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Face-to-Face Examination and Prescription Requirements Prior to the Delivery of Certain DME Items Specified in the Affordable Care Act – Revised April 2016

DME MAC Joint Publication

This FAQ is revised to update the criteria associated with the written order prior to delivery and face-to-face examination. While this document makes reference to “ACA 6407 requirements”, technically these requirements are found in the Social Security Act Section 1843(a)(11)(B) and its implementing regulation at 42 CFR 410.38. 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.

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 written order for certain items of DME (Refer to Table A for a list of items).

These ACA 6407 requirements are effective for claims for all of the specified items that require a new order on or after July 1, 2013. DME MAC enforcement of these rules related to the face-to-face examination requirement and face-to-face documentation is delayed until further notice from CMS. This face-to-face examination enforcement delay does not apply to the Comprehensive Error Rate Testing (CERT) program contractor. In addition, this delay in enforcement does not apply to the prescription requirements for a Written Order Prior to Delivery/5EO or to the requirement to include the prescriber’s NPI on the prescription.

ACA 6407 also contained a provision requiring that an MD or DO co-sign the face-to-face examination performed by a PA, NP or CNS. This requirement was eliminated by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015.

Prescription (order) Requirements

A face-to-face examination is required each time a new prescription (i.e., written order) for one of the specified items in Table A 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

The first bullet above, 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. This means that all Medicare payment requirements must be met, the same as any other item initially covered by Medicare.

ACA 6407 requires a specific written order prior to delivery for the HCPCS codes specified in Table A below. This ACA 6407-required prescription has five (5) mandatory elements. The ACA 6407- required order is referred to as a 5-element order (5EO). The 5EO must meet all of the requirements below:

- The 5EO must include all of the following elements:
 - Beneficiary's name
 - Item of DME ordered - this may be general – e.g., “hospital bed”– or may be more specific.
 - Signature of the prescribing practitioner
 - Prescribing practitioner's National Practitioner Identifier (NPI)
 - The date of the order
- The 5EO must be completed within six (6) months after the required ACA 6047 face-to-face examination; and,
- The 5EO must be received by the supplier BEFORE delivery of the listed item(s); and,
- A date stamp or equivalent must be use to document the 5EO receipt date by the supplier.

Note that the 5EO for these specified DME items requires the National Provider Identifier to be included on the prescription. Prescriptions for other DME items do not have this NPI requirement.

For items that are provided based on a 5EO, the supplier must obtain a detailed written order before submitting a claim for any associated options, accessories and/or supplies that are separately billed and not listed on the table A below.

The 5EO must be available upon request.

For any of the specified items affected by the ACA 6407 requirements to be covered by Medicare, a written, signed and dated order (5EO) must be received by the supplier prior to delivery of the item. If the supplier delivers the item prior to receipt of a written order, it will be denied as statutorily noncovered. If the written order 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.

Note that the 5EO for these specified DME items require the National Provider Identifier (NPI) of the prescribing practitioner. Prescriptions for other DME items do not have this NPI requirement. Suppliers should pay particular attention to orders that include a mix of items, some of which are subject to these new 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.

Face-To-Face Examination Requirements

The treating practitioner must have a face-to-face examination with the beneficiary in the six (6) months prior to the date of the written order for the specified 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](#) [PDF](#) and [Chapter 12 of the Medicare Claims Processing Manual](#) [PDF](#) - CMS Internet-Only Manuals, Publ. 100-02 and 100-04, respectively).

For the treating 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.
- Remember that 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 Local Coverage Determination 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) to the DMEPOS supplier before the item can be delivered.

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 the 5EO and may be no older than 6 months prior to the 5EO 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.
- The DMEPOS supplier must have documentation of the completed 5EO in their 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, all DMEPOS suppliers must provide documentation from the qualifying face-to-face examination and the completed 5EO.

A date stamp (or equivalent) is required which clearly indicates the supplier's date of receipt of the completed 5EO.

Claim Denial

Claims for the specified items subject to these face-to-face requirements and prescription requirements that do not meet the requirements specified above will be denied as statutorily noncovered - failed to meet statutory requirements.

Local Coverage Determinations (LCD) [EXT](#)

LCDs that contain items subject to these requirements are:

- Automatic External Defibrillators
- Cervical Traction Devices
- External Infusion Pumps
- Glucose Monitors
- High-frequency Chest Wall Oscillation Devices
- Hospital Beds
- Manual Wheelchairs
- Mechanical In-exsufflation Devices
- Nebulizers
- Osteogenesis Stimulators
- Oxygen
- Patient Lifts
- Pneumatic Compression Devices
- Positive Airway Pressure Devices
- Pressure Reducing Support Surfaces
- Respiratory Assist Devices
- Seat Lift Mechanisms
- Speech Generating Devices
- Transcutaneous Electrical Joint Stimulation Devices (TEJSD)
- Transcutaneous Electrical Nerve Stimulators (TENS)
- Wheelchair options and Accessories
- Wheelchair Seating

These LCDs will be updated to include the requirements at a future date.

Numerous items are not included in a specific LCD. Some have coverage criteria described by National Coverage Determinations. Others have coverage determined on a case-by-case or individual-claim basis. This article and the associated CMS publications will constitute notice of these requirements for all of the applicable codes.

Refer to the applicable LCD, NCD and/or the Supplier Manual for additional information about 5EO requirements.

TABLE A: DME List of Specified Covered Items

The DME list of Specified Covered Items is as follows. The original list was at 77 FR 44798. This original list contains some codes (codes marked with an “*”) that have been deleted or that were made not valid for Medicare while other codes (codes marked with an “**”) have had narrative changes. Updates to the list will be made as CMS releases revisions.

Refer to the Pricing, Data Analysis and Coding Contractor web site for information on coding at:

<http://www.dmepdac.com> [EXT](#)

**HCPCS
Code**

Description

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
- Portable gaseous oxygen system rental includes portable container regulator flowmeter

- 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 mode 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

- 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

Functional neuromuscular stimulator, transcutaneous, stimulation of cranial nerve stimulation

- 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

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