was conducted.

The prescriber must provide a copy of the 5EO for the item(s) ordered to you before the item(s) can be delivered.

A new face-to-face examination is required each time a new prescription for one of the specified items is ordered. A new prescription is required by Medicare:

- For all claims for purchases or initial rentals
- When there is a change in the original prescription for the accessory, supply, drug, etc.
- On a regular basis (even if there is no change in the original order) only if it is so specified in the Documentation section of a particular medical policy
- When an item is replaced
- When there is a change in the supplier, and the new supplier is unable to obtain a copy of a valid order and documentation from the original supplier.

The first bullet, "For all claims for purchases or initial rentals", includes all claims for payment of purchases and initial rentals for items not originally covered (reimbursed) by Medicare Part B. Claims for items obtained outside of Medicare Part B, e.g. from another payer prior to Medicare participation (including Medicare Advantage plans), are considered to be new initial claims for Medicare payment purposes.

Date and Timing Requirements

There are specific date and timing requirements:

- The date of the face-to-face examination must be on or before the date of 5EO and may be no older than six months prior to the prescription date.
- The date of the face-to-face examination must be on or before the date of delivery for the item(s) prescribed.
- The date of the 5EO must be on or before the date of delivery or date shipped if the shipping date is used as the date of service. The shipping date may be defined as the date the delivery/shipping service label is created or the date the item is retrieved for delivery. However, such dates should not demonstrate significant variation.
- You must have the completed 5EO in your file prior to the delivery of these items.

All other date and timing requirements specified in the *CMS Program Integrity Manual* regarding specific items or services remain unchanged.

Upon request by the contractor you must provide documentation, from the treating physician/practitioner, of the face-to-face examination and the completed 5EO.

Claim Denial

Claims for the specified items subject to ACA 6407 that do not meet the requirements specified above will be denied as statutorily noncovered – failed to meet statutory requirements.

If you deliver the item prior to receipt of the 5EO, it will be denied as statutorily noncovered. If the 5EO is not obtained prior to delivery, payment will not be made for that item even if a written order is subsequently obtained. If a similar item is subsequently provided by an unrelated supplier who has obtained a written order prior to delivery, it will be eligible for coverage.

The above face-to-face requirements apply to the HCPCS codes listed as subject to 42 CFR 410.38(g).

Refer to the Pricing, Data Analysis and Coding (PDAC) Contractor website for information on coding at www.dmepdac.com.

CONTINUED MEDICAL NEED

For all DMEPOS items, the initial justification for medical need is established at the time the item(s) is first ordered; therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are created just prior to, or at the time of, the creation of the initial prescription. For purchased items, initial months of a rental item or for initial months of ongoing supplies or drugs, information justifying reimbursement will come from this initial time period. Entries in the beneficiary's medical record must have been created prior to, or at the time of, the initial date of service to establish whether the initial reimbursement was justified based upon the applicable coverage policy.

For ongoing supplies and rental DME items, in addition to information described above that justifies the initial provision of the item(s) and/or supplies, there must be information in the beneficiary's medical record to support that the item continues to be used by the beneficiary and remains reasonable and necessary. Information used to justify continued medical need must be timely for the date of service under review. Any of the following may serve as documentation justifying continued medical need:

- A recent order by the treating practitioner for refills
- A recent change in prescription
- A properly completed CMN or DIF with an appropriate length of need specified
- Timely documentation in the beneficiary's medical record showing usage of the item

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified in policy.

CONTINUED USE

Continued use describes the ongoing utilization of supplies or a rental item by a beneficiary.

You are responsible for monitoring utilization of DMEPOS rental items and supplies. Monitoring of purchased items or capped rental items that have converted to a purchase is not required. You must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary.

Beneficiary medical records or your records may be used to confirm that a DMEPOS item continues to be used by the beneficiary. Any of the following may serve as documentation that an item submitted for reimbursement continues to be used by the beneficiary:

- Timely documentation in the beneficiary's medical record showing usage of the item, related option/accessories, and supplies.
- Your records documenting the request for refill/replacement of supplies in compliance with the refill documentation requirements section. This is deemed to be sufficient to document continued use for the base item as well.
- Your records documenting beneficiary confirmation of continued use of a rental item.

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified in policy.

5. Signature Requirements

CMS Manual System, Pub. 100-08, Medicare Program Integrity Manual, Chapter 3, §3.3.2.4

For medical review purposes, Medicare requires that services provided/ordered/certified be authenticated by the persons responsible for the care of the beneficiary in accordance with Medicare's policies. For example, if the physician's authenticated documentation corroborates the nurse's unsigned note, and the physician was the responsible party per Medicare's payment policy, medical reviewers would consider signature requirements to have been met. The method used shall be a handwritten or electronic signature. Stamped signatures are not acceptable.

The Medicare Program Integrity Manual notes several exceptions to normal signature requirements, as listed below:

EXCEPTION 1: Facsimiles of original written or electronic signatures are acceptable for the certifications of terminal illness for hospice.

EXCEPTION 2: There are some circumstances for which an order does not need to be signed. For example, orders for some clinical diagnostic tests are not required to be signed. The rules in 42 CFR 410 and Pub.100-02 chapter 15, §80.6.1 state that if the order for the clinical diagnostic test is unsigned, there must be medical documentation (e.g., a progress note) by the treating physician/practitioner that he/she intended the clinical diagnostic test be performed. This documentation showing the intent that the test be performed must be authenticated by the author via a handwritten or electronic signature.

EXCEPTION 3: Other regulations and the CMS' instructions regarding conditions of payment related to signatures (such as timeliness standards for particular benefits) take precedence. For medical review purposes, if the relevant regulation, NCD, LCD and CMS manuals are silent on whether the signature needs to be legible or present and the signature is illegible/missing, the reviewer shall follow the guidelines listed in the Medicare Program Integrity Manual, Chapter 3 to discern the identity and credentials (e.g., MD, RN, etc.) of the signator. In cases where the relevant regulation,

NCD, LCD and CMS manuals have specific signature requirements, those signature requirements take precedence.

EXCEPTION 4: CMS would permit use of a rubber stamp for signature in accordance with the Rehabilitation Act of 1973 in the case of an author with a physical disability that can provide proof to a CMS contractor of his/her inability to sign their signature due to their disability. By affixing the rubber stamp, the provider is certifying that they have reviewed the document.

6. Refills of DMEPOS Items Provided on a Recurring Basis

CMS Manual System, Pub. 100-08, Medicare Program Integrity Manual, Chapter 5, §5.2.7– 5.2.8

For DMEPOS items and supplies that are provided on a recurring basis, billing must be based on prospective, not retrospective use. The following scenarios are illustrative of this concept:

Scenario 1: The treating practitioner writes an order for enteral nutrition which translates into the dispensing of 100 units of nutrient for one month. The supplier receives the order, delivers 100 units, and bills the claim with a date of service as the date of delivery indicating 100 units. This is an example of prospective billing and is acceptable.

Scenario 2: The treating practitioner writes an order for enteral nutrition which translates into the dispensing of 100 units of nutrient for one month. The supplier receives the order and delivers 100 units. A claim is not billed. At the end of the month, the supplier determines that the beneficiary used 90 units for the month and delivers 90 units to replace the nutrient used. A claim is then submitted with a date of service as the date of delivery indicating 90 units of enteral nutrition. This is an example of retrospective billing and is not acceptable.

For DMEPOS products that are supplied as refills to the original order, you must contact the beneficiary or caregiver/designee prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, to ensure existing supplies are approaching exhaustion, and to confirm any changes/modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

You must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. You must stay attuned to changed or atypical utilization patterns on the part of their clients. You must verify with the prescribing practitioner that any changed or atypical utilization is warranted.

For delivery of refills, you must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. DME MACs allow for the processing of claims for refills delivered/shipped prior to the beneficiary exhausting his/her supply.

REFILL DOCUMENTATION

A routine refill prescription is not needed. A new prescription is needed when:

- There is a change of supplier, and the new supplier is unable to obtain a copy of a valid order and documentation from the original supplier.
- There is a change in the order for the accessory, supply, drug, etc.

- When an item is replaced.
- On a regular basis (even if there is no change in the order) only if it is so specified in the documentation section of a particular medical policy.

For items that the beneficiary obtains in-person at a retail store, the signed delivery slip or a copy of the itemized sales receipt is sufficient documentation of a request for refill.

For items that are delivered to the beneficiary, documentation of a request for refill must be either a written document received from the beneficiary or a contemporaneous written record of a phone conversation/contact between you and the beneficiary. The refill request must occur and be documented before shipment. A retrospective attestation statement by you or the beneficiary is not sufficient. The refill record must include:

- The beneficiary's name or authorized representative, if different than the beneficiary.
- A description of each item that is being requested.
- Date of refill request.
- For consumable supplies, i.e., those that are used up (e.g., ostomy or urological supplies, surgical dressings, etc.)—you must assess the quantity of each item that the beneficiary still has remaining, to document that the amount remaining will be nearly exhausted on or about the supply anniversary date.
- For non-consumable supplies, i.e., those more durable items that are not used up but may need periodic replacement (e.g., positive airway pressure and respiratory assist devices' supplies)—you must assess whether the supplies remain functional, providing replacement (a refill) only when the supply item(s) is no longer able to function. You must document the functional condition of the item(s) being refilled in sufficient detail to demonstrate the cause of the dysfunction that necessitates replacement (refill).

This information must be kept on file and be available upon request.

Note: Some policies may require additional documentation. Refer to the appropriate LCD and related Policy Article for guidance.

7. Beneficiary Authorization

CMS Manual System, Pub. 100-04, Medicare Claims Processing Manual, Chapter 1

You may only receive Medicare payment if the beneficiary assigns his or her Medicare benefits to you. Regulations authorize Medicare to pay for claims submitted by a supplier only if the beneficiary or the person authorized to request payment on the beneficiary's behalf assigns the claims to the supplier and the supplier accepts assignment. For all claims submitted on or after January 1, 2005, payment shall be made to physicians and suppliers even without a beneficiary-signed assignment of benefits (AOB) form when the service can only be paid on an assignment related basis. This includes any mandatory assignment situations and participating physician or supplier situations. When you accept assignment, you must accept Medicare's determination of the approved amount as the full fee for the service(s) rendered. For more information about beneficiary authorization, see the Chapter 6 of this manual.

8. Proof of Delivery (POD)

SUPPLIER PROOF OF DELIVERY DOCUMENTATION REQUIREMENTS

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 4, §§4.26 – 4.26.2 & Chapter 5, §5.8.B

You are required to maintain proof of delivery documentation in your files. Documentation must be maintained in your files for seven years.

Proof of delivery is one of the supplier standards as noted in 42 CFR, 424.57(c)(12) and in Chapter 2 of this manual. In certain instances, compliance with proof of delivery may be required as a condition of payment and must be available to the DME MAC, RAC, SMRC, CERT, and UPIC on request. For such items, if the supplier does not have appropriate POD documentation within the prescribed timeframes, associated claims will be denied and overpayments will be recouped. Note that non-compliance with supplier standards may also result in revocation from the Medicare program. If you consistently do not provide documentation to support your services, you may be referred to the Office of Inspector General or NSC for investigation and/or imposition of sanctions.

PROOF OF DELIVERY AND DELIVERY METHODS

For the purpose of the delivery methods noted below, **designee** is defined as:

“A person who can sign and accept the delivery of durable medical equipment on behalf of the beneficiary.”

You, your employees, or anyone else having a financial interest in the delivery of the item are prohibited from signing and accepting an item on behalf of a beneficiary (i.e., acting as a designee on behalf of the beneficiary). The relationship of the designee to the beneficiary should be noted on the delivery document that you obtain (i.e., spouse, neighbor, etc.). The signature of the designee should be legible. If the signature of the designee is not legible, you (or the shipping service) should note the name of the designee on the delivery document.

There are three methods of delivery:

1. Delivery directly to the beneficiary or authorized representative
2. Delivery via shipping or delivery service
3. Delivery of items to a nursing facility on behalf of the beneficiary

Regardless of the method of delivery, the contractor must be able to determine that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are received by a specific Medicare beneficiary.

Method 1—Direct Delivery to the Beneficiary

You may deliver directly to the beneficiary or the designee. In this case, POD to a beneficiary must be a signed and dated delivery document. The POD document must include:

- Beneficiary’s name
- Delivery address
- A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number.

- Quantity delivered
- Date delivered
- Beneficiary (or designee) signature

The date delivered on the POD must be the date that the DMEPOS item was received by the beneficiary or designee. The date of delivery may be entered by the beneficiary, designee, or you. When your delivery documents have both your entered date and a beneficiary or beneficiary's designee signature date on the POD document, the beneficiary or beneficiary's designee-entered date is the date of service. In instances where the supplies are delivered directly by you, the date the beneficiary received the DMEPOS supply must be the date of service on the claim.

Method 2—Delivery via Shipping or Delivery Service Directly to a Beneficiary

If you utilize a shipping service or mail order, the POD documentation must be a complete record tracking the item(s) from you to the beneficiary. An example of acceptable proof of delivery would include both your detailed shipping invoice and the delivery service's tracking information. Your record must be linked to the delivery service record by some clear method like the delivery service's package identification number or your invoice number for the package sent to the beneficiary.

The POD document must include:

- Beneficiary's name
- Delivery address
- Delivery service's package identification number, your invoice number, or alternative method that links your delivery documents with the delivery service's records
- A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number.
- Quantity delivered
- Date delivered
- Evidence of delivery

If you utilize a shipping service or mail order, you have two options for the DOS to use on the claim:

1. You may use the shipping date as the DOS. The shipping date is defined as the date the delivery/shipping service label is created or the date the item is retrieved by the shipping service for delivery. However, such dates should not demonstrate significant variation.
2. You may use the date of delivery as the DOS on the claim.

You may also utilize a return postage-paid delivery invoice from the beneficiary or designee as a POD. This type of POD document must contain the information specified above.

Method 3—Delivery to Nursing Facility on Behalf of a Beneficiary

For items directly delivered by you to a nursing facility or when a delivery service or mail order is used to deliver the item(s) to a nursing facility, then you must have:

1. Documentation demonstrating delivery of the item(s) to the facility by you or delivery entity; and
2. Documentation from the nursing facility demonstrating receipt and/or usage of the item(s) by the beneficiary. The quantities delivered and used by the beneficiary must justify the quantity billed.

This information must be available upon request.

EXCEPTIONS

Exceptions to the preceding statements concerning the date(s) of service on the claim occur when the items are provided in anticipation of discharge from **an inpatient facility that does not qualify as the beneficiary's home**. You may deliver DME, prosthetic, or orthotic items, **but not supplies, to a beneficiary in an inpatient facility that does not qualify as the beneficiary's home, for the purpose of fitting or training the beneficiary in the proper use of the item**. This may be done up to two days prior to the beneficiary's anticipated discharge to their home. You must bill the date of service on the claim as the date of discharge and shall use the Place of Service (POS) as 12 (home). The item must be for subsequent use in the beneficiary's home. No billing may be made for the item on those days the beneficiary was receiving training or fitting in the hospital or nursing facility.

Example:

1. A beneficiary is admitted to a hospital stay on June 1.
2. The beneficiary will require the use of a walker upon discharge and must be trained on its use while in the hospital. The walker is provided to the beneficiary in the hospital on June 5.
3. The beneficiary is discharged from the hospital on June 6.

You would then bill the claim to the DME MAC using June 6 as the date of service.

You may not bill for drugs or other DMEPOS items used by the beneficiary prior to the beneficiary's discharge from the hospital or a Medicare Part A nursing facility stay. **Billing the DME MAC for surgical dressings, urological supplies, or ostomy supplies that are provided during a stay in an inpatient facility that does not qualify as the beneficiary's home is not allowed**. These items are payable to the facility under Part A of Medicare. This prohibition applies even if the item is worn home by the beneficiary from the hospital or nursing facility. Any attempt by you and/or the facility to substitute an item that is payable to you for an item that, under statute, should be provided by the facility, may be considered to be fraudulent. These statements apply to durable medical equipment delivered to a beneficiary in hospitals, skilled nursing facilities (Place of Service = 31), or nursing facilities (Place of Service = 32).

To allow payment for the first immunosuppressive drug claim after the beneficiary is discharged from an inpatient stay, the immunosuppressive drug may be mailed by a supplier no earlier than two days before a beneficiary is discharged from an inpatient facility. Delivery must be to a valid place of service (e.g., home, custodial facility), and not another facility (e.g., inpatient or skilled nursing) that does not qualify as the beneficiary's home. You must enter the date of discharge as the date of service on the claim.

Equipment Retained From a Prior Payer

When a beneficiary receiving a DMEPOS item from another payer (including a Medicare Advantage Plan) becomes eligible for the Medicare FFS program, the first Medicare claim for that item or service is considered a new initial Medicare claim for the item. Even if there is no change in the beneficiary's medical condition, the beneficiary must meet all coverage, coding, and documentation requirements for the DMEPOS item in effect on the date of service of the initial Medicare claim.

A POD is required for all items, even those in the beneficiary's possession provided by another insurer prior to Medicare eligibility. To meet the POD requirements for a beneficiary transitioning to Medicare you, the supplier, must document:

- A statement, signed and dated by the beneficiary (or beneficiary's designee), that you have examined the item, meets the POD requirements; and
- A supplier attestation that the item meets Medicare requirements.

For the purposes of reasonable, useful lifetime and calculation of continuous use, the first day of the first rental month in which Medicare payments are made for the item (i.e., date of service) serves as the start date of the reasonable, useful lifetime and period of continuous use. In these cases, the proof of delivery documentation serves as evidence that the beneficiary is already in possession of the item.

Please refer to IOM 100-08, Chapter 4, Section 4.26 for additional information regarding all proof of delivery requirements.

9. Advance Beneficiary Notice (ABN)

CMS Manual System, Pub. 100-04, Medicare Claims Processing Manual, Chapter 20, §120 & Chapter 30, §50

An Advance Beneficiary Notice (ABN) is a written notice that you may give to a Medicare beneficiary before providing items and/or services that Medicare otherwise might pay for, but for this particular occasion is expected to deny. The ABN allows the beneficiary to make an informed consumer decision as to whether or not to receive the items or services for which he or she may have to pay out of pocket or through other insurance. An ABN should be issued prior to dispensing an item or service expected to be disallowed for the following reasons:

- Lack of medical necessity
- Prohibited, unsolicited telephone contacts
- Supplier number requirements not met
- Denial of an Advanced Determination of Medicare Coverage (ADMC) request
- Noncontracted suppliers in a competitive bidding area (CBA)

If you fail to issue a properly executed ABN, you will be held liable for the item and/or service and may not bill or collect, or must refund amounts collected, from the beneficiary.

An ABN can remain in effect up to a year for an extended course of treatment with no other new events. Once the beneficiary signs the ABN, it may not be modified or revised.

You must retain a copy of the signed ABN on file. The ABN should not be submitted with the claim, but is required when responding to an additional documentation request for a complex review, in which case CGS will conduct a face validity assessment of the ABN to ensure liability is assigned appropriately in accordance with the Limitation of Liability Provisions.

The current version of the Advanced Beneficiary Notice of Noncoverage (ABN) is form CMS-R-131 (03/2020). Other forms will be considered invalid. The ABN form CMS-R-131 (03/2020) can be found online on the Beneficiary Notice Initiative Web page at <https://www.cms.gov/Medicare/Medicare-General-Information/BN/ABN.html>.

For an ABN to be acceptable, it must:

- Be on the approved CMS-R-131 (03/2020) form;
- Clearly identify your name, address, and telephone number;
- Clearly identify the beneficiary;
- Clearly identify the particular item and/or service;
- State that you believe Medicare is likely (or certain) to deny payment for the particular item and/or service; and
- Give your reason(s) for your belief that Medicare is likely (or certain) to deny payment for the item and/or service.
- Give a reasonable estimate cost of the noncovered item and/or service
- Be signed and dated by the beneficiary or representative.

The ABN completion instructions are available in the CMS Manual System, Pub. 100-4, *Medicare Claims Processing Manual*, Chapter 30, § 50.6.3.

ABNs are not required for care that is either statutorily excluded from coverage under Medicare (i.e., care that is never covered) or fails to meet a technical benefit requirement (i.e., lacks required certification); however, the ABN form CMS-R-131 (03/2020) can be issued voluntarily.

ABNs apply to assigned and nonassigned claims, as there are financial liability provisions under Medicare law for both claim types:

Limitation of liability (LOL) applies to **assigned** claims for DMEPOS services disallowed because of medical necessity, due to prohibition on unsolicited telephone calls, no supplier number, or no ADMC. Under LOL, a beneficiary can be held liable for a service denied due to reasons cited on the ABN.

Refund requirements (RR) apply to **assigned and non-assigned** claims for DMEPOS services disallowed because of medical necessity, due to prohibition on unsolicited telephone calls, no supplier number, or no ADMC. RR state that suppliers must make refunds of any amounts collected if the beneficiary was not properly notified of possible disallowed Medicare claims. The RR provisions require that the beneficiary is notified and agrees to be financially liable.

If you render a service which Medicare considers not medically necessary to a beneficiary, you should notify the beneficiary in writing, **before rendering the service**, that Medicare is likely to deny the claim and that the beneficiary will be responsible for payment. Modifier "GA" should be indicated on the Medicare claim with the appropriate HCPCS code when it is filed. See Chapter 16 of this manual for more information about modifiers.

The following statements are examples of reasons for your belief that Medicare is likely to deny payment:

- Medicare does not usually pay for this many treatments or services
- Medicare usually does not pay for this service

- Medicare does not pay for this because it is a treatment that has yet to be proved effective (experimental)
- Medicare does not pay for this many services within this period of time
- Medicare does not pay for such an extensive treatment

General statements such as "I never know if Medicare will deny payment" are not acceptable.

The beneficiary or his or her representative has the right to appeal a claim decision if there is dissatisfaction with the amount of payment, denial of coverage for services or supplies, or if the original claim was not acted upon within a reasonable time. You have the right to appeal a claim decision when you accept assignment.

As a supplier providing items and services to Medicare beneficiaries, you may appeal an initial determination if:

- You accepted assignment on the claim; or
- You are acting as the duly authorized representative of the beneficiary.

See chapter 13 of this manual for more information about appeals.

When you furnish an upgraded item of DMEPOS and expect Medicare to reduce the level of payment based on a medical necessity partial denial of coverage for additional expenses attributable to the upgrade, you must give an ABN to the beneficiary for signature for holding the beneficiary liable for the additional expense.

For complete instructions on using an ABN, refer to the CMS Manual System, Pub. 100-04, Medicare Claims Processing Manual, Chapter 30, §50, which is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c30.pdf>. Instructions are also available on the Beneficiary Notice Initiative Web page at <https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html>.

10. Miscellaneous Documentation Issues

Repair/Maintenance/Replacement

CMS Manual System, Pub. 100-2, *Medicare Benefit Policy Manual*, Chapter 15, §§110.2 & 120; Pub. 100-8, *Medicare Program Integrity Manual*, Chapter 5, §5.8.1

Under the circumstances specified in the Medicare Benefit Policy Manual, payment may be made for repair, maintenance, replacement, and delivery of medically-required DME which the beneficiary owns or is purchasing, including equipment which had been in use before the user enrolled in Part B of the Medicare program. In addition, payments for repair and maintenance may not include payment for parts and labor covered under a manufacturer's or supplier's warranty.

Repairs to DMEPOS (Except Artificial Limbs)

CMS Manual System, Pub. 100-2, *Medicare Benefit Policy Manual*, Chapter 15, §§110.2; Pub. 100-8, *Medicare Program Integrity Manual*, Chapter 5, §5.8.1

A new Certificate of Medical Necessity (CMN) and/or physician/practitioner's order is not needed for repairs.

In the case of repairs to a beneficiary-owned DMEPOS item, if Medicare paid for the base equipment initially, medical necessity for the base equipment has been established. With respect to Medicare reimbursement for the repair, there are two documentation requirements:

1. The treating physician/practitioner must document that the DMEPOS item being repaired continues to be reasonable and necessary (see Continued Medical Need section above); and
2. Either the treating physician/practitioner or you must document that the repair itself is reasonable and necessary.

You must maintain detailed records describing the need for and nature of all repairs, including a detailed explanation of the justification for any component or part replaced, as well as the labor time to restore the item to its functionality.

A treating physician/practitioner's order and/or new Certificate of Medical Necessity (CMN), when required, is needed to reaffirm the medical necessity of the item for replacement of an item.

Repair/Replacement only Applying to Lower Limb Protheses
CMS Manual System, Pub. 100-2, *Medicare Benefit Policy Manual*, Chapter 15, §120

Adjustments and repairs of prostheses and prosthetic components are covered under the original order for the prosthetic device.

Medicare payment may be made for the replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if a treating practitioner determines that the replacement device, or replacement part of such a device, is necessary. Claims involving the replacement of a prosthesis or major component (foot, ankle, knee, socket) must be supported by a new treating practitioner's order and documentation supporting the reason for the replacement. The reason for replacement must be documented by the treating physician/practitioner, either on the order or in the medical record, and must fall under one of the following:

1. A change in the physiological condition of the **beneficiary** resulting in the need for a replacement. Examples include but are not limited to: changes in beneficiary weight, changes in the residual limb, and beneficiary functional need changes; or
2. An irreparable change in the condition of the device or in a part of the device resulting in the need for a replacement; or
3. The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

The prosthetist must retain documentation of the prosthesis or prosthetic component replaced, the reason for replacement, and a description of the labor involved irrespective of the time since the prosthesis was provided to the beneficiary. This information must be available upon request. It is recognized that there are situations where the reason for replacement includes but is not limited to: changes in the residual limb, functional need changes, or irreparable damage or wear/tear due to excessive beneficiary weight or prosthetic demands of very active amputees.

Refer to the individual medical policies for specific coverage and payment provisions.

Delivery and Service Charges

CMS Manual System, Pub. 100-4, *Medicare Claims Processing Manual*, Chapter 20, §60

Delivery and service are an integral part of the costs of doing business if you are an oxygen and durable medical equipment (DME) supplier. Such costs are ordinarily assumed to have been taken into account (along with all other overhead expenses) in setting the prices that you charge for covered items and services. As such, these costs, whether rented or purchased, have already been accounted for in the calculation of the fee schedules. Therefore, separate delivery and service charges for DMEPOS items will not be allowed except in rare and unusual circumstances when the delivery is outside the normal range of your sphere of operation. For example, a reasonable delivery charge might be allowed if you had to deliver a DMEPOS item to a beneficiary who lived outside your usual customer area and who had no access to another supplier located nearer. You must fully document these "unusual circumstances" on claims filed for delivery charges. These claims will be considered on an individual basis.

Same/Similar Equipment and Advance Beneficiary Notices (ABN)

CMS Manual System, Pub. 100-4, *Medicare Claims Processing Manual*, Chapter 30

This concerns ANSI Reason Code M3 - "Equipment is the same or similar to equipment already being used." See Chapter 17 of this manual for information about ANSI Reason Codes.

Numerous claims for durable medical equipment are denied because the equipment involved is the same as or similar to equipment already in the possession of the beneficiary. The statutory basis for denial of such claims is medical necessity; therefore, the limitation of liability provision under Section 1879 of the law applies. Backup equipment (standby and precautionary) has no coverage benefit and is considered not medically necessary. See the section *Backup Equipment* below.

Liability is assessed on claims denied based on "same or similar equipment." You are expected to be familiar with DME MAC coverage policies and any additional pertinent information that may have an impact on medical necessity determinations. In order to be protected under the limitation of liability provision, you must provide a proper advance beneficiary notice (ABN) for each item that you believe is likely to be denied as not medically necessary.

There must be a specific, identifiable reason to believe that Medicare may not pay for certain DME items (e.g., "same or similar equipment"). This means that you must obtain all the possible information from beneficiaries in order to determine whether "same or similar equipment" has previously been provided to that beneficiary. You should ask very specific questions when providing items to Medicare beneficiaries. When providing equipment to beneficiaries, the following information should always be obtained:

- The beneficiary's correct Medicare ID
- If the beneficiary has employer insurance or is enrolled in a Medicare Advantage Plan
- If the beneficiary currently has or had rental or ownership of an identical or similar item(s) in the past, you should obtain specific information about:
 - a. When the beneficiary received the item(s), and if the item(s) was returned, when and why
 - b. Who supplied the item(s)
 - c. CMN or DIF information
- Where the item will be used

- A signed and dated written order from the prescribing practitioner
- Clinical documentation that demonstrates any change in medical need

You may also access information about any previously submitted same or similar equipment through the CGS Interactive Voice Response System (IVR). This IVR information can be reached by calling 1.866.238.9650, selecting Option 2, and pressing 2 for CMN status. This option will provide CMN information on file for the procedure code entered and also CMN information on any similar equipment on file for a beneficiary. Facsimile CMN records are established in our system even for equipment which no longer requires actual CMNs (such as manual wheelchairs). For more information about the IVR, see Chapter 13 of this manual.

You should make certain that the beneficiary understands that items such as wheelchairs and power-operated vehicles are considered "similar equipment" and that Medicare will not cover both items when they are used simultaneously. You should strongly encourage the beneficiary to inform you if the medical need for the item changes and the beneficiary requires a different piece of equipment that serves a similar purpose. The Medicare program will only allow items that meet the beneficiary's current needs.

For example, if a beneficiary is renting a manual wheelchair and his/her condition worsens to the point that only a different wheelchair, such as a power wheelchair, will meet his/her medical need, coverage will be allowed for the power wheelchair and any subsequent claims for the manual wheelchair will be denied.

If there is no indication that same or similar equipment has been previously obtained, you would not have reason to provide an ABN. If the beneficiary or the beneficiary's authorized representative is unable to respond fully on the issue of "same or similar equipment," you may issue an ABN. In situations where the beneficiary is planning to use a piece of equipment as a backup (e.g., an extra wheelchair to keep in the car), you should ALWAYS obtain a signed ABN. In the event that you appeal a Medicare claim decision, you must submit a copy of the ABN with the appeal request (see Chapter 13 of this manual for information about appeals).

Same or similar rules may not necessarily apply to situations where a new device with additional technological features becomes available. The DME MAC or UPIC must evaluate whether the new feature(s) meets the beneficiary's medical need and that the need is not met by their current equipment. If the new feature or device meets a current medical need that is not met by the current equipment because the appropriate technology was not available at the time the beneficiary obtained the item, even if there has been no change in the beneficiary's condition, the five-year useful lifetime rules do not apply and the new item may be provided. However, if the new item is meeting the same medical need as the old item but in a more efficient manner or is more convenient, AND there is no change in the beneficiary's condition, Medicare will NOT reimburse for the new item.

The following examples illustrate these instructions:

1. The beneficiary receives a power wheelchair *without* power tilt/recline. Subsequently it is determined that the beneficiary needs a tilt/recline AND he/she has needed it since the provision of the initial power wheelchair. Often, the old wheelchair base will not accommodate the new tilt/recline system; therefore, in addition to the tilt/recline, you ask for a wheelchair base to be reimbursed. In this case one of the following options would apply:
 - A. If the old wheelchair is rented, an additional amount for the tilt/recline would be allowed but not a new rental period for the new wheelchair base.

- B. If the old wheelchair was purchased, only reimbursement of the tilt/recline would be allowed and not the purchase of a new wheelchair base.
2. Code E2101 represents a code for a home glucose monitor that integrates the lancing and application of blood to the glucose testing strip in one machine. The Glucose Monitors LCD allows payment for these devices for beneficiaries with manual dexterity problems. If a beneficiary had manual dexterity problems at the time that an E0607 monitor was purchased and the technology of monitors coded E2101 was not available at the time the beneficiary obtained the E0607, they would be allowed to purchase the E2101 to address their medical need for a monitor that accommodates their dexterity problem. No "same or similar" denial would apply. The E0607 did not accommodate their medical need and while their medical need did not change, technology changed such that their medical need could now be met by the new technology.

These rules apply when the new device with advanced features is classified by the same HCPCS code as the older device or when described by a different HCPCS code. If, however, the new device is described by a different code, the beneficiary must also meet the coverage criteria of the new item.

Pick-up Slips

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.12

Medicare regulation specifically forbids payments for multiple claims for rental of the same or similar equipment from either the same or a different supplier during the same rental month.

For purposes of this section, a pick-up slip is written confirmation, provided by you, that you have removed an item of DME from the beneficiary's home. When making determinations, DME MACs or UPICs must ascertain not only whether equipment is present in the home, but must determine which equipment is actually being used by the **beneficiary**. Therefore, it is inappropriate to determine, solely based on lack of a pick up slip that a piece of equipment may still be in use. Likewise, it is inappropriate for DME MACs or UPICs to deny claims solely based on lack of a pick up slip. DME MACs or UPICs should develop these claims to determine which piece of equipment is medically necessary.

Backup Equipment

Backup medical equipment is defined as an identical or similar device that is used to meet the same medical need for the beneficiary but is provided for precautionary reasons to deal with an emergency in which the primary piece of equipment malfunctions. **Medicare does not pay separately or make an additional payment for backup equipment.**

When a determination is made that if a particular piece of equipment breaks down or malfunctions it will result in immediate life-threatening consequences for the beneficiary, Medicare will place that item in the frequent and substantial servicing payment category (see Chapter 5 of this manual for information about payment categories). For items in this payment category, Medicare will reimburse for monthly rental payments for as long as the equipment is medically necessary. Consequently, you are responsible for ensuring that there is an appropriate and acceptable contingency plan to address any emergency situations or mechanical failures of the equipment.

The expectation is that an acceptable plan would involve input from the beneficiary and the treating practitioner and would take into account the severity of the beneficiary's condition and time restraints in providing emergency support. This means that you are responsible for ensuring that the beneficiary's medical needs for the use of this equipment will be met on a continuous and ongoing basis and that there is a plan to deal with any interruptions in the use of the equipment that would be

life-threatening to the beneficiary. The plan may be as simple as furnishing backup equipment; however, Medicare will not pay separately and/or make any additional payment for the backup equipment. The payment for the primary piece of equipment would include the cost of that piece of equipment and the frequent and substantial servicing plan that you must provide to ensure that the beneficiary always has a piece of equipment that is in working order. If the backup equipment is billed, it will be denied as not being reasonable and necessary.

Backup equipment must be distinguished from multiple medically necessary items that are defined as identical or similar devices, each of which meets a different medical need for the beneficiary. Although Medicare does not pay separately for backup equipment, Medicare will make separate payment for a second piece of equipment if it is required to serve a different purpose that is determined by the beneficiary's medical needs.

Examples (not all-inclusive) of situations in which multiple items may be covered are:

1. A beneficiary requires one type of ventilator (e.g., a negative pressure ventilator with a chest shell) for part of the day and needs a different type of device (e.g., positive pressure respiratory assist device with a nasal mask) during the rest of the day.
2. A beneficiary who is confined to a wheelchair requires a ventilator mounted on the wheelchair for use during the day and needs another ventilator of the same type for use while in bed. Without both pieces of equipment the beneficiary may be prone to certain medical complications, may not be able to achieve certain appropriate medical outcomes, or may not be able to use the medical equipment effectively.
3. A beneficiary requires one type of infusion pump for a particular drug (e.g., a pump with **beneficiary** control features for parenteral morphine) and needs a different type of pump for another drug (e.g., continuous infusion chemotherapy).

Examples (not all-inclusive) of situations in which a second or other multiple piece of equipment would be considered a backup and therefore would not be covered are:

1. A ventilator-dependent beneficiary is confined to bed and a second ventilator of the same or similar type is provided at the bedside as a precaution in case of malfunction of the primary ventilator.
2. The drug epoprostenol (Flolan®) is administered using an ambulatory infusion pump, and a second infusion pump is provided and billed as a precaution in case of malfunction of the primary pump. Because interruption of a continuous infusion of this drug results in immediate life-threatening consequences, a unique code, K0455, has been established for an infusion pump used to administer this drug, and the code is in the frequent and substantial servicing payment category.

Correct Coding

Correct coding is a determination that the item(s) provided to the beneficiary are billed using the appropriate HCPCS code for the item. You are required to correctly code for the items billed. An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, or MAC articles. Information that is sufficiently detailed to unambiguously identify the specific product delivered to the beneficiary and the HCPCS code used to bill for that item must be maintained by the supplier and be available upon request.

For LCDs that use ICD-10 diagnosis codes, correct coding of the ICD-10 code is required. A diagnosis is correctly coded when it meets all the coding guidelines listed in International

Classification of Diseases Guidelines (ICD), CMS ICD policy or guideline requirements, LCDs, or MAC articles. Information that is sufficiently detailed to unambiguously justify the ICD-10 code used to bill for DMEPOS items must be contained in the beneficiary's medical record and be available upon request.

Miscellaneous HCPCS Codes

Unusual services and items are generally reported to the contractor with miscellaneous HCPCS codes. These miscellaneous HCPCS codes do not have established fee schedule reimbursement rates. Each item/service is processed based on individual consideration. In these situations you must furnish documentation describing the service or item, manufacturer name, product name and number, supplier price list (PL) amount, and HCPCS code of related item (if applicable). If it is a customized option/accessory, the statement must clearly describe what was customized. When necessary, consultants' advice will be obtained.

If the description, manufacturer name, product name, and product number, supplier PL amount, and HCPCS code of related item (if applicable) are not provided with the claim, the claim will be rejected for missing information and you will be responsible for resubmitting the claims with the appropriate information.

Claims for option/accessory codes as a replacement must be submitted with the make and model name of the equipment base the item is being added to, the date of the purchase of the equipment base, and documentation of the medical necessity for the item.

The definitions of HCPCS codes are meant to be broadly inclusive. All related components are included in the codes and should generally not be billed separately unless specifically allowed in the definition or description of a HCPCS code. If you choose to bill separately for an included component, HCPCS code A9900 (miscellaneous DME supply, accessory and/or service component of another HCPCS code) must be used and will be denied as not separately payable. If an included component is billed with a miscellaneous HCPCS code, then that claim line will be rejected as incorrect coding.

11. Evidence of Medical Necessity: Power Mobility Devices (PMD)

CMS Manual System, Pub. 100-08, Medicare Program Integrity Manual, Chapter 5, §5.9.2

As the result of the way that the Social Security Act defines durable medical equipment, a power mobility device (PMD) is covered by Medicare only if the beneficiary has a mobility limitation that significantly impairs his/her ability to perform activities of daily living **within the home**. The beneficiary's mobility limitation cannot be sufficiently and safely resolved by the user of an appropriately fitted cane or walker. If the PMD is needed in the home, the beneficiary may also use it outside the home.

In order for Medicare to provide reimbursement for a PMD, there are several statutory requirements that must be met:

1. There must be an in-person practitioner-beneficiary encounter (*the in-person visit and medical examination together are often referred to as the "face-to-face" exam*). The practitioner may refer the beneficiary to a licensed/certified medical professional, such as a physical therapist (PT) or occupational therapist (OT), to perform part of the face-to-face examination. This person may have no financial relationship with the supplier.

2. The medical examination for the specific purpose of assessing the beneficiary's mobility limitation and needs must be recorded in the beneficiary's medical record.
3. The evaluation should be tailored to the individual beneficiary's conditions. The history should paint a picture of your beneficiary's functional abilities and limitations on a typical day. It should contain as much objective data as possible. The physical examination should be focused on the body systems that are responsible for the beneficiary's ambulatory difficulty or impact on the beneficiary's ambulatory ability. The evaluation must clearly distinguish the beneficiary's mobility needs within the home from their needs outside the home.
4. Documentation can also include copies of previous notes, consultations with other practitioners, and reports of pertinent laboratory, x-ray, or other diagnostic tests if they will help to support the severity of the beneficiary's ambulatory problems.
5. The prescription must only be written AFTER the in-person visit has occurred and the medical evaluation is completed. This prescription has seven required elements.
6. The prescription and medical records documenting the in-person visit and examination report must be sent to you, the equipment supplier, within 45 days of the completion of the examination. For those instances of a recently hospitalized beneficiary, you must receive the written order within 45 days after the date of discharge from the hospital.

You must document the receipt date with a date stamp or equivalent.

The written order, also referred to as the 7-element order, for the PMD must be written, signed, and dated by the treating physician or practitioner (a physician assistant, nurse practitioner, or clinical nurse specialist) who performed the face-to-face examination. The face-to-face examination requirement does not apply when only accessories for power mobility devices are being ordered.

The written order/prescription must contain the following seven 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 completion of the face-to-face examination.
4. Pertinent diagnoses/conditions that relate to the need for the PMD.
5. Length of need.
6. Prescribing physician/practitioner's signature.
7. Date the prescription was written.

Once you have determined the specific power mobility device that is appropriate for the beneficiary based on the practitioner's 7-element order, you must prepare a written document (termed a detailed product description). **This detailed product description (DPD) must comply with the requirements for a detailed written order as outlined in that section of this chapter** and the CMS Program Integrity Manual (CMS Manual System, Pub. 100-8), Chapter 5. Regardless of the form of the description, there must be sufficient detail to identify the item(s) in order to determine that the item(s) dispensed is properly coded.

The practitioner must sign and date the detailed product description and you must receive it prior to delivery of the power wheelchair or power operated vehicle. A date stamp or equivalent must be used to document your receipt date. The detailed product description must be available upon request.

An on-site home assessment must be conducted to consider the home's physical layout, doorway widths, doorway thresholds, and floor surfaces. The beneficiary's home must provide adequate access between rooms, maneuvering space, and surfaces for the operation of the PMD. The assessment must be done prior to or at the time of delivery of the PMD. The written report of this evaluation must be available on request.

You should refer to the individual medical policies for specific coverage and payment provisions.

As defined in the CMS Manual System (Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 3), if data analysis indicates potentially aberrant billing, contractors shall continue to follow the general guidance for performing medical review on claims.

For more information regarding mobility devices, please consult the appropriate LCD and Policy Article.

12. Comprehensive Error Rate Testing (CERT)

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 12

The Centers for Medicare & Medicaid Services (CMS) developed the Comprehensive Error Rate Testing (CERT) program to produce **the Medicare Fee-For-Service improper payment rate, a national, contractor-specific, and service-specific claims error rate**. The program has independent reviewers who periodically review representative random samples of Medicare claims. The independent reviewers medically review claims that are paid and claims that are denied to ensure the claim decision was appropriate. CERT was implemented in order to achieve goals of the Government Performance and Results Act of 1993, which sets performance measurements for Federal agencies.

Each month the CERT contractor selects a random sample of claims processed by each Medicare contractor, including the DME MACs. They then request medical records, Certificates of Medical Necessity, and supporting documentation from the provider of the service to verify services billed were delivered and medically necessary and that claims were processed appropriately. If you are contacted for a CERT review, you will be provided with the details regarding the needed information and how to submit it.

When no medical records or supporting documentation are received, a denial decision is made which ultimately results in a request for refund from the provider if the claim had been paid originally. These claims may be appealed through normal channels at the DME MAC (see Chapter 13 of this manual for information about appeals).

When records and/or documentation are received, the CERT contractor's medical review staff (includes nurses, physicians, and other qualified healthcare practitioners) then perform a complete review of the claims. If documentation fails to support the item(s) billed, an error is called and a refund will be requested. Documentation that supports the medical need will result in no further action needed by the provider.

Additional information about CERT may be found on the CMS website at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/index.html> or through our website at <https://www.cgsmedicare.com/jc/claims/cert/index.html>.