DME Happenings

Jurisdiction D

Issue No. 51 June 2016

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Jurisdiction D DME MAC Supplier Contacts and Resources

Phone Numbers				
Interactive Voice Response System	1-877-320-0	0390	24 hours a day, 7 days a week for Eligibility and general information	
			6 am – 8 pm CT Menu options requiring system access: Same and Similar HCPCS Lookup, Claim Status, Payment Floor, Checks, Duplicate Remittance Advice, Overpayments, Provider Enrollment, Appeals Status and CMN Status	
Supplier Contact Center	1-877-320-0	0390	8 am – 6 pm CT Monday-Friday	
Telephone Reopenings	1-877-320-0	0390	8 am – 4:30 pm CT	
Beneficiary Customer Service	1-800-633-	4227	24 hours a day/7 days a week	
Website: www.noridianmedicare.co	m/dme			
Fax				
Reopenings and Redeterminations MSP Inquiries and Refunds DME Recovery Auditor Redeterminations	6		1-701-277-7886	
Refunds to Medicare Immediate Offsets			1-701-277-7894	
DME Recovery Auditor Offsets			1-701-277-7896	
Medical Review Medical Documentation			1-701-277-7888	
CERT Medical Documentation			1-701-277-7890	
Noridian Email Addresses				
Noridian DME Customer Service		dme@r	noridian.com	
Reopenings and Redeterminations		<u>dmerec</u>	leterminations@noridian.com	
Noridian DME Endeavor		dmeendeavor@noridian.com		
Mailing Addresses				
Claims, Redetermination Requests, Correspondence, ADMC Requests and Medical Review Documentation Noridian PO Box 6727 Fargo ND 58108-6727		Noridiar Benefit PO Box	Protection-DME	
Administrative Simplification Complia Exception Requests Noridian PO Box 6737 Fargo ND 58108-6737	nce Act	C2C So Attn: D PO Box	ed Independent Contractor Jutions, Inc. ME QIC 44013 hville FL 32231-4013	
Electronic Funds Transfer Forms/ Overpayment Redeterminations/ DME Recovery Auditor Redetermination Noridian PO Box 6728 Fargo ND 58108-6728	ons	Noridia PO Box		

CONTACT US

Other DME MACs		
Jurisdiction A: NHIC, Corp	1-866-419-9458	www.medicarenhic.com
Jurisdiction B: National Government Services	1-877-299-7900	www.ngsmedicare.com
Jurisdiction C: CGS	1-866-270-4909	www.cgsmedicare.com
Other Resources		
Pricing, Data Analysis and Coding	1-877-735-1326	www.dmepdac.com
National Supplier Clearinghouse	1-866-238-9652	www.palmettogba.com/nsc
Common Electronic Data Interchange Help Desk	1-866-311-9184	www.ngscedi.com
Centers for Medicare & Medicaid Services		www.cms.gov

FYI

Automatic Mailing/Delivery of DMEPOS Reminder

Suppliers may not automatically deliver DMEPOS to beneficiaries unless the beneficiary, physician, or designated representative has requested additional supplies/equipment. The reason is to assure that the beneficiary actually needs the DMEPOS.

A beneficiary or their caregiver must specifically request refills of repetitive services and/or supplies before a supplier dispenses them. The supplier must not automatically dispense a quantity of supplies on a predetermined regular basis.

A request for refill is different than a request for a renewal of a prescription. Generally, the beneficiary or caregiver will rarely keep track of the end date of a prescription. Furthermore, the physician is not likely to keep track of this. The supplier is the one who will need to have the order on file and will know when the prescription will run out and a new order is needed. It is reasonable to expect the supplier to contact the physician and ask for a renewal of the order. Again, the supplier must not automatically mail or deliver the DMEPOS to the beneficiary until specifically requested.

Source: Internet Only Manual (IOM), Publication 100-4, Medicare Claims Processing Manual, Chapter 20, Section 200

Beneficiaries Call 1-800-MEDICARE

Suppliers are reminded that when beneficiaries need assistance with Medicare questions or claims that they should be referred to call 1-800-MEDICARE (1-800-633-4227) for assistance. The supplier contact center only handles inquiries from suppliers.

The table below provides an overview of the types of questions that are handled by 1-800-MEDICARE, along with other entities that assist beneficiaries with certain types of inquiries.

Organization	Phone Number	Types of Inquiries
1-800-MEDICARE	1-800-633-4227	General Medicare questions, ordering Medicare publications or taking a fraud and abuse complaint from a beneficiary
Social Security Administration	1-800-772-1213	Changing address, replacement Medicare card and Social Security Benefits
RRB – Railroad Retirement Board	1-800-808-0772	For Railroad Retirement beneficiaries only - RRB benefits, lost RRB card, address change, enrolling in Medicare
Coordination of Benefits	1-800-999-1118	Reporting changes in primary insurance information

Another great resource for beneficiaries is the website, http://www.medicare.gov/, where they can:

- Compare hospitals, nursing homes, home health agencies, and dialysis facilities
- Compare Medicare prescription drug plans
- Compare health plans and Medigap policies
- Complete an online request for a replacement Medicare card
- Find general information about Medicare policies and coverage
- Find doctors or suppliers in their area
- Find Medicare publications
- Register for and access MyMedicare.gov

As a registered user of MyMedicare.gov, beneficiaries can:

- View claim status (excluding Part D claims)
- Order a duplicate Medicare Summary Notice (MSN) or replacement Medicare card
- View eligibility, entitlement and preventive services information
- View enrollment information including prescription drug plans
- View or modify their drug list and pharmacy information
- View address of record with Medicare and Part B deductible status
- Access online forms, publications and messages sent to them by CMS

CMS Quarterly Provider Updates

The Quarterly Provider Update is a listing of non-regulatory changes to Medicare including Program Memoranda, manual changes, and any other instructions that could affect providers or suppliers. This comprehensive resource is published by CMS on the first business day of each quarter. Regulations and instructions published in the previous quarter are also included in the Update. The purpose of the Quarterly Provider Update is to:

- Inform providers about new developments in the Medicare program;
- Assist providers in understanding CMS programs ad complying with Medicare regulations and instructions;

- Ensure that providers have time to react and prepare for new requirements;
- Announce new or changing Medicare requirements on a predictable schedule; and
- Communicate the specific days that CMS business will be published in the Federal Register.

The Quarterly Provider Update can be accessed at http://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/index.html. Suppliers may also sign up to receive notification when regulations and program instructions are added throughout the quarter on this page.

Medicare Learning Network Matters Disclaimer Statement

Below is the Centers for Medicare & Medicaid (CMS) Medicare Learning Network (MLN) Matters Disclaimer statement that applies to all MLN Matters articles in this bulletin.

"This article was prepared as a service to the public and is not intended to grant rights or impose obligations. MLN Matters articles may contain references or links to statutes, regulations or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents."

Sources for "Jurisdiction D Happenings" Articles

The purpose of "Jurisdiction D Happenings" is to educate Noridian's Durable Medical Equipment supplier community. The educational articles can be advice written by Noridian staff or directives from CMS. Whenever Noridian publishes material from CMS, we will do our best to retain the wording given to us; however, due to limited space in our bulletins, we will occasionally edit this material. Noridian includes "Source" following CMS derived articles to allow for those interested in the original material to research it at CMS's website, <u>http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html</u>. CMS Change Requests and the date issued will be referenced within the "Source" portion of applicable articles.

CMS has implemented a series of educational articles within the Medicare Leaning Network (MLN), titled "MLN Matters", which will continue to be published in Noridian bulletins. The Medicare Learning Network is a brand name for official CMS national provider education products designed to promote national consistency of Medicare provider information developed for CMS initiatives.

CMS Manual System – Department of Health & Human Services (DHHS)

Pub 100-04 Medicare Claims Processing Transmittal 3491 Centers for Medicare & Medicaid Services (CMS) Date: April 5, 2016 Change Request 9468

Transmittal 3444, dated January 29, 2016, is being rescinded and replaced by Transmittal 3491 to amend business requirement 9468.25. All other information remains the same.

SUBJECT: Payment for Purchased Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Furnished to Medicare Beneficiaries Residing Outside the U.S. - Expatriate Beneficiaries

 SUMMARY OF CHANGES: In accordance with the Social Security Act, claims for purchased Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) provided to Medicare beneficiaries living outside the U.S. are payable as long as the delivery occurred while the beneficiary was in the U.S. at the time the service was rendered. However, Medicare claims systems are currently not designated to accept and process claims submitted for DMEPOS furnished to eligible beneficiaries living abroad (expatriate beneficiaries).

This transmittal directs the Centers for Medicare & Medicaid Services (CMS) shared systems maintainers to implement claims processing systems changes to allow expatriate beneficiary claims to process and pay for purchased items when certain criteria are met in accordance with Medicare policy.

EFFECTIVE DATE: July 1, 2016

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

IMPLEMENTATION DATE: July 5, 2016

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

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

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
Ν	20/30.9.1/Processing of Expatriate Beneficiary DMEPOS Claims for Purchased Items with the EX Modifier
R	24/90/Mandatory Electronic Submission of Medicare Claims

3. FUNDING: For Medicare Administrative Contractors (MACs):

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

4. ATTACHMENTS:

Business Requirements Manual Instruction

Attachment – Business Requirements

Pub. 100-04	Transmittal: 3491	April 5, 2016	Change Request: 9468

Transmittal 3444, dated January 29, 2016, is being rescinded and replaced by Transmittal 3491 to amend business requirement 9468.25. All other information remains the same.

SUBJECT: Payment for Purchased Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Furnished to Medicare Beneficiaries Residing Outside the U.S. - Expatriate Beneficiaries

EFFECTIVE DATE: July 1, 2016

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

IMPLEMENTATION DATE: July 5, 2016

1. GENERAL INFORMATION

A. Background: Section 1862(a)(4) of the Social Security Act (the Act) requires that no payment may be made under Part A or Part B for services "which are not provided within the U.S. (except for inpatient hospital services furnished outside the U.S. under conditions described in section 1814(f) and, subject to such conditions, limitations, and requirements are provided under or pursuant to [title 18 of the Act], physicians' services and ambulance services furnished an individual in conjunction with such inpatient hospital services but only for the period during which such inpatient hospital services were furnished)".

Currently, the Medicare claims processing systems are not designed to accept and process claims submitted for DMEPOS furnished to Medicare beneficiaries whose permanent address is abroad (expatriate beneficiaries) even if the DMEPOS is furnished in the U.S.

The purpose of this transmittal is to require the Centers for Medicare & Medicaid Services (CMS) Medicare shared system maintainers (GDIT, and Acentia), and the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) to allow expatriate beneficiary claims submitted on paper to process and pay when certain criteria are met, according to Medicare policy.

B. Policy: Medicare law (i.e., Section 1862(a)(4) of the Social Security Act (the Act)) prohibits payment for items and services furnished outside the United States except for certain limited services (see section 1814(f) of the Act). The term "United States" means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, the Northern Mariana Islands, American Samoa and, for purposes of services rendered on a ship, includes the territorial waters adjoining the land areas of the United States.

Currently, Medicare's claims processing systems are not designed to accept and process claims submitted for purchased Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) furnished *to* a Medicare beneficiary whose address is outside the United States. However, if a purchased DMEPOS item or service is provided to that beneficiary while he or she is in the United States, then that claim is not subject to the payment exclusion at section 1862(a)(4) of the Act and should be processed by Medicare's claims processing systems. The purpose of this CR is to implement the necessary coding changes so that these types of claims are accepted and processed by Medicare.

The Supplier will be required to submit paper claims directly to the DME MAC of its jurisdiction. To meet the needs of processing expatriate claims, CMS has instituted the EX modifier to identify the supplier's attestation on the claim that the beneficiary was in the U.S. at the time the service was rendered.

For beneficiary-submitted claims, submitted using the 1490S form, the beneficiary must also provide the supplier attestation, either in the form of a supplier-written statement or a copy of the supplier 1500 form including the EX modifier.

Reimbursement checks should not be sent to countries where payment is barred by Treasury Department regulations as is cited in 31 U.S.C. sec. 3329(a) and 31 CFR sec. 211.1. Currently, those countries are Cuba and North Korea.

2. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Resp	oonsib	oility						
		A/B			DME MAC	Other				
		Α	В	HHH		FISS	MCS	VMS	CWF	
9468.1	Contractors shall modify systems to accept and process paper claims submitted by suppliers/ vendors for purchased only DMEPOS for expatriate bn				X			Х		
9468.2	The contractor shall add a new indicator to the VMS claim record to allow the new expatriate (EX) modifier to be included for claims that require 4 modifiers for processing.							Х		

	Requirement	Res	ponsib	oility						
		A/B	A/B MAC				ed-Sys [.] tainers			Othe
		Α	В	HHH		FISS	MCS	VMS	CWF	
9468.3	VMS shall send the EX modifier with the claim to the CWF as an indicator to ensure accurate processing when the modifiers reported on the claim exceed the modifier limit available on the claim.							X		
9468.3.1	The contractor shall revise the values in the beneficiary state and ZIP code fields that are sent to CWF in the HUDC query for beneficiaries that reside outside of the US.							X		
9468.3.2	The contractor shall send to VMS new edit(s) when the claims does not have the EX modifier/indicator but the CWF has a foreign address, and when the claim has the EX modifier and the beneficiary resides in the U.S. This edit should be overridable.								X	
9468.3.3	The contractor shall accept the new CWF edit and allow it to be overridden.							Х		
9468.4	The contractor shall make VMS system changes that will allow the pricing state or ZIP Code to be changed by the operator when it is used for pricing an expatriate claim.							X		

Number	Requirement	Res	oonsib	oility						
					DME MAC		ed-Syst tainers			Othe
		Α	В	HHH		FISS	MCS	VMS	CWF	
9468.5	Contractors shall deny all claims for expatriate beneficiaries which do not contain the EX modifier indicating this is an expatriate claim and attesting that the beneficiary was in the U.S. when the item was supplied. Contractors shall use the following CARC and MSN:				X					
	CARC 180: Patient has not met the required residency requirements.									
	MSN 41.14: This service/ item was billed incorrectly. (Este servicio o artículo fue facturado incorrectamente.)									
	Group Code: CO									
	NOTE: For purchased items only furnished on or after July 1, 2016, contractors shall accept the EX modifier for processing. The EX modifier must be on all claims lines.									
9468.6	Contractors shall deny beneficiary-submitted 1490s claim forms for expatriate claims without an attached 1500 supplier form with the EX modifier or when written supplier attestation is not provided. Contractors shall use the following CARC and MSN:				X					
	CARC 180: Patient has not met the required residency requirements.									
	MSN 41.14: This service/ item was billed incorrectly. (Este servicio o artículo fue facturado incorrectamente.)									
	Group Code: PR									

Number	Requirement	nt Responsibility								
		A/B	MAC		DME MAC		ed-Syst tainers			Other
		Α	В	HHH		FISS	MCS	VMS	CWF	
9468.7	CEDI shall reject any claim submitted electronically with an EX modifier (indicating the claim is for an expatriate beneficiary) on any claim line(s).									CEDI
9468.8	Contractors shall relax Administration Simplification Compliance Act (ASCA) requirements for paper expatriate claims (with the EX modifier) by bypassing the ASCA edits for electronic submission requirements.				x			×		
9468.9	DME MACs shall only process paper claims submitted for expatriate beneficiaries.				Х					
9468.10	Contractors shall deny any mail order claims for expatriates, this includes National Mail Order (NMO) claims. Suppliers should not submit NMO or any mail order claims for expatriate beneficiaries.				X			X		
	CARC 180: Patient has not met the required residency requirements.									
	MSN 41.14: This service/ item was billed incorrectly. (Este servicio o artículo fue facturado incorrectamente.)									
	Group Code: CO									
K	NOTE: There is no way to determine if the beneficiary was present in the U.S. at the time of the delivery of any mail order supplies, therefore these claims will not be accepted for expatriate beneficiaries.									

Number	Requirement									
		A/B MAC			DME MAC		ed-Syst tainers			Other
		Α	В	HHH		FISS	MCS	VMS	CWF	
9468.11	Contractors shall deny an expatriate claim if a paper claim is received with a U.S. address (this includes P.O. Box or Lock Box) and an EX modifier for invalid use of a modifier.				Х					
9468.12	Contractors shall apply Competitive Bid Program rules to expatriate claims.							X		
	NOTE: An exception for the submission of paper claims and CBP is being granted for expatriate claims.									
9468.13	Contractors shall not allow expatriate claims to use the CBP traveling modifier (KT) when the EX modifier is used for an expatriate beneficiary.							X		
9468.14	The contractor shall allow APO/FPO addresses on CWF trailer 12 and on CWF HUAD unsolicited address update transactions to update the VMS Beneficiary Master file.							Х		
9468.15	Contractors shall apply all existing claims/consistency edits to expatriate beneficiary claims.				Х			Х		
9468.16	Contractors shall apply all existing policy limits for the allowed number/months for any item.				Х			Х		
9468.17	Contractors shall pay claims with the EX modifier for Expatriate beneficiaries based on supplier locality.				Х			Х		

Number	Requirement	Responsibility									
					DME MAC		ed-Sys tainers			Other	
		Α	В	HHH		FISS	MCS	VMS	CWF		
9468.18	The contractors shall reject a DMEPOS item if the claim is submitted with a foreign address, and no 'EX' indicator is present on the line item and the beneficiary has a foreign address in CWF. This edit shall have override capabilities in the detail line.				X			X	X		
	CARC 180 - Patient has not met the required residency requirements.										
9468.19	The contractors shall reject a DMEPOS item if the claim is submitted with a foreign address, and the 'EX' indicator is present on the line item and the beneficiary does not have a foreign address in CWF. This edit shall have override capabilities in the detail line.				X			X	X		
	CARC 180 - Patient has not met the required residency requirements.										
9468.20	The contractor shall create a separate file for Medicare Summary Notice (MSN) correspondence for expatriate beneficiaries and deliver it to the DME MACs. Standard format MSNs for expatriate beneficiaries shall be created in English or Spanish, depending on the beneficiary preference and will be in separate files from other MSNs.							X			
9468.20.1	The contractor shall separate MSN files that are to be created for expatriate beneficiary claims from the existing weekly process. The expatriate MSNs will generate weekly rather than on the rotating 12- week cycle.							X			

Number	Requirement	Res	oonsib	oility						
					DME MAC		ed-Sys [.] tainers			Other
		Α	В	HHH		FISS	MCS	VMS	CWF	
9468.21	Contractors shall not hold beneficiary MSNs for expatriate claims, and should send the MSN as soon as the claim comes off of the payment floor.				X					
9468.22	DME MACs shall manually label and mail MSNs to beneficiaries using the file provided by VMS.				Х					
9468.23	Contractors shall not allow payment for HCPCS codes in the following categories for expatriate beneficiaries (with the EX modifier appended):				×			X		
	- Oxygen Equipment and Supplies									
	- Parenteral and Enteral Nutrition Equipment and Supplies									
	- Rentals - capped or inexpensive, routinely purchased (IRP).									
9468.24	Contractors shall use the following messages when denying claims with modifier EX and HCPCS for Oxygen and supplies, PEN, and rentals (capped or IRP) for expatriates.				Х			X		
	CARC 180: Patient has not met the required residency requirements.									
	MSN 41.14: This service/ item was billed incorrectly. (Este servicio o artículo fue facturado incorrectamente.)									
0.400.05	Group Code: CO								X	
9468.25	The contractor shall accept the new 'EX' indicator, and shall also modify consistency edits to bypass when the claim is for an expatriate beneficiary.								Х	

Number	Requirement	Responsibility								
		A/B	A/B MAC				ed-Syst tainers			Other
		Α	В	HHH		FISS	MCS	VMS	CWF	
9468.26	The CWF contractor shall create a new two-byte field in the detail line for the DMEPOS claim.							X	X	FPS, NCH, PDAC
9468.27	The contractor shall modify existing consistency edits that read "Bene State Codes" including UR 5291 to bypass when the new 'EX' indicator is present.								X	
9468.28	The contractors shall issue a beneficiary reimbursement check if the beneficiary has paid for the DMEPOS to the most current address, with the exception of checks should not be sent to countries where payment is barred by Treasury Department regulations. (See 31 U.S.C. sec. 3329(a) and 31 CFR sec. 211.1 - Currently, those countries are Cuba and North Korea.)				×			X		

3. PROVIDER EDUCATION TABLE

Numbe	er Requirement	Responsibility				
		A/B MAC		DME	CEDI	
		Α	В	HHH	MAC	
9468.29	CR as Provider Education: Contractors shall post this entire instruction, or a direct link to this instruction, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the entire instruction must be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement it with localized information that would benefit their provider community in billing and administering the Medicare program correctly.				X	X

4. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: $\ensuremath{\mathsf{N/A}}$

"Should" denotes a recommendation.

X-Ref Requirement Number Recommendations or other supporting information:

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

5. CONTACTS

Pre-Implementation Contact(s): Diana Motsiopoulos, diana.motsiopoulos@cms.hhs.gov, Teira Canty, teira.canty@cms.hhs.gov, Frederick Grabau, frederick.grabau@cms.hhs.gov (Policy Contact)

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

6. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

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

ATTACHMENTS: 0

Medicare Claims Processing Manual

Chapter 20 – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

Table of Contents (Rev. 3491, Issued: 04-05-16)

Transmittals for Chapter 20

30.9.1 – Processing of Expatriate Beneficiary DMEPOS Claims for Purchased Items Submitted with the EX Modifier

30.9.1 – Processing of Expatriate Beneficiary DMEPOS Claims for Purchased Items Submitted with the EX Modifier

(Rev.3491, Issued: 04-05-16, Effective: 07-01-16, Implementation: 07-05-16)

In accordance with section 1862(a)(4) of the Social Security Act, claims for DMEPOS provided to Medicare beneficiaries living outside of the U.S. are payable as long as the delivery occurred while the beneficiary was in the U.S. and the item is delivered to a U.S. address.

Effective July 1, 2016, the modifier EX was developed to allow suppliers to bill Medicare for purchased only DMEPOS items that are furnished to expatriate beneficiaries. Suppliers should submit these claims based on their supplier locality, not based on the beneficiary address. By attaching the EX modifier, the supplier is attesting that the beneficiary is an expatriate beneficiary, and that the item was delivered/furnished while the beneficiary is present in the U.S., and all other billing criteria has been met.

For purchased items only furnished on or after July 1, 2016, contractors shall accept the EX modifier for processing. Contractors shall pay claims with the EX modifier for Expatriate beneficiaries based on supplier locality.

Suppliers shall append modifier EX on all lines with a line item date of service. Contractors shall automatically deny the claim(s), when all line(s) items have not been submitted with an EX modifier.

If a beneficiary-submitted claim (1490S) is received, written attestation from the supplier must also be included. Contractors shall deny the 1490S claim form with or without an EX modifier if a supplier 1500 claim form including the EX modifier or a written supplier attestation that the beneficiary was in the U.S. when the service was rendered is not included with the 1490S.

The following items for expatriate beneficiary claims are not payable and should be denied:

- Oxygen Equipment and Supplies
- Parenteral and Enteral Nutrition Equipment and Supplies
- Rentals capped or inexpensive, routinely purchased (IRP)

Contractors will apply National Mail Order (NMO) rules to expatriate claims.

NOTE: P.O. Boxes and Lock Boxes are not allowed for NMO or any delivery of supplies for expatriate claims, and must be delivered to the beneficiary residence.

National Competitive Bid Program (CBP) rules shall apply to expatriate claims. NOTE: An exception for the submission of paper claims for CBP is being granted for expatriate claims.

The supplier must send paper claims to the supplier's jurisdiction for processing. If this attestation is determined to be inaccurate, the supplier is subject to sanctions resulting from providing inaccurate information on a claim.

Medicare Claims Processing Manual

Chapter 24 – General EDI and EDI Support Requirements, Electronic Claims, and Mandatory Electronic Filing of Medicare Claims

Table of Contents (Rev.3491, Issued: 04-05-16)

Transmittals for Chapter 24

90 – Mandatory Electronic Submission of Medicare Claims

(Rev.3491, Issued: 04-05-16, Effective: 07-01-16, Implementation: 07-05-16)

Section 3 of the Administrative Simplification Compliance Act (ASCA), Pub.L. 107-105, and the implementing regulation at 42 CFR 424.32 require that all initial claims for reimbursement under Medicare, except from small providers, be submitted electronically as of October 16, 2003, with limited exceptions. Initial claims are those claims submitted to a A/B MAC or DME MAC for the first time, including resubmitted previously rejected claims, claims with paper attachments, demand bills, claims where Medicare is the secondary payer, and non-payment claims. Initial claims do not include adjustments or claim corrections submitted A/B MAC or DME MAC on previously submitted claims or appeal requests.

Medicare is prohibited from payment of claims submitted in a non-electronic manner that do not meet the limited exception criteria. Claims required to be submitted electronically effective October 16, 2003, and later must comply with the appropriate claim standards adopted for national use under HIPAA (see section 70 of this chapter). The mandatory electronic claim submission requirement does not apply to claims submitted by beneficiaries or by providers that only furnish services outside of the United States, claims submitted to Medicare managed care plans, to health plans other than Medicare, or for purchased only Expatriate beneficiary Durable Medical Equipment Prosthetics Orthotics Supplies (DMEPOS) claims.

Implementation of the Award for Jurisdiction B DME MAC Workload – Revised

MLN Matters[®] Number: MM9526 Revised Related Change Request (CR) #: CR 9526 Related CR Release Date: March 11, 2016 Effective Date: January 4, 2016 Related CR Transmittal #: R16360TN Implementation Date: July 1, 2016

The article was revised on March 17, 2016, to change the implementation date and modify language regarding submission of certain claims in paragraph 2 of the Background section.

Provider Types Affected

This MLN Matters® Article is intended for DME suppliers submitting claims to Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) for supplies and services provided to Medicare beneficiaries residing in Jurisdiction B (JB), which includes the states of Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, and Wisconsin.

What You Need to Know

Change Request (CR) 9526 announces the Centers for Medicare & Medicaid Services (CMS) awarded CGS Administrators, LLC (CGS) a new contract for the administration of Medicare Fee-for-Service claims for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) in Jurisdiction B. The incumbent is National Government Services (NGS). Make sure that your billing staffs are aware of this change.

Background

On September 3, 2015, CMS awarded CGS, a new contract for the administration of Medicare Fee-for-Service claims for DMEPOS in Jurisdiction B. CGS is based at Two Vantage Way, Nashville, Tennessee TN 37228. NGS is the incumbent contractor located at 8115 Knue Road Indianapolis, IN 46250.

Medicare DMEPOS suppliers serving Jurisdiction B beneficiaries should continue to submit their paper claims to NGS until CMS completes the transition of Jurisdiction B (JB) operations to CGS. Electronic claims should continue to be submitted to the Common Electronic Data Interchange (CEDI) both prior to and post transition.

CMS has determined that the JB workload currently processed by NGS will require a new workload number when transitioned. The JB DME MAC workload number 17013 will be effective on the implementation date of CR9526.

All relevant Medicare systems will be modified to the new JB DME workload number 17013 as of the implementation date of CR9526. Upon the release of CR9526, NGS will prepare an article explaining the DME MAC workload number changes they currently process and NGS will post this article, or a direct link to this article, on its website and include information about it in a listserv message as soon as possible but no later than 30 days prior to the effective date of applicable workload transition.

Additional Information

The official instruction, CR9526, issued to your MAC regarding this change, is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1636OTN.pdf on the CMS website.

Implementation of the Award for Jurisdiction A DME MAC Workload – Second Revision

MLN Matters® Number: MM9546 Revised Related Change Request (CR) #: CR 9546 Related CR Release Date: April 19, 2016 Effective Date: December 16, 2015 Related CR Transmittal #: R16420TN Implementation Date: July 1, 2016

This article was revised on April 22, 2016, to correct the Noridian address in the Background Section. The transmittal number, Change Request (CR) release date and link to the transmittal also changed. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for DME suppliers submitting claims to the Medicare Durable Medical Equipment Administrative Contractor (DME MACs) in Jurisdiction A, which serves Medicare beneficiaries who reside in the states of Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont, and the District of Columbia

What You Need to Know

CR 9546 announces the Centers for Medicare & Medicaid Services (CMS) awarded Noridian Healthcare Solutions, LLC (Noridian), a new contract for the administration of Medicare Fee-for-Service claims for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) in Jurisdiction A (JA). Make sure that your billing staffs are aware of these changes.

Background

On December 16, 2015, CMS awarded Noridian Healthcare Solutions, LLC (Noridian), a new contract for the administration of Medicare Fee-for-Service claims for DMEPOS in JA. Noridian is based at 900 42nd Street South, Fargo, North Dakota 58103-2146.

NHIC, Corp. (NHIC), the incumbent contractor, is located at 75 William Terry Drive, Hingham, Massachusetts 02043.

Medicare DMEPOS suppliers serving Jurisdiction A beneficiaries should continue to submit their paper claims to NHIC until CMS completes the transition of Jurisdiction A operations to Noridian. Electronic claims should continue to be submitted to the Common Electronic Data Interchange (CEDI) both prior to and post transition.

CMS has determined that the JA workload currently processed by NHIC will require a new workload number when transitioned. The JA DME MAC workload number 16013 will be effective on the implementation date of CR9546. NHIC will be preparing an article explaining the workload number changes and will post that article on their website. NHIC will also include this information in a listserv message as soon as possible, but no later than 30 days prior to the implementation of CR9546.

Additional Information

The official instruction, CR9546 issued to your MAC regarding this change is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1642OTN.pdf.

JW Modifier: Drug Amount Discarded/Not Administered to any Patient – Revised

MLN Matters® Number: MM9603 Revised Related Change Request (CR) #: CR 9603 Related CR Release Date: May 24, 2016 Effective Date: July 1, 2016 Related CR Transmittal #: R3530CP Implementation Date: July 5, 2016

This article was revised on May 25, 2016, to reflect an updated Change Request (CR). That CR updated the X-Ref Requirement number in the CR's Supporting Information Section. In the article, the CR release date, transmittal number and link to the CR was changed. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for physicians, providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs) for drugs or biologicals administered to Medicare beneficiaries.

Provider Action Needed

The Centers for Medicare & Medicaid Services (CMS) issued CR 9603 to alert MACs and providers of the change in policy regarding the use of the JW modifier for discarded Part B drugs and biologicals.

Effective July 1, 2016, providers are required to:

- Use the JW modifier for claims with unused drugs or biologicals from single use vials or single use packages that are appropriately discarded (except those provided under the Competitive Acquisition Program (CAP) for Part B drugs and biologicals) and
- Document the discarded drug or biological in the patient's medical record when submitting claims with unused Part B drugs or biologicals from single use vials or single use packages that are appropriately discarded.

Make sure that your billing staffs are aware of these changes. Remember that the JW modifier is not used on claims for CAP drugs and biologicals.

Background

The "Medicare Claims Processing Manual," Chapter 17, Section 40 provides policy detailing the use of the JW modifier for discarded Part B drugs and biologicals. The current policy allows MACs the discretion to determine whether to require the JW modifier for any claims with discarded drugs or biologicals, and the specific details regarding how the discarded drug or biological information should be documented.

Be aware in order to more effectively identify and monitor billing and payment for discarded drugs and biologicals, **CMS is revising this policy to require the uniform use of the JW modifier for all claims with discarded Part B drugs and biologicals**.

Additional Information

The official instruction, CR9603, issued to your MAC regarding this change is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3530CP.pdf.

Medicare Coverage of Substance Abuse Services

MLN Matters® Number: SE1604

Provider Types Affected

This MLN Matters[®] Special Edition article is intended for physicians, other providers, and suppliers who submit claims to Medicare Administrative Contractors (MACs) for substance abuse services provided to Medicare beneficiaries.

What You Need to Know

While there is no distinct Medicare benefit category for substance abuse treatment, such services are covered by Medicare when reasonable and necessary. The Centers for Medicare & Medicaid Services (CMS) provides a full range of services, including those services provided for substance abuse disorders. This article summarizes the available services and provides reference links to other online Medicare information with further details about these services.

Background

Services for substance abuse disorders are available under Medicare, as long as those services are reasonable and necessary. These services include:

Inpatient Treatment

- Inpatient treatment would be covered if reasonable and necessary.
- Professional services provided during that care would be paid either:
 - as part of the inpatient stay (for professional services provided by clinicians not recognized for separate billing, for instance peer counselors), or
 - separately, to the professional billing for the provided services if they are recognized under Part B and considered separate from the inpatient stay (for instance, physicians, and NPPs within their state scopes of practice).
- Any medication provided as part of inpatient treatment would be bundled into the inpatient payment and not paid separately.

Outpatient Treatment

- Similar to inpatient treatment, coverage of outpatient treatment would depend on the provider of the services.
- Pursuant to the Social Security Act, Medicare does not recognize substance abuse treatment facilities as an independent provider type, nor is there an integrated payment for the bundle of services those providers may provide (either directly, or incident to a physician's service).
- Coverage and payment would be on a service by service basis for those services that are recognized by Medicare. For instance, Medicare could pay for counseling by an enrolled licensed clinical social worker, psychologist or psychiatrist.
- Some services could be provided by auxiliary personnel incident to a physician's services.
- Medications used in an outpatient setting that are not usually self-administered may be covered under Part B if they meet all Part B requirements.

Partial Hospitalization Program (PHP)

The PHP is an intensive outpatient psychiatric day treatment program that is furnished as an alternative to inpatient psychiatric hospitalization. This means that without the PHP services, the person would otherwise be receiving inpatient psychiatric treatment. Patients admitted to a PHP must be under the care of a physician who certifies and re-certifies the need for partial hospitalization and require a minimum of 20 hours per week of PHP therapeutic services, as evidenced by their plan of care. PHPs may be available in your local hospital outpatient department and Medicare certified Community Mental Health Center (CMHCs). PHP services include:

- Individual or group psychotherapy with physicians, psychologists, or other mental health professionals authorized or licensed by the State in which they practice (for example, licensed clinical social workers, clinical nurse specialists, certified alcohol and drug counselors);
- Occupational therapy requiring the skills of a qualified occupational therapist. Occupational therapy, if required, must be a component of the physicians treatment plan for the individual;
- Services of other staff (social workers, psychiatric nurses, and others) trained to work with psychiatric patients;
- Drugs and biologicals that cannot be self-administered and are furnished for therapeutic purposes (subject to limitations specified in <u>42 CFR 410.29</u>);
- Individualized activity therapies that are not primarily recreational or diversionary. These activities must be individualized and essential for the treatment of the patient's diagnosed condition and for progress toward treatment goals;
- Family counseling services for which the primary purpose is the treatment of the patient's condition;
- Patient training and education, to the extent the training and educational activities are closely and clearly related to the individuals care and treatment of his/her diagnosed psychiatric condition; and
- Medically necessary diagnostic services related to mental health treatment.

Similar to inpatient and individual outpatient treatment, coverage of PHP services would depend on the provider of the services.

MLN Matters® Special Edition article <u>SE1512</u> titled "Partial Hospitalization Program (PHP) Claims Coding & CY2015 per Diem Payment Rates" is intended for hospitals and Community Mental Health Centers (CMHCs) that submit claims to MACs for PHP services provided to Medicare beneficiaries. In SE1512, CMS reminds hospitals and CMHCs that provide PHP services to follow existing claims coding requirements given in the "Medicare Claims Processing Manual" (Chapter 4, Section 260) at <u>http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf</u> on the CMS website.

Coverage and payment would be for those PHP services that are recognized by Medicare. For instance, Medicare could pay for psychotherapy by an enrolled licensed clinical psychologist or psychiatrist.

Substance Abuse Treatment by Suppliers of Services

There are individuals under the Medicare Part B program who are authorized as suppliers of services that are eligible to furnish substance abuse treatment services providing the services are reasonable and necessary and fall under their State scope of practice.

These suppliers of services include:

- Physicians (medical doctor or doctor of osteopathy);
- Clinical psychologists;
- Clinical social workers;
- Nurse practitioners;
- Clinical nurse specialists;
- Physician assistants; and,
- Certified nurse-midwives.

Screening, Brief Intervention, and Referral to Treatment (SBIRT) Services

SBIRT is an early intervention approach that targets individuals with nondependent substance use to provide effective strategies for intervention prior to the need for more extensive or specialized treatment. This approach differs from the primary focus of specialized treatment of individuals with more severe substance use, or those who meet the criteria for diagnosis of a substance use disorder.

SBIRT services aim to prevent the unhealthy consequences of alcohol and drug use among those who may not reach the diagnostic level of a substance use disorder, and helping those with the disease of addiction enter and stay with treatment. You may easily use SBIRT services in primary care settings, enabling you to systematically screen and assist people who may not be seeking help for a substance use problem, but whose drinking or drug use may cause or complicate their ability to successfully handle health, work, or family issues. For more information on the Medicare's SBIRT services, refer to Medicare's fact sheet, "Screening, Brief Intervention, and Referral to Treatment (SBIRT) Services" at https://www.cms.gov/

SBIRT consists of three major components:

- 1. Structured Assessment (Medicare) or Screening (Medicaid): Assessing or screening a patient for risky substance use behaviors using standardized assessment or screening tools;
- 2. Brief Intervention: Engaging a patient showing risky substance use behaviors in a short conversation, providing feedback and advice; and
- 3. Referral to Treatment: Providing a referral to brief therapy or additional treatment to patients whose assessment or screening shows a need for additional services.

The first component to the SBIRT process is assessment or screening which uses tools including the World Health Organization's Alcohol Use Disorders Identification Test (AUDIT) Manual and the Drug Abuse Screening Test (DAST). For more information on SBIRT assessment and screening tools, as well as examples of tools, visit http://www.integration.samhsa.gov/clinical-practice/sbirt/screening on the Internet.

Medicare covers only reasonable and necessary SBIRT services that meet the requirements of diagnosis or treatment of illness or injury (that is, when the service is provided to evaluate and/or treat patients with signs/symptoms of illness or injury) per the Social Security Act (Section 1862(a)(1)(A); see https://www.ssa.gov/OP_Home/ssact/title18/1862.htm on the Internet).

Medicare pays for medically reasonable and necessary SBIRT services furnished in physicians' offices (by physicians and non-physician practitioners) and outpatient hospitals. In these settings, you assess for and identify individuals with, or at-risk for, substance use-related problems and furnish limited interventions/treatment. To bill Medicare, suppliers of SBIRT services must be:

- Licensed or certified to perform mental health services by the State in which they perform the services;
- Qualified to perform the specific mental health services rendered; and
- Working within their State Scope of Practice Act.

Medicare pays for these services under the Medicare Physician Fee Schedule (PFS) and the hospital Outpatient Prospective Payment System (OPPS). For more information on Medicare's payment for SBIRT services, refer to the "Medicare Claims Processing Manual" (Chapter 4, Section 200.6) at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf on the CMS website.

Drugs Used to Treat Opioid Dependence

Medicare Part D sponsors must include coverage for Part D drugs, either by formulary inclusion or via an exception, when medically necessary for the treatment of opioid dependence. Coverage is not limited to single entity products such as Subutex[®], but must include combination products when medically necessary (for example, Suboxone[®]). For any new enrollees, CMS requires sponsors to have a transition policy to prevent any unintended interruptions in pharmacologic treatment with Part D drugs during their transition into the benefit. This transition policy, along with CMS' non-formulary exceptions/appeals requirements, should ensure that all Medicare enrollees have timely access to their medically necessary Part D drug therapies for opioid dependence.

A Part D drug is defined, in part, as "a drug that may be dispensed only upon a prescription." Consequently, methadone is not a Part D drug when used for treatment of opioid dependence because it cannot be dispensed for this purpose upon a prescription at a retail pharmacy. (NOTE: Methadone is a Part D drug when indicated for pain). State Medicaid Programs may continue to include the costs of methadone in their bundled payment to qualified drug treatment clinics or hospitals that dispense methadone for opioid dependence.

See the "Medicare Prescription Drug Benefit Manual" (Chapter 6, Section 10.8 (Drugs Used to Treat Opioid Dependence)) at <u>https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/chapter6.pdf</u> on the CMS website.

Medicare covers diagnostic clinical laboratory services that are reasonable and necessary for the diagnosis or treatment of an illness or injury. For beneficiaries being treated for substance abuse, testing for drugs of abuse when reasonable and necessary can help manage their treatment. Information on the clinical laboratory fee schedule is available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Clinical-Laboratory-Fee-Schedule-Fact-Sheet-ICN006818.pdf on the CMS website.

Additional Information

Providers may want to review the following resources:

- "Mental Health Services" Booklet: see <u>https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Mental-Health-Services-Booklet-ICN903195.pdf</u> on the CMS website.
- "Summary of Medicare Reporting and Payment of Services for Alcohol and/or Substance (Other than Tobacco) Abuse Structured Assessment and Brief Intervention (SBIRT) Services;" see <u>https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/ MLNMattersArticles/downloads/SE1013.pdf</u> on the CMS website.
- National Coverage Determinations (NCDs): Inpatient Hospital Stays for the Treatment of Alcoholism (130.1); Outpatient Hospital Services for Treatment of Alcoholism (130.2); Chemical & Electrical Aversion Therapy for Treatment of Alcoholism (130.3, 130.4); Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic (130.5); Treatment of Drug Abuse (Chemical Dependency) (130.6); Withdrawal Treatments for Narcotic Addictions (130.7): See https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1 Part2.pdf on the CMS website.
- "Medicaid Program Integrity What Is a Prescriber's Role in Preventing the Diversion of Prescription Drugs?" Fact Sheet: See <u>https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Drug-Diversion-ICN901010.pdf</u> on the CMS website.
- "Effective Strategies for Addressing Overutilization and Abuse of Prescription Drugs in Medicare Part D": See <u>https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/</u> <u>Downloads/AHIP Overutilization Strategies CMS -10192015.pdf</u> on the CMS website.
- "New Medicare Part D Opioid Drug Mapping Tool Available": See <u>https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-11-03.html</u> on the CMS website.
- "Prescription Drug Monitoring Programs: A Resource to Help Address Prescription Drug Abuse and Diversion": See https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se1250.pdf on the CMS website.
- "Calendar Year (CY) 2016 Clinical Laboratory Fee Schedule (CLFS) Final Determinations" includes CY 2016 coding and policy information for drugs of abuse): See <u>https://www.cms.gov/Medicare/</u><u>Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2016-CLFS-Codes-Final-Determinations.pdf</u> on the CMS website.
- MLN Matters[®] Number: SE1105 (Medicare Drug Screen Testing): See <u>https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1105.pdf</u> on the CMS website.
- The Prescription Opioid Epidemic (CCSQ Grand Rounds Webinar); see https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/The-Prescription-Opioid-Epidemic.pdf on the CMS website.

Prolonged Drug and Biological Infusions Started Incident to a Physician's Service Using an External Pump – Medicare Policy Clarified

MLN Matters® Number: SE1609

Provider Types Affected

This MLN Matters[®] Special Edition article is intended for all physicians and hospital outpatient departments submitting claims to Medicare Administrative Contractors (MACs) for prolonged drug and biological infusions started incident to a physician's service using an external pump. Note that this article does not apply to suppliers' claims submitted to Durable Medical Equipment MACs (DME MACs).

What You Need to Know

Medicare pays for drugs and biologicals which are not usually self-administered by the patient and furnished "incident to" physicians' services rendered to patients while in the physician's office or the hospital outpatient department. In some situations, a hospital outpatient department or physician office may:

- purchase a drug for a medically reasonable and necessary prolonged drug infusion,
- begin the drug infusion in the care setting using an external pump,
- send the patient home for a portion of the infusion, and
- have the patient return at the end of the infusion period.

In this case, the drug or biological, the administration, and the external infusion pump is billed to your MAC. However, because prolonged drug and biological infusions started incident to a physician's service using an external pump should be treated as an incident to service, it cannot be billed on suppliers' claims to DME MACs.

Background

Under section 1861(s)(2)(A) of the Social Security Act (the Act), Medicare will pay for drugs and biologicals which are furnished "incident to" a physician's professional service. Under section 1861(s)(2)(B) of the Act, Medicare will pay for drugs and biologicals which are not usually self-administered by the patient furnished as "incident to" physicians' services rendered to outpatients. In order for Medicare to pay for a drug or biological under section 1861(s)(2)(A) or (B) of the Act, the physician or hospital (respectively) must incur a cost for the drug or biological. Generally, the administration of drugs or biologicals covered by Medicare under the "incident to" benefit (1861(s)(2)(A) and (B)) will start and end while the patient is in the physician's office or the hospital outpatient department under the supervision of a physician.

However, in some situations a hospital or office may purchase a drug for a medically reasonable and necessary prolonged drug infusion, then begin the drug infusion in the care setting using an external pump, send the patient home for a portion of the infusion duration, and have the patient return at the end of the infusion period. In this case, the drug or biological continues to be covered under section 1861(s)(2)(A) and (B) of the Act and is billable to the MAC even though the entire administration of the drug or biological did not occur in the physician's office or the hospital outpatient department. Also, the drug or biological continues to meet the requirements for the "incident to" benefit as the physician or hospital incurred a cost for the drug or biological and the administration of the drug began in a physician's office or hospital "incident to" a physician's service. For the administration of the drug, the physician supervision rules under <u>42 CFR Section 410.26</u>(b) (5) and 42 CFR §410.27 (a) (1)(iv) and <u>CMS Publication 100-02</u>, <u>Chapter 15</u>, section 50.3 apply only while the patient is present in the physician's office or hospital outpatient department. CMS does not provide specific coding guidance; however, appropriate drug administration codes for this situation would describe the services that are provided by the physician or hospital (for example, intravenous infusion, patient monitoring) while the patient is in the office or the outpatient setting.

Medicare's payment for the administration of the drug or biological billed to the MAC will also include payment for equipment used in furnishing the service. Equipment, such as an external infusion pump used to begin administration of the drug or biological that the patient takes home to complete the infusion, is not separately billable as durable medical equipment for a drug or biological paid under the section 1861(s) (2)(A) and (B) incident to benefit. The MAC may direct use of a code described by CPT or an otherwise applicable HCPCS code for the drug administration service. If necessary, the MAC may direct use of a miscellaneous code for the drug administration if there is no specified code that describes the drug administration service that also accounts for the cost of equipment that the patient takes home to complete the infusion that they later return to the physician or hospital.

Noridian Medicare Portal Transition Dates

All Endeavor users are required to register for the Noridian Medicare portal. Important dates to know are listed below:

Date	Milestone	
2/26/2016	Noridian Medicare Portal Registration Launches	
3/10/2016	Last day for Endeavor registration/changes	
2/26/2016 – 4/29/2016 Endeavor Users will need to register to Noridian Medicare Portal		
4/29/2016 Final day Endeavor users will be able to be accessed		
5/1/2016	Endeavor deactivated	

Endeavor will be deactivated on May 1, 2016, and will no longer be available to the providers/suppliers to use. In preparation of this change, effective March 11, 2016, Noridian will no longer accept any new registrations or changes to your Endeavor registration. All registrations will need to be completed through the Noridian Medicare Portal at that time. To ensure you are able to maintain the current functionality that is utilized today for portal activity, complete the registration in Noridian Medicare Portal before April 29, 2016.

To learn more about the Noridian Medicare Portal, visit our website at https://med.noridianmedicare.com/. Select the appropriate Jurisdiction, line of business, and then navigate to "Browse by Topic" and select "Noridian Medicare Portal."

Noridian Medicare Portal – Dual Role Access

For providers/suppliers with fewer than 25 full-time employees, dual role access is available. The first step in obtaining this access is to ensure the Provider Administrator role is selected on Step 5 of the registration process and "Yes" is selected when being asked if your facility is a small provider/supplier. When the registration is complete, the user can then select "Manage Account", Navigate to the "Account Access and Roles" tab, and then select the option to change the role to "Provider/Supplier Administrator and End User." Once the request is completed, this access is processed by Noridian team members who research the size of the provider/supplier company before approving or denying the Dual Role access.

	Welcome Manage Account Sign Out		
Noridian Medicare Portal	Last Login on 5/1/2016 05:24 PM CDT Failed attempts: 0		
Home Manage Users			
Manage My Account			
My Profile Provider/Supplier Combinations Account Access and Role(s)	Security Settings Account History		
Current Role(s) Change Role(s)			
Provider/Supplier Administrator Provider/Supplier Administrator and End User Provider/Supplier End User			
Deactivate Acco	unt		
Request Chang	e		

When a Provider Administrator has the Dual Role, they log into the portal and first see the Administrator Main Menu where they can oversee staff access and portal usage. In the top left section of the webpage, the End User Main Menu option is made available and would be used to conduct functionality inquiries.

Administrator Main Menu End User Main Menu	Welcome Manage Account Sign Out
Noridian Noridian Medicare Portal	Last Login on 5/11/2016 09:55 AM CDT Failed attempts: 0
Health - Calattors	🗩 Contact Us 🛛 Ə Help
Home Search Users	
System Notices System Normal All Functions Available	Alerts & Notices See All >

Below are descriptions of the types of functions that are available to Dual Role users on each of their menu options.

Main Menu	Functions Available
Administrator	Pending Request Approval or Denial
	Remove User Access
	Search/Manage Users
End User	• Eligibility
	Claim Status
	Appeals Submission and Status
	Remittance Advices
	Claim-Specific
	Full Remittance (Part B only)
	Financial Information
	DME Overpayments
	Same or Similar (DME Only)
	PMD Prior Authorization (DME Only)

Additional details can be found on the Browse By Topic / Noridian Medicare Portal section of the website.

Noridian Medicare Portal Offers Diagnosis Codes and Pointers within Claim Status Functionality

Effective March 24, 2016, the Noridian Medicare Portal will display all diagnoses submitted on a claim and identify which diagnosis is indicated as the primary diagnosis per line item on a claim.

When a claim or line item denies diagnosis code related (specificity, medical necessity, etc.), users will have the ability to research at a line item level. All applicable diagnosis code(s) and pointer(s) will display. Single specific diagnosis codes identified or "pointed to" in Item 24E of the CMS-1500 Claim Form or electronic equivalent will display on the line level.



View instructions on submitting primary diagnosis codes per claim line-item are available on our website.

- <u>CMS-1500 Claim Form Instructions</u>
- <u>CMS-1500 Claim Form Tutorial</u>

Noridian Medicare Portal Registration Update – CEDI Issued Trading Partner ID Optional

Effective April 8, 2016, the Noridian Medicare Portal registration process for Jurisdiction D suppliers has changed. Of the seven-step registration process, Supplier Administrators and Supplier End Users are no longer required to enter the Trading Partner ID within Step 6 to complete the portal registration process. This field will now be optional; if it is completed, verification will occur to ensure the information matches the Trading Partner ID on file for the supplier details entered. However, suppliers who leave the field blank will be unable to allow Vendor Administrators / Vendor End Users to register for the portal to conduct inquiries on that supplier's behalf.
The below image reflects Step 6 of the registration process.

rovider/Su	pplier A	dmin Re	gistratio	n				
Step 1 🖌	Step 2	~	Step 3 🖌	Step 4 💙	Step 5 🖌	Step 6	Step 7	
Personal Information	Login to Account		Security Questions	Account Confirmation	Organization Information	Add Providers /Suppliers	Registration Request Submitted	
ding Provide	r/Supplie	r Inform	ation					
				an be entered manually. I ontinue once logged into y		s/suppliers are		
te:The .CSV file uploa	ad option is not	t available for	Provider Administr	ators.				
ings to think about	t when addin	g providers						
Enter only Group Ni	PI/PTAN/TIN o	r SSN. Individe	al combinations w	ill not be accepted.				
• Your data is not say	ved or validated	d on this page	until "Save and Co	ontinue on to Next Step" is	s selected.			
Add Providers/Su	ppliers Manu	ally (* Requ	red Fields)					
 Medicare Progr 	ram		• Trading	Partner ID 🕧				
Please Select		~						
• NPI •	PTAN	. TIN or S	SN Check N	umber · Check Amo	unt			
				s				
+ Add Anoti	her Provider/S	upplier	+ Copy Last	Provider/Supplier				
+ Add Anoti	her Provider/S	Supplier	+ Copy Last	Provider/Supplier				

This change is not applicable to Part A or Part B providers who use the portal for Noridian Jurisdiction E or Jurisdiction F.

Noridian appreciates our supplier community and apologize for the concerns and delays experienced while awaiting this registration process change.

MLN Connects® Provider eNews - March 3, 2016

MLN Connects® Provider eNews for March 3, 2016

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In This Edition:

MLN Connects® Events

 Medicare Shared Savings Program Listening Session: Proposed Rule on Revised Benchmark Rebasing Methodology – Reminder

Medicare Learning Network® Publications and Multimedia

- Provider Enrollment Revalidation: Cycle 2 MLN Matters[®] Article New
- CMS Quality Conference 2015: Industry Leaders Discuss IMPACT Act Video New
- CMS Provider Minute: Multiple Same Day Surgeries and Modifier 51 Video New
- Home Health Prospective Payment System Booklet Revised
- Suite of Products & Resources for Rural Health Providers Educational Tool Revised
- DMEPOS Quality Standards Booklet Reminder

Announcements

- Major Commitments from Healthcare Industry to Make Electronic Health Records Work Better
- Program Integrity Enhancements to the Provider Enrollment Process

DME Happenings | Noridian DME Jurisdiction D | June 2016 | Issue No. 51

FYI

- CMS to Release a Comparative Billing Report on Non-invasive Vascular Studies in March
- EHR Incentive Program Hardship Application Deadline Extended to July 1
- EHR Incentive Programs: FAQs on Public Health Reporting Requirements
- ICD-10 Next Steps Toolkit
- Antipsychotic Drug use in Nursing Homes: Trend Update
- "Savor the Flavor of Eating Right" During National Nutrition Month® and Beyond

Claims, Pricers, and Codes

 Mandatory Payment Reduction of 2% Continues until Further Notice for the Medicare FFS Program – "Sequestration"

MLN Connects® Provider eNews – March 10, 2016

MLN Connects® Provider eNews for March 10, 2016

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In This Edition:

MLN Connects® Events

- Medicare Shared Savings Program ACO: Preparing to Apply for 2017 Call Registration Opening Soon
- IMPACT Act: Data Element Library Call Registration Now Open
- Medicare Shared Savings Program ACO Application Process Call Registration Opening Soon

Medicare Learning Network® Publications and Multimedia

- Videos on Medicare Quality Reporting New
- Swing Bed Services Fact Sheet Revised
- Rural Health Clinic Fact Sheet Revised
- Diagnosis Coding: Using the ICD-9 Web-Based Training Revised

Announcements

- CMS Proposes to Test New Medicare Part B Prescription Drug Models
- HHS Reaches Goal of Tying 30 Percent of Medicare Payments to Quality Ahead of Schedule
- 2016 Value Modifier Results and Upward Payment Adjustment Factor
- Open Payments System Registration for Physicians and Teaching Hospitals
- 2015 PQRS Data Submission Deadlines
- EHR Incentive Programs: Attest to 2015 Program Requirements by March 11
- Hospice, IRF, LTCH, SNF, HHA: QIES System Downtime from March 16 through 21
- Quality of Patient Care Star Ratings TEP Call for Nominations through March 18
- Home Health Agencies: Register for HHCAHPS before April 1
- Next Generation ACO Model Second Application Cycle: Letter of Intent due May 2
- New ST PEPPER Available
- Five Ways Patients Can Become Informed Medicare Consumers
- March is Colorectal Cancer Awareness Month

Claims, Pricers, and Codes

• April 2016 Average Sales Price Files Available

DME Happenings | Noridian DME Jurisdiction D | June 2016 | Issue No. 51

MLN Connects® Provider eNews - March 17, 2016

MLN Connects® Provider eNews for March 17, 2016

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In This Edition:

MLN Connects® Events

Medicare Shared Savings Program ACO: Preparing to Apply for 2017 Call – Registration Now Open Open Payments 2016: Prepare to Review Reported Data Call – Registration Now Open IMPACT Act: Data Element Library Call – Register Now Medicare Shared Savings Program ACO Application Process Call – Registration Now Open New Audio Recording and Transcript Available

Other CMS Events

Comparative Billing Report on Modifier 25: Internal Medicine Webinar

Comparative Billing Report on Non-invasive Vascular Studies Webinar

Medicare Learning Network® Publications and Multimedia

- February 2016 Catalog Available
- Dual Eligible Beneficiaries Fact Sheet and MLN Matters® Article Revised
- Health Professional Shortage Area Physician Bonus Program Fact Sheet Revised
- SNF Consolidated Billing Web-Based Training Course Reminder
- HIPAA EDI Standards Web-Based Training Course Reminder
- Medicare-Required SNF PPS Assessments Educational Tool Reminder

Announcements

- Medicare SNF Transparency Data for CY 2013
- DMEPOS Competitive Bidding Payment Amounts and Contract Offers for Round 2 Recompete and the National Mail-Order Recompete
- Eligible Professionals and Hospitals: Submitting QRDA Files in the 2016 Reporting Period
- ICD-10: Track and Improve Your Progress
- CMS Acting Administrator Andy Slavitt's Comments at HIMSS
- HCAHPS: Measurement of the Patient Experience in Hospitals
- It Is Still Influenza Season

MLN Connects® Provider eNews - March 24, 2016

MLN Connects® Provider eNews for March 24, 2016

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In This Edition:

MLN Connects® Events

- Medicare Shared Savings Program ACO: Preparing to Apply for 2017 Call Register Now
- Open Payments 2016: Prepare to Review Reported Data Call Register Now
- IMPACT Act: Data Element Library Call Register Now

FYI

- Medicare Shared Savings Program ACO Application Process Call Register Now
- New Audio Recording and Transcript Available

Other CMS Events

• March ICD-10 Coordination and Maintenance Committee: Comments on Proposals due April 8

Medicare Learning Network® Publications and Multimedia

- Series of MLN Matters® Special Edition Articles for Chiropractors New
- Medicare Costs at a Glance: 2016 Educational Tool Revised
- PECOS for Physicians and Non-Physician Practitioners Reminder
- Medicare Enrollment for Institutional Providers Fact Sheet Reminder
- New Educational Web Guides Fast Fact

Announcements

- CMS Releases Interactive Mapping Medicare Disparities Tool
- Delivery System Reform: Making Health Care Work Better
- CMS to Release a CBR on Subsequent Nursing Facility E/M Services in April
- Next Generation ACO Model Second Application Cycle: LOI due May 2
- 2016 PQRS Educational Materials Available
- DMEPOS Suppliers: List of HCPCS Codes Affected by Section 2 of PAMPA

Claims, Pricers, and Codes

• Update to the RHC Qualifying Visit List

MLN Connects[®] Provider eNews - March 31, 2016

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In This Edition:

MLN Connects® Events

- Medicare Shared Savings Program ACO: Preparing to Apply for 2017 Call Last Chance to Register
- Open Payments 2016: Prepare to Review Reported Data Call Register Now
- IMPACT Act: Data Element Library Call Register Now
- Medicare Shared Savings Program ACO Application Process Call Register Now
- 2016 PQRS Reporting: Avoiding 2018 Negative Payment Adjustments Call Registration Now Open
- National Partnership to Improve Dementia Care and QAPI Call Registration Now Open
- New Video Slideshow Available

Medicare Learning Network® Publications and Multimedia

- Basics of Medicare Series of Web-Based Training Courses New
- Long-Term Care Hospital Prospective Payment System Booklet Revised
- Medicare Ambulance Transports Booklet Revised
- Clinical Laboratory Fee Schedule Fact Sheet Revised
- Hospital Outpatient Prospective Payment System Fact Sheet Revised

Announcements

- CMS Launches New Effort to Improve Care for Nursing Facility Residents
- Advance Care Planning: New FAQs

Claims, Pricers, and Codes

- Modifications to HCPCS Code Set
- Medicare Payment for PAP Devices

MLN Connects® Provider eNews - April 7, 2016

MLN Connects® Provider eNews for April 07, 2016

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In This Edition:

MLN Connects® Events

- Open Payments 2016: Prepare to Review Reported Data Call Last Chance to Register
- IMPACT Act: Data Element Library Call Last Chance to Register
- Medicare Shared Savings Program ACO Application Process Call Register Now
- 2016 PQRS Reporting: Avoiding 2018 Negative Payment Adjustments Call Register Now
- National Partnership to Improve Dementia Care and QAPI Call Register Now

Other CMS Events

• March ICD-10 Coordination and Maintenance Committee: Comments on Proposals due April 8

Medicare Learning Network® Publications and Multimedia

- Medicare Shared Savings Program and Rural Providers Fact Sheet Revised
- ACOs: What Providers Need to Know Fact Sheet Revised
- Improving Quality of Care for Medicare Patients: ACOs Fact Sheet Revised
- Federally Qualified Health Center Fact Sheet Revised
- Critical Access Hospital Booklet Revised
- DMEPOS Information for Pharmacies Fact Sheet Reminder
- Safeguard Your Identity and Privacy Using PECOS Fact Sheet Reminder

Announcements

- Comprehensive Care for Joint Replacement Model Launched
- CMS Invites QIN-QIOs to Submit Special Innovation Projects
- Open Payments: Physician and Teaching Hospital Review and Dispute Period Began April 1
- Join the Million Hearts® Model: Letter of Intent due April 15
- CMS to Release a CBR on Modifiers 24 and 25 for General Surgeons in April
- 2016 PQRS GPRO Registration Open through June 30
- 2015 Mid-Year QRURs Available
- Find Information on the SNF Value-Based Purchasing Program
- April Quarterly Provider Update Available
- Help Prevent Alcohol Misuse or Abuse

Claims, Pricers, and Codes

• April 2016 Outpatient PPS Pricer File Available

MLN Connects® Provider eNews - April 14, 2016

MLN Connects® Provider eNews for April 14, 2016

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In This Edition:

MLN Connects® Events

- Medicare Shared Savings Program ACO Application Process Call Last Chance to Register
- 2016 PQRS Reporting: Avoiding 2018 Negative Payment Adjustments Call Last Chance to Register
- National Partnership to Improve Dementia Care and QAPI Call Register Now
- How to Register for the 2016 PQRS Group Practice Reporting Option Call Registration Now Open
- 2015 Mid-Year QRURs Webcast Registration Now Open

Other CMS Events

- Learn about the SNF Value-Based Purchasing Program at Open Door Forum
- IRF Quality Reporting Program Provider Training

Medicare Learning Network® Publications and Multimedia

- Enforcement of the PHP 20 Hours per Week Billing Requirement MLN Matters® Article New
- Updates to Medicare's Organ Acquisition and Donation Payment Policy MLN Matters Article New
- CMS Provider Minute: CT Scans Video New
- Medicare Learning Network LM/POS FAQs Booklet New
- Medicare Quarterly Provider Compliance Newsletter Educational Tool New
- Provider Enrollment Requirements for Writing Prescriptions for Medicare Part D Drugs MLN Matters Article – Revised
- ICD-10-CM Diagnosis Codes for Bone Mass Measurement MLN Matters Article Revised
- Medicare Secondary Payer Provisions Web-Based Training Course Revised
- Infection Control: Injection Safety Web-Based Training Course Revised

Announcements

- CMS Launches Largest-Ever Multi-Payer Initiative to Improve Primary Care in America
- Submit Comments on QRDA Implementation Guide for HQR by April 18
- IRF Quality Reporting Program Data Submission Deadline: May 15
- LTCH Quality Reporting Program Data Submission Deadline: May 15
- 2016 eCQMs Annual Update Available
- EHR Incentive Programs 2016 Program Requirements: New Resources
- ICD-10 Coding Resources
- National Healthcare Decisions Day is April 16
- April is National Minority Health Month

Claims, Pricers, and Codes

- April 2016 OPPS Pricer File Update
- Updates to HCPCS Code Set

MLN Connects® Provider eNews - April 21, 2016

MLN Connects® Provider eNews for April 21, 2016

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In This Edition:

MLN Connects® Events

- National Partnership to Improve Dementia Care and QAPI Call Last Chance to Register
- How to Register for the 2016 PQRS Group Practice Reporting Option Call Register Now
- 2015 Mid-Year QRURs Webcast Register Now
- New Audio Recording and Transcript Available

Other CMS Events

- Hospice Quality Reporting Program Webinar
- EHR Incentive Programs: March HIMSS16 Presentations

Medicare Learning Network® Publications and Multimedia

- Screening Pap Tests and Pelvic Examinations Booklet New
- Hospital Value-Based Purchasing Program Fact Sheet Revised

Announcements

- Hospital Inpatient PPS and LTCH PPS Proposed Rule for FY 2017
- Check Your 2015 Open Payments Data
- IRF Quality Reporting Program Data Submission Deadline: May 15 Updated
- LTCH Quality Reporting Program Data Submission Deadline: May 15 Updated
- 2017 Medicare Shared Savings Program: Notice of Intent to Apply Due by May 31
- CMS to Release a Comparative Billing Report on Psychotherapy and E/M Services in May
- 2016 Clinical Quality Measure Electronic Reporting: Updated Files
- April is STI Awareness Month: Talk, Test, Treat

Claims, Pricers, and Codes

Rural Health Clinic Claims Processing Incorrectly

MLN Connects® Provider eNews - April 28, 2016

MLN Connects® Provider eNews for April 28, 2016

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In This Edition:

MLN Connects® Events

- How to Register for the 2016 PQRS Group Practice Reporting Option Call Last Chance to Register
- 2015 Mid-Year QRURs Webcast Register Now
- New Audio Recordings and Transcripts Available

Other CMS Events

- Comparative Billing Report on Subsequent Nursing Facility E/M Services Webinar
- Comparative Billing Report on Modifiers 24 and 25: General Surgeons Webinar

DME Happenings | Noridian DME Jurisdiction D | June 2016 | Issue No. 51

FYI

- Medicare Learning Network® Publications and Multimedia
- Acute Care Hospital Inpatient Prospective Payment System Booklet Revised
- New Educational Web Guides Fast Fact

Announcements

- IRFs: Proposed FY 2017 Payment and Policy Changes
- SNFs: Proposed FY 2017 Payment and Policy Changes
- Hospice Benefit: Proposed FY 2017 Updates to the Wage Index and Payment Rates
- Open Payments: Physician and Teaching Hospital Review and Dispute Period Began April 1
- Nursing Homes, IRFs, and LTCHs: Comment on New Quality Measures by May 6
- Hospitals: Submit Comments on New EHR Measure by May 15
- Next Generation ACO Model Letter of Intent Deadline Extended to May 20
- 2016 PQRS GPRO Registration Open through June 30
- Home Health Quality Reporting Program: Quarterly QAO Interim Reports Available
- 2015 Mid-Year QRURs Available
- Track and Improve Your ICD-10 Progress
- Hand Hygiene Day is May 5

Claims, Pricers, and Codes

- Reprocessing Claims for Audiology Services
- Prolonged Drug and Biological Infusions Using an External Pump

MLN Connects® Provider eNews Special Edition – April 28, 2016

Round 2 Recompete and National Mail-Order Recompete Contract Suppliers Announced On April 28, CMS announced the contract suppliers for Round 2 Recompete and the national mail-order recompete of the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program. These contracts will begin on July 1.

A list of Round 2 Recompete and the national mail-order recompete contract supplier locations for each product category and competitive bidding area is now available on the Competitive Bidding Implementation Contractor (<u>CBIC</u>) website. This list is current as of April 28, 2016. Contract suppliers may add or change locations on their competitive bidding contract. Updates to the <u>Medicare Supplier Directory</u> will be posted in mid-June 2016.

For more information, view the fact sheet.

MLN Connects® Provider eNews – May 5, 2016

MLN Connects® Provider eNews for May 5, 2016

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In This Edition:

MLN Connects® Events

- MACRA Listening Session: Quality Payment Program Proposed Rule Register Now
- 2015 Mid-Year QRURs Webcast Register Now
- New Audio Recordings and Transcripts Available

Medicare Learning Network® Publications and Multimedia

- Medicare Coverage of Substance Abuse Services MLN Matters® Article New
- Medicare Policy Clarified for Prolonged Drug and Biological Infusions Started Incident to a Physician's Service Using an External Pump MLN Matters Article – New

Announcements

- CMS Releases NPRM on the Medicare Access and CHIP Reauthorization Act of 2015
- DMEPOS Competitive Bidding: Round 2 Recompete/ National Mail-Order Recompete Contract Suppliers Announced
- CMS Adds New Quality Measures to Nursing Home Compare
- CMS Publishes Final Rule on Fire Safety Requirements for Certain Health Care Facilities
- CMS Finalizes its Quality Measure Development Plan
- 2017 Medicare Shared Savings Program: Notice of Intent to Apply Period Closes May 31
- New PEPPERs Available for Hospices, SNFs, IRFs, IPFs, CAHs, LTCHs
- CMS to Release a CBR on Podiatry: Nail Debridement and E/M Services in May
- Focusing on Women's Health

Claims, Pricers, and Codes

• Reprocessing of Selected Dialysis Claims

MLN Connects® Provider eNews - May 12, 2016

MLN Connects® Provider eNews for May 12, 2016

View this edition as a PDF

In This Edition:

MLN Connects® Events

• 2015 Mid-Year QRURs Webcast – Last Chance to Register

Medicare Learning Network® Publications and Multimedia

- Limiting the Scope of Review on Redeterminations and Reconsiderations of Certain Claims MLN Matters[®] Article – Revised
- Transitional Care Management Services Fact Sheet Revised
- Section 1011: Federal Reimbursement of Emergency Health Services Furnished to Undocumented Aliens Fact Sheet – Revised
- DMEPOS Competitive Bidding Program Fact Sheets Revised

Announcements

- Updates to Data Initiatives Increase Transparency of the Medicare Program
- HHS Awards over \$260 Million to Health Centers Nationwide to Build and Renovate Facilities to Serve More Patients
- Open Payments: Physician and Teaching Hospital Review and Dispute Period Ends May 15
- 2016 Electronic Clinical Quality Measures: Updated Files Available
- Teaching Hospitals: Submitting Medicare GME Affiliation Agreements
- May is National Osteoporosis Month

Claims, Pricers, and Codes

- Coinsurance Correction for Certain RHC Claims
- Billing Requirements for RHCs

DME Happenings | Noridian DME Jurisdiction D | June 2016 | Issue No. 51

MLN Connects® Provider eNews - May 19, 2016

MLN Connects® Provider eNews for May 19, 2016

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In This Edition:

MLN Connects® Events

New Audio Recordings and Transcripts Available

Other CMS Events

- Comparative Billing Report on Psychotherapy and E/M Services Webinar
- Medicare Learning Network® Publications and Multimedia
- Part C Appeals: Organization Determinations, Appeals, and Grievances WBT Revised
- Part D Coverage Determinations, Appeals, and Grievances WBT Revised
- Resources for Medicare Beneficiaries Booklet Revised
- How to Use the Searchable Medicare Physician Fee Schedule Booklet Revised
- Updated MLN Matters® Search Indices

Announcements

- 2017 Medicare Shared Savings Program: Notice of Intent to Apply Period Closes May 31
- SNF Value-Based Purchasing Program: Specifications for New Measure
- 2014 PQRS Experience Report Available
- How to Use ICD-10 and Maintain Your Progress
- Talk to Your Patients about Mental Health

MLN Connects® Provider eNews - May 26, 2016

MLN Connects® Provider eNews for May 26, 2016

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In This Edition:

MLN Connects® Events

- Physician Compare Initiative Call Registration Now Open
- New Audio Recording and Transcript Available

Other CMS Events

• Comparative Billing Report on Podiatry: Nail Debridement and E/M Services Webinar

Medicare Learning Network® Publications and Multimedia

- PECOS for DMEPOS Suppliers Fact Sheet Reminder
- New Educational Web Guides Fast Fact

Announcements

- New Quality Payment Program Webpages
- 2016 PQRS GPRO Registration Open through June 30
- Updates to IRIS Software

Telephone Reopenings: Resources for Success

This article provides the following information on Telephone Reopenings: contact information, hours of availability, required elements, items allowed through Telephone Reopenings, those that must be submitted as a redetermination, and more.

Per the Internet-Only Manual (IOM) Publication 100-04, Chapter 34, Section 10, reopenings are separate and distinct from the appeals process. Contractors should note that while clerical errors must be processed as reopenings, all decisions on granting reopenings are at the discretion of the contractor.

Section 10.6.2 of the same Publication and Chapter states a reopening must be conducted within one year from the date of the initial determination.

How do I request a Telephone Reopening?	To request a reopening via telephone, call 1-888-826-5708.
What are the hours for Telephone Reopenings?	Monday through Friday 8 a.m 4:30 p.m. CT Further closing information can be found at <u>https://med.noridianmedicare.com/</u> web/jddme/contact/holiday-schedule.
What information do I need before I can initiate a Telephone Reopening?	 Before a reopening can be completed, the caller must have all of the following information readily available as it will be verified by the Telephone Reopenings representative. If at any time the information provided does not match the information in the claims processing system, the Telephone Reopening cannot be completed. National Provider Identifier (NPI) Provider Transaction Access Number (PTAN) Last five digit of Tax ID Number (TIN) Supplier name Beneficiary's Health Insurance Claim Number (HICN) Beneficiary's date of birth Date of service (DOS) Healthcare Common Procedure Coding System (HCPCS) code(s) in question Corrective action to be taken
	Note: Claims with remark code MA130 can never be submitted as a reopening (telephone or written). Claims with remark code MA130 are considered unprocessable and do not have reopening or appeal rights. The claim is missing information that is needed for processing or was invalid and must be resubmitted.

APPEALS

What may l request as a Telephone	The following is a list of clerical errors and omissions that may be completed as a Telephone Reopening.
Reopening?	 Note: This list is not all-inclusive. Diagnosis code changes or additions Date of Service (DOS) changes HCPCS code changes Certain modifier changes or additions (not an all-inclusive list) KH KI KI KJ RR NU AU KL RT LT Note: If, upon research, any of the above change are determined too complex, the caller will be notified the request needs to be sent in writing as a redetermination with the appropriate supporting documentation.

APPEALS

What is not accepted as a Telephone	The following will not be accepted as a Telephone Reopening and must be submitted as a redetermination with supporting documentation.
Reopening?	Overutilization denials that require supporting medical records
	 Certificate of Medical Necessity (CMN) and Durable Medical Equipment Information Form (DIF) issues. Please see the article posted March 21, 2013, titled "<u>Denied Claims Requiring CMN/DIF Must be Resubmitted, Rather than</u> <u>Reopened</u>"
	Oxygen break in service (BIS) issues
	• Some manual wheelchairs and all power mobility devices (PMDs) – HCPCS K0005 and higher
	Overpayments or reductions in payment
	Medicare Secondary Payer (MSP) issues
	Claims denied for timely filing
	Reopenings past one year from the initial determination
	Complex Medical Reviews or Additional Documentation Requests
	Advance Beneficiary Notice of Noncoverage (ABN) issues and other liability issues
	Repair and labor claims
	 Miscellaneous HCPCS codes and all HCPCS codes that require manual pricing
	The following modifier changes or additions:
	 A1 through A9 K0 through K4 GA GY GZ KX EY KG RA RB RP
	Certain HCPCS codes (not all-inclusive list)
	 A4450 through A4452 E0194 E0748 E1028 J1559 J1561 J1562 K0108 K0462
What do I do when I have a large amount of corrections?	• If a supplier has more than 50 of the same correction, that are able to be completed as a reopening, the supplier should notify a Telephone Reopenings representative. The representative will gather the required information and provide further direction how to submit the request.
	 If a supplier has a least 10 DOS, the supplier can request a phone appointment for a 30 minute interval. A Telephone Reopenings representative will call the supplier at the designated time and will complete as many reopenings as possible in that time.

Where can I find more information on Telephone Reopenings?	 Supplier Manual Chapter 13 Appeals Section on the Noridian DME website IOM Publication 100-04, Chapter 34
Additional assistance available	Suppliers can email questions and concerns regarding reopenings and redeterminations to <u>dmeredeterminations@noridian.com</u> . Please note, emails containing Protected Health Information (PHI) will be returned as unprocessable.

Reconsiderations: Formal Telephone Discussion Demonstration

CMS launched a Formal Telephone Discussion Demonstration with Durable Medical Equipment (DME) suppliers in <u>Jurisdictions C and D</u> that submit Medicare Fee-For-Service claims. The demonstration will provide selected suppliers that have submitted reconsiderations (second level appeal requests) the opportunity to participate in a formal recorded telephone discussion with the DME Qualified Independent Contractor, C2C Innovative Solutions, Inc. For more information, see the <u>Formal Telephone Demonstration Fact Sheet</u>.

Redeterminations and Reconsiderations of Certain Claims – Limiting the Scope of Review – Revised

MLN Matters® Number: SE1521 Revised

This article was revised on May 9, 2016, to provide updated information regarding redetermination requests received by Medicare Administrative Contractors (MACs) or Qualified Independent Contractors (QICs) on or after April 18, 2016.

Provider Types Affected

This MLN Matters[®] Special Edition Article is intended for physicians, providers, and suppliers who submit claims to MACs for services provided to Medicare beneficiaries.

What You Need to Know

This Special Edition article is being published by the Centers for Medicare & Medicaid Services (CMS) to inform providers of the clarification CMS has given to the MACs and QICs regarding the scope of review for redeterminations (Technical Direction Letter-160305, which rescinds and replaces Technical Direction Letter-150407). This updated instruction applies to redetermination requests received by a MAC or QIC on or after April 18, 2016, and will not be applied retroactively.

Background

CMS recently provided direction to MACs and QICs regarding the applicable scope of review for redeterminations and reconsiderations for certain claims. Generally, MACs and QICs have discretion while conducting appeals to develop new issues and review all aspects of coverage and payment related to a claim or line item. As a result, in some cases where the original denial reason is cured, this expanded review of additional evidence or issues results in an unfavorable appeal decision for a different reason.

For redeterminations and reconsiderations of claims denied following a complex prepayment review, a complex post-payment review, or an automated post-payment review by a contractor, CMS has instructed

APPEALS

MACs and QICs to limit their review to the reason(s) the claim or line item at issue was initially denied. Prepayment reviews occur prior to Medicare payment, when a contractor conducts a review of the claim and/or supporting documentation to make an initial determination. Post-payment reviewed by, for example, a Zone Program Integrity Contractor (ZPIC), Recovery Auditor, MAC, or Comprehensive Error Rate Testing (CERT) contractor, and revised to deny coverage, change coding, or reduce payment. Complex reviews require a manual review of the supporting medical records to determine whether there is an improper payment. Automated reviews use claims data analysis to identify improper payments. If an appeal involves a claim or line item denied on an automated pre-payment basis, MACs and QICs may continue to develop new issues and evidence at their discretion and may issue unfavorable decisions for reasons other than those specified in the initial determination.

Please note that contractors will continue to follow existing procedures regarding claim adjustments resulting from favorable appeal decisions. These adjustments will process through CMS systems and may suspend due to system edits. Claim adjustments that do not process to payment because of additional system imposed payment limitations, conditions or restrictions (for example, frequency limits or Correct Coding Initiative edits) may result in new denials with full appeal rights. In addition, if a MAC or QIC conducts an appeal of a claim or line item that was denied on pre- or post-payment review because a provider, supplier, or beneficiary failed to submit requested documentation, the contractor will review all applicable coverage and payment requirements for the item or service at issue, including whether the item or service was medically reasonable and necessary. As a result, claims initially denied for insufficient documentation may be denied on appeal if additional documentation is submitted and it does not support medical necessity.

This clarification and instruction applies to redetermination and reconsideration requests received by a MAC or QIC on or after April 18, 2016. It will not be applied retroactively. Appellants will not be entitled to request a reopening of a previously issued redetermination or reconsideration for the purpose of applying this clarification on the scope of review. CMS encourages providers and suppliers to include any audit or review results letters with their appeal request. This will help alert contractors to appeals where this instruction applies.

Additional Information

You can find out more about appealing claims decisions in the "Medicare Claims Processing Manual" (Publication 100-04, Chapter 29 (Appeals of Claims Decisions), Section 310.4.C.1. (Conducting the Redetermination (Overview)) at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c29.pdf on the CMS website.

You can also find out more about 1) conducting a redeterminations in 42 CFR 405.948, at http://www.ecfr.gov/cgi-bin/text-idx?SID=06584dd6a5fc15094e7633ff5f6cb359&mc=true&node=pt42.2 .405&rgn=div5#se42.2.405_1948; and 2) conducting a reconsideration in 42 CFR 405.968 at http://www.ecfr.gov/cgi-bin/text-idx?SID=06584dd6a5fc15094e7633ff5f6cb359&mc=true&node=pt42.2 .405&rgn=div5#se42.2.405_1968 on the Internet.

CERT Documentation

This article is to remind suppliers they must comply with requests from the CERT Documentation Contractor for medical records needed for the Comprehensive Error Rate Testing program. An analysis of the CERT related appeals workload indicates the reason for the appeal is due to "no submission of documentation" and "submitting incorrect documentation."

Suppliers are reminded the CERT program produces national, contractor-specific and service-specific paid claim error rates, as well as a supplier compliance error rate. The paid claim error rate is a measure of the extent to which the Medicare program is paying claims correctly. The supplier compliance error rate is a measure of the extent to which suppliers are submitting claims correctly.

The CERT Documentation Contractor sends written requests for medical records to suppliers that include a checklist of the types of documentation required. The CERT Documentation Contractor will mail these letters to suppliers individually. Suppliers must submit documentation to the CERT Operations Center via fax, the preferred method, or mail at the number/address specified below.

The secure fax number for submitting documentation to the CERT Documentation Contractor is (240) 568-6222.

Mail all requested documentation to:

CERT Documentation Office Attn: CID #:xxxxxx 9090 Junction Drive, Suite 9 Annapolis Junction, MD 20701

The CID number is the CERT reference number contained in the documentation request letter.

Suppliers may call the CERT Documentation Contractor at (301) 957-2380 with questions regarding specific documentation to submit.

Suppliers must submit medical records within 75 days from the receipt date of the initial letter or claims will be denied. The supplier agreement to participate in the Medicare program requires suppliers to submit all information necessary to support the services billed on claims.

Also, Medicare patients have already given authorization to release necessary medical information in order to process claims. Therefore, Medicare suppliers do not need to obtain a patient's authorization to release medical information to the CERT Documentation Contractor.

Suppliers who fail to submit medical documentation will receive claim adjustment denials from Noridian as the services for which there is no documentation are interpreted as services not rendered.

CERT Documentation Contractor Updates

The Comprehensive Error Rate Testing (CERT) Documentation Contractor (DC) is responsible for requesting and receiving the medical record documentation from providers. Within the next several weeks the CERT DC will be making changes to their <u>website</u> that will make it easier for suppliers to obtain information on documentation requests.

The site will include the following:

- An alphabetical listing for each provider type and billing type
- Providers will be able to view and print their Documentation Request Listing
 - If printed, you should refer to the CERT Provider website to confirm the current documentation request listing.
- Documentation descriptions will be available in both English and Spanish
- Documentation Request Listings will be updated when changes are approved.

Remember, if you respond to a documentation request and submit documentation via CD, you should send the password to: <u>CERTMAIL@livanta.com</u>, in the subject line of the e-mail include the CID number. You do not need to encrypt the e-mail. If you follow this procedure it will ensure that there is no delay in processing the documentation.

Correct Coding – Powered Exoskeleton Products

DME MAC Joint Publication

Recently several products described as powered exoskeletons have been developed. These items are reported to support mobility for spinal cord injured beneficiaries who are unable to ambulate. These products are principally provided for supervised use in rehabilitation settings. Currently there are two FDA-approved products, Rewalk™ (Argo Technologies) and Indego® (Parker Hannifin Corp.). Other similar products are in development but are not yet on the market in the United States. These devices provide a powered lower limb exoskeleton enabling beneficiaries who are non-ambulatory due to spinal cord injuries to ambulate with the assistance of a cane, crutches or a walker under direct supervision and thus participate in over-ground gait training.

Although these products resemble "orthoses", for Medicare HCPCS coding purposes, brace-like products that exert a powered force across a joint are not coded as orthoses with HCPCS "L" codes but rather are coded using other HCPCS codes. Equipment used in institutional rehabilitation settings is statutorily excluded from reimbursement under the DME benefit. Claims submitted to the DME MACs for a powered exoskeleton must use HCPCS code:

• A9270 - NON-COVERED ITEM OR SERVICE

This code describes the entire product provided at initial issue. A complete, functional product must be provided at initial issue. Use of other HCPCS codes to bill for the entire items or for separate components, options, accessories and/or supplies is considered incorrect coding.

For questions about correct coding, contact the Pricing, Data Analysis and Coding (PDAC) contractor Contact Center at (877) 735-1326 during the hours of 8:30 a.m. to 4 p.m. CT, Monday through Friday, or e-mail the PDAC.

DMEPOS HCPCS Code Jurisdiction List - 2016 - Revised

MLN Matters® Number: MM9481 Revised Related Change Request (CR) #: CR9481 Related CR Release Date: May 10, 2016 Effective Date: January 1, 2016 Related CR Transmittal #: R3520CP Implementation Date: February 1, 2016

This article was revised on May 10, 2016, due to a revised Change Request (CR). The CR revised the jurisdiction for HCPCS E0781 to DME MAC only and omitted the local carrier jurisdiction for this code in the attachment to the CR. The CR release date, transmittal number and link to the CR also changed. All other information remains the same.

Provider Types Affected

This MLN Matters[®] Article is intended for providers and suppliers submitting claims to Medicare Administrative Contractors (MACs), including Durable Medical Equipment MACs for DMEPOS services provided to Medicare beneficiaries.

Provider Action Needed

CR9481 notifies suppliers that the spreadsheet containing an updated jurisdiction list of Healthcare Common Procedure Coding System (HCPCS) codes is updated annually to reflect codes that have been added or discontinued (deleted) each year. Changes in Chapter 23, Section 20.3 of the "Medicare Claims Processing Manual" are reflected in the recurring update notification. The spreadsheet for the 2016 DMEPOS Jurisdiction List is an Excel® spreadsheet and is available under the Coding Category at http://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center.html and is also attached to CR9481.

Additional Information

The official instruction, CR9481, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3520CP.pdf.

Coding Revisions to NCDs

MLN Matters® Number: MM9540 Related Change Request (CR) #: CR 9540 Related CR Release Date: April 29, 2016 Effective Date: July 1, 2016 Related CR Transmittal #: R16580TN Implementation Date: July 5, 2016, unless otherwise noted

Provider Types Affected

This MLN Matters[®] Article is intended for physicians, providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

What You Need to Know

Change Request (CR) 9540 is the 7th maintenance update of the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) conversions and other coding updates specific to National Coverage Determinations (NCDs). Edits to ICD-10 and other coding updates specific to NCDs will be included in subsequent, quarterly releases as needed. No policy-related changes are included with these updates. Any policy-related changes to NCDs continue to be implemented via the current, long-standing NCD process.

Background

The majority of the NCDs included are a result of feedback received from previous ICD-10 NCD CRs, specifically, CR7818, CR8109, CR8197, CR8691, CR9087, and CR9252. You may review the corresponding MLN Matters® Articles <u>MM7818</u>, MM8109, <u>MM8197</u>, <u>MM8691</u>, <u>MM9087</u>, and <u>MM9252</u> for these CRs on the Centers for Medicare & Medicaid Services (CMS) website. Some are the result of revisions required to other NCD-related CRs released separately.

Updated NCD coding spreadsheets related to CR9540 are available at <u>http://www.cms.gov/Medicare/</u> <u>Coverage/DeterminationProcess/downloads/CR9540.zip</u>. CR9540 updates the following 14 NCDs:

- NCD20.29 Hyperbaric Oxygen Therapy
- NCD90.1 Pharmacogenomic Testing for Warfarin Response
- NCD110.18 Aprepitant for Chemotherapy-Induced Emesis
- NCD150.3 Bone Mineral Density Studies
- NCD160.18 Vagus Nerve Stimulation for Treatment of Seizures
- NCD160.24 Deep Brain Stimulation for Essential Tremor
- NCD210.3 Colorectal Cancer Screening Tests
- NCD210.14 Screening for Lung Cancer with Low-Dose CT (CR9246)
- NCD230.18 Sacral Nerve Stimulation for Urinary Incontinence
- NCD260.1 Adult Liver Transplantation (CR9252, CR8109)
- NCD110.4 Extracorporeal Photopheresis
- NCD20.33 Transcatheter Mitral Valve Repair (CR9002, TDL150341, policyeffective August 7, 2014
- NCD220.13 Percutaneous Image-Guided Breast Biospy
- NCD220.4 Mammograms

MACs will adjust any claims already processed, if erroneously impacted by the above changes, if you bring such claims to their attention.

Additional Information

The official instruction, CR9540, issued to your MAC regarding this change is available for download at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1658OTN.pdf.

Claim Status Category and Claim Status Codes Update

MLN Matters® Number: MM9550 Related Change Request (CR) #: CR 9550 Related CR Release Date: May 20, 2016 Effective Date: October 1, 2016 Related CR Transmittal #: R3527CP Implementation Date: October 3, 2016

Provider Types Affected

This MLN Matters[®] Article is intended for physicians, other providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9550 informs MACs about the changes to Claim Status Category Codes and Claim Status Codes. Make sure that your billing staffs are aware of these changes.

Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires all covered entities to use only Claim Status Category Codes and Claim Status Codes approved by the National Code Maintenance Committee in the ASC X12 276/277 Health Care Claim Status Request and Response transaction standards adopted under HIPAA for electronically submitting health care claims status requests and responses. These codes explain the status of submitted claim(s). Proprietary codes may not be used in the ASC X12 276/277 transactions to report claim status.

The National Code Maintenance Committee meets at the beginning of each ASC X12 trimester meeting (January/February, June, and September/October) and makes decisions about additions of new codes, as well as modifications and retirement of existing codes. The Committee has decided to allow the industry 6 months for implementation of newly added or changed codes.

The codes sets are available at <u>http://www.wpc-edi.com/reference/codelists/healthcare/claim-status-category-codes/</u> and <u>http://www.wpc-edi.com/reference/codelists/healthcare/claim-status-codes/</u>.

Included in the code lists are specific details, including the date when a code was added, changed, or deleted.

All code changes approved during the June 2016 committee meeting will be posted on the above mentioned websites on or about July 1, 2016.

The Centers for Medicare & Medicaid Services (CMS) will issue future CRs regarding the need for future updates to these codes. These code changes are to be used in editing of all ASC X12 276 transactions processed on or after the date of implementation and to be reflected in the ASC X12 277 transactions issued on and after the date of implementation of CR9550.

Additional Information

The official instruction, CR9550 issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3527CP.pdf.

Coding Revisions to NCDs

MLN Matters® Number: MM9631 Related Change Request (CR) #: CR 9631 Effective Date: October 1, 2016 - unless noted differently in CR9631 Related CR Release Date: May 13, 2016 Related CR Transmittal #: R16650TN Implementation Date: October 3, 2016

Provider Types Affected

This MLN Matters® Article is intended for physicians and other providers submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

CR9631 is the 8th maintenance update of International Classification of Diseases, Tenth Revision (ICD-10) conversions and other coding updates specific to national coverage determinations (NCDs). The majority of the NCDs included are a result of feedback received from previous ICD-10 NCD CRs, specifically CR7818, CR8109, CR8197, CR8691, CR9087, CR9252, and CR9540, while others are the result of revisions required to other NCD-related CRs released separately. Review MLN Matters[®] Articles <u>MM7818</u>, <u>MM8109</u>, <u>MM8197</u>, <u>MM8691</u>, <u>MM9087</u>, <u>MM9252</u>, and <u>MM9540</u> for information pertaining to these CR's.

Background

The translations from ICD-9 to ICD-10 are not consistent one-to-one matches, nor are all ICD-10 codes appearing in a complete General Equivalence Mappings (GEMS) guide or other mapping guides appropriate when reviewed against individual NCD policies. In addition, for those policies that expressly allow MAC discretion, there may be changes to those NCDs based on current review of those NCDs against ICD-10 coding. For these reasons, there may be certain ICD-9 codes that were once considered appropriate prior to ICD-10 implementation that are no longer considered acceptable.

No policy-related changes are included with these updates. Any policy-related changes to NCDs continue to be implemented via the current, long-standing NCD process. Updated NCD coding spreadsheets related to CR9631 are available at https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/CR9631.zip.

Edits to ICD-10 and other coding updates specific to NCDs will be included in subsequent, quarterly releases as needed. No policy-related changes are included with these updates. Any policy-related changes to NCDs continue to be implemented via the current, long-standing NCD process.

To be specific, CR9631 makes adjustments to the following NCDs:

- NCD 20.4 Implantable Automatic Defibrillators
- NCD 20.7 Percutaneous Transluminal Angioplasty (PTA)
- NCD 20.9 Artificial Hearts
- NCD 20.29 Hyperbaric Oxygen Therapy
- NCD 50.3 Cochlear Implants
- NCD 110.18 Aprepitant
- NCD 210.3 Colorectal Cancer Screening
- NCD 220.4 Mammography
- NCD 230.9 Cryosurgery of Prostate
- NCD 260.9 Heart Transplants
- NCD 210.4 Smoking/Tobacco-Use Cessation Counseling
- NCD 210.4.1 Counseling to Prevent Tobacco Use

Additional Information

The official instruction, CR 9631, issued to your MAC regarding this change is available at <u>https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1665OTN.pdf</u>.

HCPCS Drug/Biological Code Changes - July 2016 Quarterly Update

MLN Matters® Number: MM9636 Related Change Request (CR) #: CR 9636 Related CR Release Date: May 6, 2016 Effective Date: July 1, 2016 Related CR Transmittal #: R3518CP Implementation Date: July 5, 2016

Provider Types Affected

This MLN Matters[®] Article is intended for physicians, providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs), including Durable Medical Equipment MACs (DME MACs) and Home Health & Hospice (HH&H) MACs for services provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9636 informs Medicare providers and suppliers that effective for claims with dates of service on or after July 1, 2016, new Healthcare Common Procedure Coding System (HCPCS) codes Q9981 (rolapitant, oral, 1mg); Q9982 (flutemetamol f18 diagnostic); and Q9983 (florbetaben f18 diagnostic) will be payable for Medicare. In addition, the HCPCS code set will contain code Q5102 (Inj., infliximab biosimilar), which is effective for dates of service on or after April 5, 2016. Claims for Q5102 must also have the modifier ZB (Pfizer/hospira). Make sure that your billing staffs are aware of these changes.

Background

The HCPCS code set is updated on a quarterly basis and CR9636 provides that effective July 1, 2016, the HCPCS codes contained in the following table will be established:

HCPCS Code	Short Description	Long Description	Type of Service (TOS) Code
Q9981	rolapitant, oral, 1mg	Rolapitant, oral, 1 mg	1
Q9982	flutemetamol f18 diagnostic	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	4
Q9983	florbetaben f18 diagnostic	Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries	4

Also, as of July 1, the HCPCS code set will contain code Q5102 (short descriptor – Inj., infliximab biosimilar – and long descriptor – Injection, Infliximab, 10 mg). Code Q5102 will be effective for dates of service on or after April 5, 2016, and will have TOS codes of 1 and P. In addition, claims for Q5102 must also have the modifier ZB (Pfizer/hospira).

Additional Information

The official instruction, CR9636, issued to your MAC regarding this change, is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3518CP.pdf.

DMEPOS CBP - July 2016 Quarterly Update

MLN Matters® Number: MM9572 Related Change Request (CR) #: CR 9572 Related CR Release Date: April 1, 2016 Effective Date: July 1, 2016 Related CR Transmittal #: R3488CP Implementation Date: July 5, 2016

Provider Types Affected

This MLN Matters® Article is intended for providers and suppliers submitting claims to Medicare Administrative Contractors (MACs) for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items or services paid under the DMEPOS fee schedule.

What You Need to Know

Change Request (CR) 9572 provides the July 2016 quarterly update for the Medicare DMEPOS fee schedule. The instructions include information, when necessary, to implement fee schedule amounts for new codes and correct any fee schedule amounts for existing codes. The Centers for Medicare & Medicaid Services (CMS) issued CR9572 to provide the DMEPOS Competitive Bidding Program (CBP) July 2016 quarterly update. CR9572 provides specific instructions to your DME MAC for implementing updates to the DMEPOS CBP Healthcare Common Procedure Coding System (HCPCS), ZIP code, and Single Payment Amount files.

Note that quarterly updates are also available at http://dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/home on the Internet. At that site, click on the quarterly updates link in the left of the page.

Background

The DMEPOS Competitive Bidding Program was mandated by Congress through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The intent is to improve the effectiveness of the Medicare methodology for setting DMEPOS payment amounts, which will reduce beneficiary out-of-pocket expenses and save the Medicare program money while ensuring beneficiary access to quality items and services.

Under the program, Medicare conducts a competition among suppliers who operate in a particular Competitive Bidding Area. Suppliers must submit a bid for selected products. Not all products or items are subject to competitive bidding. Bids are submitted electronically through a web-based application process and required documents are mailed. Bids are evaluated based on the supplier's eligibility, its financial stability and the bid price. Contracts are awarded to the Medicare suppliers who offer the best price and meet applicable quality and financial standards. Contract suppliers must agree to accept assignment on all claims for bid items and will be paid the bid price amount. The amount is derived from the median of all winning bids for an item.

Additional Information

The official instruction, CR9572 issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3488CP.pdf on the CMS website.

DMEPOS CBP: Additional Instructions for the Implementation of Round 2 Recompete of the DMEPOS CBP Program and National Mail Order Recompete

MLN Matters® Number: MM9579 Related Change Request (CR) #: CR 9579 Related CR Release Date: April 28, 2016 Effective Date: October 1, 2016 Related CR Transmittal #: R3500CP Implementation Date: October 3, 2016

Provider Types Affected

This MLN Matters[®] Article is intended for providers and suppliers submitting claims to Medicare Administrative Contractors (MACs) for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items or services paid under the DMEPOS fee schedule.

Provider Action Needed

The Centers for Medicare & Medicaid Services (CMS) issued Change Request (CR) 9579 to provide instructions detailing changes to the DMEPOS Competitive Bidding Program (CBP) regarding the clarification of the RB modifier for Medicare payment for the repair of parts furnished in Competitive Bidding Areas (CBAs) and clarification of grandfathering instructions for rentals of accessories and supplies.

Background

The purpose of CR9579 is to provide instructions for implementing the following clarifications to the DMEPOS CBP program:

Clarification of Medicare Payment for Repair Parts Furnished in Competitive Bidding Areas

Under the Medicare DMEPOS CBP, repairs of beneficiary-owned items may be performed by any Medicare-enrolled supplier. Repairs to certain, medically necessary beneficiary-owned equipment are covered when necessary to make the equipment serviceable. Labor to repair equipment is not subject to competitive bidding and is paid according to Medicare's general payment rules.

CR8181 (see related article <u>MM8181</u>) implemented claims billing and processing instructions for wheelchair accessories furnished for use with non-competitively bid wheelchair base units for beneficiaries who permanently reside in competitive bid areas. This instruction implemented use of the KY modifier in certain instances. This instruction clarifies how payment is made for repair parts furnished in competitive bidding areas.

In accordance with <u>42 CFR 414.408</u>(k)(1)(iii), payments for repair parts that are described by HCPCS codes for competitive bidding items and are furnished in CBAs are made based on the single payment amount established for the HCPCS code. Payment for such repair parts that are furnished for use in repairing base equipment that are not competitive bidding items in the area is made in accordance with 42 CFR 414.408(k)(1)(ii), which provides that payment for the part is made based on the MAC's consideration of the item under 42 CFR 414.210(e). When making payment determinations for parts described by HCPCS codes for competitive bidding items furnished for use in repairing base equipment that are not competitive bidding items for use in repairing base equipment that are not competitive bidding items for use in repairing base equipment that are not competitive bidding items for use in repairing base equipment that are not competitive bidding items for use in repairing base equipment that are not competitive bidding items for use in repairing base equipment that are not competitive bidding items for use in repairing base equipment that are not competitive bidding items for use the single payment amounts for the item in establishing the Medicare allowed amount for the repair part.

The regulations at <u>414.210(e)</u> also provide that payment for repair parts is made on a lump sum purchase basis. Therefore, effective July 1, 2016, all repair part claims billed with the RB modifier, whether within or outside a CBA, whether described by a HCPCS code that is a competitive bidding item or not, and whether described by a code for miscellaneous (not otherwise classified or specified) items or not, shall be paid on a lump sum purchase basis.

Additionally, CMS has become aware that wheelchair claims are being submitted with the following modifier combinations: the RB and KY; RB and KE; and RB and RR modifiers. If the claim is for a repair part, these three following combinations are not valid, and the claim will be returned as unprocessable.

Clarification of Grandfathering instructions

Under the Medicare DMEPOS CBP, a beneficiary who obtains competitive bidding items in a designated CBA must obtain these items from a contract supplier, unless an exception applies. One exception is that a beneficiary may continue to obtain a DME rental item(s) from a non-contract supplier if the beneficiary was receiving the rented item(s) from the non-contract supplier when the CBP took effect in the CBA. Such non-contract supplier would be considered a "grandfathered supplier" with respect to such rented item and such beneficiary for the remainder of the period during which rental payments are made (for example, for the remainder of the 13-month period of continuous use for a capped rental item). An additional exception is that a beneficiary, who continues to obtain a rented, grandfathered competitive bidding item from a non-contract, grandfathered supplier, may also obtain certain covered accessories or supplies furnished for use with such rented "grandfathered" equipment from the same non-contract, grandfathered of the period during which rental payments are made (for example, for the remainder of the period during which rental payments are made competitive bidding item from a non-contract, grandfathered supplier, may also obtain certain covered accessories or supplies furnished for use with such rented "grandfathered" equipment from the same non-contract, grandfathered supplier for the remainder of the period during which rental payments are made (for example, for the remainder of the period during which rental payments are made (for example, for the remainder of the period during which rental payments are made (for example, for the remainder of the period during which rental payments are made (for example, for the remainder of the period during which rental payments are made (for example, for the remainder of the period during which rental payments are made (for example, for the remainder of the period during which rental payments are made (for example, for the remainder of the period during which rental

For rented, grandfathered equipment in the capped rental payment class (for example, a Continuous Positive Airway Pressure (CPAP) device or manual wheelchair), after the rental payment cap for the grandfathered equipment and after the rental payment cap on the accessory (when applicable, such as, elevating leg rests) is reached, the beneficiary must obtain covered accessories and supplies (for example, CPAP masks) from a contract supplier. The supplier of the grandfathered equipment is no longer permitted to furnish the covered accessories and supplies once the rental payment cap on the grandfathered equipment is reached, with the exception of completing the rental period for accessories when the first rental month began during the rental period for the grandfathered equipment (for example, the addition of elevating leg rests during the third rental month for a grandfathered manual wheelchair). For rented, grandfathered equipment in the inexpensive or routinely purchased payment class, after the total payments for the rented, grandfathered equipment (such as a folding walker) reach the purchase fee schedule amount for the grandfathered equipment, and after the rental payment cap on the accessory is reached (when applicable), the beneficiary must obtain covered accessories (for example. seat attachment) and supplies from a contract supplier. The supplier of the grandfathered equipment is no longer permitted to furnish the covered accessories and supplies once the rental payment cap on the equipment is reached, with the exception of completing the rental period for accessories when the first rental month began during the rental period for the grandfathered equipment.

In all cases, payment for covered accessories and supplies used in conjunction with a grandfathered item is based on the single payment amount calculated for the item for the CBA in which the beneficiary maintains a permanent residence.

In summary, Medicare payment may be made to a non-contract, grandfathered supplier for furnishing certain covered accessories or supplies furnished for use with rented, grandfathered equipment, provided the non-contract supplier is also furnishing the rented equipment on a grandfathered basis. Once rental payments for the grandfathered equipment have ended, Medicare payment will no longer be made to a non-contract, grandfathered supplier for furnishing accessories or supplies with the exception of completing the rental period for rented accessories.

Additional Information

The official instruction, CR9579 issued to your MAC regarding this change is available at http://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/R3500CP.pdf.

If you have any questions, please contact your MAC at their toll-free number. That number is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html under - How Does It Work.

You may review MM 8181, "Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) National Competitive Bidding (NCB): Using the "KY" Modifier to Bill for Accessories for Non-NCB Wheelchair Base Units" (Transmittal 1184, February 8, 2013) at: <u>https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8181.pdf</u>.

You can find additional information on the DMEPOS CBP at <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/index.html?redirect=/dmeposcompetitiveBid/</u>.

information is available at <u>http://www.dmecompetitivebid.com/palmetto/cbicrd2recompete.nsf/DocsCat/</u><u>Home</u>. This site includes information on all rounds of the CBP, including product categories single payment amounts for the Round 1 Re-compete, Round 2, and the national mail-order program for diabetic testing supplies; and the ZIP codes of areas included in the CBP.

Reclassification of Certain DME HCPCS Codes Included in CBP from the Inexpensive and Routinely Purchased Payment Category to the Capped Rental Payment Category – Second Revision

MLN Matters® Number: MM8822 Revised

Related Change Request (CR) #: CR 8822

Effective Date: : July 1, 2016 - except in Round 1 Re- compete CBP areas where effective date is January 1, 2017

Related CR Release Date: April 26, 2016

Implementation Date: July 5, 2016 - except for A/B and HHH MACs where implementation is 10/3/2016

Related CR Transmittal #: R16440TN

This article was revised on April 29, 2016, due to a revised CR8822. In the article, the transmittal number, CR issue date, and the Web address for accessing CR8822 are revised. All other information is unchanged.

Provider Types Affected

This MLN Matters® Article is intended for suppliers and Home Health Agencies (HHAs) submitting claims to Durable Medical Equipment Medicare Administrative Contractors (DME MACs) or Home Health & Hospice MACs for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) provided to Medicare beneficiaries.

What You Need to Know

CR 8822 provides instructions for the upcoming reclassification of certain Durable Medical Equipment (DME) Healthcare Common Procedure Coding System (HCPCS) codes, that are included in Round 2 and Round 1 Re-compete DMEPOS CBPs, from the inexpensive and routinely purchased DME payment category to the capped rental DME payment category.

CR 8822 follows CR 8566, **Rescind and Replace of CR 8409: Reclassification of Certain Durable Medical Equipment from the Inexpensive and Routinely Purchased Payment Category to the Capped Rental Payment Category**, which was released on March 25, 2014. You can find the associated MLN Matters article at <u>https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/</u> <u>MLNMattersArticles/downloads/MM8566.pdf</u>. Make sure your billing staffs are aware of these changes.

Background

Medicare defines routinely purchased DME (set forth at 42 CFR §414.220(a)(2)) as equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. A review of expensive items that have been classified as routinely purchased equipment since 1989 (that is, new codes added to the HCPCS after 1989 for items costing more than \$150) showed inconsistencies in applying the definition.

As a result, a review of the definition of routinely purchased DME was published in the Federal Register (CMS-1526-F) along with notice of DME items (codes) requiring a revised payment category. Also in that rule, the Centers for Medicare & Medicaid Services (CMS) established that DME wheelchair accessories that are capped rental items furnished for use as part of a complex rehabilitative power wheelchair (wheelchair base codes K0835 – K0864), will be paid under the associated lump sum purchase option set forth at 42 CFR § 414.229(a)(5) and Section 1834(a)(7)(A)(iii) of the Social Security Act. If the beneficiary declines the purchase option, the supplier must furnish the items on a capped rental basis and payment will be made on a monthly rental basis in accordance with the capped rental payment rules.

In order to align the payment category with the required regulatory definition, the HCPCS codes in the table below will reclassify to the capped rental payment category effective:

- July 1, 2016: Items furnished in all areas except the nine Round 1 Re-compete CBAs; and
- January 1, 2017: Items furnished in the nine Round 1 Re-compete CBAs.

HCPCS Codes for Items Reclassified to Capped Rental DME Category

HCPCS Code	Description
E0197	Support Surfaces
E0140, E0149	Walkers
E0985, E1020, E1028, E2228, E2368, E2369, E2370, E2375, K0015, K0070	Wheelchairs Options/Accessories
E0955	Wheelchair Seating

Further Details from CR8822:

- In Round 1 Re-compete CBAs, payment for HCPCS codes shown in the above table will be made under the inexpensive and routinely purchased (IN) payment category for dates of service July 1, 2016 through December 31, 2016. Your MAC will recognize that the capped payment category requires payment of 10 percent of the purchase price for the first three months and 7.5 percent for each of the remaining rental months 4 through 13. You should also be aware that payment amounts will be based on the lower of the supplier's actual charge and the fee schedule amount. Your MAC will return as unprocessable claims for the inexpensive and routinely purchased codes described above that are billed with the KH, KI and KJ modifiers. Such unprocessable claims will be returned with Claim Adjustment Reason Code (CARC) 4 (The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.), Remittance Advice Remark Code (RARC) N519 (Invalid combination of HCPCS modifiers) and Group Code CO (Contractual Obligation).
- 2. Effective for claims with dates of service on or after July 1, 2016, for items furnished in Round 2 CBAs, your MAC will cease any IN category rental payments for the codes in the above table and start payment under the Capped Rental (CR) payment category; applying a determination of the number of rental months paid (which cannot exceed 13 rental months combined from dates of service before and after the effective date (July 1, 2016)).
- 3. Effective for claims with dates of service on or after January 1, 2017, for items furnished in Round 1 Re-compete CBAs, your MAC will cease any IN rental payments for these codes, and start payment under the Capped Rental (CR) payment category; applying a determination of the number of rental months paid (which cannot exceed 13 rental months combined from dates of service before and after the effective date (January 1, 2017)).
- 4. Effective July 1, 2016, in all areas except the nine Round 1 CBAs, your MACs will process and pay claims for wheelchair base codes K0835 K0864): E1020, E1028, E2368, E2369, E2370, E2375, K0015, and E0955 (when applicable) on a lump sum purchase basis when used with complex rehabilitative power wheelchairs.
- 5. Effective January 1, 2017 in all areas including the Round 1 Re-compete CBAs, your MACs will process and pay claims for the codes K0835 K0864): E1020, E1028, E2368, E2369, E2370, E2375, K0015, and E0955 (when applicable) on a lump sum purchase basis when used with complex rehabilitative power wheelchairs.
- 6. When Home Health/Hospice (HHHs) providers bill codes E0197, E0140, E0149, E0985, E1020, E1028, E2228, E2368, E2369, E2370, E2375, K0015, K0070 and E0955 for services outside a competitive bid area on or after July 1, 2016, payment will be made on a capped rental basis.
- 7. When HHHs bill E1020, E1028, E2368, E2369, E2370, E2375, K0015, and E0955 for services outside a competitive bid area on or after July 1, 2016, MACs will process such claims on a lump sum purchase basis, where applicable, when used with a complex rehabilitative wheelchair base (K0835-K0864). Note that for this requirement, MACs will calculate the fee for the lump sum purchase basis (NU modifier Purchase of new equipment) for these items as the rental price times ten. The fee for a used item lump sum purchase basis (UE modifier Purchase of used equipment) will be 75 percent of the purchase fee.

Contractors will not search their files but will adjust claims brought to their attention between July 1, 2016, and October 3, 2016, for previously processed claims that meet the requirements stated in 6 and 7 above.

Additional Information

The official instruction, CR 8822 issued to your MAC regarding this change is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1644OTN.pdf.

Physician Documentation Responsibilities

Suppliers are encouraged to remind physicians of their responsibility in completing and signing the Certificate of Medical Necessity (CMN). It is the physician's and supplier's responsibility to determine the medical need for, and the utilization of, all health care services. The physician and supplier should ensure that information relating to the beneficiary's condition is correct. Suppliers are also encouraged to include language in their cover letters to physicians reminding them of their responsibilities.

Source: Internet Only Manual, Publication 100-8, Medicare Program Integrity Manual, Chapter 5, Section 5.3.2

Affordable Care Act 6407 - Supplier Frequently Asked Questions -Revised

DME MAC Joint Publication

Originally published July 15, 2015

This FAQ is revised to update the criteria associated with the written order prior to delivery and face-toface examination. While this document makes reference to "ACA 6407 requirements", technically these requirements are found in the Social Security Act Section 1834(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.

ACA 6407

1. Question: What is ACA 6407?

Answer: "ACA" refers to the Affordable Care Act of 2012 and "6407" is the specific section of the Affordable Care Act which requires a face-to-face (F2F) encounter with a physician and a valid written order prior to delivery. Suppliers should review the DME MAC Joint Publication titled "Face-to-Face Examination and Prescription Requirements Prior to the Delivery of Certain DME Items Specified in the Affordable Care Act - Revised" for a complete list of affected HCPCS codes.

2. Question: When will CMS enforce the Face-to-Face requirements and five element order (5EO)?

Answer: Section 6407 of the ACA was implemented on July 1, 2013, and the DME MAC contractors began enforcement of the 5EO and NPI requirements for dates of services on or after January 1, 2014. Enforcement of the F2F requirements by the DME MACs has been postponed by CMS until a future date.

3. Question: What is the difference between "implementation" and "enforcement" regarding ACA 6407?

Answer: Implementation is the date that the provisions of ACA 6407 became effective (July 1, 2013). Enforcement is when DME MACs begin auditing claims to determine that suppliers are following the provisions of ACA 6407.

4. Question: Is the Comprehensive Error Rate Testing (CERT) contractor following the DME MAC delay in enforcement of the F2F requirements?

Answer: No. CERT has been instructed by CMS not to delay the enforcement of the F2F requirements. The CERT contractor operates under the rules of the Improper Payments Elimination and Recovery Act (IPERA) and must enforce all coverage and payment rules mandated by CMS regulations. Consequently, claims reviewed by the CERT contractor that are not compliant with the F2F requirements may result in denial or recoupment. If the CERT contractor denies for this reason, suppliers may submit a request for a redetermination.

Face-to-Face Encounter

5. Question: Do suppliers need to obtain a new F2F encounter every six months?

Answer: No, there is no requirement under ACA 6407 that a supplier obtain documentation of a new F2F encounter on a periodic basis. A F2F encounter within six months prior to the 5EO date is required for any order obtained on or after July 1, 2013.

6. Question: What if the policy has a requirement for a F2F encounter within 30-days for an item that is also on the ACA list? Must the F2F encounter be performed within the 30-days or within six months?

Answer: There is no 30-day F2F requirement. There are existing LCD requirements that require a physician encounter that must be performed for certification. The ACA F2F requirement does not replace any existing patient/physician encounters. Suppliers must meet both the ACA requirements and any certification requirements outlined in the applicable Local Coverage Determination (LCD). By meeting the LCD requirement, the ACA requirement is automatically met.

7. Question: Does the ACA F2F requirement apply to orthotics and prosthetics?

Answer: Not at this time. ACA 6407 (SSA Section 1834(a)(11)(B)) and the implementing regulation at 42 CFR 410.38 gives the Secretary the authority to specify to which HCPCS codes the face-to-face requirement and written order prior to delivery apply. CMS did not include orthotics or prosthetic codes on the list of applicable HCPCS codes. Suppliers should review the DME MAC Joint Publication titled "Face-to-Face Examination and Prescription Requirements Prior to the Delivery of Certain DME Items Specified in the Affordable Care Act - Revised" for a complete list of affected HCPCS codes.

8. Question: Must the F2F encounter specifically mention the DME item being ordered?

Answer: No. However, in order for the ACA requirements to be met, the F2F encounter must address a medical condition that supports the item ordered.

9. Question: Does the F2F encounter 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)) need to specifically state the beneficiary was there for a F2F encounter for the specific DME item, or can the beneficiary have a visit and the physician's notes show physical limitations that justify the specific DME item?

Answer: In contrast to power mobility devices, items subject to the ACA 6407 requirements do not require that the F2F encounter specify that the visit was expressly for the purpose of documenting the need for the specific item of DME. However, as noted above, there must be sufficient documentation in the medical records to support the need for the item ordered.

10. Question: Can the F2F documentation be electronically signed by the treating practitioner?

Answer: CMS has published instructions to contractors allowing electronic signatures (see CMS Program Integrity Manual, Chapter 3, Section 3.3.2.4). CMS has not provided detailed guidance defining the format or contents of an electronic signature. CMS does allow contractors to authenticate electronic signatures. We recommend that when suppliers obtain electronic records that the electronic signatures are clearly identifiable as electronic and meet the same date and credential standards as outlined in Chapter 3, Section 3.3.2.4 that are also required for a non-electronic signature for the same document type. Refer to each LCD and the Supplier Manual for additional information regarding signatures.

Five-Element Written Orders Prior to Delivery (5EO)/Face-to-Face

11. Question: What elements must be included on the 5EO for items associated with ACA 6407 HCPCS code list?

Answer: ACA 6407 requires five specific elements that must be included on the order:

- 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

A date stamp or equivalent must be used to document the 5EO receipt date by the supplier

12. Question: What date should be used for the "date of the order" on the 5EO?

Answer: Use the date the supplier is contacted by the treating practitioner (for verbal orders) or the date entered by the treating practitioner (for written dispensing orders).

13. Question: What if the treating practitioner wants to specify additional elements on the 5EO?

Answer: Nothing prohibits the treating practitioner (or the supplier) from including additional elements on the 5EO. The five elements listed above are the minimum elements required.

14. Question: Some treating practitioners indicate a future date on which to start therapy. How is this handled?

Answer: In some cases, the treating practitioner may specify a future start date for therapy that is different from the date of the order. This start date does not impact the date of the order, date of service (DOS) entered on the claim, Medicare-required forms (e.g., CMN, DIF) or refill/delivery timelines. As long as the supplier has a properly completed 5EO with a correctly determined prescription date, an item may be shipped or delivered on or after the date of the order.

15. Question: May the treating practitioner use a signature or date stamp on the 5EO?

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

16. Question: The ACA 6407 does not apply to all DMEPOS and does not apply to various supplies and accessories. How should suppliers handle those items?

Answer: For non-ACA items and items that do not require a written order prior to delivery, a standard dispensing order and detailed written order are sufficient. For ACA 6407 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. Suppliers should review the DME MAC Joint Publication titled "Face-to-Face Examination and Prescription Requirements Prior to the Delivery of Certain DME Items Specified in the Affordable Care Act - Revised" for a complete list of affected HCPCS codes.

17. Question: Can the 5EO and the F2F encounter be on the same document as long as it is in the medical record?

Answer: No. The F2F encounter and 5EO must be two separate documents. The face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans or other information as it may be appropriate).

18. Question: If the beneficiary is in the hospital, can the attending physician conduct the F2F encounter and the beneficiary's primary care physician complete the 5EO?

Answer: Yes. 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 6-months prior to the date of their prescription; and,
- Have documentation of the face-to-face examination that was conducted.

19. Question: Can the F2F encounter, 5EO and the delivery of the DME item all be completed in the same day?

Answer: Yes. However, the date stamp (or equivalent) indicating the date of receipt must clearly reflect that the 5EO was received prior to delivery of the item.

Documenting a Receipt Date

20. Question: Must the 5EO be date stamped by the supplier upon receipt?

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

21. Question: What methods are acceptable for documenting a receipt date?

Answer: The DME MACs do not specify what method may be used to indicate date of receipt; however, there must be some indicator or notation on the documents that they were received by the supplier within the required time period. Some commonly accepted methods are:

- Hardcopy date stamps
- Hand-written dates

• Facsimile headers and electronic receipt dates (see question 22 for additional information)

Regardless of the method used, it must be clear to contractor staff reviewing the claim that the date received meets the requirements in the applicable LCD.

22.Question: Can a fax header be used to document receipt of the 5EO prior to delivery, or must we use a date stamp?

Answer: We highly recommend the use of a date stamp to document receipt of the 5EO. If a fax date or equivalent is used, the information must be legible, it must be clear that the supplier is the one that received the 5EO on the date listed. Possible ways to document this would be to also submit a copy of the fax cover sheet or the header listing the "to" and "from" sender names.

5EO – Corrections to Document

23. Question: What happens if there is an error on the 5EO document and it is not noticed until after the equipment is delivered to the beneficiary?

Answer: Written order prior to delivery (WOPD) is a long-standing statutory requirement for certain items of DME. The list of items subject to WOPD (termed a 5EO for ACA 6407 items) was expanded by the Affordable Care Act Section 6407. Medicare policy stipulates that a 5EO that is missing an element is not "curable" by a provider (i.e., a provider cannot make corrections to a 5EO) except as outlined below:

- If errors in the 5EO are found prior to delivery, the supplier has two options:
 - The 5EO may be properly amended following the guidance in the Medicare Program Integrity Manual (Internet-Only Manual, Publication 100-08), Chapter 3, Section 3.3.2.5; or,
 - A new 5EO may be created and sent to the physician for signature and date.
- If errors in the 5EO are found after delivery of the item, the supplier has two options:
 - If the error is discovered prior to claim submission, the original supplier may recover the delivered item(s), obtain a compliant, complete 5EO and then may redeliver the item(s) to the beneficiary; or,
 - If the error is discovered after submitting a claim, the original supplier can recover their items and a new supplier must complete the transaction after complying with all requirements.

Because 5EO is a statutory requirement, claims denied because of a defective 5EO result in a beneficiary liability determination. Suppliers are strongly encouraged to review their 5EO documentation carefully prior to delivery to ensure that all the requirement elements are present on the document.

24. Question: Does Medicare consider a different location (with a different NPI or PTAN) another supplier?

Answer: Yes. A different location of the same company is considered a "new" supplier as that location operates and bills the Medicare program under a separate NPI/PTAN.

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: <u>http://www.dmepdac.com</u>.

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

198	
	Water pressure pad for mattress standard length and width
199	Dry pressure pad for mattress standard length and width
250	Hospital bed fixed height with any type of side rails, mattress
251	Hospital bed fixed height with any type side rails without mattress
255	Hospital bed variable height with any type side rails with mattress
256	Hospital bed variable height with any type side rails without mattress
260	Hospital bed semi-electric (Head and foot adjustment) with any type side rails with mattress
261	Hospital bed semi-electric (head and foot adjustment) with any type side rails without mattress
265	Hospital bed total electric (head, foot and height adjustments) with any type side rails with mattress
266	Hospital bed total electric (head, foot and height adjustments) with any type side rails without mattress
290	Hospital bed fixed height without rails with mattress
291	Hospital bed fixed height without rail without mattress
292	Hospital bed variable height without rail without mattress
293	Hospital bed variable height without rail with mattress
294	Hospital bed semi-electric (head and foot adjustment) without rail with mattress
295	Hospital bed semi-electric (head and foot adjustment) without rail without mattress
296	Hospital bed total electric (head, foot and height adjustments) without rail with mattress
297	Hospital bed total electric (head, foot and height adjustments) without rail without mattress
300	Pediatric crib, hospital grade, fully enclosed
0301	Hospital bed Heavy Duty extra wide, with weight capacity 350-600 lbs with any type of rail, without mattress
0302	Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, without mattress
0303	Hospital bed Heavy Duty extra wide, with weight capacity 350-600 lbs with any type of rail, with mattress
0304	Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, with mattress
0424	Stationary compressed gas Oxygen System rental; includes contents, regulator, nebulizer, cannula or mask and tubing
9431	Portable gaseous oxygen system rental includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
433	Portable liquid oxygen system
9434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, content gauge, cannula or mask, and tubing
9439	Stationary liquid oxygen system rental, includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
)441	Oxygen contents, gaseous (1 months supply)
442	Oxygen contents, liquid (1 months supply)
	251 255 256 260 261 265 266 290 291 292 293 294 295 296 297 300 301 302 303 304 424 431 433 434 439 441

HCPCS Code	Description
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

HCPCS Code	Description
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

HCPCS Code	Description
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
-2002	operation contracting between protocold messages between a and 20 minutes

HCPCS Code	Description
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 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

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

DME MAC Joint Publication

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Posted February 20, 2014

This FAQ is revised to update the criteria associated with the five-element written order prior to delivery (5EO) 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 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.

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 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 and Chapter 12 of the Medicare Claims Processing Manual - CMS Internet-Only Manuals, Publ. 100-02 and 100-04, respectively).

For the treat 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)

LCDs that contain items subject to these requirements are:

- Automatic External Defibrillators
- Cervical Traction Devices
- External Infusion Pumps
- High-frequency Chest Wall Oscillation Devices
- Home Glucose Monitors
- 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
- 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: <u>http://www.dmepdac.com</u>.

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

HCPCS Code	Description
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

HCPCS Code	Description
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

HCPCS Code	Description
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

HCPCS Code	Description
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 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

Standard Documentation Language for Local Coverage Determinations and Related Policy Articles – Revised

Joint DME MAC Publication

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Note: This is a revision to the previous article published in November 2015. This version updates the requirements for orders and face-to-face examinations, in compliance with the Affordable Care Act (ACA) Section 6407. While the Standard Documentation language 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.

The information in this document supersedes the material currently contained in the Local Coverage Determinations (LCDs) and related Policy Articles (Pas). Where there are differences between the policies and this article, this document shall take precedence. This information will be added to future revisions of all LCDs and related Policy Articles.

Many errors reported in DME MAC MR Reviews and Comprehensive Error Rate Testing (CERT) Audits arise from problems associated with submitted documentation; consequently, the DME MACs have created a standardized language for use in Local Coverage Determinations and related Policy Articles. Standardized language first appeared in 2012 and with subsequent changes in CMS and DME MAC program instructions, is being revised with this publication. The updated language will be inserted in the applicable LCDs and related PAs upcoming revisions to these policies.

The standard sections are written in a modular format to allow each policy to contain information relevant to that policy while omitting material that does not apply. As a result, all modules may not be used in every LCD. This article provides a complete listing of all of the documentation requirement modules. For example, the Certificate of Medical Necessity (CMN) sections would not be included in the DOCUMENTATION REQUIREMENTS section of an LCD for an item that does not require a CMN.

IMPORTANT

Many policies contain coverage and documentation requirements that are unique to that specific policy. Such unique information is not included in this article. It is important that suppliers review the actual LCD to be sure to have all of the relevant information necessary applicable to the item(s) provided.

In several places you will see "placeholders" like "XXX" or "###". Information specific to the policy will be inserted in these spots. Occasionally you may also see "Editor Note" comments. These notes are used to indicate where optional sections may be inserted, when applicable and formatting information.

Standard Language

LCD

COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY

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. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following indications and limitations of coverage and/or medical necessity.

Medicare does not automatically assume payment for a durable medical equipment, prosthetics, orthotics and supplies (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.

While this Standard Documentation language 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.

DWO VERBIAGE

For an item to be covered by Medicare, a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed DWO, the item will be denied as not reasonable and necessary.

ACA 5EO or WOPD

For some items in this policy to be covered by Medicare, a written order is required to be in the supplier's file prior to delivery of the specified item(s). There are two differing order requirements that may apply depending upon the specific item prescribed:

- The Affordable Care Act Section 6407 (ACA 6407) specifies the five elements that must be contained in this written order. For purposes of this policy, this order is termed the 5-element order (5EO).
- A written order prior to delivery (WOPD) that meets all of the requirements of a standard detailed written order (DWO).

If the supplier delivers an item addressed in this policy without first receiving the completed order, the item will be denied. Refer to the DOCUMENTATION REQUIREMENTS section of this LCD and/or to the NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the related Policy Article for information about these prescription requirements and the type of denial that will result from non-compliance.

REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary 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, existing supplies are approaching exhaustion, and to confirm any changes or 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. For delivery of refills, the supplier 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. (CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-08, Chapter 5, Section 5.2.8-9).

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the prescribing practitioner that any changed or atypical utilization is warranted. Regardless of utilization, a supplier must not dispense more than a XX-month quantity at a time.

DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the treating practitioner's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

PRESCRIPTION (ORDER) REQUIREMENTS GENERAL (PIM 5.2.1)

All items billed to Medicare require a prescription. An order for each item billed must be signed and dated by the prescribing practitioner, kept on file by the supplier, and made 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 (PIM 5.2.2)

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. The supplier must keep a record of the dispensing order on file. It must contain:

• Description of the item

- Beneficiary's name
- Prescribing practitioner's name
- Date of the order
- Prescribing practitioner's signature (if a written order) or supplier signature (if verbal order)

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

In some cases, the prescribing practitioner may specify a future start date for therapy that is different from the date of the order. This start date does not impact the date of the order, date of service (DOS) entered on the claim, Medicare-required forms (e.g., CMN, DME Information Form (DIF)) or refill/delivery timelines. As long as the supplier has a properly completed dispensing order with a correctly determined prescription date, an item may be shipped or delivered on or after the date of the dispensing order (except for items that require written orders prior to delivery).

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, the supplier must obtain a detailed written order before submitting a claim.

ACA 6407 PRESCRIPTION REQUIREMENTS

ACA 6407 requires a specific written order prior to delivery for the HCPCS codes specified in the table contained in the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section below. This ACA 6407-required prescription has five (5) mandatory elements. For the purposes of this policy, the ACA 6407- required order is referred to as a five-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 6407 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 used to document the 5EO receipt date by the supplier.

Note that 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 National Provider Identifier (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.

Refer to the related Policy Article NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information about the statutory requirements associated with a 5EO.

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

In some cases, the prescribing practitioner may specify a future start date for therapy that is different from the date of the order. This start date does not impact the date of the order, date of service (DOS) entered on the claim, Medicare-required forms (e.g., CMN, DIF) or refill/delivery timelines. As long as the supplier has a properly completed 5EO with a correctly determined prescription date, an item may be shipped or delivered on or after the date of the order.

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, the supplier must obtain a detailed written order (see DETAILED WRITTEN ORDER section below) before submitting a claim for any associated options, accessories and/or supplies that are separately billed.

The 5EO must be available upon request.

DETAILED WRITTEN ORDERS (PIM 5.2.3)

A detailed written order (DWO) is required before billing. Someone other than the prescribing practitioner may produce the DWO. However, the prescribing practitioner must review the content and sign and date the document. It must contain:

- Beneficiary's name
- Prescribing practitioner's name
- Date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Prescribing practitioner's signature and signature date

For items provided on a periodic basis, including drugs, the written order must include:

- Item(s) to be dispensed
- Dosage or concentration, if applicable
- Route of Administration
- Frequency of use
- Duration of infusion, if applicable
- Quantity to be dispensed
- Number of refills

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

Additional order date instructions:

- If the prescriber creates a complete and compliant DWO, only a single date the "order date" –
 is required. This order date may be the date that the prescriber signs the document (either wet signature
 or electronic signature).
- If someone other than the prescriber (e.g., DME supplier) creates the DWO then the prescription must be reviewed and, "...personally signed and dated..." by the prescriber. In this scenario, two (2) dates are required: an "order date" and a prescriber-entered "signature date".

In some cases, the prescribing practitioner may specify a future start date for therapy that is different from the date of the order. This start date does not impact the date of the order, date of service (DOS) entered on the claim, Medicare-required forms (e.g., CMN, DIF) or refill/delivery timelines. As long as the supplier has a properly completed dispensing order with a correctly determined prescription date, an item may be shipped or delivered on or after the date of the dispensing order (except for items that require written orders prior to delivery).

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. (PIM 5.9)

The detailed description in the written order may be either a narrative description or a brand name/model number.

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

The DWO must be available upon request.

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)

WRITTEN ORDERS PRIOR TO DELIVERY (PIM 5.2.4)

A written order prior to delivery (WOPD) is required for XXX. The supplier must have received a WOPD that has been both signed and dated by the prescribing practitioner and meets the requirements above for a DWO before dispensing the item.

For items that require a WOPD, the supplier must obtain a detailed written order before submitting a claim for any associated options, accessories and/or supplies that are separately billed.

NEW ORDER REQUIREMENTS (PIM 5.2.7)

A new prescription is required when:

- 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; and
- When there is a change in the supplier.

MEDICAL RECORD INFORMATION GENERAL (PIM 5.7 -5.9)

The COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY section of this LCD contains numerous reasonable and necessary (R&N) requirements. The NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the related Policy Article contains numerous non-reasonable and necessary, benefit category and statutory requirements that must be met in order for payment to be justified. Suppliers are reminded that:

Supplier-produced records, even if signed by the 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.

Information contained directly in the contemporaneous medical record is the source required to justify payment except as noted elsewhere for prescriptions and CMNs. The medical record is not limited to treating practitioner's office records but may include records from hospitals, nursing facilities, home health agencies, other healthcare professionals, etc. (not all-inclusive). 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.

CONTINUED MEDICAL NEED

For all Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (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 DOS 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 DOS 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 elsewhere in the policy.

CONTINUED USE

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

Suppliers are responsible for monitoring utilization of DMEPOS rental items and supplies. No monitoring of purchased items or capped rental items that have converted to a purchase is required. Suppliers must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary.

Beneficiary medical records or supplier 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.
- Supplier 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.
- Supplier 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 elsewhere in this policy.

REFILL DOCUMENTATION (PIM 5.2.7-9)

A routine prescription for refills is not needed. Refer to the NEW ORDER REQUIREMENTS section for additional information.

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 the supplier and beneficiary. The refill request must occur and be documented before shipment. A retrospective attestation statement by the supplier or beneficiary is not sufficient. The refill record must include:

• 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.) the supplier 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 (PAP) and Respiratory Assist Devices (RAD) supplies) the supplier must assess whether the supplies remain functional, providing replacement (a refill) only when the supply item(s) is no longer able to function. The supplier 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.

PROOF OF DELIVERY (PIM 4.26, 5.8)

Proof of delivery (POD) is a Supplier Standard. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers are required to maintain POD documentation in their files. 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.

Suppliers, their 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 signature and date the beneficiary or designee accepted delivery must be legible.

For the purpose of the delivery methods noted below, designee is defined as any person who can sign and accept the delivery of DMEPOS on behalf of the beneficiary.

Proof of delivery documentation must be available to the Medicare contractor on request. All services that do not have appropriate proof of delivery from the supplier will be denied and overpayments will be requested. Suppliers who consistently fail to provide documentation to support their services may be referred to the Office of Inspector General (OIG) for imposition of Civil Monetary Penalties or other administrative sanctions.

Suppliers are required to maintain Proof of Delivery (POD) documentation in their files. There are three methods of delivery:

- Delivery directly to the beneficiary or authorized representative
- Delivery via shipping or delivery service
- Delivery of items to a nursing facility on behalf of the beneficiary

Method 1 - Direct Delivery to the Beneficiary by the Supplier

Suppliers 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
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- 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 the supplier. When the supplier's delivery documents have both a supplier-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 the supplier, 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 the supplier utilizes a shipping service or mail order, the POD documentation must be a complete record tracking the item(s) from the DMEPOS supplier to the beneficiary. An example of acceptable proof of delivery would include both the supplier's own detailed shipping invoice and the delivery service's tracking information. The supplier's record must be linked to the delivery service record by some clear method like the delivery service's package identification number or supplier's invoice number for the package sent to the beneficiary. The POD record must include:

- Beneficiary's name
- Delivery address
- Delivery service's package identification number, supplier invoice number or alternative method that links the supplier's delivery documents with the delivery service's records
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Evidence of delivery

If a supplier utilizes a shipping service or mail order, suppliers must use the shipping date as the date of service on the claim.

Suppliers 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 the supplier to a nursing facility or when a delivery service or mail order is used to deliver the item(s) to a nursing facility, the supplier must have:

- Documentation demonstrating delivery of the item(s) to the facility by the supplier or delivery entity; and,
- 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.

CORRECT CODING (PIM 3.3)

Correct coding is a determination that the item(s) provided to the beneficiary are billed using the appropriate HCPCS code for the item. Suppliers 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.

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, the suppler:

- Must obtain a new POD as described above under "Methods of Delivery" (whichever method is applicable); or,
- Must obtain a statement, signed and dated by the beneficiary (or beneficiary's designee), attesting that the supplier has examined the DMEPOS item, it is in good working order, and that it 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.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS AFFORDABLE CARE ACT (ACA) 6407 REQUIREMENTS

ACA 6407 contains provisions that are applicable to certain specified items in this policy. In this policy the specified items are:

{Insert code table}

These items require an in-person, face-to-face interaction between the beneficiary and their treating practitioner prior to prescribing the item. This face-to-face evaluation must specifically document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered. A dispensing order is not sufficient to provide these items. A 5EO (see ACA 5EO section above) must be received prior to delivery. Refer to the related Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information about these statutory requirements.

The DMEPOS supplier must have documentation of the completed 5EO in their file prior to the delivery of these items.

Suppliers are reminded that all Medicare coverage and documentation requirements for DMEPOS also apply. There must be sufficient information included in the medical record to demonstrate that all of the applicable coverage criteria are met. This information must be available upon request.

GENERAL

CERTIFICATE OF MEDICAL NECESSITY (PIM 5.3) (Editor Note: Only for items requiring CMN)

A Certificate of Medical Necessity (CMN), which has been completed, signed, and dated by the treating practitioner, must be kept on file by the supplier and made available upon request. The CMN may act as a substitute for the detailed written order if it contains the same information as required in a detailed written order. The CMN for XXX is CMS Form ### (DME form ###). In addition to the order information that the treating practitioner enters in Section B, the supplier can use the space in Section C for a written confirmation of other details of the order or the treating practitioner can enter the other details directly.

A new CMN is not required just because the supplier changes assignment status on the submitted claim.

DME INFORMATION FORM (PIM 5.3)

A DME Information Form (DIF), which has been completed, signed, and dated by the supplier, must be kept on file and made available upon request. The DIF for XXX is CMS Form ### (DME form ###).

REPAIR/REPLACEMENT (BPM Ch. 15, §110.2)

A new Certificate of Medical Necessity (CMN) and/or treating 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:

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

The supplier 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 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 (BPM Ch. 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 practitioner, either on the order or in the medical record, and must fall under one of the following:

- A change in the physiological condition of the patient resulting in the need for a replacement. Examples include but are not limited to, changes in beneficiary weight, changes in the residual limb, beneficiary functional need changes; or,
- An irreparable change in the condition of the device, or in a part of the device resulting in the need for a replacement; or,
- 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.

MISCELLANEOUS

Refer to the Supplier Manual for additional information on documentation requirements.

APPENDICIES

PIM citations above denote references to CMS Program Integrity Manual, Internet Only Manual 100-08.

Utilization Guidelines

Refer to Coverage Indications, Limitations and/or Medical Necessity

POLICY ARTICLE

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

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. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

BENEFIT CATEGORY

DME is covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Or

Prosthetic devices are covered under the Prosthetic Devices benefit (Social Security Act §1861(s)(8)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

STATUTORY PRESCRIPTION (ORDER) REQUIREMENTS

Many DMEPOS items have statutory prescription requirements. Items with statutory order requirements are:

- All items on the ACA section 6407 product list,
- Power mobility devices, and
- Pressure reducing support surfaces.

If the supplier fails to obtain a prescription or the order fails to comply with the applicable criteria described in the DOCUMENTATION REQUIREMENTS section of the LCD, the item will be denied as statutorily excluded.

AFFORDABLE CARE ACT (ACA) 6407 REQUIREMENTS

ACA 6407 contains provisions that are applicable to specified items in this policy. In this policy the specified items are:

{Select codes from table below}

Face-to-Face Visit 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).

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 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.

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

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.

ACA 6407 Prescription Requirements:

ACA 6407 requires a written order prior to delivery for the HCPCS codes specified in the table above. This ACA 6407-required prescription has five (5) mandatory elements. For the purposes of this policy, 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 specified item(s); and,
- A date stamp or equivalent must be used to document the 5EO receipt date by the supplier.

Refer to the related Local Coverage Determination DOCUMENTATION REQUIREMENTS section for information associated with a 5EO.

Suppliers should pay particular attention to orders that include a mix of items to which ACA 6407 does and does not apply to assure that these ACA order requirements are met.

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

- Verify that the in-person visit occurred within the six 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 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.
- The DMEPOS supplier must have 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 treating practitioner 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 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 the supplier delivers 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.

CODING GUIDELINES

(Editor Note: Only use first paragraph when items require PDAC review)

The only products that may be billed using codes XXX are those for which a written Coding Verification Review has been made by the Pricing, Data Analysis, and Coding (PDAC) Contractor and subsequently published on the appropriate Product Classification List.

Suppliers should contact the Pricing, Data Analysis, and Coding (PDAC) Contractor for guidance on the correct coding of these items.

Coverage and Coding - New Oral Antiemetic Drug Varubi[®] - Revised - Effective Date July 1, 2016

Joint DME MAC Publication

The U.S. Food and Drug Administration approved Varubi® (rolapitant) on September 2, 2015. Rolapitant is a substance P/neurokinin1 (NK-1) receptor antagonist used to treat nausea and vomiting in patients undergoing emetogenic cancer chemotherapy.

The Durable Medical Equipment Medicare Administrative Contractors (DME MACs) have evaluated rolapitant and determined that it is eligible for inclusion in the DME MAC Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics) Local Coverage Determination (LCD).

For dates of service on or after September 2, 2015 and before July 1, 2016, claims for rolapitant must be billed using HCPCS Code:

Q0181 – UNSPECIFIED ORAL DOSAGE FORM, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR A IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN.

For dates of service on or after July 1, 2016, claims for rolapitant must be billed using HCPCS Code:

Q9981 - ROLAPITANT, ORAL, 1 MG

Q9981 must be billed on the same claim with dexamethasone (J8540) and an oral 5HT3 antagonist.

The use of the oral anti-emetic 3-drug combination of an FDA-approved oral NK-1 antagonist and an oral 5HT3 antagonist, in combination with dexamethasone, is covered if in addition to meeting the statutory coverage criteria specified in the related Policy Article, they are administered to beneficiaries who are receiving one or more of the anti-cancer chemotherapeutic agents listed in the LCD regarding oral anti-emetic coverage.

If the three drug combination of an oral 5HT3 antagonist, rolapitant (Q9981) and dexamethasone (J8540) are used in conjunction with one of the anticancer chemotherapeutic agents listed in the Coverage Indications, Limitations and/or Medical Necessity section of the LCD regarding oral antiemetics, a KX modifier must be added to each code. In addition to the diagnosis code corresponding to the beneficiary's cancer diagnosis, claims for these drugs must also be accompanied with a diagnosis code of an encounter for antineoplastic chemotherapy (Z51.11).

If the three drug combination of rolapitant (Q9981), an oral 5HT3 antagonist and dexamethasone (J8540) are not used in conjunction with one of the anticancer chemotherapeutic agents listed in the Coverage Indications, Limitations and/or Medical Necessity section of this policy, the GA or GZ modifier must be added to the claim lines for Q9981 and J8540 and the 5HT3 antagonist. When there is an expectation of a denial as not reasonable and necessary, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

Claim lines billed without a KX, GA, or GZ modifier will be rejected as missing information.

Please refer to the DME Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics) Local Coverage Determination, related Policy Article and Supplier Manual for further information on coverage, documentation and coding requirements.

For questions about correct coding, contact the Pricing, Data Analysis and Coding (PDAC) Contact Center at (877) 735-1326 during the hours of 8:30 a.m. to 4 p.m. CT, Monday through Friday or e-mail the PDAC by completing the DME PDAC Contact Form located on the PDAC website.

EDUCATIONAL

2016 Ask the Contractor Teleconferences

If you have a question on your mind and are not sure who to ask, the Ask the Contractor Teleconferences (ACTs) are your opportunity to speak directly to Noridian DME. Knowledgeable Noridian staff representing a variety of functions will be available to answer your questions. If we cannot answer your question during the teleconference, we will research the issue and include the answer in the posted minutes.

Upcoming 2015 ACTs: 3 p.m. CT

- March 10
- June 9
- September 8
- December 8

Toll Free number: (800) 230-1074

After placing the call for the ACT, suppliers need to provide the following:

- Conference Name: DME Jurisdiction D Ask the Contractor Teleconference
- Name
- Name of the organization represented
- State

Noridian DME Outreach and Education Newsletter

The Noridian DME Outreach and Education staff is excited to offer the following DME newsletter as a reference for locating education tools. Noridian strives to provide quality education opportunities and avenues for obtaining information critical to the DMEPOS supplier community. This newsletter was created with that goal in mind. View the <u>newsletter</u> on the Event Materials and Tutorials under Education & Outreach.

To sign up for an upcoming workshop, visit the Noridian Schedule of Events.

ENROLLMENT

Guidance on Implementing System Edits for Certain DMEPOS

MLN Matters® Number: MM9371 Related Change Request (CR) #: CR 9371 Related CR Release Date: May 20, 2016 Effective Date: October 3, 2016 Related CR Transmittal #: R16690TN Implementation Date: October 3, 2016

Provider Types Affected

This MLN Matters® Article is intended for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers submitting claims to Durable Medical Equipment Medicare Administrative Contractors (DME MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

Your claim for the DMEPOS product categories listed in the Background section (below) will be denied unless you have been identified, on your Form CMS-855S, as accredited and verified; or are currently exempt from meeting the accreditation requirements.

ENROLLMENT

Change Request (CR) 9371 provides guidance to the National Supplier Clearinghouse (NSC), the Medicare Provider Enrollment, Chain, and Ownership System (PECOS), and the ViPS Medicare System (VMS) regarding the implementation of system edits for certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

Specifically, it announces that (effective for claims with dates of service on or after October 3, 2016) VMS will develop an edit for the Healthcare Common Procedure Coding System (HCPCS) codes in the product categories named by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) as requiring accreditation by accreditation organizations designated by the Secretary of Health and Human Services.

This edit will deny your claims for these codes unless you have been identified as accredited at the time the services were rendered and verified on your Medicare Enrollment Application Form CMS-855S, or you are currently exempt from meeting the accreditation requirements as discussed in CR9371.

You should ensure that you have submitted evidence and verification of accreditation by a Secretarydesignated accreditation organization on your CMS-855S, or that you are exempt (see exempt providers below) from such accreditation requirement.

Background

Section 302 of the Medicare Modernization Act of 2003 added a new paragraph 1834(a)(20) to the Social Security Act (the Act), which required the Secretary of Health and Human Services (the Secretary) to establish and implement quality standards DMEPOS suppliers.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) added a new subparagraph that implemented quality standards, stating that the Secretary will require suppliers furnishing items and service on or after October 1, 2009 (directly or as a subcontractor for another entity) to have submitted evidence of accreditation by a Secretary-designated accreditation organization. All DMEPOS suppliers that furnish such items or services required in the new paragraph (as the Secretary determines appropriate) must comply with the quality standards in order to receive Medicare Part B payments and to retain Medicare billing privileges through a supplier billing number.

The covered items and services defined in the Act include:

- DME
- Medical supplies
- Home dialysis supplies and equipment
- Therapeutic shoes
- Parenteral and enteral nutrient, equipment and supplies
- Transfusion medicine, and
- Prosthetic devices, prosthetics, and orthotics

This subparagraph also states that eligible professionals and other persons (defined below) are exempt from meeting the September 30, 2009, accreditation deadline unless the Centers for Medicare & Medicaid Services (CMS) determines that the quality standards are specifically designed to apply to such professionals and persons.

The eligible professionals who are exempt from meeting the September 30, 2009, accreditation deadline (as defined in section 1848(k)(3)(B)) include the following practitioners:

- Physicians (as defined in Section 1861(r) of the Act)
- Physical Therapists
- Occupational Therapists
- Qualified Speech-Language Pathologists
- Physician Assistants
- Nurse Practitioners
- Clinical Nurse Specialists

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- Certified Registered Nurse Anesthetists
- Certified Nurse-Midwives
- Clinical Social Workers
- Clinical Psychologists
- Registered Dietitians, and
- Nutritional Professionals

The "other persons" who are exempt from meeting the accreditation deadline (unless CMS determines that the quality standards are specifically designed to apply to such other persons) are specifically defined as the following practitioners:

- Orthotists
- Prosthetists
- Opticians, and
- Audiologists

Therefore, all supplier types (except those listed above) who furnish items and services requiring accreditation, directly or as a subcontractor for another entity, must have submitted evidence of accreditation by an accreditation organization designated by the Secretary on or after October 1, 2009.

Some Technical Details

The DME-MACs will:

- Have an edit, for the HCPCS codes in the product categories requiring accreditation, that will deny claims paid for these codes unless the DMEPOS supplier has been identified as accredited and verified on their CMS-855S, or the DMEPOS supplier is currently exempt from meeting the accreditation requirements;
- Have an edit to automatically line item deny claims with dates of service on or after October 3, 2016 for HCPCS codes linked to the product codes which require accreditation from non-exempt DMEPOS suppliers when the date of services does not fall between the effective and expiration dates for both accreditation and product codes; and
- Exempt beneficiary submitted claims from accreditation editing

If you still have questions after learning more about the basic accreditation requirement by the DME-MACs, you will be referred to the accrediting organization or to the NSC.

The effective and expiration dates for your accreditation will be the dates provided by the accrediting organization indicating you have met all accreditation requirements.

If a claim was processed and paid prior to the effective date of CR9371 and you submit an adjustment to that claim after implementation, the adjustment should not be subject to the accreditation edits.

Additional Information

The official instruction, CR9371, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1669OTN.pdf. Attached to CR9371, you will find a list of the product categories and related HCPCS codes affected by CR9371.

ENTERAL AND PARENTERAL NUTRITION

Parenteral Nutrition (HCPCS B4185, B4197) Final Edit Effectiveness Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code B4185 and B4197. The final edit effectiveness results from July 2015 through February 2016 are as follows:

The B4185 review involved 74 claims, of which 72 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 94%.

The B4197 review involved 44 claims, of which 41 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 94%.

The top reasons for denial were:

- Documentation does not support coverage criteria.
- Documentation does not support a permanent impairment.
- Documentation was not provided to support the beneficiary had a visit within 30 days prior to certification.
- Detailed Written Order (DWO) is incomplete or missing elements.

For complete details, see <u>Parenteral Nutrition (HCPCS B4185, B4197) Final Edit Effectiveness Results of</u> <u>Service Specific Prepayment Review</u>.

Enteral Nutrition (HCPCS B4150, B4154) Final Edit Effectiveness Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code B4150 and B4154. The final edit effectiveness results from July 2015 through February 2016 are as follows:

The B4150 review involved 196 claims, of which 96 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 42%.

The B4151 review involved 104 claims, of which 42 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 43%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Documentation does not support permanent impairment.
- Documentation does not support disease of the small bowel which impairs digestion and absorption of oral diet.
- Documentation does not support a non-function or disease of structure that permit food to reach the small bowel.

For complete details, see Enteral Nutrition (HCPCS B4150, B4154) Final Edit Effectiveness Results of <u>Service Specific Prepayment Review</u>.

ENTERAL AND PARENTERAL NUTRITION

External Infusion Pumps (HCPCS E0781, E0784) Quarterly Results of Documentation Compliance Review

The Jurisdiction D DME MAC Medical Review Department is conducting a Documentation Compliance Review (DCR) of HCPCS code(s) E0781 and E0784. The quarterly edit effectiveness, from July 2015 through September 2015 are as follows:

The E0781 review involved 216 claims, of which 100 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 49%.

The E0784 review involved 105 claims, of which 31 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 29%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Detailed Written Order (DWO) is dated after the date of service with no dispensing order received.
- Proof of Delivery (POD) is after the date of service of the claim or was not received.
- DME Information Form (DIF) is invalid or was not received.
- Documentation does not support a covered indication.

For complete details, see <u>External Infusion Pumps (HCPCS E0781, E0784)</u> <u>Ouarterly Results of</u> <u>Documentation Compliance Review</u>.

External Infusion Pump (HCPCS E0781, E0784) Quarterly Results of Documentation Compliance Review

The Jurisdiction D DME MAC Medical Review Department is conducting a Documentation Compliance Review (DCR) of HCPCS codes E0781 and E0784. The quarterly edit effectiveness, from January 2016 through March 2016 are as follows:

The E0781 review involved 126 claims, of which 54 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 45%.

The E0784 review involved 91 claims, of which 24 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 26%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Detailed Written Order (DWO) was not received or is dated after the date of service with no dispensing order received.
- Proof of Delivery (POD) was not received.
- Documentation does not support a covered indication.

For complete details, see External Infusion Pump (HCPCS E0781, E0784) Quarterly Results of Documentation Compliance Review.

ENTERAL AND PARENTERAL NUTRITION

Billing for External Infusion Pumps and Drugs When Treatment Was Initiated Somewhere Other Than the Beneficiary's Home

DME MAC Joint Publication

External infusion pumps, related infusion supplies and infusion drugs used in the home setting may be covered under the Medicare Durable Medical Equipment (DME) benefit. However, these durable pumps may be used in other healthcare settings such as a physician's office or hospital outpatient facility. The DME MACs have identified situations where drug infusions initiated in settings other than the beneficiary's home have resulted in infusion pump, related infusion supplies, and/or infused drug being erroneously billed to the DME MACs. As discussed below, the place of service where the infusion therapy is initiated determines the Medicare contractor to which claims are submitted. This article will review correct billing of these items.

Infusions Started in Places of Service Other Than the Beneficiary's Home

For prolonged drug and biological infusions using an external pump, Medicare pays for drugs and biologicals which are not usually self-administered by the patient. These non-self-administered drugs are considered for reimbursement under the "incident to" provisions of the Social Security Act when the services are rendered to patients while in the physician's office or the hospital outpatient department. In some situations, a hospital outpatient department or physician office may:

- Purchase a drug for a medically reasonable and necessary prolonged drug infusion; and,
- Begin the drug infusion in the physician's office or hospital outpatient setting using an external pump; and,
- · Send the patient home for a portion of the infusion; and,
- Have the patient return at the end of the infusion period.

In these scenarios, claims must be submitted to the appropriate A/B MAC for the drug or biological, the administration, and the external infusion pump. Additional information is available in <u>MLN Matters</u>[®] <u>Special</u> <u>Edition Article 1609</u>.

In these situations, no portion of the drug or biological, infusion pump, related infusion supplies, and/or drug are billable to the DME MAC.

Infusions Started in the Beneficiary's Home

Only when external infusion pumps, drugs and related supplies are initiated and administered in the beneficiary's home may claims be billed to the DME MAC under the Durable Medical Equipment benefit. Moreover, coverage is available only for drugs specified in the DME MAC External Infusion Pumps Local Coverage Determination (LCD). The infusion pump, related infusion supplies and the infused drug must all be billed to the DME MAC. As noted in the External Infusion Pumps LCD:

Charges for drugs administered by a DME infusion pump may only be billed by the entity that actually dispenses the drug to the Medicare beneficiary and that entity must be permitted under all applicable federal, state, and local laws and regulations to dispense drugs. Only entities licensed in the state where they are physically located may bill for infusion drugs. Drugs and related supplies and equipment billed by a supplier who does not meet these criteria will be denied as not reasonable and necessary.

Home infusions covered under the Home Health or Hospice benefit must be billed to the appropriate Home Health or Hospice contractor, and not to the DME MAC.

Refer to the External Infusion Pumps LCD and related Policy Article for additional information.

Correct Coding Reminder – Duopa® (AbbVie)

Joint DME MAC Article

On January 9, 2015, Duopa[®] (AbbVie) was approved by the FDA. Duopa[®] is an enteral-suspension combination of levodopa and carbidopa, and is indicated for the treatment of Parkinson's disease (PD). Duopa[®] is administered as a continuous 16-hour infusion into the jejunum through a percutaneous endoscopic gastrostomy-jejunal tube (PEG-J), using a CADD[®]-Legacy 1400 portable infusion pump. Duopa[®] enteral suspension is supplied as a single-use cassette. Each cassette contains 20 mg levodopa and 4.63 mg carbidopa (as 5 mg of the monohydrate) per mL of enteral suspension. Each cassette contains approximately 100 mL of suspension. Per the manufacturer, the maximum recommended daily dose of Duopa[®] is 2000 mg of the levodopa component (i.e., one cassette per day) administered over 16 hours. At the end of the daily 16-hour infusion, patients will disconnect the pump from the PEG-J and take their night-time dose of oral immediate-release carbidopa-levodopa tablets.

The DME MACs have received questions about the proper unit of service (UOS) to bill for Duopa[®]. For dates of service on or after January 9, 2015, through December 31, 2015, claims for Duopa[®] must be submitted using the DME miscellaneous code J7799 (NOC DRUGS, OTHER THAN INHALATION DRUGS, ADMINISTERED THROUGH DME). When billing J7799, one (1) unit of service (UOS) is one cassette.

A unique HCPCS code was created for Duopa® with claims for dates of service on or after January 1, 2016. The new code is:

J7340 - CARBIDOPA 5 MG/LEVODOPA 20 MG ENTERAL SUSPENSION

The UOS for code J7340 is the same UOS used previously with the miscellaneous code J7799. When billing code J7340, one (1) UOS = 100 ml. (1 cassette). The HCPCS narrative will be revised in an upcoming HCPCS coding update.

This instruction is included in the External Infusion Pump LCD related Policy Article. Refer to the External Infusion Pump LCD and related Policy Article for additional coverage, coding and documentation requirements.

For questions about correct coding, contact the Pricing, Data Analysis and Coding (PDAC) contractor Contact Center at (877) 735-1326 during the hours of 8:30 a.m. to 4 p.m. CT, Monday through Friday, or e-mail the PDAC by completing the DME PDAC Contact Form.

External Infusion Pumps (HCPCS J1817, J2260) Notification of Service Specific Prepayment Probe Review

Noridian Jurisdiction D, DME MAC, Medical Review will be initiating a service specific prepayment probe review of claims for each of the following HCPCS codes:

J1817: INSULIN FOR ADMINISTRATION THROUGH DME (I.E., INSULIN PUMP) PER 50 UNITS

J2260: INJECTION, MILRINONE LACTATE, 5 MG

Service specific prepayment probe reviews are used to determine the extent of potential problem areas across multiple suppliers. This review is being initiated based on a high Comprehensive Error Rate Testing (CERT) error rate.

For complete details, see External Infusion Pumps (HCPCS J1817, J2260) Notification of Service Specific <u>Prepayment Probe Review</u>.

GLUCOSE MONITORS

Blood Glucose Test Strips (HCPCS A4253) Final Edit Effectiveness Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code A4253. The final edit effectiveness results from July 2015 through February 2016 are as follows:

The A4253 review involved 2,724 claims, of which 2,604 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 88%.

The top reasons for denial were:

- Medical documentation was not received.
- Documentation does not support the actual testing frequency that corroborates with the quantity of supplies that have been dispensed.
- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Documentation does not support the beneficiary had been evaluated by the physician and documented the reason for additional materials being requested.

For complete details, see <u>Blood Glucose Test Strips (HCPCS A4253) Final Edit Effectiveness Results of</u> <u>Service Specific Prepayment Review</u>.

Blood Glucose Test Strips (HCPCS A4253) Quarterly Results of Documentation Compliance Review

The Jurisdiction D DME MAC Medical Review Department is conducting a documentation compliance review of HCPCS codes A4253KS and A4253KX. The quarterly edit effectiveness, from December 2015 through February 2016 are as follows:

The A4253KS review involved 12,414 claims, of which 7,551 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 57%.

The A4253KX review involved 5,151 claims, of which 4,504 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 58%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Documentation does not support high utilization criteria.
- Proof of Delivery (POD) was not received.
- Detailed Written Order (DWO) was not received.
- Incorrect modifier was billed on the claim.

For complete details, see <u>Blood Glucose Test Strips (HCPCS A4253)</u> <u>Quarterly Results of Documentation</u> <u>Compliance Review</u>.

GLUCOSE MONITORS

National Mail Order Competitive Bid Program – Medicare Reimbursement for Diabetic Testing Supplies Delivered or Mailed to a Beneficiaries' Home

Glucose monitors and testing supplies can be provided by any Medicare enrolled supplier, however, only suppliers who were awarded a contract through the National Mail Order (NMO) Competitive Bid (CB) program will be reimbursed by Medicare for diabetic testing supplies delivered or mailed to the beneficiaries' home. If the supplies are shipped or delivered by any means to the beneficiary's home, then the supplier that furnished the supplies must be a contract supplier.

The term mail-order means items shipped or delivered to the beneficiary's residence by any method. This includes, but is not limited to, shipping by any method as well, as delivery by a courier or by a supplier's own vehicle and only contracted suppliers in the CB program are included in "mail order."

Suppliers are required to use the KL modifier on each claim for diabetic supplies that have been delivered by any means. Suppliers that furnish diabetic testing supplies on a mail-order basis that do not attach the KL modifier could be subject to significant penalties.

Beneficiaries may also choose to pick up diabetic testing supplies in person from a retail pharmacy location or other local supplier storefront. The only diabetic supplies not included in the CB NMO program are those that are purchased directly by a beneficiary or caregiver going to an enrolled DMEPOS supplier storefront. The only entity that can bill for these non-mail-order diabetic supplies is the entity from which the beneficiary or caregiver directly purchased the supplies.

Only mail order suppliers may utilize method 2 proof of delivery. All non-contract suppliers must utilize method 1 proof of delivery because of the requirement of the beneficiary to pick up supplies from the supplier's storefront: Local Coverage Determination Glucose Monitors L33822

For additional information on the Competitive Bidding Program, visit the <u>DMEPOS Competitive Bid website.</u> (Program Integrity Manual 4.26, 5.8)

HOSPITAL BEDS

Hospital Beds (HCPCS E0250) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code E0250. The quarterly edit effectiveness results from October 2015 through January 2016 are as follows:

• The E0920 review involved 51 claims, of which 26 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 57%.

The top reasons for denial were:

- Detailed Written Order (DWO) is incomplete or missing elements.
- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Proof of Delivery (POD) is invalid.
- Date of Service (DOS) does not match the discharge date of the patient's Medicare Part A stay.

For complete details, please see <u>Hospital Beds (HCPCS E0250)</u> Quarterly Results of Service Specific <u>Prepayment Review</u>.

HOSPITAL BEDS

Hospital Beds (HCPCS E0260) Final Edit Effectiveness Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code E0260. The final edit effectiveness results from July 2015 through February 2016 are as follows:

The E0260 review involved 555 claims, of which 396 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 74%.

The top reasons for denial were:

- Documentation does not support coverage criteria for a semi-electric bed.
- Documentation does not support coverage criteria for a fixed height bed.
- Documentation does not contain a valid date stamp or similar.
- Proof of Delivery (POD) is invalid.

For complete details, see <u>Hospital Beds (HCPCS E0260)</u> Final Edit Effectiveness Results of Service <u>Specific Prepayment Review</u>.

IMMUNOSUPPRESSIVE DRUGS

Immunosuppressive Drugs (HCPCS J7507, J7517, J7518, J7520) Quarterly Results of Documentation Compliance Review

The Jurisdiction D DME MAC Medical Review Department is conducting a Documentation Compliance Review (DCR) of HCPCS codes J7507, J7517, J7518 and J7520. The quarterly edit effectiveness, from October 2015 through December 2015 are as follows:

The J7507 review involved 3,594 claims, of which 1,303 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 32%.

The J7517 review involved 2,086 claims, of which 746 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 34%.

The J7518 review involved 1,789 claims, of which 563 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 31%.

The J7520 review involved 436 claims, of which 169 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 35%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Refill request was not received.
- Proof of Delivery (POD) is invalid or was not submitted.
- Detailed Written Order (DWO) was not received.

For complete details, see <u>Immunosuppressive Drugs (HCPCS J7507, J7517, J7518, J7520)</u> Quarterly <u>Results of Documentation Compliance Review</u>.

LCD AND POLICY ARTICLE REVISION SUMMARIES

LCD and Policy Article Revisions Summary for March 3, 2016

Outlined below are the principal changes to a DME MAC Local Coverage Determinations (LCDs) and Policy Articles (PAs) that have been revised and posted. The policies included are Ankle-Foot/Knee-Ankle-Foot Orthosis, Bowel Management Devices, External Infusion Pumps, Immunosuppressive Drugs, Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics), Parenteral Nutrition, Respiratory Assist Devices, Wheelchair Options/Accessories. Please review the entire LCD and related PA for complete information.

Ankle-Foot/Knee-Ankle-Foot Orthosis

Revision Effective Date: 01/01/2016: COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Added: L4361 "clerical correction" HCPCS CODES: Revised: L1902 and L1904 long narrative description

DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to remove start date verbiage from Prescription Requirements (Effective 11/5/2015) Moved: Repair/Replacement verbiage to correct location Updated: Miscellaneous section when billing L2999

Policy Article Revision Effective Date: 01/01/2016 CODING GUIDELINES: Added: L4361 "clerical correction"

Bowel Management Devices

Revision Effective Date: 01/01/2016 COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Replaced: Miscellaneous HCPCS Code A4335 with new code A4337 HCPCS CODES: Added: HCPCS Code A4337 DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation language to remove start date verbiage from Prescription Requirements (Effective 11/05/2015)

Policy Article Revision Effective Date: 01/01/2016 CODING GUIDELINES: Replaced: Miscellaneous HCPCS Code A4335 with new code A4337

External Infusion Pumps

Revision Effective Date: 01/01/2016 COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Added: HCPCS CODE J1575 to Subcutaneous immune globulin coverage Added: HCPCS CODE J7340 to Levodopa-Carbidopa coverage Updated: HCPCS CODE J9039 to Blinatumomab coverage Updated: HCPCS Code Q9977 crosswalked to J7999 HCPCS CODES: Group 3 Codes: Added: HCPCS Code J1575, J7340, J9039 (previously J7799) Deleted: HCPCS Code Q9977 ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Group 3 Codes: Added: ICD-10 Code D83.1 to Group 3 Codes Group 3 Paragraph: Added: HCPCS Code J1575

LCD AND POLICY ARTICLE REVISION SUMMARIES

Group 4 Paragraph: Added: HCPCS Code J7340 Group 5 Paragraph: Added: HCPCS Code J9039 DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation language to remove start date verbiage from Prescription Requirements (Effective 11/5/2015)

Policy Article

Revision Effective Date: 01/01/2016 NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Revised: Standard Documentation Language to remove start date verbiage from Prescription Requirements (Effective 11/5/2015) CODING GUIDELINES: Updated: HCPCS Code Q9977 cross-walked to J7999 Added: J1575, J7340, J9039 (previously J7799) Updated: Billing instructions, by HCPCS code, based on dates of service

Immunosuppressive Drugs

Revision Effective Date: 01/01/2016 HCPCS CODES: Added: J7503 and J7512 Updated: J7508 narrative Deleted: J7506 DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to remove start date verbiage from Prescription Requirements (Effective 11/5/2015)

Policy Article

Revision Effective Dates: 01/01/2016 CODING GUIDELINES: Removed: J7506 from billing example, replaced with J7510

Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics)

Revision Effective Date: 01/01/2016 COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Updated: 3-drug regimen billing instructions HCPCS CODES: Added: HCPCS code J8655 Deleted: HCPCS code Q9978 DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to remove start date verbiage from Prescription Requirements (Effective 11/5/2015) POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: J8655 to modifier billing instructions Added: End date for HCPCS code Q9975 Added: Q0181 for billing rolapitant on or after 09/02/2015 KX. GA AND GZ MODIFIERS: Added: Rolapitant (Q0181) to guidelines Added: J8655 to guidelines

Policy Article Revision Effective Date: 01/01/2016 NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Revised: Covered 3-drug combination regimen CODING GUIDELINES: Added: J8655 Added: End date of 12/31/2015 for Q9978 Added: Q0181 for billing rolapitant effective on or after 09/02/2015

LCD AND POLICY ARTICLE REVISION SUMMARIES

Parenteral Nutrition

Revision Effective Date: 01/01/2016 HCPCS CODES: Group 1 codes: Updated: HCPCS Code B5000, B5100, B5200 narrative description DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation language to remove start date verbiage from Prescription Requirements (Effective 11/05/2015)

Policy Article Removed: Effective Date from Policy Article title

Respiratory Assist Devices

Revision Effective Date: 01/01/2016 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Replaced: HCPCS Codes E0450, E0460-E0464 with new HCPCS Codes E0465, E0466 DOCUMENTATION REQUIREMENTS Revised: Standard Documentation language to remove start date verbiage from Prescription Requirements (Effective 11/05/2015)

Policy Article

Revision Effective Date: 11/05/2015 NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Revised: Standard Documentation language to remove start date verbiage from Prescription Requirements

Wheelchair Options/Accessories

Revision Effective Date: 01/01/2016 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Added: HCPCS code E1012 to Power Tilt and/or Recline Seating Systems range HCPCS CODES: Added: HCPCS code E1012 Revised: K0017 and K0018 long narrative description DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to remove start date verbiage from Prescription Requirements (Effective 11/5/2015)

Policy Article Revision Effective Date: 01/01/2016 NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Revised: Standard Documentation Language to remove start date verbiage from Prescription Requirements (Effective 11/5/2015) CODING GUIDELINES: Added: HCPCS code E1012 Added: HCPCS code E1012 to bundling table

Note: The information contained in this article is only a summary of revisions to the LCD and Policy Article. For complete information on any topic, you must review the LCD and/or Policy Article.

LCD and Policy Article Revisions Summary for March 17, 2016

Outlined below are the principal changes to a DME MAC Local Coverage Determination (LCD) and a Policy Article (PA) that have been revised and posted. The policy included is Urological Supplies. Please review the entire LCD and related PA for complete information.

Urological Supplies

Revision Effective Date: 01/01/2016 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Added: Non-reimbursement language for the inFlow™ Intraurethral Valve-Pump system (A4335) DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to remove start date verbiage from Prescription Requirements (Effective 11/05/2015)

Policy Article Revision Effective Date: 01/01/2016 CODING GUIDELINES: Added: Coding guidelines for the inFlow™ Intraurethral Valve-Pump (A4335)

Note: The information contained in this article is only a summary of revisions to the LCD and Policy Article. For complete information on any topic, you must review the LCD and/or Policy Article.

LCD and Policy Article Revisions Summary for May 19, 2016

Outlined below are the principal changes to DME MAC Local Coverage Determinations (LCDs) and a Policy Article (PA) that have been revised and posted. The policy included is Knee Orthoses. Please review the entire LCDs and related PA for complete information.

Knee Orthoses

Revision Effective Date: 06/02/2016

ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Added: HCPCS Codes L1832 and L1833 to Group 2 Diagnoses Added: Initial, Subsequent, and Sequela ICD-10s to Group 2 and Group 4 Removed: ICD-10 Non-specific femur codes S72.426B & S72.426C – entered in error DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation language (Effective 04/28/2016) ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Added: HCPCS Codes L1832 and L1833 to Group 2 Diagnoses Added: Initial, Subsequent, and Sequela ICD-10s to Group 2 and Group 4 Removed: ICD-10 Non-specific femur codes S72.426B & S72.426C – entered in error DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation language (Effective 04/28/2016)

Policy Article

Revision Effective Date: 06/02/2016

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Added: Definitions from CMS DMEPOS Quality Standards (42 CFR 424.57) and 42 CFR 414.402 CODING GUIDELINES: Added: Custom fabricated orthosis definitions Added: Definition of K0672

Note: The information contained in this article is only a summary of revisions to the LCDs and Policy Article. For complete information on any topic, you must review the LCDs and/or Policy Article.

MANUAL WHEELCHAIRS

Correct Coding – Manual Wheelchair Bases – Revised

DME MAC Joint Publication

Posted February 14, 2014

Revised April 14, 2016

This replaces a previous version published February 14, 2014.

Recently, manual wheelchair coding applications describing products that are not complete, functional manual wheelchairs have been received by the Pricing, Data Analysis and Coding (PDAC) contractor.

For Medicare coding purposes, all manual wheelchair base codes describe a complete product. A complete manual wheelchair base includes:

- A complete frame
- Propulsion wheels
- Casters
- Brakes
- A sling seat, seat pan which can accommodate a wheelchair seat cushion, or a seat frame structured in such a way as to be capable of accepting a seating system
- A sling back, other seat back support which can accommodate a wheelchair back cushion, or a back frame structured in such a way as to be capable of accepting a back system
- Standard leg and footrests
- Armrests
- Safety accessories (other than those separately billable in the Wheelchair Accessories Local Coverage Determination)

The bundling table contained in the Wheelchair Options and Accessories LCD related Policy Article CODING GUIDELINES section describes the items included as part of the following bases:

- Rollabout Chair (E1031)
- Transport Chairs (E1037, E1038, E1039)
- Manual Wheelchair Bases (E1161, E1229, E1231, E1232, E1233, E1234, E1235, E1236, E1237, E1238, K0001, K0002, K0003, K0004, K0005, K0006, K0007, K0009)

PDAC coding applications for manual wheelchairs that describe incomplete products will receive a "No HCPCS Code Assigned" determination. If the manual wheelchair base is incomplete, any accessories associated with the application will not be processed.

For questions about correct coding, contact the PDAC contractor Contact Center at (877) 735-1326 during the hours of 8:30 a.m. to 4 p.m. CT, Monday through Friday, or e-mail the PDAC by completing the DME PDAC Contact Form.
MOBILITY DEVICES

Manual Wheelchair (HCPCS K0001, K0003) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS codes K0001 and K0003. The quarterly edit effectiveness results from October 2015 through January 2016 are as follows:

- The K0001 review involved 875 claims, of which 526 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 54%.
- The K0003 review involved 195 claims, of which 154 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 70%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Documentation does not support that the beneficiary has a caregiver who is available, willing and able to provide assistance with the wheelchair.
- Documentation does not support that the beneficiary has sufficient upper extremity function and other physical and mental capabilities needed to safely self-propel the manual wheelchair.
- Documentation does not support that the beneficiary's mobility limitation cannot be sufficiently resolved by the use of an appropriately fitted cane or walker.
- Documentation does not support coverage criteria for K0003.

For complete details, see <u>Manual Wheelchair (HCPCS K0001, K0003)</u> <u>Quarterly Results of Service Specific</u> <u>Prepayment Review</u>.

MODIFIERS

Correct Coding – JW Modifier Use – Effective for Claims with Dates of Service On or After July 1, 2016

Joint DME MAC Publication

The Centers for Medicare & Medicaid Services (CMS) recently issued updated guidance on the billing of drug wastage to REQUIRE use of the JW modifier (DRUG AMOUNT DISCARDED/NOT ADMINISTERED TO ANY PATIENT). For the Durable Medical Equipment Medicare Administrative Contractors (DME MACs), the JW modifier only applies to the following Local Coverage Determinations (LCDs):

- External Infusion Pumps
- Intravenous Immunoglobulin (IVIG)
- Nebulizers

These LCDs will be updated to include the JW modifier requirements. Required use of the JW modifier is effective for claims with dates of service (DOS) on or after July 1, 2016.

The Medicare Claims Processing Manual (Internet-only Manual 100-04), Chapter 17, Section 40 contains information on the use of the JW modifier for discarded drugs and biologicals. The Medicare program provides payment for the amount of a single use vial or other single use package of drug or biological discarded, in addition to the dose administered, up to the amount of the drug or biological. There are two scenarios that can occur:

Scenario 1

When the HCPCS code Unit of Service (UOS) is less than the drug quantity contained in the single use vial or single dose package, the following applies:

- The quantity administered is billed on one claim line without the JW modifier; and,
- The quantity discarded is billed on a separate claim line with the JW modifier.

MODIFIERS

In this scenario, the JW modifier must be billed on a separate line to provide payment for the amount of discarded drug or biological. For example:

- A single use vial is labeled to contain 100 mg of a drug.
- The drug's HCPCS code UOS is 1 UOS = 1 mg.
- 95 mg of the 100 mg in the vial are administered to the beneficiary.
- 5 mg remaining in the vial are discarded.
- The 95 mg dose is billed on one claim line as 95 UOS.
- The discarded 5 mg is billed as 5 UOS on a separate claim line with the JW modifier.
- Both claim line items would be processed for payment.

Scenario 2

When the HCPCS code UOS is equal to or greater than the total of the actual dose and the amount discarded, use of the JW modifier is not permitted. If the quantity of drug administered is less that a full UOS, the billed UOS is rounded to the appropriate UOS. For example:

- A single use vial is labeled to contain 100 mg of a drug.
- The drug's HCPCS code UOS is 1 UOS = 100 mg.
- 70 mg of the 100 mg in the vial are administered to the beneficiary.
- 30 mg remaining in the vial are discarded.
- The 70 mg dose is billed correctly by rounding up to one UOS (representing the entire 100 mg vial) on a single line item.
- The single line item of 1 UOS would be processed for payment of the combined total 100 mg of administered and discarded drug.
- The discarded 30 mg must not be billed as another 1 UOS on a separate line item with the JW modifier. Billing an additional 1 UOS for the discarded drug with the JW modifier is incorrect billing and will result in an overpayment.

Multi-use vials are not subject to payment for discarded amounts of drug or biological.

Claims for drugs billed to Medicare must use drug dosage formulations and/or unit dose sizes that minimize wastage. Providers and suppliers are expected to use drugs or biologicals most efficiently, in a clinically appropriate manner. Only when the most efficient combination of dosage forms are used and there is drug remaining may a supplier bill the discarded amount using the JW modifier on the claim line for the UOS not administered to the patient. Because of the HCPCS code descriptors and the associated UOS for DMEPOS items, the DME MACs expect rare use of the JW modifier on claims.

The JW modifier is used in conjunction with other modifiers listed in the applicable LCDs. For example, suppliers must add a JW modifier to codes for nebulizer drugs, in conjunction with the KX modifier, only if all of the criteria in the "Coverage Indications, Limitations and/or Medical Necessity" section of the Nebulizer LCD have been met.

NEBULIZERS

CERT Errors – Nebulizers and Drugs

The Comprehensive Error Rate Testing (CERT) Review Contractor is currently reviewing claims for nebulizers and related drugs. Noridian has reviewed the top CERT error comments in efforts to assist suppliers in how to prevent or eliminate these errors, particularly for inhalation drugs. The majority of the CERT denial reasons relate to the physician's detailed written order, clinical records supporting the medical need of the drugs and proof of delivery issues. View <u>CERT Errors – Nebulizers and Drugs</u> for complete information.

Nebulizer Inhalation Drugs (HCPCS J7605, J7626) Quarterly Results of Documentation Compliance Review

The Jurisdiction D DME MAC Medical Review Department is conducting a Documentation Compliance Review (DCR) of HCPCS codes J7605 and J7626. The quarterly edit effectiveness, from October 2015 through December 2015 are as follows:

- The J7605 review involved 3,169 claims, of which 1,004 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 30%.
- The J7626 review involved 5,622 claims, of which 2,041 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 33%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Medical documentation was not received.
- Proof of Delivery (POD) is invalid.
- Refill request was not received.

For complete details, see <u>Nebulizer Inhalation Drugs (HCPCS J7605, J7626)</u> Quarterly Results of <u>Documentation Compliance Review</u>.

Nebulizer Inhalation Drugs (HCPCS J7605, J7626) Quarterly Results of Documentation Compliance Review

The Jurisdiction D DME MAC Medical Review Department is conducting a Documentation Compliance Review (DCR) of HCPCS codes J7605 and J7626. The quarterly edit effectiveness, from January 2016 through March 2016 are as follows:

- The J7605 review involved 6,255 claims, of which 1,881 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 26%.
- The J7626 review involved 9,152 claims, of which 3,262 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 34%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Medical documentation was not received.
- Proof of Delivery (POD) is invalid.
- Refill requirements were not met.

For complete details, see <u>Nebulizer Inhalation Drugs (HCPCS J7605, J7626)</u> <u>Quarterly Results of</u> <u>Documentation Compliance Review</u>.

Negative Pressure Wound Therapy Pumps (HCPCS E2402) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code(s) E2402. The quarterly edit effectiveness results from July 2015 through October 2015 are as follows:

• The E2402 review involved 312 claims, of which 199 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 60%.

The top reasons for denial were:

- Documentation does not include a statement from the treating physician describing the initial condition of the wound efforts.
- Medical documentation was not received.
- Medical records do not support the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other typical wound treatments.
- Medical records do not support evaluation of a provision for the beneficiary's adequate nutritional status.

For complete details, see <u>Negative Pressure Wound Therapy Pumps</u> (HCPCS E2402) Quarterly Results of <u>Service Specific Prepayment Review</u>.

Negative Pressure Wound Therapy Pumps (HCPCS E2402) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code(s) E2402. The quarterly edit effectiveness results from October 2015 through January 2016 are as follows:

• The E2402 review involved 251 claims, of which 170 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 64%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Documentation does not include a statement from the treating phsyician describing the initial condition of the wound efforts.
- Documnetation does not support the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other typical wound treatments.
- Signature requirements were not met.

For complete details, see <u>Negative Pressure Wound Therapy Pumps (HCPCS E2402)</u> <u>Quarterly Results of</u> <u>Service Specific Prepayment Review</u>.

Ankle-Foot Orthosis (HCPCS L1960, L1970, L4360) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS codes L1960, L1970 and L4360. The quarterly edit effectiveness results from September 2015 through December 2015 are as follows:

- The L1960 review involved 205 claims, of which 155 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 75%.
- The L1970 review involved 341 claims, of which 257 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 73%.
- The L4360 review involved 606 claims, of which 596 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 98%.

The top reasons for denial were:

- Documentation insufficient to support that modifications were made for the custom fitted item billed.
- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Proof of Delivery (POD) is invalid or was not submitted.
- Medical records do not provide detailed documentation to support medical necessity of a custom fabricated rather than a prefabricated orthosis.
- Documentation insufficient to support custom fabricated coverage criteria.
- Documentation insufficient to support basic coverage criteria.

For complete details, see <u>Ankle-Foot Orthosis (HCPCS L1960, L1970, L4360)</u> <u>Quarterly Results of Service</u> <u>Specific Prepayment Review</u>.

Ankle/Foot Orthosis (HCPCS L1960, L1970, L4360) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS codes L1960, L1970 and L4360. The quarterly edit effectiveness results from December 2015 through March 2016 are as follows:

- The L1960 review involved 196 claims, of which 137 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 69%.
- The L1970 review involved 324 claims, of which 234 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 70%.
- The L4360 review involved 488 claims, of which 484 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 99%.

The top reasons for denial were:

- Documentation does not support that modifications were made for the custom fitted item billed.
- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Documentation does not support medical necessity of custom fabricated rather than prefabricated orthosis.
- Proof of Delivery (POD) was not received.
- Documentation does not support basic coverage criteria.
- Documentation does not support custom fabricated coverage criteria.

For complete details, see <u>Ankle/Foot Orthosis (HCPCS L1960, L1970, L4360)</u> <u>Quarterly Results of Service</u> <u>Specific Prepayment Review</u>.

Correct Coding – LIM innovations Infinite Socket[™] – Revised

DME MAC Joint Publication

This is a revision to the original article, posted May 21, 2015. This article changes the previously published benefit determination and code assignment.

Infinite Socket[™] (LIM innovations) is an open-frame above-knee socket design that has recently become available. This product uses struts that extend from a base to an adjustable brim enclosing an inner shell to form the structure of the socket. It is custom-fabricated from a model of the patient's residual limb.

The existing HCPCS L-codes used for above-knee lower limb prosthesis sockets describe items which enclose the residual limb to provide the stability, proprioception, and suspension necessary for the effective use of the artificial limb. Although the LIM innovations Infinite Socket[™] is different in design from traditional sockets described by the existing L-codes, it has been determined that this product is an effective alternative and that existing HCPCS codes appropriately describe the product. The correct combination of codes to bill Medicare for this item are:

Base code:

If this product is included as part of a complete prosthesis, the base socket is included as part of the prosthesis base code. Chose the appropriate base code depending upon the type provided.

L5321 – SOCKET ABOVE KNEE, MOLDED SOCKET, OPEN END, SACH FOOT, ENDOSKELETAL SYSTEM, SINGLE AXIS KNEE.

L5590 – PREPARATORY, ABOVE KNEE - KNEE DISARTICULATION ISCHIAL LEVEL SOCKET, NON-ALIGNABLE SYSTEM, PYLON NO COVER, SACH FOOT, LAMINATED SOCKET, MOLDED TO MODEL

The add-on codes discussed below (L5631, L5649, L5950, and choice of suspension) must be included on the same claim for the complete prosthesis i.e., the claim that includes one of the above codes. Do not use L5321 or L5590 for billing a replacement socket for an existing prosthesis.

If this product is provided as a replacement to an existing socket, in addition to the add-on codes below (L5631, L5649, L5950, and choice of suspension), for the base code, use:

L5701 – REPLACEMENT, SOCKET, ABOVE KNEE/KNEE DISARTICULATION, INCLUDING ATTACHMENT PLATE, MOLDED TO PATIENT MODEL.

Addition codes:

Use on all claims in addition to the base code:

L5631 – ADDITION TO LOWER EXTREMITY, ABOVE KNEE OR KNEE DISARTICULATION, ACRYLIC SOCKET

L5649 - ADDITION TO LOWER EXTREMITY, ISCHIAL CONTAINMENT/NARROW M-L SOCKET

L5950 – ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE, ULTRALIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL).

HCPCS code L5999 (LOWER EXTREMITY PROSTHESIS, NOT OTHERWISE SPECIFIED) must not be used to bill for features or functions included in the socket. The combination of base and addition codes listed above include all the features and functions of the base device. Use of L5999 in this manner is incorrect coding (unbundling).

HCPCS add-on L-codes used to describe the type of suspension incorporated into the socket may be added to the claim. Use of more than one type of suspension is considered incorrect billing, (same/similar item).

ORTHOTICS AND PROSTHETICS

HCPCS codes describing features that may not be necessary on all sockets may only be used when the feature is provided for the individual beneficiary. Some examples of features that are not automatically included in every socket or for all beneficiaries are (not all-inclusive):

L5651 – ADDITION TO LOWER EXTREMITY, ABOVE KNEE, FLEXIBLE INNER SOCKET, EXTERNAL FRAME

L5920 – ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE OR HIP DISARTICULATION, ALIGNABLE SYSTEM

The prosthetic record must include specific, detailed information justifying the need for each additional feature.

Test sockets (L5624 - ADDITION TO LOWER EXTREMITY, TEST SOCKET, ABOVE KNEE) are not necessary for the production of this socket design. Claims for L5624 in conjunction with this socket design are considered incorrect billing.

Refer to the Lower Limb Prosthesis Local Coverage Determination and related Policy Article for additional information on coverage, coding and documentation for artificial limbs.

For questions about correct coding, contact the Pricing, Data Analysis and Coding (PDAC) contractor Contact Center at (877) 735-1326 during the hours of 8:30 a.m. to 40 p.m. CT, Monday through Friday, or e-mail the PDAC by completing the <u>DME PDAC Contact Form</u>.

Correct Coding – Martin Bionics Socket-less Socket™

DME MAC Joint Publication

The Socket-less Socket[™] (Martin Bionics) is an open frame above-knee socket design. This product uses a combination of fixed and floating struts attached to a base and connected by adjustable straps to form the structure of the socket. The product is supplied as a prefabricated kit and fit directly to the beneficiary.

The existing HCPCS L-codes for base prosthesis and replacement sockets used for above-knee lower limb prosthesis sockets are not appropriate for this product. Existing base and socket codes describe items that enclose the residual limb to provide the stability, proprioception, and suspension necessary for the effective use of the artificial limb. These codes describe custom fabricated (molded to a patient model) sockets. The appropriate code for the Socket-less Socket™ is:

L5999 - LOWER EXTREMITY PROSTHESIS, NOT OTHERWISE SPECIFIED

Code L5999 is billed as 1 unit of service (UOS) to describe all features and functions of the entire Socket[™] product. Use of multiple NOC codes or other L codes, except as specified below, is considered unbundling. When code L5999 is billed, the claim must include a narrative description of the item that includes:

- Manufacturer, and the brand name or number
- Information describing whether this socket is a new socket included as part of a complete prosthesis or a replacement socket for an existing prosthesis. If the socket is part of a complete prosthesis, specify whether the preparatory (L5590) or definitive (L5321) base code was used for the base prosthesis

This information must be entered in the narrative field of the electronic claim.

HCPCS add-on L-codes used to describe the type of suspension incorporated into the socket may be added to the claim. Use of more than one type of suspension is considered incorrect billing, (same/similar item).

HCPCS codes describing features that may not be necessary on all sockets may only be used when the feature is provided for the individual beneficiary. An example of a feature that is not automatically included in every socket or for all beneficiaries are (not all-inclusive) is L5920 - ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE OR HIP DISARTICULATION, ALIGNABLE SYSTEM. The prosthetic record must include specific, detailed information justifying the need for each additional feature.

Test sockets (L5624 - ADDITION TO LOWER EXTREMITY, TEST SOCKET, ABOVE KNEE) are not necessary for the production of this socket design. Claims for L5624 in conjunction with this socket design are considered incorrect billing.

ORTHOTICS AND PROSTHETICS

Refer to the Lower Limb Prosthesis Local Coverage Determination and related Policy Article for additional information on coverage, coding and documentation for artificial limbs.

For questions about correct coding, contact the Pricing, Data Analysis and Coding (PDAC) contractor Contact Center at (877) 735-1326 during the hours of 8:30 a.m. to 4 p.m. CT, Monday through Friday, or e-mail the PDAC by completing the DME PDAC Contact Form.

Hand-Finger Orthoses – Use of CG Modifier – Revised

Joint DME MAC Publication

This replaces a previous version published April 8, 2010.

Elastic garments do not meet the statutory definition of a brace. Codes L3923 (Hand finger orthosis, without joints, may include soft interface, straps, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise) and L3924 (Hand finger orthosis, without joints, may include soft interface, straps, prefabricated, off-the-shelf) include both elastic and non-elastic items.

Elastic garments may be made of a variety of materials, including but not limited to neoprene or spandex (elastane, Lycra®). If a garment made with elastic material has a rigid plastic or metal component, it is considered a non-elastic orthosis for purposes of coverage and coding.

If a hand-finger garment is made primarily of elastic material, it must be billed with code A4466 (Garment, belt, sleeve or other covering, elastic or similar stretchable material, any type, each) and not code L3923 or L3924. Claims billed with code A4466 will be denied as non-covered, no benefit category. If code L3923 or L3924 orthosis has a rigid plastic or metal component, the supplier must add the CG modifier (policy criteria applied) to the code. Claims for L3923 or L3924 billed without a CG modifier will be rejected as incorrect coding.

For questions about correct coding, contact the Pricing, Data Analysis, and Coding contractor (PDAC) at (877) 735-1326 during the hours of 8:30 a.m. to 4 p.m. CT, Monday through Friday, or e-mail the PDAC by completing the <u>DME PDAC Contact Form</u>.

Knee Orthoses (HCPCS L1833) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code L1833. The quarterly edit effectiveness results from June 2015 through August 2015 are as follows:

• The L1833 review involved 734 claims, of which 719 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 98%.

The top reasons for denial were:

- Documentation does not support knee instability or that the beneficiary is ambulatory.
- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Invalid or missing diagnosis code.
- Proof of Delivery (POD) is invalid.

For complete details, see <u>Knee Orthoses (HCPCS L1833)</u> <u>Quarterly Results of Service Specific Prepayment</u> <u>Review</u>.

Knee Orthosis (HCPCS L1833) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code L1833. The quarterly edit effectiveness results from September 2015 through December 2015 are as follows:

• The L1833 review involved 912 claims, of which 893 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 98%.

The top reasons for denial were:

- Documentation does not support knee instability or that the beneficiary is ambulatory.
- Invalid or missing diagnosis code.
- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Proof of Delivery (POD) is invalid.

For complete details, see <u>Knee Orthosis (HCPCS L1833)</u> <u>Quarterly Results of Service Specific Prepayment</u> <u>Review</u>.

Lower Limb Prosthesis (HCPCS L5980, L5981, L5987) Final Edit Effectiveness Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code L5980, L5981 and L5987. The final edit effectiveness results from June 2015 through February 2016 are as follows:

- The L5980 review involved 19 claims, of which 19 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 88%.
- The L5981 review involved 51 claims, of which 46 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 81%.
- The L5987 review involved 41 claims, of which 36 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 79%

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Documentation does not support medical need for replacement item.
- Documentation does not support the functional level billed.
- Documentation does not support basic coverage criteria.
- Detailed Written Order (DWO) is incomplete or missing elements.

For complete details, see Lower Limb Prosthesis (HCPCS L5980, L5981, L5987) Final Edit Effectiveness Results of Service Specific Prepayment Review.

ORTHOTICS AND PROSTHETICS

Spinal Orthoses (HCPCS L0450, L0452, L0454-L0458, L0460, L0462, L0464, L0466-L0470, L0472, L0480, L0482, L0484, L0486, L0488, L0490-L0492) Notification of Service Specific Prepayment Probe Review

Noridian Jurisdiction D, DME MAC, Medical Review will be initiating a service specific prepayment probe review of claims for each of the following HCPCS codes: L0450, L0452, L0454, L0455, L0456, L0457, L0458, L0460, L0462, L0464, L0466, L0467, L0468, L0469, L0470, L0472, L0480, L0482, L0484, L0486, L0488, L0490, L0491 and L0492.

Service specific prepayment probe reviews are used to determine the extent of potential problem areas across multiple suppliers. This review is being initiated based on data analysis.

For complete details, see <u>Spinal Orthoses (HCPCS L0450, L0452, L0454-L0458, L0460, L0462, L0464, L0466-L0470, L0472, L0480, L0482, L0484, L0486, L0488, L0490-L0492) Notification of Service Specific Prepayment Probe Review.</u>

Spinal Orthoses (HCPCS L0621, L0623) Notification of Service Specific Prepayment Probe Review

Noridian Jurisdiction D, DME MAC, Medical Review will be initiating a service specific prepayment probe review of claims for each of the following HCPCS codes:

L0621: SACROILIAC ORTHOSIS, FLEXIBLE, PROVIDES PELVIC-SACRAL SUPPORT, REDUCES MOTION ABOUT THE SACROILIAC JOINT, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PENDULOUS ABDOMEN DESIGN, PREFABRICATED, OFF-THE-SHELF

L0623: SACROILIAC ORTHOSIS, PROVIDES PELVIC-SACRAL SUPPORT, WITH RIGID OR SEMI-RIGID PANELS OVER THE SACRUM AND ABDOMEN, REDUCES MOTION ABOUT THE SACROILIAC JOINT, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PENDULOUS ABDOMEN DESIGN, PREFABRICATED, OFF-THE-SHELF

Service specific prepayment probe reviews are used to determine the extent of potential problem areas across multiple suppliers. This review is being initiated based on data analysis.

For complete details, see <u>Spinal Orthoses (HCPCS L0621, L0623)</u> Notification of <u>Service Specific</u> <u>Prepayment Probe Review</u>.

Spinal Orthoses (HCPCS L0625, L0626, L0627, L0641, L0642) Notification of Service Specific Prepayment Probe Review

Noridian Jurisdiction D, DME MAC, Medical Review will be initiating a service specific prepayment probe review of claims for HCPCS codes: L0625, L0626, L0627, L0641, L0642.

Service specific prepayment probe reviews are used to determine the extent of potential problem areas across multiple suppliers. This review is being initiated based on data analysis.

For complete details, see <u>Spinal Orthoses (HCPCS L0625, L0626, L0627, L0641, L0642)</u> Notification of <u>Service Specific Prepayment Probe Review</u>.

Spinal Orthoses (HCPCS L0628- L0640, L0643, L0648-L0651) Notification of Service Specific Prepayment Probe Review

Noridian Jurisdiction D, DME MAC, Medical Review will be initiating a service specific prepayment probe review of claims for HCPCS codes: L0628, L0629, L0630, L0631, L0632, L0633, L0634, L0635, L0636, L0637, L0638, L0639, L0640, L0643, L0648, L0649, L0650 and L0651.

Service specific prepayment probe reviews are used to determine the extent of potential problem areas across multiple suppliers. This review is being initiated based on data analysis.

For complete details, see <u>Spinal Orthoses (HCPCS L0628- L0640, L0643, L0648-L0651) Notification of</u> <u>Service Specific Prepayment Probe Review</u>.

Spinal Orthoses (HCPCS L0631, L0637) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code(s) L0631 and L0637. The quarterly edit effectiveness results from September 2015 through December 2015 are as follows:

- The L0631 review involved 184 claims, of which 178 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 97%.
- The L0637 review involved 217 claims, of which 217 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 100%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Documentation is insufficient to support that modifications were made for the custom fitted item billed.
- Proof of Delivery (POD) is invalid.
- Documentation does not support coverage criteria.

For complete details, see <u>Spinal Orthoses (HCPCS L0631, L0637)</u> <u>Quarterly Results of Service Specific</u> <u>Prepayment Review</u>.

Spinal Orthoses (HCPCS L0631, L0637) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS codes L0631 and L0637. The quarterly edit effectiveness results from December 2015 through March 2016 are as follows:

- The L0631 review involved 139 claims, of which 138 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 99%.
- The L0637 review involved 152 claims, of which 146 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 94%.

The top reasons for denial were:

- Documentation does not support that modifications were made for the custom fitted item billed.
- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Proof of Delivery (POD) is invalid.
- Documentation does not support coverage criteria.
- The item billed is not a PDAC approved item that has received written coding verification review from the PDAC contractor.

For complete details, see <u>Spinal Orthoses (HCPCS L0631, L0637)</u> <u>Quarterly Results of Service Specific</u> <u>Prepayment Review</u>.

Spinal Orthoses (HCPCS L0648, L0650) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS codes L0648 and L0650. The quarterly edit effectiveness results from July 2015 through October 2015 are as follows:

- The L0648 review involved 344 claims, of which 257 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 75%.
- The L0650 review involved 454 claims, of which 368 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 80%.

The top reasons for denial were:

- Documentation does not support coverage criteria.
- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Proof of Delivery (POD) is invalid.
- Medical documentation was not received.

For complete details, see <u>Spinal Orthoses (HCPCS L0648, L0650)</u> <u>Quarterly Results of Service Specific</u> <u>Prepayment Review</u>.

Spinal Orthoses (HCPCS L0648, L0650) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code(s) L0648 and L0650. The quarterly edit effectiveness results from October 2015 through January 2016 are as follows:

- The L0648 review involved 405 claims, of which 313 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 77%.
- The L0650 review involved 634 claims, of which 539 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 85%.

The top reasons for denial were:

- Documentation does not support coverage criteria.
- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Proof of Delivery (POD) is invalid.
- Medical documentation was not received.

For complete details, see <u>Spinal Orthoses (HCPCS L0648, L0650)</u> <u>Quarterly Results of Service Specific</u> <u>Prepayment Review</u>.

Refunds to Medicare

When submitting a voluntary refund to Medicare, please include the Overpayment Refund Form found on the Forms page of the Noridian DME website. This form provides Medicare with the necessary information to process the refund properly. This is an interactive form which Noridian has created to make it easy for you to type and print out. We've included a highlight button to ensure you don't miss required fields. When filling out the form, be sure to refer to the Overpayment Refund Form instructions.

Processing of the refund will be delayed if adequate information is not included. Medicare may contact the supplier directly to find out this information before processing the refund. If the specific patient name, Medicare number or claim number information is not provided, no appeal rights can be afforded.

Suppliers are also reminded that "The acceptance of a voluntary refund in no way affects or limits the rights of the Federal Government or any of its agencies or agents to pursue any appropriate criminal, civil, or administrative remedies arising from or relating to these or any other claims."

Source: Transmittal 50, Change Request 3274, dated July 30, 2004

OXYGEN

Oxygen and Oxygen Equipment (HCPCS E0431) Results of Service Specific Prepayment Probe Review

The Jurisdiction D, DME MAC, Medical Review Department completed a service specific prepayment probe review of HCPCS codes E0431. This review was initiated based on a high Comprehensive Error Rate Testing (CERT) error rate.

The E0431 review involved 94 claims, of which 53 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 46%.

The top reasons for denial were:

- Documentation does not support a severe underlying lung disease.
- Detailed Written Order Prior to Delivery (WOPD) is incomplete or missing elements.
- Documentation does not support that alternative treatment measures have been tried or considered and deemed clinically ineffective prior to initiating home oxygen therapy.
- Documentation does not support the treating physician has determined that the beneficiary has a severe lung disease or hypoxia related symptoms that might be expected to improve with oxygen therapy.

For complete details, see Oxygen and Oxygen Equipment (HCPCS E0431) Results of Service Specific Prepayment Probe Review.

Oxygen and Oxygen Equipment (HCPCS E0434, E0439) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code(s) E0434 and E0439. The quarterly edit effectiveness results from October 2015 through January 2016 are as follows:

- The E0434 review involved 76 claims, of which 44 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 40%.
- The E0439 review involved 106 claims, of which 60 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 60%.

The top reasons for denial were:

• Documentation does not support that alternative treatment measures have been tried or considered and deemed clinically ineffective prior to initiating home oxygen therapy.

OXYGEN

- Documentation does not support the treating physician has determined that the beneficiary has a severe lung disease or hypoxia related symptoms that might be expected to improve with oxygen therapy.
- Written Order Prior to Delivery (WOPD) does not contain a date stamp or similar indicating supplier's date of receipt.
- Documentation does not support the beneficiary was seen and evaluated by the treating physician within 30 days prior to the date of initial certification.
- Documentation was not received in response to the Additional Documentation Request (ADR) letter.

For complete details, see <u>Oxygen and Oxygen Equipment (HCPCS E0434, E0439)</u> <u>Ouarterly Results of</u> <u>Service Specific Prepayment Review</u>.

Oxygen and Oxygen Equipment (HCPCS E1390) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code E1390. The quarterly edit effectiveness results from December 2015 through March 2016 are as follows:

• The E1390 review involved 1,755 claims, of which 982 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 55%.

The top reasons for denial were:

- Documentation does not support that alternative treatment measures have been tried or considered and deemed clinically ineffective prior to initiating home oxygen therapy.
- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Documentation does not support a severe underlying lung disease.
- Documentation does not support that the treating physician has determined that the beneficiary has a severe lung disease or hypoxia related symptoms that might be expected to improve with oxygen therapy.

For complete details, see Oxygen and Oxygen Equipment (HCPCS E1390) Quarterly Results of Service Specific Prepayment Review.

Oxygen (HCPCS E1390) Quarterly Results of Documentation Compliance Review

The Jurisdiction D DME MAC Medical Review Department is conducting a Documentation Compliance Review (DCR) of HCPCS code E1390. The quarterly edit effectiveness, from September 2015 through November 2015 are as follows:

• The E1390 review involved 5,665 claims, of which 1,192 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 24%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Documentation does not support an office visit occurred within 30 days.
- Proof of Delivery (POD) is prior to the date of service of the claim.
- Documentation does not support the initial evaluation was within 30 days from the initial date of the claim.

For complete details, see <u>Oxygen (HCPCS E1390)</u> <u>Quarterly Results of Documentation Compliance</u> <u>Review</u>.

OXYGEN

Oxygen (HCPCS E1390) Quarterly Results of Documentation Compliance Review

The Jurisdiction D DME MAC Medical Review Department is conducting a Documentation Compliance Review (DCR) of HCPCS code(s) E1390. The quarterly edit effectiveness, from December 2015 through February 2016 are as follows:

• The E1390 review involved 2,280 claims, of which 443 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 21%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Documentation was not received to support a recent physician evaluation.
- Proof of Delivery (POD) was not submitted or was dated prior to the date of service of the claim.
- Detailed Written Order (DWO) is dated after the date of service with no dispensing order received.

For complete details, see <u>Oxygen (HCPCS E1390)</u> <u>Quarterly Results of Documentation Compliance</u> <u>Review</u>.

PAP DEVICES

PAP Devices (HCPCS E0601KH, E0601KJ) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS codes E0601KH and E0601KJ. The quarterly edit effectiveness results from July 2015 through November 2015 are as follows:

- The E0601KH review involved 3,525 claims, of which 1,638 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 43%.
- The E0601KJ review involved 2,362 claims, of which 1,338 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 60%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Documentation does not support coverage criteria for coverage beyond the first three months.
- Documentation does not contain a valid date stamp or similar.
- Documentation does not include a face-to-face clinical evaluation of the beneficiary by the treating physician prior to the sleep test to assess the beneficiary for obstructive sleep apnea.
- Documentation does not include a sleep test that meets criteria.

For complete details, see <u>Positive Airway Pressure (PAP) Devices (HCPCS E0601KH, E0601KJ) Quarterly</u> <u>Results of Service Specific Prepayment Review</u>.

PATIENT LIFTS

Patient Lifts (HCPCS E0636) Results of Service Specific Prepayment Probe Review

The Jurisdiction D, DME MAC, Medical Review Department completed a service specific prepayment probe review of HCPCS code(s) E0636. This review was initiated based on data analysis that identified changes in billing patterns.

The E0636 review involved 107 claims, of which 107 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 100%.

The top reasons for denial were:

- Documentation does not support the beneficiary would be bed confined without the use of a lift.
- Documentation does not support the beneficiary requires transfer between bed and a chair, wheelchair or commode.
- Documentation does not support the beneficiary requires supine positioning for transfers.
- The item billed is not a Pricing, Data Analysis, and Coding (PDAC) approved item that has received written coding verification review from the PDAC contractor.

For complete details, see <u>Patient Lifts (HCPCS E0636) Results of Service Specific Prepayment Probe</u> <u>Review</u>.

PRESSURE REDUCING SUPPORT SURFACES

Pressure Reducing Support Surfaces – Group 1 (HCPCS E0181, E0185) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS codes E0181 and E0185. The quarterly edit effectiveness results from October 2015 through February 2016 are as follows:

- The E0181 review involved 218 claims, of which 91 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 56%.
- The E0185 review involved 142 claims, of which 61 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 45%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Documentation does not support coverage criteria.
- Documentation does not contain a valid date stamp or similar.
- Detailed Written Order (DWO) is incomplete or missing elements.

For complete details, see <u>Pressure Reducing Support Surfaces – Group 1 (HCPCS E0181, E0185) Quarterly</u> <u>Results of Service Specific Prepayment Review</u>.

Coverage Criteria – DME on Demand

DME on Demand is a pre-recorded online presentation for DME suppliers that enable the viewer to watch and listen to the presentation at his/her convenience.

This session will include:

- Coverage
- Coverage Requirements
- Pseuduophakia
- Aphakia
- Contact Lenses
- Medically Necessary Options
- Polycarbonate Lenses V2784
- UV Protections V2755
- Noncovered Options
- Replacement Lenses and Frames
- Resources

Viewing Presentation

To view this presentation, go to the <u>Event Materials and Tutorials page</u>. All DME on Demand presentations will be listed under the Self-Paced/DME on Demand column.

If you have additional questions regarding this training session, contact us at <u>dmeworkshops@noridian.com</u>.

Refractive Lenses DME on Demands

DME on Demand is a pre-recorded online presentation for DME suppliers that enable the viewer to watch and listen to the presentation at his/her convenience.

Coding and Documentation

- Coding
- Modifiers
- Modifiers KX, GA, GY or GZ
- Documentation
- Beneficiary Authorization
- Mandatory Claims Submission
- Orders
- Proof of Deliver
- Resources

Beneficiary Preference Items

- Beneficiary Preferences Feature
- EY Modifer
- Beneficiary Preference Examples

Deluxe Frames Upgrade

- Billing for Deluxe Frames
- Deluxe Frames
- Billing Deluxe Frames Examples

Viewing Presentation

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REIMBURSEMENT

DMEPOS Fee Schedule - April 2016 Quarterly Update

MLN Matters® Number: MM9554

Related Change Request (CR) #: CR 9554

Related CR Release Date: February 26, 2016

Effective Date: April 1, 2016

Related CR Transmittal #: R3472CP

Implementation Date: April 4, 2016

Provider Types Affected

This MLN Matters[®] Article is intended for providers and suppliers submitting claims to Medicare Administrative Contractors (MACs) for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items or services paid under the DMEPOS fee schedule.

What You Need to Know

Change Request (CR) 9554 provides the April quarterly update for the Medicare DMEPOS fee schedule. The instructions include information, when necessary, to implement fee schedule amounts for new codes and correct any fee schedule amounts for existing codes. Because there are no updates from the previous quarter (January through March 2016), an April update to the 2016 DMEPOS and Parenteral and Enteral Nutrition (PEN) fee schedule files is not scheduled for release. However, an April 2016 DMEPOS Rural ZIP code file containing Quarter Two, 2016 rural ZIP Code changes is being provided to the MACs.

The <u>April 2016 DMEPOS Rural ZIP code Public Use File (PUF)</u>, containing the rural ZIP codes effective for Quarter 2, 2016, will be available for State Medicaid Agencies, managed care organizations, and other interested parties shortly after the release of the above file.

Background

The Centers for Medicare & Medicaid Services (CMS) updates the DMEPOS fee schedule on an annual basis in accordance with statute and regulations. The update process for the DMEPOS fee schedule is located in the "Medicare Claims Processing Manual," <u>Chapter 23</u>, Section 60.

Payment on a fee schedule basis is required for Durable Medical Equipment (DME), prosthetic devices, orthotics, prosthetics and surgical dressings by §1834(a), (h), and (i) of the Social Security Act (the Act). Also, payment on a fee schedule basis is a regulatory requirement at 42 CFR §414.102 for Parenteral and Enteral Nutrition (PEN), splints and casts, and Intraocular Lenses (IOLs) inserted in a physician's office.

Additionally, Section 1834(a)(1)(F)(ii) of the Act mandates adjustments to the fee schedule amounts for certain items furnished on or after January 1, 2016, in areas that are not competitive bid areas, based on information from Competitive Bidding Programs (CBPs) for DME. Section 1842(s)(3)(B) provides authority for making adjustments to the fee schedule amount for enteral nutrients, equipment and supplies (enteral nutrition) based on information from CBPs. CMS issued a final rule on November 6, 2014 (79 FR 66223), on the methodologies for adjusting DMEPOS fee schedule amounts using information from CBPs.

REIMBURSEMENT

CMS issued a final rule on November 6, 2014 (79 FR 66223), on the methodologies for adjusting DMEPOS fee schedule amounts using information from CBPs. The CBP product categories, HCPCS codes and Single Payment Amounts (SPAs) included in each Round of the CBP are available on the <u>Competitive Bidding</u> <u>Implementation Contractor (CBIC) website</u>.

The DMEPOS and PEN fee schedule files contain HCPCS codes that are subject to the adjusted payment amount methodologies discussed above as well as codes that are not subject to the fee schedule CBP adjustments. To apply the adjusted fees rural payment rule for areas within the contiguous United States, the DMEPOS and PEN fee schedule files have been updated, effective January 1, 2016, to include rural payment amounts for certain HCPCS codes.

Beginning January 1, 2016, the ZIP code associated with the address used for pricing a DMEPOS claim determines the rural fee schedule payment applicability for codes with rural and non-rural adjusted fee schedule amounts based on information from the competitive bidding program. ZIP codes for non-continental Metropolitan Statistical Areas (MSA) are not included in the DMEPOS Rural ZIP code file.

The DMEPOS Rural ZIP code file is updated on a quarterly basis as necessary. Program instructions on these changes are available in MLN® Matters 9431 (<u>MM9431</u>) entitled "Calendar Year (CY) 2016 Update for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule" based on Transmittal 3416, Change Request (CR) 9431, dated November 23, 2015.

Additional Information

The official instruction, CR9554, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3472CP.pdf on the CMS website.

THERAPEUTIC SHOES

Therapeutic Shoes (HCPCS A5500) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code A5500. The quarterly edit effectiveness results from December 2015 through March 2016 are as follows:

• The A5500 review involved 3,660 claims, of which 2,934 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 80%.

The top reasons for denial were:

- Documentation of in-person with supplier at the time of delivery is incomplete.
- Documentation does not support that the certifying physician has documented in the beneficiary's medical record one of the specified conditions.
- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Documentation does not support that the certifying physician has certified that indications one and two are met and that he/she is treating the beneficiary under a comprehensive plan of care for his/her diabetes and that the beneficiary needs diabetic shoes.

For complete details, see <u>Therapeutic Shoes (HCPCS A5500)</u> Quarterly Results of Service Specific <u>Prepayment Review</u>.

Therapeutic Shoes for Persons with Diabetes – Clarification of Criterion 5

Due to high improper payment rates, Noridian is providing clarification regarding the in-person evaluation of the beneficiary by the supplier at the time of delivery.

Per the Local Coverage Determination (LCD), "The in-person evaluation of the beneficiary by the supplier at the time of delivery...must be conducted with the beneficiary wearing the shoes and inserts and must document that the shoes/inserts/modifications fit properly."

Additionally, the Policy Article (PA) provides further clarification by stating, "At the time of in-person delivery to the beneficiary of the items selected, the supplier must conduct an objective assessment of the fit of the shoe and inserts and document the results. A beneficiary's subjective statements regarding fit as the sole documentation of the in-person delivery does not meet this criterion."

The following questions and answers will assist to determine if an objective assessment of the fit of the shoes and the inserts is properly documented by the supplier at the time of delivery.

1. Question: Does the documentation need to indicate the beneficiary is wearing the shoes and inserts?

Answer: Yes. The supplier must conduct the in-person evaluation at the time of delivery with the beneficiary wearing the shoes and inserts.

2. Question: Does the objective assessment include the therapeutic shoes and inserts?

Answer: Yes. Suppliers must document that the shoes/inserts/modifications fit properly at the time of delivery.

3. Question: Are the following comments such as, "good fit", "fits well", or "beneficiary states shoes are comfortable" examples of objective documentation?

Answer: No. Per the PA, a beneficiary's subjective statement regarding fit as the sole documentation of the in-person delivery does not meet this criterion. Suppliers must objectively document the assessment of the fit of the shoes and inserts to indicate how the shoes were a "good fit."

Suppliers are encouraged to review the LCD and PA specific to <u>Therapeutic Shoes for Persons with</u> <u>Diabetes [PDF]</u> for a complete listing of Medicare coverage criteria requirements or for additional questions, please contact the Supplier Contact Center at 877-320-0390.

UPDATES

RARC, CARC, MREP, and PC Print Update

MLN Matters® Number: MM9466 Related Change Request (CR) #: CR 9466 Related CR Release Date: April 1, 2016 Effective Date: July 1, 2016 Related CR Transmittal #: R3489CP Implementation Date: July 5, 2016

Provider Types Affected

This MLN Matters® Article is intended for physicians, providers, and suppliers who submit claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

CR9466 updates the Claim Adjustment Reason Code (CARC) and Remittance Advice Remark Code (RARC) lists. It also instructs Medicare system maintainers to update Medicare Remit Easy Print (MREP) and PC Print. Make sure that your billing staffs are aware of these changes and obtain the updated MREP or PC Print software if they use that software.

Background

The Health Insurance Portability and Accountability Act (HIPAA) of 1996, instructs health plans to be able to conduct standard electronic transactions adopted under HIPAA using valid standard codes. Medicare policy states that CARCs and RARCs, as appropriate, that provide either supplemental explanation for a monetary adjustment or policy information that generally applies to the monetary adjustment of a claim or service, are required in the remittance advice and coordination of benefits transactions.

The Centers for Medicare & Medicaid Services (CMS) instructs MACs and Shared Systems, if appropriate, to conduct updates based on the code update schedule that results in publication of updated code lists three times a year (around March 1, July 1, and November 1).

Medicare's Shared System Maintainers (SSMs) are responsible for implementing appropriate code deactivation, making sure that any deactivated code is not used in original business messages, but the deactivated code in derivative messages is allowed. SSMs must make sure that Medicare does not report any deactivated code on or before the effective date for deactivation as posted on the Washington Publishing Company (WPC) website. If any new or modified code has an effective date past the implementation date specified in CR9466, MACs will implement on the date specified on the WPC website. The WPC website is available at http://www.wpc-edi.com/Reference on the Internet.

In case of any discrepancy in the code text as posted on WPC website and as reported in any CR, the WPC version should be implemented.

CR9466 advises the SSMs and MACs to perform the updates posted on the WPC based on the March 1, 2016 CARC and RARC code change lists.

Additional Information

The official instruction, CR9466, issued to your MAC regarding this change, is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3489CP.pdf on the CMS website.

Correct Remittance Advice Messages – Updates to Pub. 100-04, Chapters 3, 6, 7 and 15

MLN Matters® Number: MM9562 Related Change Request (CR) #: CR 9562 Related CR Release Date: March 18, 2016 Effective Date: June 20, 2016 Related CR Transmittal #: R3481CP Implementation Date: June 20, 2016

Provider Types Affected

This MLN Matters® Article is intended for physicians, other providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs) for services to Medicare beneficiaries.

What You Need to Know

Change Request (CR) 9562 informs MACs about revisions to Chapters 3, 6, 7 and 15 of the "Medicare Claims Processing Manual" to ensure that all remittance advice coding is consistent with nationally standard operating rules. It also provides a format for consistently showing remittance advice coding throughout the manual. CR9562 does not reflect any change in Medicare policy.

Background

Section 1171 of the Social Security Act requires a standard set of operating rules to regulate the health insurance industry's use of Electronic Data Interchange (EDI) transactions. Operating Rule 360: Uniform Use of CARCs and RARCs, regulates the way in which group codes, Claims Adjustment Reason Codes (CARCs) and Remittance Advice Remark Codes (RARCs) may be used. The rule requires specific codes which are to be used in combination with one another if one of the named business scenarios applies. This rule is authored by the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE).

Medicare and all other payers must comply with the CAQH CORE-developed code combinations. CR8424 established a standard format for presenting these code combinations in the "Medicare Claims Processing Manual." CR9562 updates Chapters 3, 6, 7 and 15 of the manual to reflect the standard format and to correct any non-compliant code combinations. CR9562 does not reflect any change in Medicare policy.

Additional Information

The official instruction, CR9562, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3481CP.pdf on the CMS website. The revised manual chapters are included in CR9562.

Updates to Pub. 100-04, Chapters 1 and 16 to Correct Remittance Advice Messages

MLN Matters® Number: MM9578 Related Change Request (CR) #: CR 9578 Related CR Release Date: April 29, 2016 Effective Date: October 1, 2016 Related CR Transmittal #: R3510CP Implementation Date: October 3, 2016

Provider Types Affected

This MLN Matters[®] Article is intended for physicians, providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

If Change Request (CR) 9578 updates Chapter 1 and Chapter 16 of the "Medicare Claims Processing Manual" to reflect the standard format and to correct any non-compliant remittance advice code combinations. Make sure that your billing staffs are aware of the corrected code combinations.

Background

Section 1171 of the Social Security Act requires a standard set of operating rules to regulate the health insurance industry's use of Electronic Data Interchange (EDI) transactions. Operating Rule 360: Uniform Use of CARCs and RARCs, regulates the way in which group codes, Claims Adjustment Reason Codes (CARCs), and Remittance Advice Remark Codes (RARCs) may be used. The rule requires specific codes which are to be used in combination with one another if one of the named business scenarios applies. This rule is authored by the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE).

Medicare and all other payers must comply with the CAQH CORE-developed code combinations. The business scenario for each payment adjustment must be defined, if applicable, and a valid code combination selected for all remittance advice messages.

UPDATES

CR9578 makes the following code revisions:

- 1. When a MAC rejects an out of jurisdiction professional claim as unprocessable, the following codes are used:
 - Group Code of CO
 - CARC 109, and
 - RARC N104
- 2. When a MAC rejects misdirected Railroad Retirement Board claims as unprocessable, the following codes are used:
 - Group Code of CO
 - CARC 109, and
 - RARC N105
- 3. When a MAC rejects misdirected United Mine Workers Association claims as unprocessable, the following codes are used:
 - Group Code CO
 - CARC 109, and
 - RARC N127
- 4. In the above 3 situations, RARC MA130 was used previously, but will no longer be used in these situations.

Additional Information

The official instruction, CR9578 issued to your MAC regarding this change is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3510CP.pdf. The revised manual Chapters 1 and 16 are attached to CR9578.

Medicare's Organ Acquisition and Donation Payment Policy – Update

MLN Matters[®] Number: SE1608

Provider Types Affected

This MLN Matters® Special Edition article is intended for all providers and suppliers who submit claims or Medicare cost reports (MCRs) to Medicare Administrative Contractors (MACs) for organ procurement, transplant, and histocompatibility laboratory services provided to Medicare beneficiaries.

What You Need to Know

This article is intended to assist providers and suppliers by offering information and resources to clarify Medicare's organ acquisition and donation payment policy for organ procurement, transplant, and histocompatibility laboratory services provided to Medicare beneficiaries. The information does not convey any new or changed policy, but conveys clarification language in the "Provider Reimbursement Manual (PRM)," CMS Pub. 15-1, chapter 31. This clarification is provided to ensure appropriate reporting of organ acquisition costs, including those in a living Kidney Paired Donation (KPD) exchange, to achieve proper Medicare reimbursement.

Background

CMS issued chapter 31 of the PRM to clarify Medicare's payment policy regarding organ acquisition costs, formerly found in chapter 27, sections 2770 through 2775.4. In response to questions raised by the transplant community, chapter 31 clarifies the accounting and reporting of KPD exchange costs in the MCR. The chapter also clarifies the appropriate methodology for counting organs.

- Section 3106 clarifies the accounting for costs of services in a living KPD exchange, provides a detailed example of an exchange, and summarizes the example in a chart.
- Section 3115 clarifies the methodology for counting organs, including those procured and transplanted en bloc.

Highlights from Section 3106, Kidney Paired Donations

- KPDs are similar to directed living donations; however, when the living donor and recipient do not match, they can consent to participate in a KPD matching program that matches living donor/recipient pairs with other living donor/recipient pairs. KPD exchanges can occur when two or more living donor/recipient pairs match each other; often, the living donor and matched recipient are at different certified transplant centers (CTCs).
- The costs of all hospital and physician services for pre-transplant living donor and recipient evaluations become acquisition costs and are included in the MCR of the recipient's CTC. Similarly, when a recipient and donor do not match and elect to participate in a KPD matching program, the costs of the initial living donor evaluations are incurred by the original intended recipient's CTC, regardless of whether the living donor actually donates to their original intended recipient, a KPD matched recipient, or does not donate at all.
- In a KPD exchange, once the donor is matched with a recipient, any additional tests requested by the recipient's CTC, but performed by the donor's CTC are billed as charges reduced to cost to the recipient's CTC and included as acquisition costs on the MCR of the recipient CTC. This is true regardless of whether an actual donation occurs.
- When a donor's CTC procures and sends a kidney to a recipient's CTC, the donor's CTC bills the recipient's CTC the donor CTC's charges reduced to cost for the reasonable costs associated with procuring, packaging, and transporting the kidney. The donor's CTC records these costs on its MCR as kidney acquisition costs and offsets any payments received from the recipient's CTC against its kidney acquisition costs. The recipient's CTC records as part of its kidney acquisition costs, the amounts billed by the donor's CTC for the reasonable costs associated with procuring, packaging, and transporting the reasonable costs associated with procuring, packaging, and transporting the organ as well as any additional testing performed and billed by the donor's CTC. These costs must be reasonable and necessary.
- When a donor's CTC does not procure a kidney, but the donor travels to the recipient's CTC for the procurement, the reasonable costs associated with the procurement are included on the MCR of the recipient's CTC. Travel expenses of the living donor are not allowable Medicare costs.

Highlights from Section 3115, Counting Organs

- Organ procurement organizations (OPOs) and CTCs are responsible for accurately counting both Medicare and non-Medicare organs to ensure that costs are properly allocated on the MCR. The OPO and CTC must count organs procured and transplanted en bloc (two organs transplanted as one unit) as one organ. This can include, but is not limited to, en bloc kidneys and en bloc lungs.
- Medicare usable organs include organs transplanted into Medicare beneficiaries (excluding Medicare Advantage beneficiaries), organs that had partial payments by a primary insurance payer in addition to Medicare, organs sent to other CTCs, organs sent to OPOs and kidneys sent to military renal transplant centers (MRTCs) that have a reciprocal sharing agreement with the OPO in effect prior to March 3, 1988, and approved by the contractor. Medicare usable organs do not include organs used for research, organs sent to veterans' hospitals, organs sent outside the United States, organs transplanted into non-Medicare beneficiaries, organs that were totally paid by primary insurance other than Medicare, organs that were paid by a Medicare Advantage plan, organs procured from a non-certified OPO and kidneys sent to MRTCs that do not have a reciprocal sharing agreement with the OPO in effect prior to March 3, 1988, and approved by the contractor.
- Kidneys counted as Medicare kidneys include those sent to CTCs, certified OPOs, or MRTCs (with a reciprocal sharing agreement with the OPO in effect prior to March 3, 1988, and approved by the contractor). It does not include kidneys sent to foreign countries, VA hospitals, or MRTCs (without a reciprocal sharing agreement with the OPO in effect prior to March 3, 1988, and approved by the contractor), or those used for research.

Information and Resources

The following resources are available to find additional information regarding Medicare's organ acquisition and donation payment policy:

- PRM Transmittal 471 containing CMS Pub. 15-1, chapter 31;
- PRM CMS Pub. 15-2, chapters 33 and 40;
- "Medicare Claims Processing Manual" CMS Pub. 100-04; and
- "Medicare Benefit Policy Manual" CMS Pub. 100-02.

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UROGLOGICAL SUPPLIES

Urological Supplies (HCPCS A4351, A4353, A4358) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS codes A4351, A4353 and A4358. The quarterly edit effectiveness results from July 2015 through October 2015 are as follows:

- The A4351 review involved 2,823 claims, of which 1,577 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 52%.
- The A4353 review involved 333 claims, of which 269 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 74%.
- The A4358 review involved 2,013 claims, of which 1,570 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 73%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Medical documentation was not received.
- Documentation does not support a permanent urinary incontinence or retention.
- Refill request was not received.
- Detailed Written Order (DWO) is incomplete or missing elements.
- Documentation does not support that the beneficiary requires catheterization and meets at least one of the outlined criteria.

For complete details, see <u>Urological Supplies (HCPCS A4351, A4353, A4358)</u> <u>Quarterly Results of Service</u> <u>Specific Prepayment Review</u>.

Urological Supplies (HCPCS A4357) Final Edit Effectiveness Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code A4357. The final edit effectiveness results from July 2015 through March 2016 are as follows:

• The A4357 review involved 639 claims, of which 473 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 78%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Medical documentation was not received.
- Detailed Written Order (DWO) is incomplete or missing elements.
- Documentation does not support a permanent urinary incontinence or retention.

For complete details, see <u>Urological Supplies (HCPCS A4357)</u> Final Edit Effectiveness Results of Service <u>Specific Prepayment Review</u>.

UROGLOGICAL SUPPLIES

Urological Supplies (HCPCS A4357) Final Edit Effectiveness Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code A4357. The final edit effectiveness results from July 2015 through March 2016 are as follows:

• The A4357 review involved 639 claims, of which 473 were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 78%.

The top reasons for denial were:

- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Medical documentation was not received.
- Detailed Written Order (DWO) is incomplete or missing elements.
- Documentation does not support a permanent urinary incontinence or retention.

For complete details, see <u>Urological Supplies (HCPCS A4357) Final Edit Effectiveness Results of Service</u> <u>Specific Prepayment Review</u>.

VACUUM ERECTION DEVICES

Vacuum Erection Devices (HCPCS L7900) Final Edit Effectiveness Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code L7900. The final edit effectiveness results from November 2015 through March 2016 are as follows:

• The L7900 review involved seven claims, of which seven were denied. Based on dollars, this resulted in an overall claim potential improper payment rate of 100%.

The top reasons for denial were:

- Documentation does not support coverage criteria.
- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Detailed Written Order Prior to Delivery (WOPD) was not received.
- Advance Beneficiary Notice (ABN) was not properly executed.

For complete details, see <u>Vacuum Erection Devices (HCPCS L7900)</u> Final Edit Effectiveness Results of <u>Service Specific Prepayment Review</u>.

Correct Coding and Coverage of Ventilators – Revised May 2016

Joint DME MAC Publication

Originally published December 03, 2015

This article has been revised to reflect clarifications on coding and coverage requirements for ventilators in the Frequent and Substantial Servicing (FSS) payment category and to remove ventilator codes that were retired effective January 1, 2016.

Ventilator technology has evolved to the point where it is possible to have a single device capable of operating in numerous modes, from basic continuous positive pressure (CPAP and bi-level PAP) to traditional pressure and volume ventilator modes. This creates the possibility that one piece of equipment may be able to replace numerous and different pieces of equipment. Equipment with multifunction capability creates the possibility of errors in claims submitted for these items. This article will discuss the application of Medicare proper coding and payment rules for ventilators.

HCPCS Coding

Effective for claims with date of service (DOS) on or after January 1, 2016, all products classified as ventilators must be billed using one of the following HCPCS codes:

E0465 - HOME VENTILATOR, ANY TYPE, USED WITH INVASIVE INTERFACE, (E.G., TRACHEOSTOMY TUBE)

E0466 - HOME VENTILATOR, ANY TYPE, USED WITH NON-INVASIVE INTERFACE, (E.G., MASK, CHEST SHELL)

Products previously assigned to HCPCS codes E0450 and E0463 must use HCPCS code E0465. Products previously assigned to HCPCS codes E0460, E0461 and E0464 must use HCPCS code E0466. The Pricing, Data Analysis and Coding (PDAC) will update the product classification listing in a future update.

Suppliers are reminded that the payment policy requirements for the FSS payment category prohibits FSS payment for devices used to deliver continuous and/or intermittent positive airway pressure, regardless of the illness treated by the device. (Social Security Act 1834(a)(3)(A)) This means that products currently classified as HCPCS code E0465 or E0466 when used to provide CPAP or bi-level PAP (with or without backup rate) therapy, regardless of the underlying medical condition, may not be paid in the FSS payment category. General principles of correct coding require that products assigned to a specific HCPCS code only be billed using the assigned code. Thus, using the HCPCS codes for CPAP (E0601) or bi-level PAP (E0470, E0471) devices for a ventilator (E0465, E0466) used to provide CPAP or bi-level PAP therapy is incorrect coding. Claims for ventilators billed using the CPAP or bi-level PAP device HCPCS codes will be denied as incorrect coding.

Suppliers are encouraged to be sure that the correct category of product is provided and billed to avoid errors in HCPCS coding.

Coverage

Items may only be covered based upon the reasonable and necessary (R&N) criteria applicable to the product. The Centers for Medicare & Medicaid Services (CMS) National Coverage Determination Manual (Internet-Only Manual, Publication 100-03) in Chapter 1, Part 4, Section 280.1 stipulates that ventilators are covered for the following conditions:

[N]euromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease.

These ventilator-related disease groups overlap conditions described in the Respiratory Assist Devices LCD used to determine coverage for bi-level PAP devices. Each of these disease categories are conditions where the specific presentation of the disease can vary from patient to patient. For conditions such as these, the specific treatment plan for any individual patient will vary as well. Choice of an appropriate treatment plan, including the determination to use a ventilator vs. a bi-level PAP device, is made based upon the specifics of each individual beneficiary's medical condition. In the event of a claim review, there must be sufficient detailed information in the medical record to justify the treatment selected.

VENTILATORS

Upgrades

An upgrade is defined as an item that goes beyond what is medically necessary under Medicare's coverage requirements. In some cases, CMS policy that allows for billing of upgrade modifiers can be used when providing an item or service that is considered beyond what is medically necessary. This is NOT applicable to ventilators in the situations described above.

Although the use of a ventilator to treat any of the conditions contained in the PAP or RAD LCDs is considered "more than is medically necessary", the upgrade billing provisions may not be used to provide a ventilator for conditions described in the PAP or RAD LCDs. CPAP and bi-level PAP items are in the Capped Rental payment category while ventilators are in the FSS payment category. Upgrade billing across different payment categories is not possible. Claims for items billed for upgrade across different payment categories will be rejected as unprocessable.

Payment Category

Ventilators are classified in the FSS payment category. FSS items are those for which there must be frequent and substantial servicing in order to avoid risk to the patient's health (Social Security Act §1834(a) (3) (A)). The monthly rental payment for items in this pricing category is all-inclusive meaning there is no separate payment by Medicare for any options, accessories or supplies used with a ventilator. In addition, all necessary maintenance, servicing, repairs and replacement are also included in the monthly rental. Claims for these items and/or services will be denied as unbundling.

Coverage of Second Ventilator

Medicare does not cover spare or back-up equipment. Claims for backup equipment will be denied as not reasonable and necessary - same/similar equipment.

Backup equipment must be distinguished from multiple medically necessary items which 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 a separate payment for a second piece of equipment if it is required to serve a different medical purpose that is determined by the beneficiary's medical needs.

The following are examples of situations in which a beneficiary would qualify for both a primary ventilator and a secondary ventilator:

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 ventilator (e.g. positive pressure ventilator with a nasal mask) during the rest of the day.

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 two 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.

Refer to the PAP and RAD LCDs and related Policy Articles and to the DME MAC Supplier Manuals for additional information on coverage, coding and documentation of these items.

For questions about correct coding, contact the PDAC Contact Center at (877) 735-1326 during the hours of 8:30 a.m. to 4 p.m. CT, Monday through Friday, or e-mail the PDAC by completing Contact Form located on the PDAC website.



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