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RE: FACE-TO-FACE AND WRITTEN ORDER REQUIREMENTS FOR HIGH COST DME - REVISED

This Dear Physician Letter 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 it's 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.

Dear Physician:

For certain specified items of durable medical equipment (see Table A), the Affordable Care Act requires:

- An in-person, face-to-face examination with the treating 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))* and,
- 2. The treating practitioner must document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered; and,
- 3. The face-to-face examination must have occurred sometime during the six (6) months prior to the date of the order for the item.
- * The Medicare Access and SCHIP Reauthorization Act of 2015 eliminated the ACA requirement that the NP, PA, or CNS face-to-face examination documentation be co-signed by an MD or DO.

The purpose of this letter is to provide additional details of these requirements.

Medicare rules stipulate that a face-to-face examination meeting the requirements discussed below be performed each time a new prescription (i.e., written order) for one of the specified items in Table A is written. A new prescription is required by Medicare:

· For all claims for purchases or initial rentals

- When an item is replaced
- When there is a change in the original order for the accessory, supply, drug, etc.
- When there is a change in the supplier
- 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

These requirements are effective for all new Medicare orders for the specified items in the Table A created on or after July 1, 2013.

Prescription (order) Requirements

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

Face-To-Face Examination Requirements

For Medicare beneficiaries, 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 and Chapter 12 of the Medicare Claims Processing Manual - 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 in-person visit occurred within the six (6) months prior to the date of their prescription; and,
- Have documentation of the face-to-face examination that was conducted.

Date and Timing Requirements

There are specific date and timing issues:

- 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 (prescription) must be on or before the date of delivery or Date of Service (DOS).
- · ALL DMEPOS suppliers must have the completed 5EO in their file BEFORE 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.

This letter is intended to be a general summary. It is not intended to take the place of the law, regulations, or national and local coverage determinations. Detailed information about these requirements can be found on the CMS website http://www.cms.gov or on the DME contractors' website.

Sincerely,

Wilfred Mamuya, MD, PhD Medical Director, DME MAC Jurisdiction A NHIC, Corp.

Stacey V. Brennan, MD, FAAFP Medical Director, DME MAC Jurisdiction B National Government Services Robert D. Hoover, Jr., MD, MPH, FACP Medical Director, DME MAC Jurisdiction C CGS Administrators, LLC

Peter Gurk, MD Medical Director, DME MAC Jurisdiction D Noridian Healthcare Solutions

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 that have been deleted or that were made not valid for Medicare (*) in the interim while some other codes 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.

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
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, liquid (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 E04670 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 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 Nebulizer, ultrasonic, large volume E0580 Nebulizer, ultrasonic, large volume E0580 Nebulizer with compressor & heater E0691 Continuous airway pressure device E0601 Continuous airway pressure device E0602 Separate Seat lift mechanism for patient owned furniture electric E0629 Separate seat lift mechanism for patient owned furniture electric E0629 Separate seat lift mechanism for patient owned furniture non-electric	HCPCS Code	Description
E0442 Oxygen contents, liquid (1 months supply) E0443 Portable Oxygen contents, gas (1 months supply) E0444 Portable oxygen contents, gas (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 vent 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 E0580 Nebulizer with compressor E0575 Nebulizer, ultrasonic, large volume E0580 Nebulizer with compressor & heater E0601 Continuous airway pressure device E0607 Home blood glucose monitor E0627 Seat lift mechanism incorporated lift-chair E0629 Separate seat lift mechanism for patient owned furniture electric	E0439	
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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	E0601	Continuous airway pressure device
E0628 Separate Seat lift mechanism for patient owned furniture electric E0629 Separate seat lift mechanism for patient owned furniture non-electric	E0607	Home blood glucose monitor
E0629 Separate seat lift mechanism for patient owned furniture non-electric	E0627	Seat lift mechanism incorporated lift-chair
	E0628	Separate Seat lift mechanism for patient owned furniture electric
E0636 Multi positional patient support system, with integrated lift, patient accessible controls	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	E0650	Pneumatic compressor non-segmental home model
E0651 Pneumatic compressor segmental home model without calibrated gradient pressure	E0651	Pneumatic compressor segmental home model without calibrated gradient pressure
E0652 Pneumatic compressor segmental home model with 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	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	E0656	Non- segmental pneumatic appliance for use with pneumatic compressor on trunk
E0657 Non- segmental pneumatic appliance for use with pneumatic compressor chest	E0657	Non- segmental pneumatic appliance for use with pneumatic compressor chest
E0660 Non- segmental pneumatic appliance for use with pneumatic compressor on full leg	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	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	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	E0667	Segmental pneumatic appliance for use with pneumatic compressor on full-leg
E0668 Segmental pneumatic appliance for use with pneumatic compressor on full arm	E0668	Segmental pneumatic appliance for use with pneumatic compressor on full arm
E0669 Segmental pneumatic appliance for use with pneumatic compressor on half leg	E0669	Segmental pneumatic appliance for use with pneumatic compressor on half leg
E0671 Segmental gradient pressure pneumatic appliance full leg	E0671	Segmental gradient pressure pneumatic appliance full leg

Description
Segmental gradient pressure pneumatic appliance full arm
Segmental gradient pressure pneumatic appliance half leg
Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency
Ultraviolet light therapy system panel treatment 4 foot panel
Ultraviolet light therapy system panel treatment 6 foot panel
Ultraviolet multidirectional light therapy system in 6 foot cabinet
Transcutaneous electrical nerve stimulation, two lead, local stimulation
Transcutaneous electrical nerve stimulation, four or more leads, for multiple nerve stimulation
Form fitting conductive garment for delivery of TENS or NMES
Incontinence treatment system, Pelvic floor stimulator, monitor, sensor, and/or trainer
Neuromuscular stimulator for scoliosis
Neuromuscular stimulator electric shock unit
Osteogenesis stimulator, electrical, non-invasive, other than spine application.
Osteogenesis stimulator, electrical, non-invasive, spinal application
Osteogenesis stimulator, electrical, surgically implanted
Osteogenesis stimulator, low intensity ultrasound, non-invasive
Transcutaneous electrical joint stimulation system including all accessories
Functional neuromuscular stimulator, transcutaneous stimulations of muscles of ambulation with computer controls
FDA approved nerve stimulator for treatment of nausea & vomiting
Infusion pumps, implantable, Non-programmable
Infusion pump, implantable, Programmable
External ambulatory infusion pump
Implantable programmable infusion pump, replacement
Tract frame attach to headboard, cervical traction
Traction equipment cervical, free-standing stand/frame, pneumatic, applying traction force to other than mandible
Traction stand, free standing, cervical traction
Cervical traction equipment not requiring additional stand or frame
Cervical traction device, cervical collar with inflatable air bladder
Manual wheelchair accessory, one-arm drive attachment
Manual wheelchair accessory-adapter for Amputee
Manual wheelchair accessory, shoulder harness/strap
Manual wheelchair accessory wheel lock brake extension handle
Manual wheelchair accessory, headrest extension
Manual wheelchair accessory, hand rim with projections
Commode seat, wheelchair
Narrowing device wheelchair
Manual wheelchair accessory anti-tipping device
Manual wheelchair accessory, adjustable height, detachable armrest
Manual wheelchair accessory anti-rollback device
Manual wheelchair accessory positioning belt/safety belt/ pelvic strap
Manual wheelchair accessory safety vest

HCPCS Code	Description
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

HCPCS Code	Description
K0001	Standard wheelchair
K0002	Standard hemi (low seat) wheelchair
K0003	Lightweight wheelchair
K0004	High strength Itwt 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