DME Happenings

Jurisdiction D
Issue No. 43
June 2014

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This Bulletin should be shared with all health care practitioners and managerial members of the provider/supplier staff. Bulletins are available at no-cost from our website at: http://www.noridianmedicare.com

Don't be left in the dark, sign up for the Noridian e-mail listing to receive updates that contain the latest Medicare news. Visit the Noridian website and select "Noridian E-mail Newsletter Sign Up" at the bottom of the left-hand navigation menu.

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Healthcare Solutions

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Noridian Healthcare Solutions, LLC

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Jurisdiction D DME MAC Supplier Contacts and Resources

Phone Numbers		
Interactive Voice Response System	1-877-320-0390	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	1-877-320-0390	8 am – 6 pm CT Monday-Friday
Beneficiary Customer Service	1-800-633-4227	24 hours a day/7 days a week
Telephone Reopenings	1-888-826-5708	8 am – 4:30 pm CT
Website: www.noridianmedicare.com/dme		
Fax		
Reopenings and Redeterminations MSP Inquiries and Refunds DME Recovery Auditor Redeterminations		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@noridian.com
Reopenings and Redeterminations		dmeredeterminations@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		**Benefit Protection** Noridian Benefit Protection-DME PO Box 6736 Fargo ND 58108-6736
Administrative Simplification Compliance Act Exception Requests Noridian PO Box 6737 Fargo ND 58108-6737		**Qualified Independent Contractor** C2C Solutions, Inc. Attn: DME QIC PO Box 44013 Jacksonville FL 32231-4013
Electronic Funds Transfer Forms/ Overpayment Redeterminations/ DME Recovery Auditor Redeterminations Noridian PO Box 6728 Fargo ND 58108-6728		**DME Recovery Auditor Overpayments** Noridian PO Box 6759 Fargo ND 58108-6759

Other DME MACs		
Jurisdiction A: NHIC, Corp	1-866-419-9458	www.medicarenhic.com/dme
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

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 Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 184	**Date: April 11, 2014**
	Change Request 8665

Transmittal 184 is being re-issued to change the Implementation Date from July 14, 2014 to May 12, 2014. The transmittal number, issue date and all other information remain the same.

SUBJECT: Clarification to Pub. 100-02, Medicare Benefit Policy Manual Regarding Antigens and Deletion of Section 13.14 from Chapter 13 of Pub. 100-08, Medicare Program Integrity Manual

I. SUMMARY OF CHANGES: This change request serves to make the Medicare Benefit Policy Manual provisions consistent with regulatory requirements. Additionally, revisions are being made to Chapter 13 of the Program Integrity Manual (PIM) to accurately reflect CMS's plan to implement section 731 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).

EFFECTIVE DATE: January 1, 2001 - (Antigen Update); February 24, 2014 - (Section 13.14 deletion)
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: May 12, 2014

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

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	15/50/4.4.1/Antigens
R	16/90/Routine Services and Appliances

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

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-02	Transmittal: 184	Date: April 11, 2014	Change Request: 8665

Transmittal 184 is being re-issued to change the Implementation Date from July 14, 2014 to May 12, 2014. The transmittal number, issue date and all other information remain the same.

SUBJECT: Clarification to Pub. 100-02, Medicare Benefit Policy Manual Regarding Antigens and Deletion of Section 13.14 from Chapter 13 of Pub. 100-08, Medicare Program Integrity Manual

EFFECTIVE DATE: January 1, 2001 - (Antigen Update); February 24, 2014 - (Section 13.14 deletion)
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: May 12, 2014

I. GENERAL INFORMATION

A. Background: Section 1861(s)(2)(G) the Social Security Act (the Act) authorizes Medicare coverage of "antigens (subject to quantity limitations prescribed in regulations by the Secretary)". Implementing regulations were established at 42 CFR 410.68 to identify a reasonable supply of antigens is considered to be not more than a 12-month supply.

B. Policy: This change request serves to make the Medicare Benefit Policy Manual provisions regarding a reasonable supply of antigens consistent with the regulatory requirements mentioned above.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
8665 - 02.1	Contractors shall be aware of the corrections in Pub. 100-02, chapter 15, section 50.4.4.1 and chapter 16, section 90, to align with 42 CFR 410.68, which identifies a reasonable supply of antigens is considered to be not more than a 12-month supply of antigens that has been prepared for a particular patient at any one time. **NOTE:** All other aspects of these sections remain the same.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
8665 - 02.2	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 1 week of the release of this instruction. 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	X	X	

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s): Cheryl Gilbreath, 410-786-5919 or Cheryl.Gilbreath@cms.hhs.gov (Coverage), Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage)

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

VI. 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.

Medicare Benefit Policy Manual
Chapter 15 – Covered Medical and Other Health Services

50.4.4.1 - Antigens
(Rev. 184, Issued: 04-11-14, Effective: 07-14-14, Implementation: 05-12-14)

Payment may be made for a reasonable supply of antigens that have been prepared for a particular patient if: (1) the antigens are prepared by a physician who is a doctor of medicine or osteopathy, and (2) the physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen.

Antigens must be administered in accordance with the plan of treatment and by a doctor of medicine or osteopathy or by a properly instructed person (who could be the patient) under the supervision of the doctor. The associations of allergists that CMS consulted advised that a reasonable supply of antigens is considered to be not more than a 12-*month* supply of antigens that has been prepared for a particular patient at any one time. The purpose of the reasonable supply limitation is to assure that the antigens retain their potency and effectiveness over the period in which they are to be administered to the patient. (See §§20.2 and 50.2.)

Medicare Benefit Policy Manual
Chapter 16 - General Exclusions From Coverage

90 - Routine Services and Appliances
(Rev. 184, Issued: 04-11-14, Effective: 07-14-14, Implementation: 05-12-14)

Routine physical checkups; eyeglasses, contact lenses, and eye examinations for the purpose of prescribing, fitting, or changing eyeglasses; eye refractions by whatever practitioner and for whatever purpose performed; hearing aids and examinations for hearing aids; and immunizations are not covered.

The routine physical checkup exclusion applies to (a) examinations performed without relationship to treatment or diagnosis for a specific illness, symptom, complaint, or injury; and (b) examinations required by third parties such as insurance companies, business establishments, or Government agencies.

The routine physical checkup exclusion does not apply to the following services (as noted in section 42 CFR 411.15(a)(1)):

- Screening mammography,
- Colorectal cancer screening tests,
- Screening pelvic exams,
- Prostate cancer screening tests,
- Glaucoma screening exams,
- Ultrasound screening for abdominal aortic aneurysms (AAA),
- cardiovascular disease screening tests,
- diabetes screening tests,
- screening electrocardiogram,
- Initial preventive physical examinations,
- Annual wellness visits providing personalized prevention plan services, and
- Additional preventive services that meet the criteria specified in 42 CFR 410.64.

If the claim is for a diagnostic test or examination performed solely for the purpose of establishing a claim under title IV of Public Law 91-173, "Black Lung Benefits," the service is not covered under Medicare and the claimant should be advised to contact their Social Security office regarding the filing of a claim for reimbursement under the "Black Lung" program.

The exclusions apply to eyeglasses or contact lenses, and eye examinations for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses for refractive errors. The exclusions do not apply to physicians' services (and services incident to a physicians' service) performed in conjunction with an eye disease, as for example, glaucoma or cataracts, or to post-surgical prosthetic lenses which are customarily used during convalescence from eye surgery in which the lens of the eye was removed, or to permanent prosthetic lenses required by an individual lacking the organic lens of the eye, whether by surgical removal or congenital disease. Such prosthetic lens is a replacement for an internal body organ - the lens of the eye. (See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §120).

Expenses for all refractive procedures, whether performed by an ophthalmologist (or any other physician) or an optometrist and without regard to the reason for performance of the refraction, are excluded from coverage.

A. Immunizations

Vaccinations or inoculations are excluded as immunizations unless they are either:

- Directly related to the treatment of an injury or direct exposure to a disease or condition, such as antirabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin sera, or immune globulin. (In the absence of injury or direct exposure, preventive immunization (vaccination or inoculation) against such diseases as smallpox, polio, diphtheria, etc., is not covered.); or

- Specifically covered by statute, as described in the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §50.4.4.2.

B. Antigens

Prior to the Omnibus Reconciliation Act of 1980, a physician who prepared an antigen for a patient could not be reimbursed for that service unless the physician also administered the antigen to the patient. Effective January 1, 1981, payment may be made for a reasonable supply of antigens that have been prepared for a particular patient even though they have not been administered to the patient by the same physician who prepared them if:

- The antigens are prepared by a physician who is a doctor of medicine or osteopathy, and

- The physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen.

A reasonable supply of antigens is considered to be not more than a 12-*month* supply of antigens that has been prepared for a particular patient at any one time. The purpose of the reasonable supply limitation is to assure that the antigens retain their potency and effectiveness over the period in which they are to be administered to the patient. (See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §50.4.4.1)

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.
- 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."

Modifying Daily Common Working File to Medicare Beneficiary Database File to Include Diagnosis Codes on HETS 270/271 Transactions

MLN Matters® Number: MM8456 Rescinded
Related Change Request (CR) #: CR 8456
Related CR Release Date: May 16, 2014
Effective Date: October 1, 2014
Related CR Transmittal #: R1386OTN
Implementation Date: October 6, 2014

Note: This article was rescinded on May 20, 2014, as a result of a revision to CR8456, issued on May 16. The CR revision eliminated the need for provider education. As a result, this article is rescinded.

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

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, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html. 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.

Supplier Manual Updates

The following table outlines updates to the DME MAC Jurisdiction D Online Supplier Manual. The content is ordered with the most current changes appearing on top.

Chapter	Subheading	Supplier Manual Update	Change Date
3	Requirements of New Orders	Removed information in regards to two or more suppliers merging	05/21/14
8	CEDI Helpdesk	Added support information	03/12/14
11	MSPRC	Added section	03/12/14
15	Options for Refunding DME Noridian	Added section On the Claims page	03/12/14

Supplier Contact Center and Telephone Reopenings Holiday and Training Closures

Supplier Contact Center

The Noridian Customer Service team (1-877-320-0390) will be closed for the entire day (8 a.m. through 6 p.m. CT) in recognition of holidays. Additionally, the Customer Service team will be closed three days each month to receive training from 9:30 a.m. – 12 p.m. CT. The holiday and training closures are provided below. The Interactive Voice Recognition (IVR) [PDF] system (1-877-320-0390) and Endeavor, the Noridian DME Jurisdiction D supplier portal, will each continue to be available on these dates to assist suppliers with their claim status, eligibility, remittance advice, same and/or similar inquiries.

Event	Date	Closure Timeframe
Off-the-Phone Training	March 21, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	March 28, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	April 11, 2014	9:30 a.m. – 12 p.m. CT
Good Friday	April 18, 2014	Entire Day Closed 8 a.m. – 6 p.m. CT
Off-the-Phone Training	April 25, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	May 9, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	May 16, 2014	9:30 a.m. – 12 p.m. CT

Event	Date	Closure Timeframe
Off-the-Phone Training	May 23, 2014	9:30 a.m. – 12 p.m. CT
Memorial Day	May 26, 2014	Entire Day Closed 8 a.m. – 6 p.m. CT
Off-the-Phone Training	June 13, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	June 20, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	June 27, 2014	9:30 a.m. – 12 p.m. CT
Independence Day	July 4, 2012	Entire Day Closed 8 a.m. – 6 p.m. CT
Off-the-Phone Training	July 11, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	July 18, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	July 25, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	August 8, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	August 15, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	August 22, 2014	9:30 a.m. – 12 p.m. CT
Labor Day	September 1, 2014	Entire Day Closed 8 a.m. – 6 p.m. CT
Off-the-Phone Training	September 12, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	September 19, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	September 26, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	October 10, 2014	9:30 a.m. – 12 p.m. CT
Columbus Day Training	October 13, 2014	2:00 p.m. – 6 p.m. CT
Off-the-Phone Training	October 17, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	October 24, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	November 14, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	November 21, 2014	9:30 a.m. – 12 p.m. CT
Thanksgiving	November 27 and 28	Entire Day Closed 8 a.m. – 6 p.m. CT
Off-the-Phone Training	December 12, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	December 19, 2014	9:30 a.m. – 12 p.m. CT
Christmas	December 24, 2012	12 – 6 p.m. CT
Christmas	December 25, 2012	Entire Day Closed 8 a.m. – 6 p.m. CT

Telephone Reopenings

The Noridian Telephone Reopening Team will be closed for the entire day (8 a.m. through 4:30 p.m. CT) in recognition of holidays. Additionally, the Telephone Reopening team will be closed the first Friday of each month between 8 a.m. and 10 a.m. CT and the second through fourth Fridays of each month from 9:30 a.m. – 12 p.m. to receive training. The holiday and training closures are provided below.

Event	Date	Closure Timeframe
Off-the-Phone Training	March 21, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	March 28, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	April 4, 2014	8:30 a.m. – 10 a.m. CT
Off-the-Phone Training	April 11, 2014	9:30 a.m. – 12 p.m. CT
Good Friday	April 18, 2014	Entire Day Closed 8 a.m. – 4:30 p.m. CT

Event	Date	Closure Timeframe
Off-the-Phone Training	April 25, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	May 2, 2014	8:30 a.m. – 10 a.m. CT
Off-the-Phone Training	May 9, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	May 16, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	May 23, 2014	9:30 a.m. – 12 p.m. CT
Memorial Day	May 26, 2014	Entire Day Closed 8 a.m. – 4:30 p.m. CT
Off-the-Phone Training	June 6, 2014	8:30 a.m. – 10 a.m. CT
Off-the-Phone Training	June 13, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	June 20, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	June 27, 2014	9:30 a.m. – 12 p.m. CT
Independence Day	July 4, 2012	Entire Day Closed 8 a.m. – 4:30 p.m. CT
Off-the-Phone Training	July 11, 2014	9:30 a.m. – 12 p.m. CT
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Off-the-Phone Training	July 25, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	August 1, 2014	8:30 a.m. – 10 a.m. CT
Off-the-Phone Training	August 8, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	August 15, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	August 22, 2014	9:30 a.m. – 12 p.m. CT
Labor Day	September 1, 2014	Entire Day Closed 8 a.m. – 4:30 p.m. CT
Off-the-Phone Training	September 5, 2014	8:30 a.m. – 10 a.m. CT
Off-the-Phone Training	September 12, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	September 19, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	September 26, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	October 3, 2014	8:30 a.m. – 10 a.m. CT
Off-the-Phone Training	October 10, 2014	9:30 a.m. – 12 p.m. CT
Columbus Day Training	October 13, 2014	2:00 p.m. – 4:30 p.m. CT
Off-the-Phone Training	October 17, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	October 24, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	November 7, 2014	8:30 a.m. – 10 a.m. CT
Off-the-Phone Training	November 14, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	November 21, 2014	9:30 a.m. – 12 p.m. CT
Thanksgiving	November 27 and 28	Entire Day Closed 8 a.m. – 4:30 p.m. CT
Off-the-Phone Training	December 5, 2014	8:30 a.m. – 10 a.m. CT
Off-the-Phone Training	December 12, 2014	9:30 a.m. – 12 p.m. CT
Off-the-Phone Training	December 19, 2014	9:30 a.m. – 12 p.m. CT
Christmas	December 24, 2014	12 – 4:30 p.m. CT
Christmas	December 25, 2014	Entire Day Closed 8 a.m. – 4:30 p.m. CT

Chapter 29 Appeals Update

MLN Matters® Number: MM8588
Related CR Release Date: April 11, 2014
Related CR Transmittal #: R2926CP
Related Change Request (CR) #: CR 8588
Effective Date: July 14, 2014
Implementation Date: July 14, 2014

Provider Types Affected

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

Provider Action Needed

This article is based on Change Request (CR) 8588, which updates the "Medicare Claims Processing Manual" (Chapter 29 (Appeals of Claims Decisions)) with various policy clarifications. Make sure that your billing staffs are aware of these updates.

Background

Change Request (CR) 8588 revises the "Medicare Claims Processing Manual" (Publication 100-04, Chapter 29 (Appeals of Claims Decisions)) and adds various policy clarifications regarding appeals of claims decisions. These revisions include:

- A definition of spouse following the June 2013 Supreme Court ruling that invalidated Section 3 of the Defense of Marriage Act (DOMA) (Section 110).
- Clarification of existing instructions regarding:
  - The submission of appointment of representative written instruments (Section 270.1.3).
  - The handling and reporting of defective or missing appointment instruments (Section 270.1.6).
  - Signature requirements for appointment of representative instruments (Section 270.1.2).

A copy of the revised "Medicare Claims Processing Manual" (Chapter 29 (Appeals of Claims Decisions)) s included as an attachment to CR 8588.

Additional Information

The official instruction, CR 8588, issued to your MAC regarding this change is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2926CP.pdf on the CMS website.

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 https://www.noridianmedicare.com/dme/contact/holiday.html.
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 first and last name • 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.

How do I request a Telephone Reopening?	To request a reopening via telephone, call 1 888 826 5708.

What may I request as a Telephone Reopening?	The following is a list of clerical errors and omissions that may be completed as a Telephone 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
	  • 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.

How do I request a Telephone Reopening?	To request a reopening via telephone, call 1 888 826 5708.

What is not accepted as a Telephone Reopening?	The following will not be accepted as a Telephone Reopening and must be submitted as a redetermination with supporting documentation.
	• 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 "Denied Claims Requiring CMN/DIF Must be Resubmitted, Rather than Reopened"
	• 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

APPEALS

How do I request a Telephone Reopening?	To request a reopening via telephone, call 1 888 826 5708.
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 dmeredeterminations@noridian.com. Please note, emails containing Protected Health Information (PHI) will be returned as unprocessable.

BILLING

Billing Reminder: Modifier Usage for Urological Supplies – Revised

DME MAC Joint Publication

The Urological Supplies Local Coverage Determination (LCD) provides the use of modifiers with each submitted Healthcare Common Procedural Coding System (HCPCS) code. The use of the modifiers will indicate whether the applicable payment criteria are met (KX modifier), and provide information related to the coverage and/or liability (GA, GZ and GY modifiers) when the policy criteria are not met. This article reflects the appropriate use of each modifier to ensure correct use. Instructions for the GA and GZ modifiers were recently included in this LCD for proper consideration of usage (December 2013).

Proper selection of the correct G modifier requires an assessment of the possible cause for a denial. Some criteria are based upon statutory requirements. Failure to meet a statutory requirement justifies the use of the GY modifier. When Reasonable and Necessary (R&N) criteria are not met, either the GA or GZ modifier is appropriate based upon Advance Beneficiary Notice of Noncoverage (ABN) status.

Urological supplies are payable under the Prosthetic Device benefit (Social Security Act § 1861(s)(8)). Urinary catheters and external urinary collection devices are covered to drain or collect urine for a beneficiary who has permanent urinary incontinence or permanent urinary retention. Permanent urinary retention is defined as retention that is not expected to be medically or surgically corrected in the affected beneficiary within 3 months. These requirements are statutory benefit requirements. When a beneficiary does not meet these requirements, the GY modifier must be used.

Aside from the above statutory coverage criteria, the remaining payment requirements are classified as R&N requirements. Examples (not all-inclusive) include utilization limits, medical necessity criteria for sterile kits, correct coding, etc. For those situations where R&N criteria are not met, either the GA or GZ modifier would be the appropriate choice depending upon ABN status.

Use of these modifiers is mandatory. Claim lines billed without a KX, GA, GY or GZ modifier will be rejected as missing information.

KX – Requirements specified in the medical policy have been met
The KX modifier must be appended to a catheter code, an external urinary collection device or a supply item when all of the statutory and R&N requirements have been met. Suppliers are not required to secure all of the required documentation prior to claim submission, however, appending the KX modifier to each of the urological codes billed serves as an attestation by the supplier that the requirements for its use have been met.

GA – Waiver of liability (expected to be denied as not reasonable and necessary, ABN on file)
When a Medicare claim denial is expected because an item or service does not meet the R&N criteria, the supplier must issue an ABN to the beneficiary before furnishing the item or service. When the beneficiary accepts financial responsibility and signs a valid ABN, the supplier submits the claim to Medicare appending modifier GA to each corresponding HCPCS code. Modifier GA indicates that the supplier has a waiver of liability statement on file. Modifier GA must not be submitted if a valid ABN is not issued. Claims submitted with the GA modifier will receive a medical necessity denial holding the beneficiary liable.

GZ – Item or service not reasonable and necessary (expected to be denied as not reasonable and necessary, no ABN on file)
When a Medicare claim denial is expected because an item or service does not meet the R&N criteria, the supplier is expected to issue an ABN to the beneficiary. If the supplier chooses to accept liability for the expected denial, the supplier must append the GZ modifier to each corresponding HCPCS code. Modifier GZ indicates that the supplier does not have a waiver of liability statement on file. Claims submitted with the GZ modifier will receive a medical necessity denial holding the supplier liable.

GY – Item or service statutorily excluded or does not meet the definition of any Medicare benefit
The GY modifier indicates that an item or service is statutorily excluded or does not meet the definition of any Medicare benefit. For urological supplies, the prosthetic benefit requires that the beneficiary must have a permanent impairment of urination. In cases where the statutory criteria are not met, suppliers are required to code their claims for urological supplies with the GY modifier. Claims submitted with the GY modifier will be denied as statutorily noncovered holding the beneficiary liable for the excluded services. Refer to the Urological Supplies LCD and related Policy Article for additional information about the payment rules, coding and documentation requirements.

Correct Coding – Lithium Batteries

The DME MACs have recently noted confusion on the part of DMEPOS suppliers regarding the proper billing of lithium batteries. There are two types of lithium batteries - Lithium batteries and Lithium Ion batteries. Lithium ion batteries are commonly used in consumer electronic devices and are rechargeable. Standard lithium batteries are disposable, non-rechargeable batteries. Suppliers must take care to properly distinguish between lithium ion and lithium batteries when billing claims to Medicare.

The following HCPCS codes are used to correctly code lithium batteries:

A4235	Replacement battery, lithium, for use with medically necessary home blood glucose monitor owned by patient, each
A4601	Lithium ion battery for non-prosthetic use, replacement
E2397	Power wheelchair accessory, lithium-based battery, each
K0604	Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each
K0605	Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each
L7367	Lithium ion battery, replacement

Code A4235 describes a lithium battery, not a lithium ion battery. This code is used to bill lithium batteries for glucose monitors, regardless of the voltage.

Codes K0604 and K0605 describe lithium batteries commonly used in external insulin infusion pumps. Note that each code has an associated voltage. Claims for lithium batteries for external insulin infusion pumps (E0784) that do not use a voltage described by either code K0604 and K0605 must be billed using code A9999.

Code A4601 describes a lithium ion battery, not a lithium battery. Suppliers billing code A4601 must include, in the claim narrative field:

- The type of base DME item for which A4601 is being used.
- The manufacturer, model number, and manufacturer's suggested retail price (MSRP) for the battery.

Codes E2397 and L7367 describe lithium ion batteries for power wheelchairs and prosthetics, respectively.

Refer to the Contractor Supplier Manual, applicable Local Coverage Determination and related Policy Article for additional information about other coverage, coding and documentation requirements.

For questions about correct coding, contact the PDAC Contact Center at (877) 735-1326 during the hours of 8:30 a.m. to 4:00 p.m. CT, Monday through Friday, or e-mail the PDAC by completing the DME PDAC Contact Form located on the PDAC website: https://www.dmepdac.com.

Denial Letters for Religious Nonmedical Health Care Institution Services Not Covered by Medicare

MLN Matters® Number: MM8559
Related Change Request (CR) #: CR 8559
Related CR Release Date: April 11, 2014
Related CR Transmittal #: R2930CP
Effective Date: July 14, 2014
Implementation Date: July 14, 2014

Provider Types Affected

This MLN Matters® Article is intended for Religious Nonmedical Health Care Institutions (RNHCIs) submitting claims to Medicare Durable Medical Equipment Medicare Administrative Contractors (DME/MACs) and A/B Medicare Administrative Contractors (MACs)) for services to Medicare beneficiaries.

Provider Action Needed

This article is based on Change Request (CR) 8559 which informs MACs about revisions to Medicare systems edits related to diagnosis coding instructions on RNHCI claims. It also adds instructions regarding requests for denial letters when RNHCIs provide a level of care that is not covered by Medicare to a beneficiary who does not desire to submit a Notice of Election (NOE) for the sole purpose of obtaining that specific service, which may be covered by another insurer. Make sure that your billing staffs are aware of these changes.

Background

Diagnosis Code Reporting

While coding of diagnoses is not consistent with the nonmedical nature of Religious Nonmedical Heath Care Institution (RNHCI) services, the presence of diagnosis codes is a requirement for standard claims transactions. CR 8350 created editing in Medicare systems to ensure the following unspecified diagnosis codes are reported on RHNCI claims:

- Prior to the implementation of ICD-10: Principal Diagnosis: 799.9 and Other Diagnosis: V62.6
- After the implementation of ICD-10: Principal Diagnosis: R69 and Other Diagnosis: Z53.1

After consultation with the industry, Original Medicare has determined that an additional ICD-10 code should be available for reporting as an Other Diagnosis on RNHCI claims. CR8559 revises Medicare systems to allow RNHCI claims to report as the Other Diagnosis either Z53.1 or Z53.29, "procedure and treatment not carried out because of patient's decision for other reasons."

Denial Notices for Non-covered Levels of RNHCI Care

In order to avoid having the RNHCI issue an inappropriate NOE, the RNHCI may request in writing a denial notice from the appropriate MAC. In response, the MAC will provide the RNHCI with a manual denial letter. This letter may then be submitted to a secondary insurer as evidence of a prior Medicare denial.

RNHCI facilities sometimes provide services to Medicare beneficiaries that do not qualify for Medicare coverage and for which the beneficiary may seek payment from another insurer. The other insurer may require a denial from Medicare before making payment for these services. Medicare systems require submission of a Notice of Election (NOE) before any RNHCI claims can be processed. In order for a claim requesting a denial notice to be processed, the RNHCI would need to inappropriately submit an NOE, since the beneficiary is not requesting Medicare coverage of RNHCI services.

Additional Information

The official instruction, CR 8559 issued to your MAC regarding this change may be viewed at http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2930CP.pdf on the CMS website.

Mandatory Reporting of 8-Digit Clinical Trial Number on Claims – Revised

MLN Matters® Number: MM8401 Revised
Related CR Release Date: May 13, 2014
Related CR Transmittal #: R2955CP
Related Change Request (CR) #: CR 8401
Effective Date: January 1, 2014
Implementation Date: January 6, 2014

Note: This article was revised on June 9, 2014, to emphasize that coding "CT" in front of the clinical trial number applies ONLY to paper claims. The "CT" is not to be coded on electronic claims. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for physicians, providers, and suppliers submitting claims to Medicare contractors (Fiscal Intermediaries (FIs), carriers, Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) and A/B MACs) for items and services provided in clinical trials to Medicare beneficiaries.

Provider Action Needed

This article is based on CR 8401, which informs you that, effective January 1, 2014, it will be mandatory to report a clinical trial number on claims for items and services provided in clinical trials that are qualified for coverage as specified in the "Medicare National Coverage Determination (NCD) Manual," Section 310.1.

The clinical trial number to be reported is the same number that has been reported voluntarily since the implementation of CR 5790, dated January 18, 2008. That is the number assigned by the National Library of Medicine (NLM) http://clinicaltrials.gov/ website when a new study appears in the NLM Clinical Trials data base. Make sure that your billing staffs are aware of this requirement.

Background

CR 5790, Transmittal 310, dated January 18, 2008, titled "Requirements for Including an 8- Digit Clinical Trial Number on Claims" is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R310OTN.pdf on the CMS website. The MLN Matters® Article for CR5790 is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM5790.pdf on the CMS website.

This number is listed prominently on each specific study's page and is always preceded by the letters 'NCT'.

The Centers for Medicare & Medicaid Services (CMS) uses this number to identify all items and services provided to beneficiaries during their participation in a clinical trial, clinical study, or registry. Furthermore, this identifier permits CMS to better track Medicare payments, ensure that the information gained from the research is used to inform coverage decisions, and make certain that the research focuses on issues of importance to the Medicare population.

Suppliers may verify the validity of a trial/study/registry by consulting CMS's clinical trials/registry website at http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/index.html on the CMS website.

For institutional claims that are submitted on the electronic claim 837I, the 8-digit number should be placed in Loop 2300 REF02 (REF01=P4) when a clinical trial claim includes:

- Condition code 30.

- ICD-9 code of V70.7/ICD-10 code Z00.6 (in either the primary or secondary positions).
- Modifier Q0 and/or Q1, as appropriate (outpatient claims only).

For professional claims, the 8-digit clinical trial number preceded by the 2 alpha characters of CT (use CT only on paper claims) must be placed in Field 19 of the paper claim Form CMS-1500 (e.g., CT12345678) or the electronic equivalent 837P in Loop 2300 REF02(REF01=P4) **(do not use CT on the electronic claim, e.g., 12345678)** when a clinical trial claim includes:

- ICD-9 code of V70.7/ICD-10 code Z00.6 (in either the primary or secondary positions) and
- Modifier Q0 and/or Q1, as appropriate (outpatient claims only).

Medicare Part B clinical trial/registry/study claims with dates of service on and after January 1, 2014, not containing an 8-digit clinical trial number will be returned as unprocessable to the provider for inclusion of the trial number using the messages listed below.

- Claim Adjustment Reason Code (CARC) 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either National Council for Prescription Drug Programs (NCPDP) Reject Reason Code, or Remittance Advice Remark Code (RARC) that is not an ALERT.)"
- RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services."
- RARC MA130: "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."
- Group Code-Contractual Obligation (CO).

Note: This is a reminder/clarification that clinical trials that are also investigational device exemption (IDE) trials must continue to report the associated IDE number on the claim form as well.

Additional Information

The official instruction, CR 8401, issued to your Medicare contractor regarding this change, may be viewed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2955CP.pdf on the CMS website.

See MLN Matters® Article SE1344 (http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1344.pdf) for information on an interim alternative method of satisfying the requirement in CR 8401 for providers who do not have the ability to submit the clinical trial number for trial related claims.

MyoPro™ – Coding Reminder

Joint DME MAC Article

The MyoPro™ (Myomo, Inc.) is an upper extremity device that incorporates muscle sensors and an electric motor to augment patient-initiated movement. According to the company's website, the MyoPro is "designed to enable individuals to self-initiate and control movements of a partially paralyzed or weakened arm using their own muscle signals. When the user tries to bend their arm, sensors in the brace detect the weak muscle signal, which activates the motor to move the arm in the desired direction."

Upon evaluation of this product, the DME MACs and the PDAC have determined that:

- This item falls within the Durable Medical Equipment benefit category, not within the Braces benefit.
- This device must be coded as A9300 – EXERCISE EQUIPMENT.

Exercise equipment is non-covered by Medicare. Claims for A9300 will be denied as non-covered (no Medicare benefit).

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 the DME PDAC Contact Form located on the PDAC website.

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.

MLN Connect Provider eNews

March 20, 2014

View the complete issue of the MLN Connects™ Provider eNews for March 20, 2014.

MLN Connects™ National Provider Calls

- Medicare Shared Savings Program ACO: Preparing to Apply for 2015 – Registration Now Open
- Standardized Readmission Ratio for Dialysis Facilities: National Dry Run – Registration Opening Soon

CMS Events

- Volunteers Sought for ICD-10 End-to-End Testing: July 21–25

Announcements

- The Flu Season Is Not Over: It's Not Too Late to Get a Flu Vaccine
- 12 Days Remaining for Hospice Providers to Submit FY 2015 Reporting Cycle HQRP data

- Medicare EHR Incentive Program: Eligible Professionals Must Attest by March 31 to Receive 2013 Incentive

Claims, Pricers, and Codes

- Medicare Only Accepting Revised CMS 1500 Claim Form (02/12) Starting April 1
- Part A Provider Coordination of Benefits Error Code 000000

MLN Educational Products

- "Screening and Diagnostic Mammography" Booklet – Revised
- "Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse" Booklet – Revised

March 27, 2014

Click to view the complete issue of the MLN Connects™ Provider eNews for March 27, 2014.

MLN Connects™ National Provider Calls

- Medicare Shared Savings Program ACO: Preparing to Apply for 2015 – Register Now
- How to Register for the PQRS Group Practice Reporting Option in 2014 – Registration Now Open
- Standardized Readmission Ratio for Dialysis Facilities: National Dry Run – Registration Now Open

CMS Events

- Hospice Item Set Data Collection Training Video Now Available

Announcements

- Medicare Care Choices Model Launched: Hospice Organizations Can Apply Through June 19
- ESRD QIP Website Improvements: New Resources for Providers
- 5 Days Remaining for Hospice Providers to Submit FY 2015 Reporting Cycle HQRP Data
- Submit Suggestions for Advanced Diagnostic Imaging Program
- EHR Incentive Program: Medicare EPs Must Attest by March 31 to Receive 2013 Incentive
- EHR Incentive Program: Medicare Eligible Hospitals Must Take Action by April 1 to Avoid 2015 Payment Adjustment
- EHR Incentive Program: Important Payment Adjustment Information for Medicare Eligible Professionals

MLN Educational Products

- Spring 2014 Version of The Medicare Learning Network® (MLN) Catalog – Now Available
- "Psychiatry and Psychotherapy Services" MLN Matters® Article – Re-Issued
- "Intensive Behavioral Therapy (IBT)" Booklet - Revised
- "Communicating With Your Medicare Patients" Fact Sheet – Revised

April 3, 2014

MLN Connects™ Provider eNews for April 3, 2014

MLN Connects™ National Provider Calls

- Medicare Shared Savings Program ACO: Preparing to Apply for 2015 – Last Chance to Register
- How to Register for the PQRS Group Practice Reporting Option in 2014 – Last Chance to Register
- Standardized Readmission Ratio for Dialysis Facilities: National Dry Run – Register Now
- National Partnership to Improve Dementia Care in Nursing Homes – Registration Now Open
- New MLN Connects™ National Provider Call Transcripts and Audio Recordings

Announcements

- Hospital Outpatient Supervision Level Designations: April 30 Deadline for Comments
- Physicians and Teaching Hospitals Do Not Need to Take Action Now in Open Payments
- PV-PQRS Registration System is Now Open
- 2-Midnight Rule: Provider Resources
- Submit Your 2014 PQRS Quality Measures through the Registry Reporting Method
- New Security Risk Assessment Tool Helps Providers Ensure HIPAA Compliance
- CMS Posts 2014 Eligible Hospital Electronic Clinical Quality Measure Annual Update

Claims, Pricers, and Codes

- Appeals for Cancelled Claims Related to Medicare Beneficiaries Classified as "Unlawfully Present" in the U.S.
- Mandatory Payment Reduction of 2% Continues through March 31, 2015, for the Medicare FFS Program – "Sequestration"
- Adjustment of Community Mental Health Center Claims for Telehealth Originating Facility Fees
- Incorrect Overpayments and Denials for Some New Patient Visit Claims

MLN Educational Products

- "Medicare Quarterly Provider Compliance Newsletter [Volume 4, Issue 3]" Educational Tool – Released
- "Quick Reference Information: The ABCs of Providing the Initial Preventive Physical Examination" Educational Tool – Revised
- "Quick Reference Information: The ABCs of Providing the Annual Wellness Visit" Educational Tool – Revised
- "Medicare Coverage of Items and Services Furnished to Beneficiaries in Custody Under a Penal Authority" Fact Sheet – Reminder
- New MLN Provider Compliance Fast Fact
- MLN Product Available in Electronic Publication Format

April 10, 2014

MLN Connects™ Provider eNews for April 10, 2014

MLN Connects™ National Provider Calls

- Standardized Readmission Ratio for Dialysis Facilities: National Dry Run – Last Chance to Register
- Medicare Shared Savings Program ACO Application Process – Registration Now Open
- National Partnership to Improve Dementia Care in Nursing Homes – Register Now

Announcements

- Medicare Coverage Includes Screening and Counseling for Alcohol Misuse
- Historic Release of Data Gives Consumers Unprecedented Transparency on the Medical Services Physicians Provide and How Much They are Paid
- Participation Rises in Medicare PQRS and eRx Incentive Program
- Probe and Educate Clarifications: Timeframes for Additional Documentation Requests and Education
- EHR Incentive Programs: New Meaningful Use Calculator Helps Providers Attest to Stage 2
- Review New and Updated FAQs for the EHR Incentive Programs

Claims, Pricers, and Codes

- CMS Releases Modifications to HCPCS Code Set
- SNFs and Changes in Part B Payment Methodology for Certain DME

MLN Educational Products

- "Updating Beneficiary Information with the Benefits Coordination & Recovery Center (formerly known as the Coordination of Benefits Contractor)" MLN Matters® Article – Released
- "Basic Medicare Information for Providers and Suppliers" Guide – Revised
- "Mental Health Services" Booklet – Revised
- New MLN Educational Web Guides Fast Fact

April 24, 2014

MLN Connects™ Provider eNews for April 24, 2014

MLN Connects™ National Provider Calls

- Individualized Quality Control Plan for CLIA Laboratory Non-Waived Testing – Register Now
- National Partnership to Improve Dementia Care in Nursing Homes – Register Now
- Stage 2 Meaningful Use Requirements, Reporting Options, and Data Submission Processes for Eligible Professionals – Registration Opening Soon
- New MLN Connects™ National Provider Call Transcripts and Audio Recordings

CMS Events

- Webinar for Comparative Billing Report on Diabetic Testing Supplies

Announcements

- Data from Inpatient Psychiatric Facilities Increase Transparency for Consumers Evaluating Facilities
- CMS National Dry Run of the Standardized Readmission Ratio for Dialysis Facilities Ends May 2
- CMS to Begin Accepting Suggestions for Potential PQRS Measures in May
- Hospice Item Set Manual: Change Table for V1.00.0 to V1.01 Now Available
- CMS to Release a Comparative Billing Report on Diabetic Testing Supplies in April
- Learn About the Special EHR Reporting Periods for Eligible Professionals in 2014
- EHR Incentive Program: Hardship Exception Applications due July 1 for Eligible Professionals
- EHR Incentive Programs: Eligible Professionals Should Review Changes in Stage 1 Meaningful Use Criteria

Claims, Pricers, and Codes

- April 2014 Outpatient Prospective Payment System Pricer File Update

MLN Educational Products

- "Provider Compliance Tips for Computed Tomography (CT Scans)" Fact Sheet – Released
- "Part C Appeals: Organization Determinations, Appeals & Grievances" Web-Based Training Course – Released
- "Part D Coverage Determinations, Appeals & Grievances" Web-Based Training Course – Released
- "Duplicate Claims – Outpatient" Podcast – Released
- "The Basics of Medicare Enrollment for Physicians and Other Part B Suppliers" Fact Sheet – Revised
- MLN Products Available in Electronic Publication Format

May 1, 2014

MLN Connects™ Provider eNews for May 1, 2014

MLN Connects™ National Provider Calls

- Individualized Quality Control Plan for CLIA Laboratory Non-Waived Testing – Register Now
- National Partnership to Improve Dementia Care in Nursing Homes – Register Now
- Review of the New Medicare PPS for Federally Qualified Health Centers – Registration Now Open
- Stage 2 Meaningful Use Requirements, Reporting Options, and Data Submission Processes for Eligible Professionals – Registration Now Open
- New MLN Connects™ National Provider Call Transcript and Audio Recording

CMS Events

- Inpatient Rehabilitation Facility Quality Reporting Program Training

Announcements

- CMS Finalizes a Medicare Prospective Payment System for Federally Qualified Health Centers
- Interactive Tool Allows Easier Access to Physician Data
- Notices of Intent to Apply for the Medicare Shared Savings Program 2015 Program Start Date Due by May 30
- Ordering and Referring Denial Edits Will Apply to Certifying Physicians for HHAs Beginning July 7
- New DOTPA Reports Available
- CMS is Accepting Suggestions for PQRS Measures
- New Fact Sheet Available on How to Avoid the 2016 PQRS Payment Adjustment
- PQRS Participants: New Email Address for QualityNet Help Desk

Claims, Pricers, and Codes

- Preventive Services Payable to RHCs and FQHCs

MLN Educational Products

- "HIPAA EDI Standards" Web-Based Training Course – Revised
- MLN Products Available in Electronic Publication Format
- New MLN Provider Compliance Fast Fact
- New MLN Educational Web Guides Fast Fact

May 2, 2014

ICD-10 Compliance Date

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. No. 113-93) was enacted, which said that the Secretary may not adopt ICD-10 prior to October 1, 2015. Accordingly, the U.S. Department of Health and Human Services expects to release an interim final rule in the near future that will include a new compliance date that would require the use of ICD-10 beginning October 1, 2015. The rule will also require HIPAA covered entities to continue to use ICD-9-CM through September 30, 2015.

July ICD-10 End-to-End Testing Canceled: Additional Testing Planned for 2015

CMS planned to conduct ICD-10 testing during the week of July 21 through 25, 2014, to give a sample group of providers the opportunity to participate in end-to-end testing with Medicare Administrative Contractors (MACs) and the Common Electronic Data Interchange (CEDI) contractor. The July testing has been canceled due to the ICD-10 implementation delay. Additional opportunities for end-to-end testing will be available in 2015.

May 8, 2014

Click to view the Complete MLN Connects™ Provider eNews for May 8, 2014

MLN Connects™ National Provider Calls

- Individualized Quality Control Plan for CLIA Laboratory Non-Waived Testing – Register Now
- National Partnership to Improve Dementia Care in Nursing Homes – Register Now
- Review of the New Medicare PPS for Federally Qualified Health Centers – Register Now
- Stage 2 Meaningful Use Requirements, Reporting Options, and Data Submission Processes for Eligible Professionals – Register Now
- New MLN Connects™ National Provider Call Transcript and Audio Recording

CMS Events

- Recorded Hospice Item Set Technical Training Modules Available

Announcements

- CMS Proposes Updates to the Wage Index and Payment Rates for the Medicare Hospice Benefit
- Proposed FY 2015 Payment and Policy Changes for Medicare Skilled Nursing Facilities
- Proposed FY 2015 Medicare Payment and Policy Changes for Inpatient Psychiatric Facilities
- Proposed FY 2015 Payment and Policy Changes for Medicare Inpatient Rehabilitation Facilities
- Empowering Women's Health
- Open Payments: Physician and Teaching Hospital Registration Begins June 1
- New Feature: Online Unlock Account Feature for PECOS, NPPES, and EHR
- Physician Self-Referral Law: Expansion Exception Request
- EHR Incentive Program Eligible Professionals: Hardship Exception Applications due July 1
- Register for the Group Practice Reporting Option for 2014 PQRS Participation by September 30

Claims, Pricers, and Codes

- CY 2014 Home Health PPS PC Pricer Available
- Adjustments to CMHC Claims Incorrectly Processed
- Adjustments to Correct Home Health Claim Payments
- Mass Adjustments to Inpatient Psychiatric Facility Claims with Teaching Adjustment Amounts Not Displaying Correctly

MLN Educational Products

- "Medicare Shared Savings Program and Rural Providers" Fact Sheet – Revised
- "Summary of Final Rule Provisions for Accountable Care Organizations under the Medicare Shared Savings Program" Fact Sheet – Revised
- "Advance Payment Accountable Care Organization" Fact Sheet – Revised
- "Power Mobility Devices (PMDs): Complying with Documentation & Coverage Requirements" Fact Sheet – Revised
- "Methodology for Determining Shared Savings and Losses under the Medicare Shared Savings Program" Fact Sheet - Revised
- "The Basics of Internet-based Provider Enrollment, Chain and Ownership System (PECOS) for Provider and Supplier Organizations" Fact Sheet – Revised
- "The Basics of Medicare Enrollment for Institutional Providers" Fact Sheet – Revised
- "Accountable Care Organizations: What Providers Need to Know" Fact Sheet – Revised

- "Improving Quality of Care for Medicare Patients: Accountable Care Organizations" Fact Sheet – Revised
- "Medical Privacy of Protected Health Information" Fact Sheet – Reminder
- MLN Publications Now Available in Hard Copy Format

May 15, 2014

Click to view the Complete MLN Connects™ Provider eNews for May 15, 2014

MLN Connects™ National Provider Calls

- Individualized Quality Control Plan for CLIA Laboratory Non-Waived Testing – Last Chance to Register
- National Partnership to Improve Dementia Care in Nursing Homes – Last Chance to Register
- Review of the New Medicare PPS for Federally Qualified Health Centers – Last Chance to Register
- Stage 2 Meaningful Use Requirements, Reporting Options, and Data Submission Processes for Eligible Professionals – Register Now
- More ICD-10 Coding Basics – Registration Now Open

CMS Events

- Special Open Door Forum: Suggested Electronic Clinical Template for Home Health
- Webinar for Comparative Billing Report on Ambulance: Ground Transportation
- HART User Tool Training Modules Available for Hospice Quality Reporting Program

Announcements

- Reforms of Regulatory Requirements to Save Health Care Providers $660 Million Annually
- New HHS Data Show Quality Improvements Saved 15,000 lives and $4 Billion in Health Spending
- Quality Improvement Organization Program Advisory
- Notices of Intent to Apply for the Medicare Shared Savings Program 2015 Program Start Date Due by May 30
- New PEPPER Release for SNFs, Hospices, CAHs, LTCHs, IPFs, IRFs and PHPs
- CMS to Release a Comparative Billing Report on Ambulance: Ground Transportation in May
- Physician Self-Referral Law: Expansion Exception Request

Claims, Pricers, and Codes

- Acute Inpatient PPS FY 2014.6 Pricer Software Release Available
- Hold and Adjustments to Method II CAH Claims that Include Services for a Surgical Assistant
- Mass Adjustments to Inpatient Psychiatric Facility Claims with Teaching Adjustment Amounts Not Displaying Correctly

MLN Educational Products

- "Screening and Diagnostic Mammography" Booklet – Revised
- "Telehealth Services" Fact Sheet – Revised
- "Ambulatory Surgical Center Fee Schedule" Fact Sheet – Revised
- MLN Products Available in Electronic Publication Format

May 22, 2014

MLN Connects™ Provider eNews for May 22, 2014

MLN Connects™ National Provider Calls

- Stage 2 Meaningful Use Requirements, Reporting Options, and Data Submission Processes for Eligible Professionals – Last Chance to Register
- More ICD–10 Coding Basics – Register Now
- Medicare Shared Savings Program ACO: Application Review – Registration Now Open
- Open Payments (the Sunshine Act): Updates for Physicians and Teaching Hospitals – Registration Opening Soon
- PQRS: 2014 Qualified Clinical Data Registry – Registration Now Open

Announcements

- "Mind Your Health" – Recognizing the Importance of Mental Health
- "Generations of Strength" – Preventing Osteoporosis Among Medicare Beneficiaries
- CMS Rule to Help Providers Make Use of Certified EHR Technology
- User ID Reminder for 2015 Medicare Shared Savings Program Applicants
- Am I Eligible to Order and Refer Medicare Items and Services?
- Registration for Hospice User IDs Began May 19
- Medicare GME Affiliation Agreements: July 1 Deadline
- CMS is Accepting Suggestions for PQRS Measures
- Learn About the Special EHR Reporting Periods for Eligible Professionals in 2014
- Medicare EHR Incentive Program: Review Steps for Submitting Stage 2 Meaningful Use Data
- New Resources Explain How to Report Once for Multiple Medicare Quality Reporting Programs

Claims, Pricers, and Codes

- 2015 ICD–10–CM, ICD–10–PCS, and ICD–9–CM Files Available
- Partial Code Freeze for ICD–9–CM and ICD–10 Extended
- Demonstration Allows Public Input on Requests to Discontinue Level II HCPCS Codes
- FY 2014 Inpatient PPS PC Pricer: New Provider Data
- Revision to the Replacement of Home Oxygen Services in the Event that Supplier Exits the Medicare Oxygen Business

MLN Educational Products

- New MLN Educational Web Guides Fast Fact
- Subscribe to the MLN Educational Products and MLN Matters® Electronic Mailing Lists

May 29, 2014

MLN Connects™ Provider eNews for May 29, 2014

MLN Connects™ National Provider Calls

- More ICD-10 Coding Basics - Last Chance to Register
- Medicare Shared Savings Program ACO: Application Review - Register Now
- Open Payments (the Sunshine Act): CMS Registration Overview - Registration Now Open
- PQRS: 2014 Qualified Clinical Data Registry - Register Now

Announcements

- Prior Authorization to Ensure Beneficiary Access and Help Reduce Improper Payments
- Application Deadlines for the 2015 Medicare Shared Savings Program
- Hospice Item Set Implementation Begins July 1
- Updated Information on Post-Acute Transfer Adjusted Cases in IPPS Proposed Rule
- Submit Your 2014 PQRS Quality Measures through the GPRO Web Interface Method

Claims, Pricers, and Codes

- 2015 GEMs and Reimbursement Mappings for ICD-10 Now Available

MLN Educational Products

- "Proper Use of Modifier 59" MLN Matters® Article - Released
- "Medical Privacy of Protected Health Information" Fact Sheet - Reminder
- New MLN Provider Compliance Fast Fact
- Electronic Publications Now Available

June 2, 2014

Successful Results from CMS ICD-10 Acknowledgement Testing Week

Additional testing scheduled for next year

This past March, CMS conducted a successful ICD-10 testing week. Testers submitted more than 127,000 claims with ICD-10 codes to the Medicare Fee-For-Service (FFS) claims systems and received electronic acknowledgements confirming that their claims were accepted.

Approximately 2,600 participating providers, suppliers, billing companies and clearinghouses participated in the testing week, representing about five percent of all submitters. Clearinghouses, which submit claims on behalf of providers, were the largest group of testers, submitting 50 percent of all test claims. Other testers included large and small physician practices, small and large hospitals, labs, ambulatory surgical centers, dialysis facilities, home health providers, and ambulance providers.

Nationally, CMS accepted 89 percent of the test claims, with some regions reporting acceptance rates as high as 99 percent. The normal FFS Medicare claims acceptance rates average 95-98 percent. Testing did not identify any issues with the Medicare FFS claims systems.

This testing week allowed an opportunity for testers and CMS alike to learn valuable lessons about ICD-10 claims processing. In many cases, testers intentionally included such errors in their claims to make sure that the claim would be rejected, a process often referred to as negative testing. To be processed correctly, all claims must have a valid diagnosis code that matches the date of service and a valid national provider identifier. Additionally, the claims using ICD-10 had to have an ICD-10 companion qualifier code and the claims using ICD-9 had to use the ICD-9 qualifier code. Claims that did not meet these requirements were rejected.

HHS expects to release an interim final rule in the near future that will include a new compliance date that would require the use of ICD-10 beginning October 1, 2015. The rule will also require HIPAA covered entities to continue to use ICD-9-CM through September 30, 2015. Providers, suppliers, billing companies, and clearinghouses are welcome to submit acknowledgement test claims anytime up to the anticipated October 1, 2015 implementation date. Submitters should contact their local Medicare Administrative Contractor (MAC) for more information about acknowledgment testing. However, those who submit claims may want to delay acknowledgement testing until after October 6, 2014, when Medicare updates its systems.

CMS will be conducting end-to-end testing in 2015. Details about this testing will be released soon.

June 5, 2014

MLN Connects™ Provider eNews for June 5, 2014

MLN Connects™ National Provider Calls

- Medicare Shared Savings Program ACO: Application Review – Last Chance to Register
- Open Payments (the Sunshine Act): CMS Registration Overview – Last Chance to Register
- PQRS: 2014 Qualified Clinical Data Registry – Register Now
- New Medicare PPS for Federally Qualified Health Centers: Operational Requirements – Registration Now Open
- New MLN Connects™ National Provider Call Transcripts and Audio Recordings

CMS Events

- PERM Cycle 3 Provider Education Webinar/Conference Call Sessions
- ICD-10 Documentation and Coding Concepts Webcast: Orthopedics

Announcements

- Successful Results from CMS ICD-10 Acknowledgement Testing Week
- Men's Health is not Just a Man's Issue
- HHS Releases New Data and Tools to Increase Transparency on Hospital Utilization and Other Trends
- 2015 Medicare Shared Savings Program Application Now Available: Form CMS-20037 Due by June 9
- Hospices: Begin Collecting HIS Data July 1 to Avoid Reduction in FY 2016 Annual Payment Update
- CMS is Accepting Suggestions for PQRS Measures
- Medicare EHR Incentive Program: Eligible Professionals Must Submit Hardship Exception Applications by July 1
- CMS Posts 2014 Eligible Professional Electronic Clinical Quality Measure Update

Claims, Pricers, and Codes

- Updated ESRD PPS Consolidated Billing List Now Available
- 2015 ICD-10-CM, ICD-10-PCS, and ICD-9-CM Files Available

MLN Educational Products

- "What Is Medicare?" Video – Released
- "Proper Use of Modifier 59" MLN Matters® Article – Revised
- "Medicare-Covered Part A and Part B Services Furnished Outside the United States" Fact Sheet – Revised
- "Items and Services That Are Not Covered Under the Medicare Program" Booklet – Revised
- "Quick Reference Information: Preventive Services" Educational Tool – Reminder
- "Quick Reference Information: Medicare Immunization Billing" Educational Tool – Reminder
- MLN Products Available In Electronic Publication Format

Quarterly Update for DMEPOS Competitive Bidding Program – July 2014

MLN Matters® Number: MM8702
Related Change Request (CR) #: CR 8702
Related CR Release Date: May 1, 2014
Related CR Transmittal #: R2940CP
Effective Date: July 1, 2014
Implementation Date: July 7, 2014

Provider Types Affected

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

Provider Action Needed

The Centers for Medicare & Medicaid Services (CMS) issued Change Request (CR) 8702 to provide the DMEPOS Competitive Bidding Program (CBP) July 2014 quarterly update. CR8702 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.

Background

Section 302 of the Medicare Modernization Act of 2003 (MMA) established requirements for a new CBP for certain DMEPOS. Under the program, DMEPOS suppliers compete to become Medicare contract suppliers by submitting bids to furnish certain items in competitive bidding areas (CBAs). CMS awards contracts to enough suppliers to meet beneficiary demand for the bid items. The new, lower payment amounts resulting from the competition replace the Medicare DMEPOS fee schedule amounts for the bid items in these areas. All contract suppliers must comply with Medicare enrollment rules, be licensed and accredited, and meet financial standards. The program sets more appropriate payment amounts for DMEPOS items while ensuring continued access to quality items and services, the result being reduced beneficiary out-of-pocket expenses and savings to taxpayers and the Medicare program.

Under the MMA, the DMEPOS Competitive Bidding Program was to be phased in so that competition under the program would first occur in 10 Metropolitan Statistical Areas (MSAs) in 2007. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) temporarily delayed the program in 2008 and made certain limited changes. In accordance with MIPPA, CMS conducted the supplier competition again in nine areas in 2009, referring to it as the Round 1Rebid. The Round 1 Rebid contracts and prices became effective on January 1, 2011.

MIPPA also delayed the competition for Round 2 from 2009 to 2011 and authorized national mail order competitions after 2010. The Affordable Care Act of 2010 expanded the number of Round 2 MSAs from 70 to 91. Contracts and prices for Round 2 and the national mail-order program for diabetic testing supplies became effective on July 1, 2013.

CMS is required by law to recompete contracts for the DMEPOS Competitive Bidding Program at least once every three years. The Round 1 Rebid contract period for all product categories except mail-order diabetic supplies expired on December 31, 2013. (The Round 1 Rebid mail-order diabetic supply contracts expired on December 31, 2012.) On January 1, 2014, new contracts for the Round 1 Recompete became effective in the same CBAs as the Round 1 Rebid.

Additional Information

The official instruction, CR 8702 issued to your MAC regarding this change is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2940CP.pdf on the CMS website.

Quarterly Update for DMEPOS Competitive Bidding Program – October 2014

MLN Matters® Number: MM8676
Related Change Request (CR) #: CR 8676
Related CR Release Date: May 23, 2014
Related CR Transmittal #: R2968CP
Effective Date: October 1, 2014
Implementation Date: October 6, 2014

Provider Types Affected

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

What You Need to Know

The Centers for Medicare & Medicaid Services (CMS) issued Change Request (CR) 8676 to provide the DMEPOS Competitive Bidding Program (CBP) October 2014 quarterly update. CR 8676 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.

Background

Section 302 of the Medicare Modernization Act of 2003 (MMA) established requirements for a new CBP for certain DMEPOS. Under the program, DMEPOS suppliers compete to become Medicare contract suppliers by submitting bids to furnish certain items in competitive bidding areas. CMS awards contracts to enough suppliers to meet beneficiary demand for the bid items. The new, lower payment amounts resulting from the competition replace the Medicare DMEPOS fee schedule amounts for the bid items in these areas. All contract suppliers must comply with Medicare enrollment rules, be licensed and accredited, and meet financial standards. The program sets more appropriate payment amounts for DMEPOS items while ensuring continued access to quality items and services, the result being reduced beneficiary out-of-pocket expenses and savings to taxpayers and the Medicare program.

Under the MMA, the DMEPOS Competitive Bidding Program was to be phased in so that competition under the program would first occur in 10 areas in 2007. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) temporarily delayed the program in 2008 and made certain limited changes. In accordance with MIPPA, CMS conducted the supplier competition again in nine areas in 2009, referring to it as the Round One Rebid. The Round One Rebid contracts and prices became effective on January 1, 2011 in the nine areas.

MIPPA also delayed the competition for Round Two from 2009 to 2011 and authorized national mail order competitions after 2010. The Affordable Care Act of 2010 expanded the number of Round Two MSAs from 70 to 91 and specified that all areas of the country be subject either to DMEPOS competitive bidding or payment rate adjustments using competitively bid rates by 2016. The contracts and prices for Round 2 and the national mail-order program for diabetic testing supplies became effective on July 1, 2013.

CMS is required by law to recompete contracts for the DMEPOS Competitive Bidding Program at least once every three years. The Round One Rebid contract period for all product categories except mail-order diabetic supplies expired on December 31, 2013. (The Round One Rebid mail-order diabetic supply contracts expired on December 31, 2012.) On January 1, 2014, new contracts for the Round One Recompete became effective in the same competitive bidding areas as the Round One Rebid.

Additional Information

The official instruction, CR 8676 issued to your DME MAC regarding this change is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2968CP.pdf on the CMS website.

Beneficiary Information Updated with the Benefits Coordination & Recovery Center

MLN Matters® Number: SE1416

This article replaces article SE1205. There are no changes to the processes that were described in SE1205. The key change is that the Coordination of Benefits Contractor (COBC) is now known as the Benefits Coordination and Recovery Center (BCRC) and there is new contact, address, and Web address information at the end of this article that is associated with this process and the BCRC.

Provider Types Affected

This MLN Matters® Special Edition Article is intended for physicians, other providers, and suppliers who provide products or services to Medicare beneficiaries with insurance in addition to Medicare. It updates MLN Matters® Article SE1205 to provide information regarding the Benefits Coordination & Recovery Center (BCRC), which has replaced the former Coordination of Benefits Contractor.

Provider Action Needed

A new Medicare Secondary Payer (MSP) initiative will affect how you may update beneficiary information to the BCRC.

This article describes initiatives that both the Centers for Medicare & Medicaid Services (CMS) and the BCRC are undertaking to maintain the most up-to-date and accurate beneficiary MSP information on Medicare's Common Working File (CWF).

You should make sure that your appropriate staffs are aware of these options for updating a beneficiary's MSP information and that they are aware of new contact information at the end of this article for the BCRC.

Background

There has been considerable discussion about the accuracy of beneficiary Medicare Secondary Payer (MSP) information on the CWF and who is responsible for keeping that information updated. Further, providers have stated that the update is not accepted when they attempt to update beneficiary information with the BCRC by phone. Therefore (as noted below), CMS and the BCRC are both undertaking initiatives to resolve the issue and maintain the most up-to-date and accurate beneficiary information with regard to MSP.

CMS Initiatives

In compliance with Section 111 of the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Extension Act of 2007 (known as Section 111 of the MMSEA), CMS has implemented a process through which private insurers (both Group Health Plans (GHP) and Non Group Health Plans (NGHP)) submit coverage information to the BCRC when they also provide coverage to a Medicare beneficiary. A private GHP insurer reporting under Section 111 is known as a Responsible Reporting Entity (RRE), and the BCRC receives Section 111 data input files from approximately 1,500 GHP insurers, and each file can include large numbers of individual coverage records. This information permits CMS to more accurately determine who (either the private insurer or Medicare) has primary, or secondary, claims coverage responsibility.

Occasionally, information submitted to the BCRC from any number of sources, including GHP RREs, service providers, and beneficiaries themselves can conflict with MSP information previously reported to the BCRC. To reduce such conflicts in the future, CMS has developed and implemented a data management "Reporting Hierarchy" process, which the BCRC administers (effective April 1, 2011). An explanation of the Hierarchy rules can be found within the MMSEA Section 111 GHP User Guide available at http://go.cms.gov/MIRGHPUserGuide on the CMS website.

BCRC Initiatives

The BCRC works closely with GHP RREs and other reporters in order to reduce "hierarchy" conflicts in future reporting. The following steps are in place to help providers update MSP records:

- **Provider attempting update with the beneficiary in the office:**
  The first time a call is made to update the record after April 4, 2011, it will be updated via the telephone call. For any subsequent calls made to update the record after April 4, 2011, no update will be made on the call, but two options are available: 1) Proof of information can be faxed or mailed on the insurer or employer's company letterhead, and the update will be made in 10-15 business days; or 2) You can contact the insurer or employer organization that last updated the record.
- **Provider attempting update when the beneficiary is not in the office:**
  No update will be made from a telephone call. The provider has three options to have the record updated:
  1. Have the Beneficiary contact BCRC.
  2. Contact the Beneficiary's insurer to resolve the issue.
  3. Fax or mail proof of information on the insurer or employer's company letterhead and the update will be made in 10-15 business days.
- **Provider with new information:**
  The BCRC will take new information for a Beneficiary, but if the new information requires changes to an existing record, two options are available:
  4. The Beneficiary will need to call to close out the record.
  5. Fax or mail proof of information on the insurer or employer's company letterhead and the update will be made in 10-15 business days.
- **Provider update for deceased beneficiary:**
  A **single** update can be made by ONE provider for a Deceased Beneficiary, once the date of death has been confirmed. Any subsequent updates would need to be handled by a family member with the appropriate documentation, including a death certificate.

Additional Information

An explanation of the GHP RRE Hierarchy rules can be found within the MMSEA Section 111 GHP User Guide at http://go.cms.gov/MIRGHPUserGuide on the CMS website. General information about GHP Mandatory Insurer Reporting is available at http://go.cms.gov/mirghp on the CMS website.

The BCRC's contact information is:

Telephone: 1-855-798-2627 (8 AM to 8 PM Eastern Time)
Fax: 1-405-869-3307 (address the fax to Medicare- MSP General Correspondence)

Mailing address:

Medicare – MSP General Correspondence
P.O. Box 138897
Oklahoma City, OK 73113-8897

Beneficiary Information Updated with Coordination of Benefits Contractor

MLN Matters® Number: SE1205 Rescinded

This article was rescinded and replaced by MLN Matters® Article SE1416 on April 3, 2014.
That article is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1416.pdf on the CMS website.

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

Documentation Submission for DME

Noridian has identified a growing trend in documentation submission errors. This article provides direction for proper submission for various documents, including the contact information to use when submitting documents. To ensure documents are received and processed in a timely manner, follow these guidelines:

1. Send the correct form with the documentation, when applicable.
2. Do not send information multiple times. Suppliers may call the Contact Center a few days after sending a fax to verify receipt. Please see the contact information below.
3. Each ADR submission should address only one claim, inquiry, or response.
4. When submitting documentation via fax, please include a cover sheet with the following information: total number of pages, DME department name, supplier name, and supplier contact information. Please use the fax number or address provided on the form/ADR letter.
5. When submitting documentation in response to an ADR letter, include the letter with the documentation.
6. Multiple responses cannot be consolidated by Noridian when submitted at separate times for a single claim, inquiry, appeal, etc. When responding to a request for documentation, please submit all requested documents as one response.
7. Review the clarity of the documents submitted to ensure the contents will not be distorted. For example, highlighting, shading, or previously faxed pages may be distorted or too light/dark if re-faxed.

Submission Methods

Endeavor
https://www.noridianmedicare.com/dme/claims/endeavor.html

esMD (electronic submission of medical documentation)
http://www.cms.gov/esmd

Mailing Address
Noridian
PO Box 6727
Fargo ND 58108-6727

Courier Address
Noridian
PO Box 6727
900 42nd St S
Fargo ND 58103-2146

PMD Prior Authorization Requests Mailing Address
Noridian
Attn: DME PMD Prior Authorization
PO Box 6742
Fargo ND 58108-6742

DOCUMENTATION

Faxed Documentation

When sending documentation via fax, include the appropriate form, when applicable. Verify that the correct fax number is being used, as each form/letter has a different fax number.

Additional Noridian Jurisdiction D DME MAC phone, mail, fax, and e-mail contact information is available at: https://www.noridianmedicare.com/dme/contact/ and by calling Customer Service at 1-877-320-0390.

DRUGS/BIOLOGICALS

Immunosuppressive Drugs (HCPCS J7507, J7517, J7518, J7520) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D DME MAC Medical Review Department is conducting a service specific review of HCPCS codes J7507, J7517, J7518 and J7520. The quarterly edit effectiveness results from January 2014 through March 2014 are as follows:

- The J7507 review involved 4,677 claims, of which 3,576 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 70%.
- The J7517 review involved 3,072 claims, of which 2,376 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 72%.
- The J7518 review involved 2,020 claims, of which 1,413 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 65%.
- The J7520 review involved 567 claims, of which 423 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 72%.

Top Denial Reasons

- The requested documentation was not received by the contractor within the allotted timeframe
- There was no refill request submitted or the refill request submitted was invalid
- The proof of delivery submitted was invalid
- There was no order submitted

Going Forward

Based on the results of this review, Noridian will continue with the Prepayment Service Specific Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Immunosuppressive Drug Local Coverage Determination (LCD) L68 and Policy Article A25366.

Suppliers can also review a specific policy Documentation Checklist for Immunosuppressive Drugs on the Noridian website.

Noridian also provides educational offerings by scheduling supplier workshops, training opportunities, and presentations.

Information about probe/error validation reviews may be found in Chapter 3 of CMS Publication 100-8, Program Integrity Manual (PIM).

Policy Education

The requested documentation was not received by the contractor within the allotted timeframe. Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R 424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide records may not only be a claim denial but also referral to the NSC. The supplier standards can be found in 424 CFR Section 424.57(c).

There was no refill request submitted or the refill request submitted was invalid.
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 should 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., PAP and RAD supplies) - the supplier should assess whether the supplies remain functional, providing replacement (a refill) only when the supply item(s) is no longer able to function. 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.

The proof of delivery submitted was invalid.
Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and 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 durable medical equipment 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 OIG for imposition of Civil Monetary Penalties or other administrative sanctions.

Suppliers are required to maintain POD documentation in their files. There are three methods of delivery.

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 slip. The POD record 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 and date of signature

The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. 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 the following:

- 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 record must contain the information specified above.

Method 3—Delivery to Nursing Facility on Behalf of a Beneficiary
When a supplier delivers items directly to a nursing facility, the documentation described for Method 1 (see above) is required.

When a delivery service or mail order is used to deliver the item to a nursing facility, the documentation described for Method 2 (see above) is required.

Regardless the method of delivery, for those beneficiaries that are residents of a nursing facility, information from the nursing facility showing that the item(s) delivered for the beneficiary's use were actually provided to and used by the beneficiary must be available upon request.

There was no order submitted.
All items billed to Medicare require a prescription. An order for each item billed must be signed and dated by the treating physician, 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.

Equipment and supplies may be delivered upon receipt of a dispensing order except for those items that require a written order prior to delivery. 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 Physician's name
- Date of the order and the start date, if the start date is different from the date of the order
- Physician 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 physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

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

The dispensing order must be available upon request.

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

- A detailed written order (DWO) is required before billing. Someone other than the ordering physician may produce the DWO. However, the ordering physician must review the content and sign and date the document. It must contain:
- Beneficiary's name
- Physician's name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Physician 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 date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state "PRN" or "as needed" utilization estimates for replacement frequency, use, or consumption are not acceptable. (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.

2014 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 2014 ACT: 3 p.m. CT

Date	Topic
July 15, 2014	Orthotics & Prosthetics
September 18, 2014	Appeals
November 20, 2014	Respiratory
January 29, 2015	General

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

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.

To view these presentations, go to the Education Tools page under Training and Events. All DME on Demand presentations will be listed under the Presentations column. If you have additional questions regarding this training session, contact us at dmeworkshops@noridian.com.

Power Mobility Devices Basic Coverage Criteria A-C

- PMD Coverage
- Criterion A
- Criterion B
- Criterion C
- Vague Documentation

Functional Level Modifiers (K0-K4)

- Functional Level
- K0 Modifier
- K1 Modifier
- K2 Modifier
- K3 Modifier
- K4 Modifier
- Medical Review
- Resources

esMD

- What is esMD
- What type of request can be sent?
- What can accept esMD transactions?
- Getting started
- Health Information Handlers (HIH)
- History of esMD
- Future of esMD
- FAQs
- Resources

ADMC

- Eligible Manual Wheelchairs
- Eligible Power Wheelchairs
- ADMC Form
- Documents
- ADMC Process
- Approved Decision
- Negative Decision
- Resources

A1-A9 Modifiers

- Coverage
- A1-A9 Modifiers
- A9 Modifier
- Exceptions
- Reopenings and Appeals
- Resources

Wheelchair Seating Coverage Criteria

- Wheelchair Seating
- Headrest E0955
- General Use Cushions
- Skin Protection Seat Cushions
- Positioning Items
- Combination Skin Protection and Positioning

PMD Captain's Chair vs Solid/Sling Back Base Chair

- Power Mobility Devices
- Sling Seat/Back Definition
- Solid Seat/Back Definition
- Captain's Chair Definition

- PMD with Captain's Chair
- PMD with Sling/Solid Back
- Determining Appropriate Seating System

Clinical Trials

- Clinical Trial Policies
- Three NCDs for Clinical Trials
- TENS NCD
- Home Oxygen NCD
- Cluster Headaches NCD
- Billing Requirements
- Mandatory Reporting
- Resources

Live Online Question and Answer Session

Noridian is excited for suppliers to be able to take advantage of the newest educational opportunity in order to get your questions answered. Noridian Education Representatives will be available for a weekly 1-hour live online question and answer (Q&A) session. These sessions will consist of one hour for suppliers to type in questions via WebEx® and get them answered. This Live Q&A will not have an audio portion as questions will only be answered via written communication. Each session will be devoted to a specific topic (e.g. policy, documentation requirements, etc.) to be announced prior to the weekly session. Suppliers will need to register for the event in order to attend at https://www.noridianmedicare.com/dme/train/online_qa_session.html.

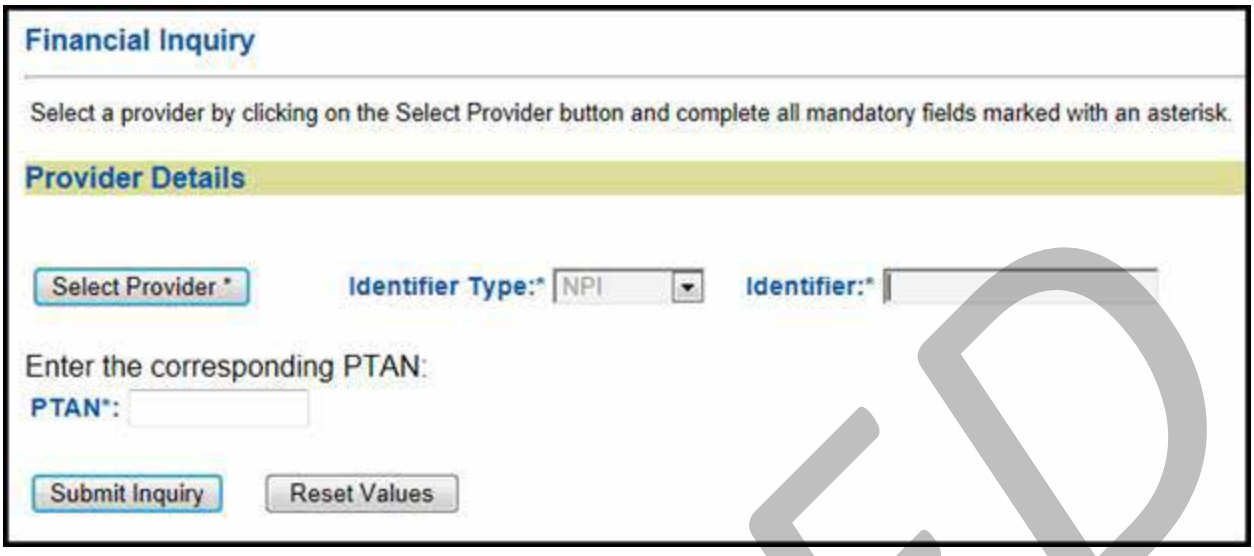
On Monday, June 2 between 3:00–4:00 pm CST, please join the Noridian education team with your questions regarding respiratory equipment and supplies. A brief introduction will be given at the top of the hour then the remainder of the hour will be devoted to responding to questions on Oxygen, PAP, RAD and Nebulizers. Suppliers are encouraged to join anytime between 3:00 and 4:00 to have their questions addressed. As the education team is responding to questions, some important respiratory facts will be scrolling on your screen for review. Register at https://www.noridianmedicare.com/dme/train/online_qa_session.html and mark your calendars now to attend. We look forward to this unique opportunity to offer suppliers another source of education.

Please visit our website to view additional dates and topics.

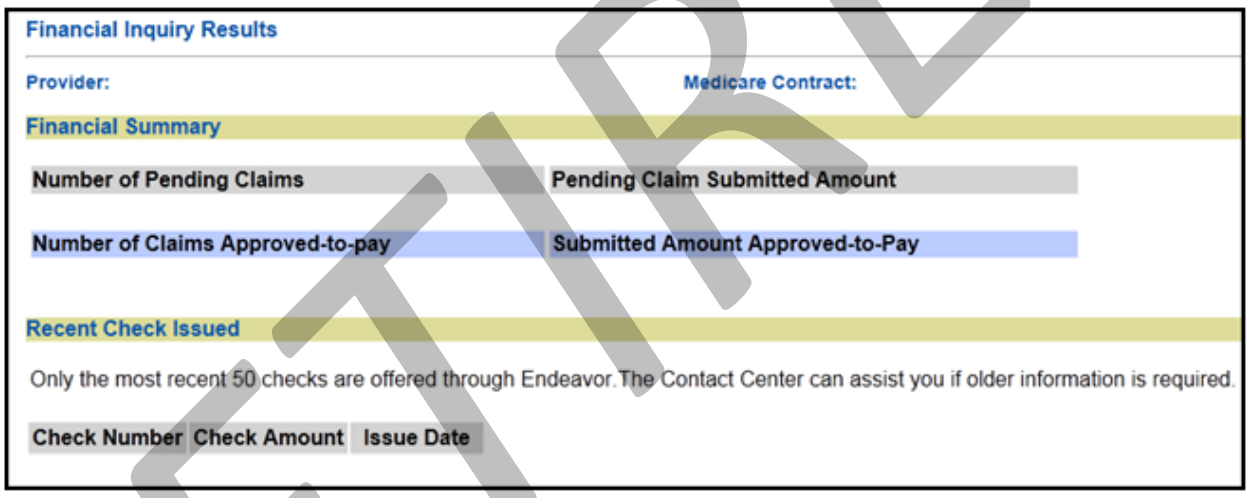
Endeavor Offers Financial Information – Recent 50 Checks and Payment Floor

Noridian's online portal, Endeavor, now offers providers the most recent fifty checks issued to the user's National Provider Identifier (NPI)/ Provider Transaction Access Number (PTAN). It also offers the number of pending claims and the submitted amount with the number of claims approved-to-pay and submitted amount that is approved-to-pay.

Users must use the drop down menu to indicate the NPI and enter the PTAN crosswalked to that NPI.



This function is automatically added for Endeavor users that already have access to claim status and/or remittance advices.



Tax Identification Number Validation in Endeavor

Effective April 5, 2014, to further verify validity of our Endeavor users, all new user registrations will require a primary Tax Identification Number (TIN).

If you are current Endeavor user with an active account, you will be prompted to provide this information during the annual recertification of your account or anytime Noridian is adding/changing information on the user's account based on request.

NOTE: TIN must be associated with at least one of the National Provider Identifiers (NPIs) on user account.

If you have questions or concerns, email dmeendeavor@noridian.com.

Enteral (HCPCS B4035) 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 B4035. The final edit effectiveness results from July 2013 through April 2014 are as follows:

The B4035 review involved 1,366 claims, of which 1,107 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 80%.

Top Denial Reasons

- There was no documentation received in response to Additional Documentation Request letter.
- The proof of delivery submitted was not valid.
- The refill requirements were not met for the corresponding nutrition resulting in the kits being denied.
- The physician order submitted has incomplete or missing elements.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Enteral Nutrition Local Coverage Determination (LCD) L11568 and Policy Article A25361.

Suppliers can also review specific policy resources for Enteral Nutrition on the Noridian website. There, you will find information related to proper documentation requirements including a physician letter, documentation checklists, FAQs, and a presentation used during web-based workshops.

Suppliers can also review a specific policy Documentation Checklist for Enteral Nutrition on the Noridian website.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM), Chapter 3.

Policy Education

There was no documentation received in response to Additional Documentation Request letter.
Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R §424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide records may not only be a claim denial but also referral to the NSC.

The proof of delivery submitted was not valid.
Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and 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 durable medical equipment 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 OIG for imposition of Civil Monetary Penalties or other administrative sanctions.

Suppliers are required to maintain 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 slip. The POD record 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 and date of signature

The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. 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 record must contain the information specified above.

Method 3 – Delivery to Nursing Facility on Behalf of a Beneficiary
When a supplier delivers items directly to a nursing facility, the documentation described for Method 1 (see above) is required.

When a delivery service or mail order is used to deliver the item to a nursing facility, the documentation described for Method 2 (see above) is required.

Regardless the method of delivery, for those beneficiaries that are residents of a nursing facility, information from the nursing facility showing that the item(s) delivered for the beneficiary's use were actually provided to and used by the beneficiary must be available upon request.

The refill requirements were not met for the corresponding nutrition resulting in the kits being denied.

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/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. 100-8, Chapter 5, Section 5.2.6).

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.

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

- There is a change of supplier
- There is a change in the item(s), frequency of use, or amount prescribed
- There is a change in the length of need or a previously established length of need expires
- State law requires a prescription renewal

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 should assess the quantity of each item that the beneficiary still has remaining to document that the amount remaining will be nearly exhausted on or about the supply anniversary date.
- For non-consumable supplies i.e., those more durable items that are not used up but may need periodic replacement (e.g., Positive Airway Pressure and Respiratory Assist Device supplies) – The supplier should assess whether the supplies remain functional, providing replacement (a refill) only when the supply item(s) is no longer able to function . 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.

If the coverage requirements for enteral nutrition are met, medically necessary nutrients, administration supplies, and equipment are covered.

The physician order submitted has incomplete or missing elements.
A detailed written order (DWO) is required before billing. Someone other than the ordering physician may produce the DWO. However, the ordering physician must review the content and sign and date the document. It must contain

- Beneficiary's name
- Physician's name
- Date of the order and the start date, if start date is different from the date of the order

- Detailed description of the item(s) (see below for specific requirements for selected items)
- Physician 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

Equipment and supplies may be delivered upon receipt of a dispensing order except for those items that require a written order prior to delivery. 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 physician's name
- Date of the order and the start date, if the start date is different from the date of the order
- Physician 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 physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

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

The dispensing order must be available upon request. For items that are provided based on a dispensing order, the supplier must obtain a detailed written order before submitting a claim.

Enteral and Parenteral Nutrition Calculators Available

Noridian has created new tools to assist in determining the correct number of units to submit for Enteral and Parenteral Nutrition claims. Calculators are now available at https://www.noridianmedicare.com/dme/coverage/resources/nutrition_calculators.html.

These calculators allow the supplier to enter DME Information Form (DIF) values to assist in determining the correct units of service (UOS) in relation to nutrition claims. Calculators for Parenteral Nutrition include amino acids, lipids and home mix solutions.

For Enteral Nutrition, suppliers are now able to determine the correct UOS for claim submission. A separate Enteral Nutrition Calories Calculator is also available to assist in determining the correct calories per day to enter on the DIF. This calculator will use values from the order to determine the calories per day. Each calculator indicates the applicable HCPCS codes for which units are calculated.

Enteral Nutrition (HCPCS B4154) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D, DME MAC, Medical Review Department is conducting a service specific review of HCPCS code B4154. The quarterly edit effectiveness results from December 2013 through March 2014 are as follows:

The B4154 review involved 1,060 claims, of which 829 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 75%.

Top Denial Reasons

- The detailed written order submitted was incomplete or missing elements
- There was no documentation received in response to Additional Documentation Request (ADR)
- The refill documentation provided was incomplete or missing elements
- There was no proof of delivery submitted or the proof of delivery submitted was invalid

Going Forward

Based on the results of this review, Noridian will continue with the Prepayment Service Specific Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Enteral Nutrition Local Coverage Determination (LCD) L11568 and Policy Article A25361.

Suppliers can also review specific policy resources for Enteral Nutrition on the Noridian website. There, you will find information related to proper documentation requirements including a physician letter, documentation checklists, FAQs, and a presentation used during Web-based workshops.

Suppliers can also review a specific policy Documentation Checklist for Enteral Nutrition on the Noridian website.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations.

Information about probe/error validation reviews may be found in chapter 3 of CMS Publication 100-8, Program Integrity Manual (PIM).

Policy Education

The detailed written order submitted was incomplete or missing elements.
A detailed written order (DWO) is required before billing. Someone other than the ordering physician may produce the DWO. However, the ordering physician must review the content and sign and date the document. It must contain:

- Beneficiary's name
- Physician's name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Physician 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

Equipment and supplies may be delivered upon receipt of a dispensing order except for those items that require a written order prior to delivery. 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 physician's name

- Date of the order and the start date, if the start date is different from the date of the order
- Physician 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 physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

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

The dispensing order must be available upon request.

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

There was no documentation received in response to the additional documentation request (ADR).
Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R §424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide records may not only be a claim denial but also referral to the NSC.

The refill documentation provided was incomplete or missing elements.
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/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. 100-8, Chapter 5, Section 5.2.6).

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.

There was no proof of delivery submitted or the proof of delivery submitted was invalid.
Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and 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 durable medical equipment 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 OIG for imposition of Civil Monetary Penalties or other administrative sanctions.

Suppliers are required to maintain 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 slip. The POD record 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 and date of signature

The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. 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

ENROLLMENT

Implementation of Fingerprint-Based Background Checks

MLN Matters® Number: SE1417

Provider Types Affected

This MLN Matters® Special Edition article is intended for providers and suppliers who submit claims to Durable Medical Equipment Medicare Administrative Contractors (DME MACs) and Home Health and Hospice (HH&H) MACs for services provided to Medicare beneficiaries.

Provider Action Needed

This Special Edition article is being provided by the Centers for Medicare & Medicaid Services (CMS) to announce the implementation of fingerprint-based background checks as part of enhanced enrollment screening provisions contained in Section 640 of the Affordable Care Act.

Once fully implemented, the fingerprint-based background check will be completed on all individuals with a 5 percent or greater ownership interest in a provider or supplier that falls under the high risk category. Note that the high level of risk category will be applied to providers and suppliers who are newly enrolling Durable Medicare Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers or Home Health Agencies (HHA). It will also be applied to providers and suppliers who have been elevated to the high risk category in accordance with enrollment screening regulations.

Background

As part of the enhanced enrollment screening provisions contained in the Affordable Care Act (see http://www.gpo.gov/fdsys/pkg/BILLS-111hr3590enr/pdf/BILLS-111hr3590 enr.pdf), the Centers for Medicare & Medicaid Services (CMS) is implementing fingerprint-based background checks. The fingerprint-based background checks will be used to detect bad actors who are attempting to enroll in the Medicare program and to remove those currently enrolled. Once fully implemented, the fingerprint-based background check will be completed on all individuals with a 5 percent or greater ownership interest in a provider or supplier that falls under the high risk category.

Please refer to 42 CFR 424.518(c)(3) at http://www.ecfr.gov/cgi-bin/text-idx?SID=a39ae0804106965d82b5ae6413ba550e&node=42:3.0.1.1.11.12.5.11&rgn=div8 on the Internet and the "Medicare Program Integrity Manual" (Chapter 15 (Medicare Enrollment), Section 15.19.2.1C (Screening Categories-Background-High)) at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c15.pdf on the CMS website.

Note: The high level of risk category will be applied to providers and suppliers who are newly enrolling Durable Medicare Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers or Home Health Agencies (HHA). It will also apply to providers and suppliers who have been elevated to the high risk category in accordance with enrollment screening regulations.

The fingerprint-based background check implementation will be phased in beginning in 2014. Initially, not all providers and suppliers in the "high" level of risk category will be a part of the fingerprint-based background check requirement.

Applicable providers and suppliers will receive notification of the fingerprint requirements from their MAC. The MAC will send a notification letter to the applicable providers or suppliers listing all 5% or greater owners who are required to be fingerprinted. The notification letter will be mailed to the provider or supplier's correspondence address and the special payments address on file with Medicare. Generally, an individual will be required to be fingerprinted only once, but CMS reserves the right to request additional fingerprints if needed.

The relevant individuals will have 30 days from the date of the notification letter to be fingerprinted. If the provider or supplier finds a discrepancy in the ownership listing, the provider or supplier should contact their MAC immediately to communicate the discrepancy and take the appropriate action to update the enrollment record to correctly reflect the ownership information.

The notification letter will identify contact information for the Fingerprint-Based Background Check Contractor (FBBC). The relevant individual(s) are required to contact the FBBC prior to being fingerprinted to ensure the fingerprints are accurately submitted to the Federal Bureau of Investigation (FBI) and results are properly returned to CMS.

Providers/suppliers may contact the FBBC by telephone or by accessing the FBBC's website. Contact information for the FBBC will be provided in the notification letter received from the MAC. Once contacted, the FBBC will provide at least three fingerprint locations convenient to the relevant individual's location. One of these locations will be a local, state, or federal law enforcement facility.

The relevant individuals who are required to undergo the fingerprint-based background check will incur the cost of having their fingerprints taken, and the cost may vary depending on location. Once an individual has submitted his/her fingerprints, if that individual is subsequently required to undergo a fingerprint-based background check in accordance with 42 CFR 424.518(c), CMS will, to the extent possible, rerun the

fingerprint-based background check rather than requiring resubmission of fingerprints. You can review 42 CFR 424.518(c) at http://www.ecfr.gov/cgi-bin/textidx?SID=f14b263d1175a355d736e9f38f3a6baf&node=42:3.0.1.1.11.12.5.11&rgn=div8 on the Internet.

Fingerprinting can be completed on the FD-258 form or electronically at certain locations. CMS strongly encourages all required applicants to provide electronic fingerprints, but CMS will accept the FD-258 card instead. If the FD-258 form is submitted, the FBBC will convert the paper form to electronic submission to the FBI. You can review the FD-258 form at http://www.fbi.gov/about-us/cjis/criminal-history-summary-checks/standardfingerprint-form-fd-258 on the Internet.

Once the fingerprint process is complete, the fingerprints will be forwarded to the FBI for processing. Within 24 hours of receipt, the FBI will compile the background history based on the fingerprints and will share the results with the FBBC. CMS, through the FBBC, will assess the law enforcement data provided for the fingerprinted individuals. The FBBC will review each record and provide a fitness recommendation to CMS. CMS will assess the recommendation and make a final determination.

All fingerprint data will be stored according to:

- Federal requirements;
- FBI Security and Management Control Outsourcing Standards for Channelers and
- Non-Channelers; and
- The FBI Criminal Justice Information Services (CJIS) Security Policy.

The FBBC will maintain Federal Information Systems Management Act (FISMA) certification and comply with the FBI (CJIS) Security Policy. All data will be secured in accordance with the Privacy Act of 1974 and the FBI CJIS Security Policy.

CMS will rely on existing authority to deny enrollment applications and revoke existing Medicare billing privileges per 42 CFR §424.530(a) and §424.535(a) (http://www.ecfr.gov/cgi-bin/text-idx?SID=f14b263d1175a355d736e9f38f3a6baf&node=42:3.0.1.1.11.12.515&rgn=div8) if an individual who maintains a 5% or greater direct or indirect ownership interest in a provider or supplier has submitted an enrollment application that contains false or misleading information. Providers or suppliers will be notified by CMS if the assessment of the fingerprint based background check results in the denial of its enrollment application or revocation of its existing Medicare billing privileges.

Update to Surety Bond Collection Procedures

MLN Matters® Number: MM8636
Related Change Request (CR) #: CR 8636
Related CR Release Date: May 16, 2014
Related CR Transmittal #: R517PI
Effective Date: June 17, 2014
Implementation Date: June 17, 2014

Provider Types Affected

This MLN Matters® Article is intended for Durable Medical Equipment. Prosthetics, Orthotics and Supplies (DMEPOS) suppliers that submit claims to Durable Medical Equipment Medicare Administrative Contractors (DME MACs) and are required to obtain and maintain a surety bond as a condition of their enrollment in the Medicare program.

Provider Action Needed

This article is based on Change Request (CR) 8636, which outlines revised procedures to be used in the surety bond collection process. Be certain you are aware of these clarifications.

Background

For purposes of the surety bond requirement, 42 Code of Federal Regulations (CFR) section 424.57(a) defines an "unpaid claim" as an overpayment (including accrued interest, as applicable) made by the Medicare program to the DMEPOS supplier for which the supplier is responsible.

Key Points of CR8636

The following describe the revised procedures involved in making a claim against a surety bond.

- If 45 days have passed since the initial demand letter was sent to the DMEPOS supplier, full payment has not been received, and the supplier has a surety bond, the DME MAC will (subject to the situations described in Pub. 100-08, chapter 15, section 15.21.7.1(A)(2)(b)(1) through (5)) send an "Intent to Refer" (ITR) letter to the supplier and a copy thereof to the supplier's surety. The letter and copy will be sent no earlier than the 45th day and no later than the 60th day after the initial demand letter was sent.
- If the DME MAC does not receive full payment from the supplier within 30 days of sending the ITR letter (and subject to the situations described in Pub. 100-08, chapter 15, section 15.21.7.1(A)(2)(b)(1) through (5)), the contractor will notify the surety via letter that payment of the claim must be made to CMS within 45 days from the date of the surety letter. The DME MAC will send the surety letter no earlier than 30 days and no later than 75 days after sending the ITR letter.
- Between 8 and 12 calendar days after sending the surety letter, the DME MAC will contact the surety by telephone or e-mail to determine whether the surety received the letter.
- If the surety fails to make full payment within the 45-day timeframe, the DME MAC will (1) continue collection efforts and (2) notify the appropriate Center for Program Integrity (CPI) liaison via e-mail of the surety's failure to make payment.

Additional Information

The official instruction regarding this change, CR 8636, is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R517PI.pdf on the CMS website.

Interested parties are strongly encouraged to read this instruction in full, as it contains additional information about the revised collection procedures.

Medicare's surety bond requirements are summarized in detail in article MM6392 at: http://www.cms.gov/outreach-and-education/medicare-learning-networkmln/mlnmattersarticles/downloads/MM6392.pdf on the CMS website.

Also, you may want to review MM6854 at http://www.cms.gov/outreach-andeducation/medicare-learning-networkmln/mlnmattersarticles/downloads/MM6854.pdf which clarifies situations where surety bonds must be reported to the National Supplier Clearinghouse.

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

This revision adds information clarifying who may perform the in-person visit and the responsibilities of the ordering physician.

As a condition for payment, Section 6407 of the Affordable Care Act (ACA) requires that a physician (MD, DO or 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).

FACE-TO-FACE VISITS

A 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 prescription for the accessory, supply, drug, etc.
- If a local coverage determination (LCD) requires periodic prescription renewal (i.e., policy requires a new prescription on a scheduled or periodic basis)
- When an item is replaced
- When there is a change in the supplier
- When required by state law

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.

These Affordable Care Act requirements are effective for claims for all of the specified items that require a new order (prescription) on or after July 1, 2013. Enforcement of these rules related to the face-to-face examination requirement and face-to-face documentation is delayed until a date to be announced by CMS in Calendar Year 2014. This delay in enforcement does not apply to the prescription requirements for a Written Order Prior to Delivery or to the requirement to include the prescriber's NPI on the prescription.

ACA 6407 also contains provisions requiring that a physician verify that a face-to-face examination performed by a PA, NP or CNS was done within the 6 months prior to the creation of a prescription for the specified item(s). This article does not address these provisions in detail. Additional information addressing physician verification will be forthcoming.

Face-To-Face Examination Requirements

The physician 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).

The DMEPOS supplier must have documentation of both the face-to-face visit and completed written order prior to delivery (WOPD) in their file prior to the delivery of these items.

For the physician prescribing a specified DME item:

- The face-to-face examination with the beneficiary must be conducted within the six (6) months prior to the date of the prescription.
- The face-to-face examination must document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered.
- Remember that all Medicare coverage and documentation requirements for DMEPOS also apply. There must be sufficient medical information included in the medical record to demonstrate that the applicable coverage criteria are met. Refer to the applicable Local Coverage Determination for information about the medical necessity criteria for the item(s) being ordered.
- The treating practitioner that conducted the face-to-face examination does not need to be the prescriber for the DME item. However the prescriber must:
  - Verify that the in-person visit occurred within the 6-months prior to the date of their prescription, and
  - Have documentation of the face-to-face examination that was conducted.
- The prescriber must provide a copy of the face-to-face examination and the prescription for the item(s) to the DMEPOS supplier before the item can be delivered.

Prescription (order) Requirements

These specified items require a written order that must be obtained prior to delivery (WOPD). A WOPD is a standard Medicare detailed written order, which must be completed and in the DMEPOS supplier's possession BEFORE the item is delivered. The prescription (order) for the DME must include all of the items below:

- Beneficiary's name,
- Physician's Name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item
- The prescribing practitioner's National Provider Identifier (NPI),
- The signature of the ordering practitioner
- Signature date

For any of the specified 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, if applicable

Frequency of use

Duration of infusion, if applicable

Quantity to be dispensed

Number of refills, if applicable

For any of the specified items affected by this face-to-face requirement to be covered by Medicare, a written, signed and dated order 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 prescriptions for these specified DME items require the National Provider Identifier to be included on the prescription. Prescriptions for other DME items do not have this NPI requirement. 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.

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 written order (prescription) and may be no older than 6 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 written order must be on or before the date of delivery.
- The DMEPOS supplier must have documentation of both the face-to-face visit and the completed WOPD in their file prior to the delivery of these items.

A date stamp (or similar) is required which clearly indicates the supplier's date of receipt of both the face-to-face record and the completed WOPD with the prescribing physician's signature and signature date. It is recommended that both documents be separately date-stamped to avoid any confusion regarding the receipt date of these documents.

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 In-exsufflation Devices
- Manual Wheelchairs
- 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 Nerve Stimulators (TENS)
- Wheelchair options and Accessories

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 WOPD 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 www.dmepdac.com.

HCPCS Code	Description
E0185	Gel or gel-like pressure mattress pad
E0188	Synthetic sheepskin pad
E0189	Lamb's wool sheepskin pad
E0194	Air fluidized bed
E0197	Air pressure pad for mattress standard length and width
E0198	Water pressure pad for mattress standard length and width
E0199	Dry pressure pad for mattress standard length and width
E0250	Hospital bed fixed height with any type of side rails, mattress
E0251	Hospital bed fixed height with any type side rails without mattress
E0255	Hospital bed variable height with any type side rails with mattress
E0256	Hospital bed variable height with any type side rails without mattress
E0260	Hospital bed semi-electric (Head and foot adjustment) with any type side rails with mattress
E0261	Hospital bed semi-electric (head and foot adjustment) with any type side rails without mattress
E0265	Hospital bed total electric (head, foot and height adjustments) with any type side rails with mattress
E0266	Hospital bed total electric (head, foot and height adjustments) with any type side rails without mattress
E0290	Hospital bed fixed height without rails with mattress
E0291	Hospital bed fixed height without rail without mattress
E0292	Hospital bed variable height without rail without mattress
E0293	Hospital bed variable height without rail with mattress
E0294	Hospital bed semi-electric (head and foot adjustment) without rail with mattress
E0295	Hospital bed semi-electric (head and foot adjustment) without rail without mattress
E0296	Hospital bed total electric (head, foot and height adjustments) without rail with mattress
E0297	Hospital bed total electric (head, foot and height adjustments) without rail without mattress
E0300	Pediatric crib, hospital grade, fully enclosed
E0301	Hospital bed Heavy Duty extra wide, with weight capacity 350-600 lbs with any type of rail, without mattress
E0302	Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, without mattress
E0303	Hospital bed Heavy Duty extra wide, with weight capacity 350-600 lbs with any type of rail, with mattress
E0304	Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, with mattress
E0424	Stationary compressed gas Oxygen System rental; includes contents, regulator, nebulizer, cannula or mask and tubing
E0431	Portable gaseous oxygen system rental includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
E0433	Portable liquid oxygen system
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, content gauge, cannula or mask, and tubing

E0439	Stationary liquid oxygen system rental, includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0441	Oxygen contents, gaseous (1 months supply)
E0442	Oxygen contents, liquid (1 months supply)
E0443	Portable Oxygen contents, gas (1 months supply)
E0444	Portable oxygen contents, liquid (1 months supply)
E0450	Volume control ventilator without pressure support used with invasive interface
E0457	Chest shell
E0459	Chest wrap
E0460	Negative pressure ventilator portable or stationary
E0461	Volume control ventilator without pressure support node for a noninvasive interface
E0462	Rocking bed with or without side rail
E0463	Pressure support ventilator with volume control mode used for invasive surfaces
E0464	Pressure support vent with volume control mode used for noninvasive surfaces
E0470	Respiratory Assist Device, bi-level pressure capability, without backup rate used non-invasive interface
E0471	Respiratory Assist Device, bi-level pressure capability, with backup rate for a non-invasive interface
E0472	Respiratory Assist Device, bi-level pressure capability, with backup rate for invasive interface
E0480	Percussor electric/pneumatic home model
E0482	Cough stimulating device, alternating positive and negative airway pressure
E0483	High Frequency chest wall oscillation air pulse generator system
E0484	Oscillatory positive expiratory device, non-electric
E0570	Nebulizer with compressor
E0575	Nebulizer, ultrasonic, large volume
E0580	Nebulizer, durable, glass or autoclavable plastic, bottle type for use with regulator or flowmeter
E0585	Nebulizer with compressor & heater
E0601	Continuous airway pressure device
E0607	Home blood glucose monitor
E0627	Seat lift mechanism incorporated lift-chair
E0628	Separate Seat lift mechanism for patient owned furniture electric
E0629	Separate seat lift mechanism for patient owned furniture non-electric
E0636	Multi positional patient support system, with integrated lift, patient accessible controls
E0650	Pneumatic compressor non-segmental home model
E0651	Pneumatic compressor segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor segmental home model with calibrated gradient pressure
E0655	Non- segmental pneumatic appliance for use with pneumatic compressor on half arm
E0656	Non- segmental pneumatic appliance for use with pneumatic compressor on trunk
E0657	Non- segmental pneumatic appliance for use with pneumatic compressor chest
E0660	Non- segmental pneumatic appliance for use with pneumatic compressor on full leg
E0665	Non- segmental pneumatic appliance for use with pneumatic compressor on full arm

E0666	Non- segmental pneumatic appliance for use with pneumatic compressor on half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor on full-leg
E0668	Segmental pneumatic appliance for use with pneumatic compressor on full arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor on half leg
E0671	Segmental gradient pressure pneumatic appliance full leg
E0672	Segmental gradient pressure pneumatic appliance full arm
E0673	Segmental gradient pressure pneumatic appliance half leg
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency
E0692	Ultraviolet light therapy system panel treatment 4 foot panel
E0693	Ultraviolet light therapy system panel treatment 6 foot panel
E0694	Ultraviolet multidirectional light therapy system in 6 foot cabinet
E0720	Transcutaneous electrical nerve stimulation, two lead, local stimulation
E0730	Transcutaneous electrical nerve stimulation, four or more leads, for multiple nerve stimulation
E0731	Form fitting conductive garment for delivery of TENS or NMES
E0740	Incontinence treatment system, Pelvic floor stimulator, monitor, sensor, and/or trainer
E0744	Neuromuscular stimulator for scoliosis
E0745	Neuromuscular stimulator electric shock unit
E0747	Osteogenesis stimulator, electrical, non-invasive, other than spine application.
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal application
E0749	Osteogenesis stimulator, electrical, surgically implanted
E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive
E0762	Transcutaneous electrical joint stimulation system including all accessories
E0764	Functional neuromuscular stimulator, transcutaneous stimulations of muscles of ambulation with computer controls
E0765	FDA approved nerve stimulator for treatment of nausea & vomiting
E0782	Infusion pumps, implantable, Non-programmable
E0783	Infusion pump, implantable, Programmable
E0784	External ambulatory infusion pump
E0786	Implantable programmable infusion pump, replacement
E0840	Tract frame attach to headboard, cervical traction
E0849	Traction equipment cervical, free-standing stand/frame, pneumatic, applying traction force to other than mandible
E0850	Traction stand, free standing, cervical traction
E0855	Cervical traction equipment not requiring additional stand or frame
E0856	Cervical traction device, cervical collar with inflatable air bladder
E0958**	Manual wheelchair accessory, one-arm drive attachment
E0959**	Manual wheelchair accessory-adapter for Amputee
E0960**	Manual wheelchair accessory, shoulder harness/strap
E0961**	Manual wheelchair accessory wheel lock brake extension handle
E0966**	Manual wheelchair accessory, headrest extension

E0967**	Manual wheelchair accessory, hand rim with projections
E0968*	Commode seat, wheelchair
E0969*	Narrowing device wheelchair
E0971**	Manual wheelchair accessory anti-tipping device
E0973**	Manual wheelchair accessory, adjustable height, detachable armrest
E0974**	Manual wheelchair accessory anti-rollback device
E0978*	Manual wheelchair accessory positioning belt/safety belt/ pelvic strap
E0980*	Manual wheelchair accessory safety vest
E0981**	Manual wheelchair accessory Seat upholstery, replacement only
E0982**	Manual wheelchair accessory, back upholstery, replacement only
E0983**	Manual wheelchair accessory power add on to convert manual wheelchair to motorized wheelchair, joystick control
E0984**	Manual wheelchair accessory power add on to convert manual wheelchair to motorized wheelchair, Tiller control
E0985	Wheelchair accessory, seat lift mechanism
E0986**	Manual wheelchair accessory, push activated power assist
E0990**	Manual wheelchair accessory, elevating leg rest
E0992**	Manual wheelchair accessory, elevating leg rest solid seat insert
E0994*	Arm rest
E1014	Reclining back, addition to pediatric size wheelchair
E1015	Shock absorber for manual wheelchair
E1020	Residual limb support system for wheelchair
E1028**	Wheelchair accessory, manual swing away, retractable or removable mounting hardware for joystick, other control interface or positioning accessory
E1029**	Wheelchair accessory, ventilator tray
E1030**	Wheelchair accessory, ventilator tray, gimbaled
E1031	Rollabout chair, any and all types with castors 5" or greater
E1035**	Multi-positional patient transfer system with integrated seat operated by care giver
E1036**	Patient transfer system
E1037	Transport chair, pediatric size
E1038**	Transport chair, adult size up to 300lb
E1039**	Transport chair, adult size heavy duty >300lb
E1161	Manual Adult size wheelchair includes tilt in space
E1227*	Special height arm for wheelchair
E1228*	Special back height for wheelchair
E1232	Wheelchair, pediatric size, tilt-in-space, folding, adjustable with seating system
E1233**	Wheelchair, pediatric size, tilt-in-space, folding, adjustable without seating system
E1234	Wheelchair, pediatric size, tilt-in-space, folding, adjustable without seating system
E1235	Wheelchair, pediatric size, rigid, adjustable, with seating system
E1236	Wheelchair, pediatric size, folding, adjustable, with seating system
E1237	Wheelchair, pediatric size, rigid, adjustable, without seating system
E1238	Wheelchair, pediatric size, folding, adjustable, without seating system

E1296*	Special sized wheelchair seat height
E1297*	Special sized wheelchair seat depth by upholstery
E1298*	Special sized wheelchair seat depth and/or width by construction
E1310**	Whirlpool non-portable
E2502**	Speech Generating Devices prerecord messages between 8 and 20 Minutes
E2506**	Speech Generating Devices prerecord messages over 40 minutes
E2508**	Speech Generating Devices message through spelling, manual type
E2510**	Speech Generating Devices synthesized with multiple message methods
E2227**	Rigid pediatric wheelchair adjustable
K0001	Standard wheelchair
K0002	Standard hemi (low seat) wheelchair
K0003	Lightweight wheelchair
K0004	High strength ltwt wheelchair
K0005	Ultra Lightweight wheelchair
K0006	Heavy duty wheelchair
K0007	Extra heavy duty wheelchair
K0009	Other manual wheelchair/base
K0606**	AED garment with electronic analysis
K0730	Controlled dose inhalation drug delivery system

Face-to-Face Written Order Prior to Delivery Physician Letter Revision

05/22/2014

Re: Face-to-Face and Written Order Requirements for High Cost DME - Revised to add information clarifying who may perform the in-person visit and the responsibilities of the ordering physician.

Dear Physician,

For certain specified items of durable medical equipment the Affordable Care Act requires that an in-person, face-to-face examination (F2F) documenting the need for the item must have occurred sometime during the six (6) months prior to the order for the item. The purpose of this letter is to provide a summary of these requirements.

A F2F examination meeting the requirements discussed below is required each time a new prescription for one of the specified items is required. A new prescription is required by Medicare:

- For all claims for purchases or initial rentals
- 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 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_
- When required by state law_

These requirements are effective for all new orders (prescriptions) for the specified items created on or after July 1, 2013.

Face-To-Face Examination Requirements

The physician 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 physician prescribing a specified DME item:

- The face-to-face examination with the beneficiary must be conducted within the six (6) months prior to the date of the prescription.
- The face-to-face examination must document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered.
- Remember that all Medicare coverage and documentation requirements for DMEPOS also apply. There must be sufficient medical information included in the medical record to demonstrate that the applicable coverage criteria are met. Refer to the applicable Local Coverage Determination for information about the medical necessity criteria for the item(s) being ordered.
- The treating practitioner that conducted the face-to-face examination does not need to be the prescriber for the DME item. However the prescriber must
  - Verify that the in-person visit occurred within the 6-months prior to the date of their prescription, and
  - Have documentation of the face-to-face examination that was conducted.
- The prescriber must provide a copy of the face-to-face examination and the prescription for the item(s) to the DMEPOS supplier before the item can be delivered.

Prescription (order) Requirements

These items require a written order prior to delivery (WOPD). A WOPD is the standard Medicare detailed written order, which must be completed and in the DMEPOS supplier's possession BEFORE the item can be delivered. The prescription (order) for the DME must meet all requirements for a WOPD and include all of the items below:

- Beneficiary's name,
- Physician's Name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item
- The prescribing practitioner's National Provider Identifier (NPI),
- The signature of the ordering practitioner
- Signature date

For any of the specified 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, if applicable
- Frequency of use
- Duration of infusion, if applicable
- Quantity to be dispensed
- Number of refills, if applicable

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

Date and Timing Requirements

There are specific date and timing issues:

- The date of the F2F must be on or before the date of the written order (prescription) and may be no older than 6 months prior to the prescription date.
- The date of the F2F must be on or before the date of delivery for the item(s) prescribed.
- The date of the written order must be on or before the date of delivery (DOS).
- ALL DMEPOS suppliers must have documentation of both the face-to-face visit and the completed WOPD in their file prior to the delivery of these items.

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

Sincerely,

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Medical Director, DME MAC, Jurisdiction A
NHIC, Corp.

Robert D. Hoover, Jr., MD, MPH, FACP
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TABLE A: DME List of Specified Covered Items

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

Refer to the Pricing, Data Analysis and Coding Contractor web site for information on coding at www.dmepdac.com.

HCPCS Code	Description
E0185	Gel or gel-like pressure mattress pad
E0188	Synthetic sheepskin pad
E0189	Lamb's wool sheepskin pad
E0194	Air fluidized bed
E0197	Air pressure pad for mattress standard length and width
E0198	Water pressure pad for mattress standard length and width
E0199	Dry pressure pad for mattress standard length and width
E0250	Hospital bed fixed height with any type of side rails, mattress
E0251	Hospital bed fixed height with any type side rails without mattress
E0255	Hospital bed variable height with any type side rails with mattress
E0256	Hospital bed variable height with any type side rails without mattress
E0260	Hospital bed semi-electric (Head and foot adjustment) with any type side rails with mattress
E0261	Hospital bed semi-electric (head and foot adjustment) with any type side rails without mattress
E0265	Hospital bed total electric (head, foot and height adjustments) with any type side rails with mattress

E0266	Hospital bed total electric (head, foot and height adjustments) with any type side rails without mattress
E0290	Hospital bed fixed height without rails with mattress
E0291	Hospital bed fixed height without rail without mattress
E0292	Hospital bed variable height without rail without mattress
E0293	Hospital bed variable height without rail with mattress
E0294	Hospital bed semi-electric (head and foot adjustment) without rail with mattress
E0295	Hospital bed semi-electric (head and foot adjustment) without rail without mattress
E0296	Hospital bed total electric (head, foot and height adjustments) without rail with mattress
E0297	Hospital bed total electric (head, foot and height adjustments) without rail without mattress
E0300	Pediatric crib, hospital grade, fully enclosed
E0301	Hospital bed Heavy Duty extra wide, with weight capacity 350-600 lbs with any type of rail, without mattress
E0302	Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, without mattress
E0303	Hospital bed Heavy Duty extra wide, with weight capacity 350-600 lbs with any type of rail, with mattress
E0304	Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, with mattress
E0424	Stationary compressed gas Oxygen System rental; includes contents, regulator, nebulizer, cannula or mask and tubing
E0431	Portable gaseous oxygen system rental includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
E0433	Portable liquid oxygen system
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, content gauge, cannula or mask, and tubing
E0439	Stationary liquid oxygen system rental, includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0441	Oxygen contents, gaseous (1 months supply)
E0442	Oxygen contents, liquid (1 months supply)
E0443	Portable Oxygen contents, gas (1 months supply)
E0444	Portable oxygen contents, liquid (1 months supply)
E0450	Volume control ventilator without pressure support used with invasive interface
E0457	Chest shell
E0459	Chest wrap
E0460	Negative pressure ventilator portable or stationary
E0461	Volume control ventilator without pressure support node for a noninvasive interface
E0462	Rocking bed with or without side rail
E0463	Pressure support ventilator with volume control mode used for invasive surfaces

E0464	Pressure support vent with volume control mode used for noninvasive surfaces
E0470	Respiratory Assist Device, bi-level pressure capability, without backup rate used non-invasive interface
E0471	Respiratory Assist Device, bi-level pressure capability, with backup rate for a non-invasive interface
E0472	Respiratory Assist Device, bi-level pressure capability, with backup rate for invasive interface
E0480	Percussor electric/pneumatic home model
E0482	Cough stimulating device, alternating positive and negative airway pressure
E0483	High Frequency chest wall oscillation air pulse generator system
E0484	Oscillatory positive expiratory device, non-electric
E0570	Nebulizer with compressor
E0575	Nebulizer, ultrasonic, large volume
E0580	Nebulizer, durable, glass or autoclavable plastic, bottle type for use with regulator or flowmeter
E0585	Nebulizer with compressor & heater
E0601	Continuous airway pressure device
E0607	Home blood glucose monitor
E0627	Seat lift mechanism incorporated lift-chair
E0628	Separate Seat lift mechanism for patient owned furniture electric
E0629	Separate seat lift mechanism for patient owned furniture non-electric
E0636	Multi positional patient support system, with integrated lift, patient accessible controls
E0650	Pneumatic compressor non-segmental home model
E0651	Pneumatic compressor segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor segmental home model with calibrated gradient pressure
E0655	Non- segmental pneumatic appliance for use with pneumatic compressor on half arm
E0656	Non- segmental pneumatic appliance for use with pneumatic compressor on trunk
E0657	Non- segmental pneumatic appliance for use with pneumatic compressor chest
E0660	Non- segmental pneumatic appliance for use with pneumatic compressor on full leg
E0665	Non- segmental pneumatic appliance for use with pneumatic compressor on full arm
E0666	Non- segmental pneumatic appliance for use with pneumatic compressor on half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor on full-leg
E0668	Segmental pneumatic appliance for use with pneumatic compressor on full arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor on half leg
E0671	Segmental gradient pressure pneumatic appliance full leg
E0672	Segmental gradient pressure pneumatic appliance full arm

E0673	Segmental gradient pressure pneumatic appliance half leg
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency
E0692	Ultraviolet light therapy system panel treatment 4 foot panel
E0693	Ultraviolet light therapy system panel treatment 6 foot panel
E0694	Ultraviolet multidirectional light therapy system in 6 foot cabinet
E0720	Transcutaneous electrical nerve stimulation, two lead, local stimulation
E0730	Transcutaneous electrical nerve stimulation, four or more leads, for multiple nerve stimulation
E0731	Form fitting conductive garment for delivery of TENS or NMES
E0740	Incontinence treatment system, Pelvic floor stimulator, monitor, sensor, and/or trainer
E0744	Neuromuscular stimulator for scoliosis
E0745	Neuromuscular stimulator electric shock unit
E0747	Osteogenesis stimulator, electrical, non-invasive, other than spine application.
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal application
E0749	Osteogenesis stimulator, electrical, surgically implanted
E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive
E0762	Transcutaneous electrical joint stimulation system including all accessories
E0764	Functional neuromuscular stimulator, transcutaneous stimulations of muscles of ambulation with computer controls
E0765	FDA approved nerve stimulator for treatment of nausea & vomiting
E0782	Infusion pumps, implantable, Non-programmable
E0783	Infusion pump, implantable, Programmable
E0784	External ambulatory infusion pump
E0786	Implantable programmable infusion pump, replacement
E0840	Tract frame attach to headboard, cervical traction
E0849	Traction equipment cervical, free-standing stand/frame, pneumatic, applying traction force to other than mandible
E0850	Traction stand, free standing, cervical traction
E0855	Cervical traction equipment not requiring additional stand or frame
E0856	Cervical traction device, cervical collar with inflatable air bladder
E0958**	Manual wheelchair accessory, one-arm drive attachment
E0959**	Manual wheelchair accessory-adapter for Amputee
E0960**	Manual wheelchair accessory, shoulder harness/strap
E0961**	Manual wheelchair accessory wheel lock brake extension handle
E0966**	Manual wheelchair accessory, headrest extension
E0967**	Manual wheelchair accessory, hand rim with projections
E0968*	Commode seat, wheelchair
E0969*	Narrowing device wheelchair
E0971**	Manual wheelchair accessory anti-tipping device
E0973**	Manual wheelchair accessory, adjustable height, detachable armrest

E0974**	Manual wheelchair accessory anti-rollback device
E0978*	Manual wheelchair accessory positioning belt/safety belt/ pelvic strap
E0980*	Manual wheelchair accessory safety vest
E0981**	Manual wheelchair accessory Seat upholstery, replacement only
E0982**	Manual wheelchair accessory, back upholstery, replacement only
E0983**	Manual wheelchair accessory power add on to convert manual wheelchair to motorized wheelchair, joystick control
E0984**	Manual wheelchair accessory power add on to convert manual wheelchair to motorized wheelchair, Tiller control
E0985	Wheelchair accessory, seat lift mechanism
E0986**	Manual wheelchair accessory, push activated power assist
E0990**	Manual wheelchair accessory, elevating leg rest
E0992**	Manual wheelchair accessory, elevating leg rest solid seat insert
E0994*	Arm rest
E1014	Reclining back, addition to pediatric size wheelchair
E1015	Shock absorber for manual wheelchair
E1020	Residual limb support system for wheelchair
E1028**	Wheelchair accessory, manual swing away, retractable or removable mounting hardware for joystick, other control interface or positioning accessory
E1029**	Wheelchair accessory, ventilator tray
E1030**	Wheelchair accessory, ventilator tray, gimbaled
E1031	Rollabout chair, any and all types with castors 5" or greater
E1035**	Multi-positional patient transfer system with integrated seat operated by care giver
E1036**	Patient transfer system
E1037	Transport chair, pediatric size
E1038**	Transport chair, adult size up to 300lb
E1039**	Transport chair, adult size heavy duty >300lb
E1161	Manual Adult size wheelchair includes tilt in space
E1227*	Special height arm for wheelchair
E1228*	Special back height for wheelchair
E1232	Wheelchair, pediatric size, tilt-in-space, folding, adjustable with seating system
E1233**	Wheelchair, pediatric size, tilt-in-space, folding, adjustable without seating system
E1234	Wheelchair, pediatric size, tilt-in-space, folding, adjustable without seating system
E1235	Wheelchair, pediatric size, rigid, adjustable, with seating system
E1236	Wheelchair, pediatric size, folding, adjustable, with seating system
E1237	Wheelchair, pediatric size, rigid, adjustable, without seating system
E1238	Wheelchair, pediatric size, folding, adjustable, without seating system
E1296*	Special sized wheelchair seat height

E1297*	Special sized wheelchair seat depth by upholstery
E1298*	Special sized wheelchair seat depth and/or width by construction
E1310**	Whirlpool non-portable
E2502**	Speech Generating Devices prerecord messages between 8 and 20 Minutes
E2506**	Speech Generating Devices prerecord messages over 40 minutes
E2508**	Speech Generating Devices message through spelling, manual type
E2510**	Speech Generating Devices synthesized with multiple message methods
E2227**	Rigid pediatric wheelchair adjustable
K0001	Standard wheelchair
K0002	Standard hemi (low seat) wheelchair
K0003	Lightweight wheelchair
K0004	High strength ltwt wheelchair
K0005	Ultra Lightweight wheelchair
K0006	Heavy duty wheelchair
K0007	Extra heavy duty wheelchair
K0009	Other manual wheelchair/base
K0606**	AED garment with electronic analysis
K0730	Controlled dose inhalation drug delivery system

In-person Visit Requirement for Section 6407 of the Affordable Care Act – Clarification

Joint DME MAC Publication

Section 6407 of the Affordable Care Act (ACA 6407) requires that an in-person or face-to-face encounter must occur within the six months preceding the written order. There have been questions about whether this in-person visit must be conducted by the prescribing physician or whether an in in-person visit with another treating practitioner may be acceptable to fulfil this requirement.

CMS has clarified that the treating practitioner that conducted the face-to-face examination does not need to be the prescriber of the order for the DME item. However the prescriber must have knowledge and documentation of the face-to-face examination that was conducted.

Refer to the previously published bulletin and the applicable medical policy for additional information about ACA 6407.

This information will be updated in the previously published material.

Blood Glucoses Test or Reagent Strips (HCPCS A4253) Quarterly Results of Documentation Compliance Review Results

The Jurisdiction D DME MAC Medical Review Department is conducting a documentation compliance review of HCPCS code A4253. A documentation compliance review is a nonclinical, technical review verifying that submitted documentation meets payment requirements according to Local Coverage Determinations (LCD) for that DMEPOS item. The quarterly edit effectiveness, from December 1, 2013, through February 28, 2014, resulted in an overall error rate of 82%.

Top Denial Reasons

- The requested documentation was not received by the contractor within the allotted timeframe.
- The order submitted was invalid.
- The refill requirements were not met.
- The documentation submitted did not support the actual testing frequency that corroborates the quantity of supplies that were dispensed.

Going Forward

Based on the results of this review, Noridian will continue with the Documentation Compliance Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Glucose Monitors Local Coverage Determination (LCD) L196 and Policy Article A33673.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations. Educational training and events are located at https://www.noridianmedicare.com/dme/train/.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM), Chapter 3 located at http://www.cms.gov/manuals/downloads/pim83c03.pdf.

Policy Education

The requested documentation was not received by the contractor within the allotted timeframe.
Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R §424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide records may not only be a claim denial but also referral to the NSC. 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 patient's medical records will reflect the need for the care provided. The patient's medical records include the physician'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.

The order submitted was invalid.
The Program Integrity Manual (PIM) 5.2.2 states that equipment and supplies may be delivered upon receipt of a dispensing order except for those items that require a written order prior to delivery. 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 Physician's name
- Date of the order and the start date, if the start date is different from the date of the order
- Physician 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 physician (for verbal orders) or the date entered by the physician (for written dispensing orders). Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4. The dispensing order must be available upon request. For items that are provided based on a dispensing order, the supplier must obtain a detailed written order before submitting a claim.

The PIM 5.2.3 states that a detailed written order (DWO) is required before billing. Someone other than the ordering physician may produce the DWO. However, the ordering physician must review the content and sign and date the document. It must contain:

- Beneficiary's name
- Physician's name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Physician 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, if applicable

For the "date of the order" described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders). Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state "PRN" or "as needed" utilization estimates for replacement frequency, use, or consumption are not acceptable (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.

The refill requirements were not met.
For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products (A4233 - A4236, A4253, A4256, A4258 and A4259) 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. 100-8, Chapter 5, Section 5.2.6).

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 ordering physicians that any changed or atypical utilization is warranted. Regardless of utilization, a supplier must not dispense more than a three (3)-month quantity at a time.

The documentation submitted did not support the actual testing frequency that corroborates the quantity of supplies that were dispensed.
Criterion C for high utilization - If refills of quantities of supplies that exceed the utilization guidelines are dispensed, there must be documentation in the physician's records (e.g., a specific narrative statement that adequately documents the frequency at which the beneficiary is actually testing or a copy of the beneficiary's log) that the beneficiary is actually testing at a frequency that corroborates the quantity of supplies that have been dispensed. If the beneficiary is regularly using quantities of supplies that exceed the utilization guidelines, new documentation must be present at least every six months.

Blood Glucose Test or Reagent Strips (HCPCS A4253) Quarterly 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 quarterly edit effectiveness results from January 2014 through April 2014 are as follows:

The A4253 review involved 2,941 claims, of which 2,901 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 96%.

Top Denial Reasons

- No documentation was received in response to the Additional Documentation Request letters.
- No physician's medical office records were received.
- Documentation submitted did not support the actual testing frequency that corroborates with the quantity of supplies that have been dispensed.
- Proof of delivery requirements were not met.

Going Forward

Based on the results of this review, Noridian will continue with the Prepayment Service Specific Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Blood Glucose Test or Reagent Strips Local Coverage Determination (LCD) L196 and Policy Article A33673.

Suppliers can also review specific policy resources for Blood Glucose Test or Reagent Strips on the Noridian website. There, you will find information related to proper documentation requirements including a physician letter, documentation checklists, FAQs, and a presentation used during web-based workshops.

Suppliers can also review a specific policy Documentation Checklist for Blood Glucose Test or Reagent Strips on the Noridian website.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM), Chapter 3.

Policy Education

No documentation was received in response to the Additional Documentation Request letters.
Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R §424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide records may not only be a claim denial but also referral to the NSC.

No physician's medical office records were received.
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 physician'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.

General (PIM 5.7–5.9)
The Nonmedical 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 ordering physician, 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 physician'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.

Documentation submitted did not support the actual testing frequency that corroborates with the quantity of supplies that have been dispensed.
For services performed on or after 11/01/12 – (Criterion C for high utilization)- If refills of quantities of supplies that exceed the utilization guidelines are dispensed, there must be documentation in the physician's records (e.g., a specific narrative statement that adequately documents the frequency at which the beneficiary is actually testing or a copy of the beneficiary's log) that the beneficiary is actually testing at a frequency that corroborates the quantity of supplies that have been dispensed. If the beneficiary is regularly using quantities of supplies that exceed the utilization guidelines, new documentation must be present at least every six months.

Proof of delivery requirements were not met.
Proof of Delivery (PIM 4.26, 5.8)
Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and 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 OIG for imposition of Civil Monetary Penalties or other administrative sanctions.

Suppliers are required to maintain POD documentation in their files. For glucose monitors and supplies, there are two methods of delivery:

- Delivery directly to the beneficiary or authorized representative
- Delivery via shipping or delivery service

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 slip. The POD record 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 and date of signature

The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. In instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS item 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 record must contain the information specified above.

Access Updates to ICD-10 LCDs in CMS MCD

MLN Matters® Number: SE1421

Provider Types Affected

This article is intended for all physicians, providers, and suppliers who submit claims to Medicare Administrative Contractors (MACs), including Home Health & Hospice MACs (HH&H MACs), and Durable Medical Equipment MACs (DME MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

This MLN Matters® Special Edition article is intended to convey information on how to access updates to International Classification of Diseases, 10th Edition (ICD-10) Local Coverage Determinations (LCDs) in the Centers for Medicare & Medicaid Services (CMS) Medicare Coverage Database (MCD).

Background

MACs may develop an LCD to further define a National Coverage Determination (NCD) or in the absence of a specific NCD. An LCD is a coverage decision made at a MAC's own discretion to provide guidance to the public and the medical community within a specified geographic area. An LCD cannot conflict with an NCD. An LCD is an administrative and educational tool that can assist you in submitting correct claims for payment by:

- Outlining coverage criteria;
- Defining medical necessity; and
- Providing references upon which a policy (LCD) is based and codes that describe covered and/or noncovered services when the codes are integral to the discussion of medical necessity.

The MCD

To access the CMS MCD, visit http://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx on the CMS website.

Use the following steps to access the list of LCDs with ICD-10 codes:

1. On the CMS MCD Homepage, click on the "Indexes" tab at the top of the page;
2. Select "Local Coverage";
3. Select one of the three display options for LCDs ("LCDs by Contractor," "LCDs by State," or "LCDs Listed Alphabetically");
4. If you choose LCDs by Contractor, click on that link;
5. Select a MAC;
6. In the Document types, checkmark the square for "Future LCDs/Future Contract Number LCDs";
7. Click the "Submit" button;
8. Click on the Contractor name; and
9. A list of Future Effective LCDs will display. Those LCDs with a 10/01/2014 Effective Date are ICD-10 LCDs.

Notes:

1. The ICD-10 updates are labeled "future" as the policies are not yet in effect. These updates are subject to change as necessitated by code updates and policy revisions.
2. It is expected that the 10/01/2014 Effective Dates will be changed to 10/01/2015 in mid-2014.

Printing Documents on the CMS MCD

All documents on the CMS MCD may be printed. Use the following steps to print a document:

1. Open the document; and
2. In the upper right-hand corner, click on the "Print" button or use "Control + P." Alternatively, click on the "Need a PDF?" button and click on the "Save a Copy" icon on the bottom of your screen or use "Shift + Control + S."

Additional Information

For an in-depth review on how to use the CMS MCD, refer to the Medicare Learning Network® publication titled "How to Use the Medicare Coverage Database" located at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedicareCvrgeDatabase_ICN901346.pdf on the CMS website.

Changes to Local Coverage Determinations – ICD-10 Updates

Joint DME MAC Publication

The DME MACs are providing notice that all ICD-10 LCDs and associated ICD-10 articles will be updated in the Medicare Coverage Database no later than 04/10/14. For LCDs and related Policy Articles that translate ICD-9 codes to the appropriate ICD-10 code, there is no requirement for the public comment process.

The following LCDs and related Policy Articles have ICD-9 to ICD-10 translations and will receive new LCD/Article ID numbers:

- Ankle-Foot/Knee-Ankle-Foot Orthosis
- Automatic External Defibrillators
- External Breast Prostheses
- Glucose Monitors
- High Frequency Chest Wall Oscillation Devices
- Immunosuppressive Drugs – Policy Article
- Intravenous Immune Globulin – Policy Article
- Knee Orthoses
- Mechanical In-exsufflation Devices
- Nebulizers
- Oral Anticancer Drugs – Policy Article
- Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics) – Policy Article
- Oral Appliances for Obstructive Sleep Apnea
- Orthopedic Footwear
- Osteogenesis Stimulators
- Ostomy Supplies – Policy Article
- Oxygen and Oxygen Equipment
- Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea
- Pressure Reducing Support Surfaces – Group 2
- Pressure Reducing Support Surfaces – Group 3
- Refractive Lenses
- Suction Pumps
- Therapeutic Shoes for Persons with Diabetes – Policy Article

- Tracheostomy Care Supplies – Policy Article
- Transcutaneous Electrical Nerve Stimulators (TENS)
- Urological Supplies
- Wheelchair Seating
- VED – DRAFT

All LCDs and related Policy Articles will receive a new LCD/Article ID number. The Centers for Medicare & Medicaid (CMS) has determined that although new LCD numbers will be assigned to the ICD-10 LCD policies, the policies shall not be considered new policies. CMS considers this type of update to be a coding revision that does not change the intent of coverage/non-coverage within an LCD. Therefore, if a MAC only translates ICD-9 codes to the appropriate ICD-10 code, the policy does not need to be sent through the public Comment and notice process.

CMS Releases "Road to 10" Online Resource for Small Practices

CMS has released "Road to 10," an online resource built with the help of providers in small practices. This tool is intended to help small medical practices jumpstart their ICD-10 transition. "Road to 10" includes specialty references and gives providers the capability to build ICD-10 action plans tailored for their practice needs. The "Road to 10" resources can be found at www.roadto10.org.

ICD-10 Conversion/Coding Infrastructure Revisions/ICD-9 Updates to NCDs – Maintenance CR

MLN Matters® Number: MM 8691

Related CR Release Date: May 23, 2014

Related CR Transmittal #: R1388OTN

Related Change Request (CR) #: CR 8691

Effective Date: July 1, 2014 (ICD-9 updates, local system edits), October 1, 2014 (designated ICD-9 shared system edits), October 1 2015 (or whenever ICD-10 is implemented) (ICD-10 updates) determined for ICD-10

Implementation Date: July 7, 2014 (designated ICD-9 updates, local system edits, October 6, 2014 (or whenever ICD-10 is implemented (ICD-10 updates) to be determined for ICD-10

Provider Types Affected

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

Provider Action Needed

This article is based on Change Request (CR) 8691 which is the first maintenance update of ICD-10 conversions and 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, and CR8197. Links to related MLN Matters® Articles MM7818, MM8109, and MM8197 are available in the additional information section of this article. Some are the result of revisions required to other NCD-related CRs released separately that also included ICD-10.

Edits to ICD-10 coding specific to NCDs will be included in subsequent, quarterly recurring updates. No policy-related changes are included with these recurring updates. Any policy-related changes to NCDs continue to be implemented via the current, long-standing NCD process. Make sure that your billing staffs are aware of these changes to the following 29 NCDs:

20.5 ECU Using Protein A Columns, 20.7 PTA, 20.20 ECP Therapy, 20.29 HBO Therapy, 50.3 Cochlear Implants, 70.2.1 Diabetic Peripheral Neuropathy, 80.2 Photodynamic Therapy, 80.2.1 OPT, 80.3

Photosensitive Drugs, 80.3.1 Verteporfin, 100.1 Bariatric Surgery, 110.8.1 Stem Cell Transplants, 110.4 Extracorpreal Photopheresis, 110.10 IV Iron Therapy, 150.3 Bone Mineral Density, 160.18 VNS, 160.24 Deep Brain Stimulation, 160.27 TENS for CLBP, 180.1 MNT, 190.1 Histocompatibility Testing, 190.8 Lymphocyte Mitogen Response Assay, 190.11 Home PT/INR, 210.1 PSA Screening Tests, 210.2 Screening Pap/Pelvic Exams, 210.3 Colorectal Cancer Screens, 210.10 Screening for STIs, 250.4 Treatment for AKs, 250.3 IVIG for Autoimmune Blistering Disease, 250.5 Dermal Injections for Facial LDS

Background

The purpose of CR8691 is to both create and update NCD editing, both hard-coded shared system edits as well as local MAC edits, that contain either ICD-9 diagnosis/procedure codes or ICD-10 diagnosis/procedure codes, or both, plus all associated coding infrastructure such as HCPCS/CPT codes, reason/remark codes, frequency edits, Place of Service (POS)/Type of Bill (TOB)/provider specialties, etc. The requirements described in CR8691 reflect the operational changes that are necessary to implement the conversion of the Medicare systems from ICD-9 to ICD-10 specific to the 29 NCD spreadsheets attached to CR8691.

Additional Information

The official instruction, CR8691 issued to your MAC regarding this change is available at http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1388OTN.pdf on the CMS website. Note that there are 29 spreadsheets attached to CR8691 and those spreadsheets relate to 9 NCDs and provide pertinent policy/coding information necessary to implement ICD-10.

MM7818 is available for review at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7818.pdf on the CMS website.

MM8109 is available for review at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8109.pdf on the CMS website.

MM8197 is available for review at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8197.pdf on the CMS website.

ICD-10 Limited End-to-End Testing with Submitters

MLN Matters® Number: MM8602 Rescinded
Related Change Request (CR) #: CR 8602
Related CR Release Date: February 21, 2014
Related CR Transmittal #: R1352OTN
Effective Date: July 7, 2014
Implementation Date: July 7, 2014

Note: This article was rescinded on May 7, 2014, since the related CR8602 was rescinded.

ICD-10 Updates to Local Coverage Determinations (LCDs) and Policy Articles (PAs)

As promised in our March 20, 2014 publication, all LCDs and PAs have been updated and are included in the Medicare Coverage Database and on Noridian's Future LCD and Policy Articles webpage. To keep separate the ICD-9s from the ICD-10s, all ICD-10 LCDs and PAs (with and without diagnosis codes) have been assigned new ID numbers, and have an effective date of October 1, 2014. Also, note the Draft LCDs have been assigned active LCD ID numbers but remain drafts.

The Centers for Medicare & Medicaid (CMS) has determined that although new LCD numbers are assigned, the policies shall not be considered new policies. CMS considers this type of update to be a coding revision that does not change the intent of coverage/non-coverage within an LCD.

For more information, CMS has dedicated a page to ICD-10 on www.cms.gov. This page is updated regularly, usually at least once per week, and houses resources, articles and products concerning ICD-10. Suppliers can check the latest news specific to ICD-10 as well as reference applicable Medicare Learning

Network (MLN) publications. Follow this link to access the ICD-10 page: http://www.cms.gov/Medicare/Coding/ICD10/Medicare-Fee-for-Service-Provider-Resources.html.

The following list of LCDs and related PAs contains diagnoses that have been updated to ICD-10 codes.

- L33686 Ankle-Foot/Knee-Ankle-Foot Orthosis
- L33690 Automatic External Defibrillators
- L34824 DRAFT Vacuum Erection Devices (VED)
- L33317 External Breast Prostheses
- L33822 Glucose Monitors
- L33785 High Frequency Chest Wall Oscillation Devices
- L33824 Immunosuppressive Drugs – Policy Article
- L33610 Intravenous Immune Globulin – Policy Article
- L33318 Knee Orthoses
- L33795 Mechanical In-exsufflation Devices
- L33370 Nebulizers
- A52479 Oral Anticancer Drugs – Policy Article
- A52480 Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics) – Policy Article
- L33611 Oral Appliances for Obstructive Sleep Apnea
- L33641 Orthopedic Footwear
- L33796 Osteogenesis Stimulators
- L33828 Ostomy Supplies – Policy Article
- L33797 Oxygen and Oxygen Equipment
- L33718 Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea
- L33642 Pressure Reducing Support Surfaces – Group 2
- L33692 Pressure Reducing Support Surfaces – Group 3
- L33793 Refractive Lenses
- L33612 Suction Pumps
- L33369 Therapeutic Shoes for Persons with Diabetes – Policy Article
- L33832 Tracheostomy Care Supplies – Policy Article
- L33802 Transcutaneous Electrical Nerve Stimulators (TENS)
- L33803 Urological Supplies
- L33312 Wheelchair Seating

LCD and Policy Article Revisions Summaries

Outlined below are the principal changes to DME MAC Local Coverage Determinations (LCDs) and a Policy Articles (PA) that have been revised and posted. Please review the entire LCD and each related PA for complete information.

March 20, 2014

Cervical Traction Devices

LCD

Revision Effective Date: 11/01/2013 (March 2014 Publication)

COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:

Added: Information that item(s) in policy are subject to ACA 6407 requirements (effective 07/01/2013)

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:

Added: ACA 6407 information (requirements effective 07/01/2013)

Policy Article

Revision Effective Date: 11/01/2013 (March 2014 Publication)

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added: ACA 6407 requirements (effective 07/01/2013)

Lower Limb Prostheses

LCD

Revision Effective Date: 01/01/2014

COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:

Added: Non-coverage guidance for L5969

HCPCS CODES AND MODIFIERS:

Added: L5969

Revised: HCPCS Narrative of L5668

Policy Article

Revision Effective Date: 01/01/2014

CODING GUIDELINES:

Added: Instructions for use of code L5969

Added: Requirement for PDAC coding verification for L5969

Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics)

LCD

Revision Effective Date: 01/01/14

HCPCS CODES AND MODIFIERS:

Added: Q0161

Discontinued: Q0165, Q0168, Q0170, Q0171, Q0172, Q0176 and Q0178

Power Mobility Devices

LCD

Revision Effective Date: 11/01/2013 (March 2014 Publication)

COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:

Added: Information that item(s) in policy are subject to ACA 6407 requirements (effective 07/01/2013)

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:

Added: ACA 6407 information (requirements effective 07/01/2013)

Policy Article

Revision Effective Date: 11/01/2013 (March 2014 Publication)

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added: ACA 6407 requirements (effective 07/01/2013)

Pressure Reducing Support Surfaces – Group 1

LCD

Revision Effective Date: 11/01/2013 (March 2014 Publication)

COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:

Added: Information that item(s) in policy are subject to ACA 6407 requirements (effective 07/01/2013)

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:

Added: ACA 6407 information (requirements effective 07/01/2013)

Policy Article

Revision Effective Date: 11/01/2013 (March 2014 Publication)

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added: ACA 6407 requirements (effective 07/01/2013)

Respiratory Assist Devices

LCD

Revision Effective Date: 11/01/2013 (March 2014 Publication)

COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:

Added: Information that item(s) in policy are subject to ACA 6407 requirements (effective 07/01/2013)

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:

Added: ACA 6407 information (requirements effective 07/01/2013)

Policy Article

Revision Effective Date: 11/01/2013 (March 2014 Publication)

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added: ACA 6407 requirements (effective 07/01/2013)

Seat Lift Mechanisms

LCD

Revision Effective Date: 11/01/2013 (March 2014 Publication)

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:

Added: ACA 6407 information (requirements effective 07/01/2013)

Policy Article

Revision Effective Date: 11/01/2013 (March 2014 Publications)

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added: ACA 6407 requirements (effective 07/01/2013)

Transcutaneous Electrical Nerve Stimulators (TENS)

LCD

Revision Effective Date: 11/01/2013 (March 2014 Publication)

COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:

Revised: Specific ICD-9 diagnosis codes contained in the narrative are replaced with a reference to the applicable diagnosis code tables

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:

Added: ACA 6407 information (requirements effective 07/01/2013)

Policy Article

Revision Effective Date: 11/01/2013 (March 2014 Publication)

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Revised: ACA 6407 requirements (effective 07/01/2013)

Wheelchair Seating

LCD

Revision Effective Date: 11/01/2013 (March 2014 Publication)

COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:

Added: Information that item(s) in policy are subject to ACA 6407 requirements (effective 07/01/2013)

Revised: Specific ICD-9 diagnosis codes contained in the narrative are replaced with a reference to the applicable diagnosis code tables

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:

Added: ACA 6407 information (requirements effective 07/01/2013)

Revised: Specific ICD-9 diagnosis codes contained in the narrative are replaced with a reference to the applicable diagnosis code tables

Policy Article

Revision Effective Date: 11/01/2013 (March 2014 Publication)

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added: ACA 6407 requirements (effective 07/01/2013)

CODING GUIDELINES:

Changed: Clerical change from "vertical" to "horizontal" regarding HCPCS E2613-E2616

March 27, 2014

Ankle-Foot/Knee-Ankle-Foot Orthosis

LCD

Revision Effective Date: 01/01/2014
COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:

Added: References to off-the-shelf (OTS) and custom fitted

Added: New and revised 2014 HCPCS codes to coverage statements

Revised: Specific ICD-9 diagnosis codes contained in the narrative are replaced with a reference to the applicable diagnosis code tables

HCPCS CODES AND MODIFIERS:

Added: L4361, L4387, L4397

For the following codes, the descriptor was changed: L1902, L1904, L1906, L1907, L4350, L4360, L4370, L4386, L4396, L4398

DOCUMENTATION REQUIREMENTS:

Added: Documentation requirement for custom fitted vs. OTS

Policy Article

Revision Effective Date: 01/01/2014

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added: Correct coding statement for prefabricated orthoses

Added: Denial statement for incorrect coding

CODING GUIDELINES:

Added: Definitions of off-the-shelf and custom fitted

Added: Respective off-the-shelf and custom fitted codes to coding statements

Added: Definitions for minimal self-adjustment, substantial modification and kits

Knee Orthoses

LCD

Revision Effective Date: 01/01/2014

COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:

Added: References to off-the-shelf (OTS) and custom fitted

Added: HCPCS codes for OTS and custom fitted to their respective coverage statements, including correct coding statement for custom fitted items

Added: HCPCS codes to the Tables for Addition Codes-Eligible for Separate Payment, and Not Reasonable and Necessary

Revised: Specific ICD-9 diagnosis codes contained in the narrative are replaced with a reference to the applicable diagnosis code tables

HCPCS CODES AND MODIFIERS:

Added: L1812, L1833, L1848

For the following codes, the descriptor was changed: L1810, L1830, L1832, L1836, L1843, L1845, L1847, L1850

DOCUMENTATION REQUIREMENTS:

Added: Documentation requirement for custom fitted vs. OTS

Policy Article

Revision Effective Date: 01/01/2014

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added: Correct coding statement for prefabricated orthoses

Added: Denial statement for incorrect coding

Added: L1812 and L1833 to the reasonable useful lifetime table

CODING GUIDELINES:

Added: Definitions for off-the-shelf and custom fitted

Added: Definitions for minimal self-adjustment, substantial modification and kits

Added: L1812, L1833, L1848 base codes and the not separately payable codes to the table

Oral Anticancer Drugs

Policy Article

Revision Effective Date: 03/01/2014

ICD-9 CODES THAT ARE COVERED:

Deleted: ICD-9 diagnosis code V23.89. Inadvertent addition of an inappropriate ICD-9-CM code

Pneumatic Compression Devices

LCD

Revision Effective Date: 11/01/2013 (March 2014 Publication)

COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:

Added: Information that item(s) in policy are subject to ACA 6407 requirements (effective 07/01/2013)

POLICY SPECIFIC DOCUMENTATION

REQUIREMENTS:

Added: ACA 6407 information (requirements effective 07/01/2013)

Policy Article

Revision Effective Date: 11/01/2013 (March 2014 Publication)

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added: ACA 6407 information (requirements effective 07/01/2013)

Spinal Orthoses: TLSO and LSO LCD

Revision Effective Date: 01/01/2014

COVERAGE INDICATIONS, LIMITATIONS, and/or MEDICAL NECESSITY:

Added: References to off-the-shelf (OTS) and custom fitted

Added: HCPCS codes for OTS and custom fitted to their respective coverage statements, including correct coding statement for custom fitted items

HCPCS CODES AND MODIFIERS:

Added: L0455, L0457, L0467, L0469, L0623, L0641, L0642, L0643, L0648, L0649, L0650 and L0651

Revised: HCPCS Narrative of L0450, L0454, L0456, L0460, L0466, L0468, L0621, L0625, L0626, L0627, L0628, L0630, L0631, L0633, L0637, L0639 and L0984

DOCUMENTATION REQUIREMENTS:

Added: Documentation requirement for custom fitted vs. OTS

LCD AND PA REVISIONS SUMMARY

Policy Article

Revision Effective Date: 01/01/2014

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added: Correct coding statement for prefabricated orthoses

CODING GUIDELINES:

Added: Definitions for off-the-shelf and custom fitted

Added: Definitions for minimal self-adjustment, substantial modification and kits

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

June 12, 2014

The following three draft Local Coverage Determinations and Policy Articles have been finalized:

- Transcutaneous Electrical Joint Stimulation Devices (TEJSD)
- Tumor Treatment Field Therapy (TTFT)
- Vacuum Erection Devices (VED)

Each of these medical policies will be effective for claims with dates of service on or after August 1, 2014. The notice period start date is June 12, 2014 and the notice period end date is July 31, 2014.

Please review each entire LCD and related Policy Article for coverage, coding and documentation requirements. Also, review the Response to Comments Summary attached to each LCD.

MOBILITY DEVICES

ATP RESNA Certification Requirement Reminder

Suppliers should include verification of Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) certification for the Assistive Technology Professional (ATP) involved in the selection of the wheelchair with documentation submitted in response to additional documentation requests (ADRs) for complex medical review. This is in order to ensure that the following stated requirements are fulfilled.

The following wheelchairs and accessories require that the following items are provided by a Rehabilitative Technology Supplier (RTS) that employs a RESNA-certified ATP who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the patient:

- K0005: Manual ultra-lightweight wheelchair
- E1161: Tilt-in-space manual wheelchair
- K0835–K0840: Group 2 Single Power Option PWC
- K0841–K0843: Group 2 Multiple Power Option PWC
- K0848–K0855: Group 3 PWC with no power options
- E0986: Push-rim activated power assist device
- E2227: A gear reduction drive wheel
- E0988: Lever activated wheel drive
- E1002–E1010: Power tilt and/or recline seating systems

Additional Resources for further clarification of this requirement:

- FAQ – Power Mobility Devices- Supplier ATP Involvement
- Local Coverage Determination (LCD) for Manual Wheelchair Bases LCD L11454 and related Policy Article (PA) A25378
- LCD for Power Mobility Devices L23598 and related PA A41127
- LCD for Wheelchair Options/Accessories L11462 and related PA A19846

Manual Wheelchairs (HCPCS K0001, K0003, K0004) 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, K0003 and K0004. The quarterly edit effectiveness results from January 2014 through April 2014 are as follows:

- The K0001 review involved 772 claims, of which 704 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 89%.
- The K0003 review involved 423 claims, of which 402 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 95%.
- The K0004 review involved 196 claims, of which 185 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 91%.

Top Denial Reasons

- Invalid or missing home assessment to show the beneficiary's home provides adequate access between rooms, maneuvering space, and surfaces for use of the manual wheelchair that is provided.
- Insufficient or no documentation to show the resolution of the beneficiary's mobility limitations cannot be made with a cane or walker.
- Medical records do not support the beneficiary requires a lightweight wheelchair (K0003).
- Medical records do not support the beneficiary requires a high strength light weight wheelchair (K0004).
- Requested documentation was not received.
- Insufficient or no documentation to support the beneficiary's mobility limitation impairment to mobility-related activities of daily living (MRADLs).
- Insufficient or no documentation to support wheelchair use will significantly improve the beneficiary's ability to participate in MRADLs.

Going Forward

Based on the results of this review, Noridian will continue with the Prepayment Service Specific Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Manual Wheelchair Bases Local Coverage Determination (LCD) L11454 and Policy Article A25378.

Suppliers can also review a specific policy Documentation Checklist for Manual Wheelchair Bases on the Noridian website.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM) Chapter 3.

Policy Education

Invalid or missing home assessment to show the beneficiary's home provides adequate access between rooms, maneuvering space, and surfaces for use of the manual wheelchair that is provided.
Documentation must support Criterion C: The beneficiary's home provides adequate access between rooms, maneuvering space, and surfaces for use of the manual wheelchair that is provided.

Information about whether the beneficiary's home can accommodate the wheelchair (Criterion C), also called the home assessment, must be fully documented in the medical record or elsewhere by the supplier. For manual wheelchairs, the home assessment may be done directly by visiting the beneficiary's home or indirectly based upon information provided by the beneficiary or their designee. When the home assessment is based upon indirectly obtained information, the supplier must, at the time of delivery, verify that the item delivered meets the requirements specified in criterion C. Issues such as the physical layout of the home, surfaces to be traversed, and obstacles must be addressed by and documented in the home assessment. Information from the beneficiary's medical record and the supplier's records must be available upon request.

Insufficient or no documentation to show the resolution of the beneficiary's mobility limitations cannot be made with a cane or walker.
The documentation must support Criterion B: The beneficiary's mobility limitation cannot be sufficiently resolved by the use of an appropriately fitted cane or walker.

Medical records do not support the beneficiary requires a lightweight wheelchair (K0003).

Medical records do not support the beneficiary requires a high strength light weight wheelchair (K0004).
A lightweight wheelchair (K0003) is covered when the documentation supports that the beneficiary meets both criteria:

- Cannot self-propel in a standard wheelchair in the home; and
- The beneficiary can and does self-propel in a lightweight wheelchair

A high strength lightweight wheelchair (K0004) is covered when the documentation supports that the beneficiary meets criteria (1) or (2):

- The beneficiary self-propels the wheelchair while engaging in frequent activities in the home that cannot be performed in a standard or lightweight wheelchair; or
- The beneficiary requires a seat width, depth or height that cannot be accommodated in a standard, lightweight or hemi-wheelchair, and spends at least two hours per day in the wheelchair.

Requested documentation was not received.
Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R §424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide records may not only be a claim denial but also referral to the NSC.

Insufficient or no documentation to support the beneficiary's mobility limitation impairment to mobility-related activities of daily living (MRADLs).
Documentation provided must support Criterion A: The beneficiary has a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home. A mobility limitation is one that:

- Prevents the beneficiary from accomplishing an MRADL entirely, or
- Places the beneficiary at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL; or
- Prevents the beneficiary from completing an MRADL within a reasonable time frame.

Insufficient or no documentation to support wheelchair use will significantly improve the beneficiary's ability to participate in MRADLs.
The documentation must support Criterion D: Use of a manual wheelchair will significantly improve the beneficiary's ability to participate in MRADLs and the beneficiary will use it on a regular basis in the home.

Power Mobility Devices (HCPCS K0823 and All Related Accessories) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D DME MAC Medical Review Department is conducting a service specific review of HCPCS code K0823. The quarterly edit effectiveness results from January 2014 through April 2014 are as follows:

The K0823 review involved 265 claims, of which 167 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 63%.

Top Denial Reasons

- The documentation submitted does not support the beneficiary does not have sufficient upper extremity function to self propel an optimally configured manual wheelchair.
- The face-to-face examination submitted was incomplete or missing elements
- The documentation submitted contained no detailed product description or the detailed product description submitted was invalid
- The documentation submitted does not support the beneficiary's mobility limitation cannot be sufficiently and safely resolved by the use of an appropriately fitted cane or walker
- The 7-element order submitted was incomplete or missing elements

Going Forward

Based on the results of this review, Noridian will continue with the Prepayment Service Specific Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Power Mobility Devices Local Coverage Determination (LCD) L23598 and Policy Article A41127

Suppliers can also review specific policy resources for Power Mobility Devices on the Noridian Website. There, you will find information related to proper documentation requirements including a physician letter, documentation checklists, FAQs, and a presentation used during web-based workshops.

Suppliers can also review a specific policy Documentation Checklist for Power Mobility Devices on the Noridian website.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM), Chapter 3.

Policy Education

The documentation submitted does not support the beneficiary does not have sufficient upper extremity function to self propel an optimally configured manual wheelchair.
The beneficiary's medical records do not support criterion C.

- The beneficiary does not have sufficient upper extremity function to self-propel an optimally-configured manual wheelchair in the home to perform mobility related activities of daily living (MRADL) during a typical day.
    - Limitations of strength, endurance, range of motion, or coordination, presence of pain, or deformity or absence of one or both upper extremities are relevant to the assessment of upper extremity function.

- An optimally-configured manual wheelchair is one with an appropriate wheelbase, device weight, seating options, and other appropriate non-powered accessories.

The face-to-face examination submitted was incomplete or missing elements.
For a power operated vehicle (POV) or power wheelchair (PWC) to be covered, the treating physician must conduct a face-to-face examination of the beneficiary before writing the order and the supplier must receive a written report of this examination within 45 days after completion of the face-to-face examination and prior to delivery of the device.

The report should provide pertinent information about the following elements, but may include other details. Each element would not have to be addressed in every evaluation.

- History of the present condition(s) and past medical history that is relevant to mobility needs
  - Symptoms that limit ambulation
  - Diagnoses that are responsible for these symptoms
  - Medications or other treatment for these symptoms
  - Progression of ambulation difficulty over time
  - Other diagnoses that may relate to ambulatory problems
  - How far the beneficiary can walk without stopping
  - Pace of ambulation
  - What ambulatory assistance (cane, walker, wheelchair, caregiver) is currently used
  - What has changed to now require use of a power mobility device
  - Ability to stand up from a seated position without assistance
  - Description of the home setting and the ability to perform activities of daily living in the home
- Physical examination that is relevant to mobility needs
  - Weight and height
  - Cardiopulmonary examination
  - Musculoskeletal examination
    - Arm and leg strength and range of motion
  - Neurological examination
    - Gait
    - Balance and coordination

The evaluation should be tailored to the individual beneficiary's conditions. The history should paint a picture of the beneficiary's functional abilities and limitations on a typical day. It should contain as much objective data as possible. The physical examination should be focused on the body systems that are responsible for the beneficiary's ambulatory difficulty or impact on the beneficiary's ambulatory ability.

Physicians shall document the examination in a detailed narrative note in their charts in the format that they use for other entries. The note must clearly indicate that a major reason for the visit was a mobility examination.

If the report of a licensed/certified medical professional (LCMP) examination is to be considered as part of the face-to-face examination (see Policy Article), there must be a signed and dated attestation by the supplier or LCMP that the LCMP has no financial relationship with the supplier.

A date stamp or equivalent must be used to document the date that the supplier receives the report of the face-to-face examination. The written report of this examination must be available upon request.

The documentation submitted contained no detailed product description or the detailed product description submitted was invalid.
Once the supplier has determined the specific power mobility device that is appropriate for the beneficiary based on the physician's 7-element order, the supplier must prepare a written document (termed a detailed product description).

This detailed product description (DPD) must comply with the requirements for a detailed written order as outlined in the Supplier Manual and CMS' Program Integrity Manual (Internet-Only Manual, Pub. 100-8), Chapter 5. Regardless of the form of the description, there must be sufficient detail to identify the item(s) in order to determine that the item(s) dispensed is properly coded.

The physician must sign and date the detailed product description and the supplier must receive it prior to delivery of the PWC or POV. A date stamp or equivalent must be used to document the supplier receipt date. The detailed product description must be available on request.

The documentation submitted does not support the beneficiary's mobility limitation cannot be sufficiently and safely resolved by the use of an appropriately fitted cane or walker.
The beneficiary's medical records do not support criterion B.

- The patient's mobility limitation cannot be sufficiently and safely resolved by the use of an appropriately fitted cane or walker.

The 7-element order submitted was incomplete or missing elements.
The order, referred to as the 7-element order that the supplier must receive within 45 days after completion of the face-to-face examination (see Policy Article) must contain all of the following elements:

- Beneficiary's name
- Description of the item that is ordered. This may be general – e.g., "power operated vehicle", "power wheelchair", or "power mobility device"– or may be more specific.
- Date of the face-to-face examination
- Pertinent diagnoses/conditions that relate to the need for the POV or power wheelchair
- Length of need
- Physician's signature
- Date of physician signature

The Supplier may provide a template order listing the seven required elements but is prohibited from completing any part of it. The treating physician completing the face-to-face requirements must write the 7-element order. The 7-element order may only be written after the completion of the face-to-face exam requirements. Refer to the Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information regarding the statutory requirements for PMDs.

A date stamp or equivalent must be used to document receipt date. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, added section 1834(a)(1)(E)(iv) which provides that payment may not be made for a motorized or power wheelchair unless the practitioner who has conducted the face-to-face examination him or herself writes the 7-element order. It is a statutory requirement that all items of the 7-element order be entered specifically by and only by the practitioner who has conducted the face-to-face requirements.

For a POV or power wheelchair to be covered, the supplier must receive from the treating physician a written order, termed the 7-element order, containing all the elements specified in the Documentation Requirements section of the Local Coverage Determination within 45 days after completion of the physician's face-to-face examination and prior to delivery of the device. (Exception: If the examination is performed during a hospital or nursing home stay, the supplier must receive the order within 45 days after discharge.) If these requirements are not met, the claim will be denied as noncovered.

Power Mobility Devices (HCPCS K0823 and All Related Accessories) Quarterly Results of Service Specific Prepayment Review Results

The Jurisdiction D DME MAC Medical Review Department is conducting a service specific complex review of HCPCS codes K0823 and all related accessories. The quarterly edit effectiveness results from October 2013 through January 2014 are as follows:

The K0823 review involved 211 claims, of which 152 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 70%.

Top Denial Reasons

- The documentation submitted does not support the beneficiary does not have sufficient upper extremity function to self propel an optimally configured manual wheelchair.
- The face-to-face examination submitted was incomplete or missing elements.
- The documentation submitted contained no detailed product description or the detailed product description submitted was invalid.
- The 7-element order submitted was incomplete or missing elements.

Going Forward

Based on the results of this review, Noridian will continue with the Prepayment Service Specific Review.

Education Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Power Mobility Devices Local Coverage Determination (LCD) L23598 and Policy Article A41127.

Suppliers can also review specific policy resources for Power Mobility Devices on the Noridian website located at https://www.noridianmedicare.com/dme/coverage/resources/power_mobility_devices.html. There, you will find information related to proper documentation requirements including a physician letter, documentation checklists, FAQs, and a presentation used during web-based workshops.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations. Educational training and events are located at https://www.noridianmedicare.com/dme/train/.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM), Chapter 3 located at http://www.cms.gov/manuals/downloads/pim83c03.pdf.

Policy Education

The documentation submitted does not support the beneficiary does not have sufficient upper extremity function to self propel an optimally configured manual wheelchair.
The beneficiary's medical records do not support criterion C. The beneficiary does not have sufficient upper extremity function to self-propel an optimally-configured manual wheelchair in the home to perform mobility related activities of daily living (MRADL) during a typical day. Limitations of strength, endurance, range of motion, or coordination, presence of pain, or deformity or absence of one or both upper extremities are relevant to the assessment of upper extremity function. An optimally-configured manual wheelchair is one with an appropriate wheelbase, device weight, seating options, and other appropriate non-powered accessories.

The face-to-face examination submitted was incomplete or missing elements.
For a power operated vehicle (POV) or power wheelchair (PWC) to be covered, the treating physician must conduct a face-to-face examination of the beneficiary before writing the order and the supplier must receive a written report of this examination within 45 days after completion of the face-to-face examination and prior to delivery of the device. The report should provide pertinent information about the following elements, but may include other details. Each element would not have to be addressed in every evaluation.

History of the present condition(s) and past medical history that is relevant to mobility needs

- Symptoms that limit ambulation
- Diagnoses that are responsible for these symptoms

- Medications or other treatment for these symptoms
- Progression of ambulation difficulty over time
- Other diagnoses that may relate to ambulatory problems
- How far the beneficiary can walk without stopping
- Pace of ambulation
- What ambulatory assistance (cane, walker, wheelchair, caregiver) is currently used
- What has changed to now require use of a power mobility device
- Ability to stand up from a seated position without assistance
- Description of the home setting and the ability to perform activities of daily living in the home
- Physical examination that is relevant to mobility needs
- Weight and height
- Cardiopulmonary examination
- Musculoskeletal examination
- Arm and leg strength and range of motion
- Neurological examination
- Gait
- Balance and coordination

The evaluation should be tailored to the individual beneficiary's conditions. The history should paint a picture of the beneficiary's functional abilities and limitations on a typical day. It should contain as much objective data as possible. The physical examination should be focused on the body systems that are responsible for the beneficiary's ambulatory difficulty or impact on the beneficiary's ambulatory ability. Physicians shall document the examination in a detailed narrative note in their charts in the format that they use for other entries. The note must clearly indicate that a major reason for the visit was a mobility examination. If the report of a licensed/certified medical professional (LCMP) examination is to be considered as part of the face-to-face examination (see Policy Article), there must be a signed and dated attestation by the supplier or LCMP that the LCMP has no financial relationship with the supplier. A date stamp or equivalent must be used to document the date that the supplier receives the report of the face-to-face examination. The written report of this examination must be available upon request.

The documentation submitted contained no detailed product description or the detailed product description submitted was invalid.
Once the supplier has determined the specific power mobility device that is appropriate for the beneficiary based on the physician's 7-element order, the supplier must prepare a written document (termed a detailed product description). This detailed product description (DPD) must comply with the requirements for a detailed written order as outlined in the Supplier Manual and CMS' Program Integrity Manual (Internet-Only Manual, Pub. 100-8), Chapter 5. Regardless of the form of the description, there must be sufficient detail to identify the item(s) in order to determine that the item(s) dispensed is properly coded. The physician must sign and date the detailed product description and the supplier must receive it prior to delivery of the PWC or POV. A date stamp or equivalent must be used to document the supplier receipt date. The detailed product description must be available on request."

The 7-element order submitted was incomplete or missing elements.
The order, referred to as the 7-element order that the supplier must receive within 45 days after completion of the face-to-face examination (see Policy Article) must contain all of the following elements:

1. Beneficiary's name
2. Description of the item that is ordered. This may be general – e.g., "power operated vehicle", "power wheelchair", or "power mobility device"– or may be more specific.
3. Date of the face-to-face examination
4. Pertinent diagnoses/conditions that relate to the need for the POV or power wheelchair

5. Length of need
6. Physician's signature
7. Date of physician signature

The supplier may provide a template order listing the seven required elements but is prohibited from completing any part of it. The treating physician completing the face-to-face requirements must write the 7-element order. The 7-element order may only be written after the completion of the face-to-face exam requirements. Refer to the Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information regarding the statutory requirements for PMDs. A date stamp or equivalent must be used to document receipt date.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, added section 1834(a)(1)(E)(iv) which provides that payment may not be made for a motorized or power wheelchair unless the practitioner who has conducted the face-to-face examination him or herself writes the 7-element order. It is a statutory requirement that all items of the 7-element order be entered specifically by and only by the practitioner who has conducted the face-to-face requirements.

For a POV or power wheelchair to be covered, the supplier must receive from the treating physician a written order, termed the 7-element order, containing all the elements specified in the Documentation Requirements section of the Local Coverage Determination within 45 days after completion of the physician's face-to-face examination and prior to delivery of the device. (Exception: If the examination is performed during a hospital or nursing home stay, the supplier must receive the order within 45 days after discharge.) If these requirements are not met, the claim will be denied as noncovered.

NEBULIZERS

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

The Jurisdiction D DME MAC Medical Review Department is conducting a documentation compliance review of HCPCS code J7605 and J7626, nebulizer inhalation drugs. A documentation compliance review is a nonclinical, technical review verifying that submitted documentation meets payment requirements according to Local Coverage Determinations (LCD) for that DMEPOS item. The quarterly edit effectiveness, from January 1 through March 31, 2014, resulted in an overall error rate of 31%.

Top Denial Reasons

- Requested documentation was not received by the contractor within the allotted timeframe.
- There were no medical records submitted to support the management of obstructive pulmonary disease (ICD-9 diagnosis codes 491.0–508.9)
- The order submitted was invalid.
- The refill requirements were not met.

Going Forward

Based on the results of this review, Noridian will continue with the Documentation Compliance Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Nebulizer Local Coverage Determination (LCD) L11488 and Policy Article A24942.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM) chapter 3.

Policy Education

Documentation not received within the correct time frame.
Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R §424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide records may not only be a claim denial but also referral to the National Supplier Clearinghouse (NSC). 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 patient's medical records will reflect the need for the care provided. The patient's medical records include the physician'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.

There were no medical records submitted to support the management of obstructive pulmonary disease (ICD-9 diagnosis codes 491.0–508.9).
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 patient's medical records will reflect the need for the care provided. The patient's medical records include the physician'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.

The order submitted was invalid.
DISPENSING ORDERS (PIM 5.2.2)
Equipment and supplies may be delivered upon receipt of a dispensing order except for those items that require a written order prior to delivery. 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 Physician's name
- Date of the order and the start date, if the start date is different from the date of the order
- Physician 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 physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

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

The dispensing order must be available upon request.

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

DETAILED WRITTEN ORDERS (PIM 5.2.3)
A detailed written order (DWO) is required before billing. Someone other than the ordering physician may produce the DWO. However, the ordering physician must review the content and sign and date the document. It must contain:

- Beneficiary's name
- Physician's name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Physician 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, if applicable

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

Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state "PRN" or "as needed" utilization estimates for replacement frequency, use, or consumption are not acceptable. (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.

The refill requirements were not met.
For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products (A4233–A4236, A4253, A4256, A4258 and A4259) 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. 100-8, Chapter 5, Section 5.2.6).

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 ordering physicians that any changed or atypical utilization is warranted. Regardless of utilization, a supplier must not dispense more than a three (3)-month quantity at a time.

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 should 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., PAP and RAD supplies) - the supplier should assess whether the supplies remain functional, providing replacement (a refill) only when the supply item(s) is no longer able to function. Document the functional condition of the item(s) being refilled in sufficient detail to demonstrate the cause of the dysfunction that necessitates replacement (refill).

ORTHOTICS AND PROSTHETICS

Additional States Requiring Payment Edits for DMEPOS Suppliers of Prosthetics and Certain Custom-Fabricated Orthotics. Update to CR3959 and CR8390.

MLN Matters® Number: MM8730
Related Change Request (CR) #: CR 8730
Related CR Release Date: May 16, 2014
Related CR Transmittal #: R1385OTN
Effective Date: March 3, 2014
Implementation: June 17, 2014

Provider Types Affected

This MLN Matters® Article is intended for DMEPOS suppliers in Alabama, Arkansas, Florida, Georgia, Illinois, Kentucky, Mississippi, New Jersey, Ohio, Oklahoma, Rhode Island, Tennessee, Texas, Washington, North Dakota, Iowa, and Pennsylvania who bill Durable Medical Equipment Medicare Administrative Contractors (DME MACs) for Prosthetics and Orthotics (P&O) provided to Medicare beneficiaries.

Provider Action Needed

The Centers for Medicare & Medicaid Services (CMS) issued Change Request (CR) 8730 announce the three additional states that require the use of a licensed/certified orthotist or prosthetist for furnishing of P&O. The states are North Dakota, Iowa, and Pennsylvania.

Background

CMS issued Transmittal 656, CR3959 on August 19, 2005. This CR instructed Durable Medical Equipment Regional Contractors (DMERCs, since changed to DME MACs) to implement claims processing edits to ensure compliance with CMS regulations found at 42 CFR Section 424.57(c)(1). Such regulations require DMEPOS suppliers wishing to bill Medicare to operate their business and furnish Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements.

As a result of CR3959, the DME MACs implemented an edit which was programmed to deny claims for prosthetics and certain custom-fabricated orthotics when those items were furnished by personnel who were not licensed/certified as a orthotist or prosthetist by the State in which they practice. At the time CR3959 was issued and the DME MACs implemented the edit, there were nine states requiring the use of a licensed/certified orthotist or prosthetist for furnishing of orthotics or prosthetics. Since that time, five additional states have instituted requirements for the use of a licensed/certified orthotist or prosthetist for furnishing of orthotics or prosthetics. These five states are Arkansas, Georgia, Kentucky, Mississippi, and Tennessee. CR8390 instructed the DME MACs to revise the programming edits so that Arkansas, Georgia, Kentucky, Mississippi, and Tennessee are added to the logic, in accordance with CR3959.

CR8730 requires DME MACs to revise the programming edits so that North Dakota, Iowa, and Pennsylvania are added to the logic, in accordance with CRs 3959 and 8390.

In the 17 states that have indicated that provision of prosthetics and orthotics must be made by licensed/certified orthotist or prosthetist, Medicare payment may only be made for prosthetics and certain custom-fabricated orthotics when furnished by physicians, pedorthists, physical therapists, occupational therapists, orthotics personnel, and prosthetics personnel. These specialties will bill for Medicare services when State law permits such entity to furnish an item of prosthetic or orthotic using the following codes:

- Medical Supply Company with Orthotics Personnel – Specialty Code 51;
- Medical Supply Company with Prosthetics Personnel – Specialty Code 52;
- Medical Supply Company with Orthotics and Prosthetics Personnel – Specialty Code 53;
- Orthotics Personnel – Specialty Code 55;
- Prosthetics Personnel – Specialty Code 56;
- Orthotics Personnel, Prosthetics Personnel, and Pedorthists – Specialty Code 57;
- Physical Therapist – Specialty Code 65;
- Occupational Therapist – Specialty Code 67;
- Pedorthic Personnel - Specialty Code B2;
- Medical Supply Company with Pedorthic Personnel - Specialty Code B3;
- Ocularist – Specialty Code B5; and
- All Physician Specialty Code listed in the "Medicare Claims Processing Manual," Chapter 26, Section10.8.2, which is available at http://www.cms.gov/Regulationsand-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf on the CMS website.

If a supplier is located in one of the applicable states, that supplier must be properly enrolled with the National Supplier Clearinghouse (NSC) to ensure the correct specialty code(s) is on file in order to submit a claim to Medicare for the prosthetics and custom-fabricated orthotics. Failure to be properly enrolled will result in the claim being denied. A copy of the State license should be sent to the NSC if the supplier is in one of the seventeen states requiring a license.

If a supplier should need to update its' file with the correct specialty, the supplier must submit a "Change of Information" on Form CMS-855S to the NSC along with all applicable licenses or certifications. That form is available at http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855s.pdf on the CMS website. The NSC is responsible for maintaining a central data repository for information regarding suppliers. The NSC transmits this repository to the four DME MACs. The effective date for the new or revised specialty code for P&O claims will be the date the NSC issues the specialty code. The new or revised specialty code will not be applied retroactively.

Additional Information

The official instruction, CR8730 issued to your DME MAC regarding this change, is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1385OTN.pdf on the CMS website.

To review the article related to CR8390, visit http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8390.pdf on the CMS website.

To review the CR3959, visit http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM3959.pdf on the CMS website.

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

The Jurisdiction D DME MAC Medical Review Department is conducting a widespread complex review of HCPC codes L1970, L1960 and L4360. The quarterly edit effectiveness results from December 2013 through March 2014 are as follows:

- The L1970 review involved 328 claims, of which 280 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 86%.

- The L1960 review involved 232 claims, of which 199 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 88%.
- The L4360 review involved 1,454 claims, of which 1,142 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 80%.

Top Denial Reasons

- The treating physician's records did not provide detailed documentation to support medical necessity of a custom orthosis rather than a prefabricated orthosis.
- Documentation submitted was insufficient to support custom coverage criteria.
- Documentation submitted was insufficient to support basic coverage criteria
- There was no detailed written order or dispensing order provided

Going Forward

Based on the high error rate, Noridian will continue with the Prepayment Widespread Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Ankle-Foot/Ankle-Knee-Foot Orthosis Local Coverage Determination (LCD) L142 and Policy Article A19800.

Suppliers can also review a specific policy Documentation Checklist for Ankle-Foot/Ankle-Knee-Foot Orthosis on the Noridian website.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Chapter 3 of the Program Integrity Manual (PIM).

Policy Education

The treating physician's records did not provide detailed documentation to support medical necessity of a custom orthosis rather than a prefabricated orthosis.
For custom-fabricated orthoses, there must be detailed documentation in the treating physician's records to support medical necessity of custom-fabricated rather than a prefabricated orthosis. This information will be corroborated by the functional evaluation in the orthotist or prosthetist's records. This information must be available upon request.

Documentation submitted was insufficient to support custom coverage criteria.
AFO's and KAFO's that are custom-fabricated are covered for ambulatory beneficiaries when the basic coverage criteria and one of the following criteria are met:

- The beneficiary could not be fit with a prefabricated AFO; or,
- The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months); or,
- There is a need to control the knee, ankle or foot in more than one plane; or,
- The beneficiary has a documented neurological, circulatory, or orthopedic status that requires custom fabricating over a model to prevent tissue injury; or,
- The beneficiary has a healing fracture which lacks anatomical integrity or anthropometric proportions.

If a custom-fabricated orthosis is provided but basic coverage criteria and the additional criteria 1-5 for a custom-fabricated orthosis are not met, the custom-fabricated orthosis will be denied as not reasonable and necessary.

Documentation submitted was insufficient to support basic coverage criteria.
Ankle-foot orthoses (AFO) described by codes L1900, L1902–L1990, L2106–L2116, L4350, L4360, L4386 and L4631 are covered for ambulatory beneficiaries with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the potential to benefit functionally.

There was no detailed written order or dispensing order provided.
All items billed to Medicare require a prescription. An order for each new or full replacement item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Equipment and supplies may be delivered upon receipt of a dispensing order except for those items that require a written order prior to delivery. 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 Physician's name
- Date of the order and the start date, if the start date is different from the date of the order
- Physician signature (if a written order) or supplier signature (if verbal order)

For items that are provided based on a dispensing order, the supplier must obtain a detailed written order before submitting a claim. Detailed written order (DWO) is required before billing. Someone other than the ordering physician may produce the DWO. However, the ordering physician must review the content and sign and date the document. It must contain:

- Beneficiary's name
- Physician's name
- Date of the order and start date, if start date different than date of order
- Detailed description of the item(s)
- Physician signature and signature date

Correct Coding – Billing of Powered L-Coded Items

DME MAC Joint Publication

There are an increasing number of L-coded items, both orthotic and prosthetic components, which are electrically powered. Errors associated with correct coding these items have been identified in recent reviews.

Billing Of Batteries and Chargers Concurrently With a Powered Base Item

Powered base items are those that contain the power source (battery). At the time that a base item is billed, all necessary batteries and/or battery chargers are considered as included in the payment for the powered base item. There is no separate payment for batteries (L7360, L7364, L7367, and L8505) and/or battery chargers (L7362, l7366, L7368) billed concurrently with a powered base item.

Payment for items listed in Column II are included in the payment for each Column I code. Claims for Column II items billed with the provision of a Column I item will be denied as unbundling.

Column I	Column II
Base codes with battery, charger and/or power included L2005 L3904 L5781 L5782 L5856 L5857 L5858 L5859 L5973 L6025 L6920 – L6975 L8500 L8510	Batteries L7360 L7364 L7367 L8505 Chargers L7362 L7366 L7368

Billing of Powered Add-Ons

Many powered base items are used concurrently with add-on items that derive power from the power source contained in the base item. At the time that an add-on to a base item is billed, all necessary batteries and/or battery chargers are considered as included in the payment for the powered base item. There is no separate payment for batteries (L7360, L7364, L7367, and L8505) and/or battery chargers (L7362, l7366, L7368) billed concurrently with a powered base item or associated add-ons.

Payment for items listed in Column III are included in the payment for each Column II code. Claims for Column III items billed with the provision of a Column I item will be denied as unbundling.

Column I	Column II	Column III
Add-on codes used with base codes L5969 L6621 L6638 L6646 L6648 L6880 – L6885 L7007 – L7261	Base codes with battery, charger and/or power included L2005 L3904 L5781 L5782 L5856 L5857 L5858 L5859 L5973 L6025 L6920 – L6975 L8500 L8510	Batteries L7360 L7364 L7367 L8505 Chargers L7362 L7366 L7368

These correct coding tables will be effective for claims with DOS on or after 05/01/2014.

Refer to the applicable Local Coverage Determination, related Policy Article and Supplier Manual for additional information.

HCPCS	NARRATIVE DESCRIPTION
L2005	KNEE ANKLE FOOT ORTHOSIS, ANY MATERIAL, SINGLE OR DOUBLE UPRIGHT, STANCE CONTROL, AUTOMATIC LOCK AND SWING PHASE RELEASE, ANY TYPE ACTIVATION, INCLUDES ANKLE JOINT, ANY TYPE, CUSTOM FABRICATED
L3904	WRIST HAND FINGER ORTHOSIS, EXTERNAL POWERED, ELECTRIC, CUSTOM-FABRICATED

L5781	ADDITION TO LOWER LIMB PROSTHESIS, VACUUM PUMP, RESIDUAL LIMB VOLUME MANAGEMENT AND MOISTURE EVACUATION SYSTEM
L5782	ADDITION TO LOWER LIMB PROSTHESIS, VACUUM PUMP, RESIDUAL LIMB VOLUME MANAGEMENT AND MOISTURE EVACUATION SYSTEM, HEAVY DUTY
L5856	ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, MICROPROCESSOR CONTROL FEATURE, SWING AND STANCE PHASE, INCLUDES ELECTRONIC SENSOR(S), ANY TYPE
L5857	ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, MICROPROCESSORCONTROL FEATURE, SWING PHASE ONLY, INCLUDES ELECTRONIC SENSOR(S), ANY TYPE
L5858	ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE SHIN SYSTEM, MICROPROCESSOR CONTROL FEATURE, STANCE PHASE ONLY, INCLUDES ELECTRONIC SENSOR(S), ANY TYPE
L5859	ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, POWERED AND PROGRAMMABLE FLEXION/EXTENSION ASSIST CONTROL, INCLUDES ANY TYPE MOTOR(S)
L5969	ADDITION, ENDOSKELETAL ANKLE-FOOT OR ANKLE SYSTEM, POWER ASSIST, INCLUDES ANY TYPE MOTOR(S)
L5973	ENDOSKELETAL ANKLE FOOT SYSTEM, MICROPROCESSOR CONTROLLED FEATURE, DORSIFLEXION AND/OR PLANTAR FLEXION CONTROL, INCLUDES POWER SOURCE
L6025	ELBOW DISARTICULATION, MOLDED SOCKET WITH EXPANDABLE INTERFACE, OUTSIDE LOCKING HINGES, FOREARM
L6621	UPPER EXTREMITY PROSTHESIS ADDITION, FLEXION/EXTENSION WRIST WITH OR WITHOUT FRICTION, FOR USE WITH EXTERNAL POWERED TERMINAL DEVICE
L6638	EXTREMITY ADDITION TO PROSTHESIS, ELECTRIC LOCKING FEATURE, ONLY FOR USE WITH MANUALLY POWERED ELBOW
L6646	UPPER EXTREMITY ADDITION, SHOULDER JOINT, MULTIPOSITIONAL LOCKING, FLEXION, ADJUSTABLE ABDUCTION FRICTION CONTROL, FOR USE WITH BODY POWERED OR EXTERNAL POWERED SYSTEM
L6648	UPPER EXTREMITY ADDITION, SHOULDER LOCK MECHANISM, EXTERNAL POWERED ACTUATOR
L6880	ELECTRIC HAND, SWITCH OR MYOLELECTRIC CONTROLLED, INDEPENDENTLY ARTICULATING DIGITS, ANY GRASP PATTERN OR COMBINATION OF GRASP PATTERNS, INCLUDES MOTOR(S)
L6881	AUTOMATIC GRASP FEATURE, ADDITION TO UPPER LIMB ELECTRIC PROSTHETIC TERMINAL DEVICE
L6882	MICROPROCESSOR CONTROL FEATURE, ADDITION TO UPPER LIMB PROSTHETIC TERMINAL DEVICE
L6883	REPLACEMENT SOCKET, BELOW ELBOW/WRIST DISARTICULATION, MOLDED TO PATIENT MODEL, FOR USE WITH OR WITHOUT EXTERNAL POWER
L6884	REPLACEMENT SOCKET, ABOVE ELBOW/ELBOW DISARTICULATION, MOLDED TO PATIENT MODEL, FOR USE WITH OR WITHOUT EXTERNAL POWER
L6885	REPLACEMENT SOCKET, SHOULDER DISARTICULATION/INTERSCAPULAR THORACIC, MOLDED TO PATIENT MODEL, FOR USE WITH OR WITHOUT EXTERNAL POWER
L6920	WRIST DISARTICULATION, EXTERNAL POWER, SELF-SUSPENDED INNER SOCKET, REMOVABLE FOREARM SHELL, OTTO BOCK OR EQUAL, SWITCH, CABLES, TWO BATTERIES AND ONE CHARGER, SWITCH CONTROL OF TERMINAL DEVICE

L6925	WRIST DISARTICULATION, EXTERNAL POWER, SELF-SUSPENDED INNER SOCKET, REMOVABLE FOREARM SHELL, OTTO BOCK OR EQUAL ELECTRODES, CABLES, TWO BATTERIES AND ONE CHARGER, MYOELECTRONIC CONTROL OF TERMINAL DEVICE
L6930	BELOW ELBOW, EXTERNAL POWER, SELF-SUSPENDED INNER SOCKET, REMOVABLE FOREARM SHELL, OTTO BOCK OR EQUAL SWITCH, CABLES, TWO BATTERIES AND ONE CHARGER, SWITCH CONTROL OF TERMINAL DEVICE
L6935	BELOW ELBOW, EXTERNAL POWER, SELF-SUSPENDED INNER SOCKET, REMOVABLE FOREARM SHELL, OTTO BOCK OR EQUAL ELECTRODES, CABLES, TWO BATTERIES AND ONE CHARGER, MYOELECTRONIC CONTROL OF TERMINAL DEVICE
L6940	ELBOW DISARTICULATION, EXTERNAL POWER, MOLDED INNER SOCKET, REMOVABLE HUMERAL SHELL, OUTSIDE LOCKING HINGES, FOREARM, OTTO BOCK OR EQUAL SWITCH, CABLES, TWO BATTERIES AND ONE CHARGER, SWITCH CONTROL OF TERMINAL DEVICE
L6945	ELBOW DISARTICULATION, EXTERNAL POWER, MOLDED INNER SOCKET, REMOVABLE HUMERAL SHELL, OUTSIDE LOCKING HINGES, FOREARM, OTTO BOCK OR EQUAL ELECTRODES, CABLES, TWO BATTERIES AND ONE CHARGER, MYOELECTRONIC CONTROL OF TERMINAL DEVICE
L6950	ABOVE ELBOW, EXTERNAL POWER, MOLDED INNER SOCKET, REMOVABLE HUMERAL SHELL, INTERNAL LOCKING ELBOW, FOREARM, OTTO BOCK OR EQUAL SWITCH, CABLES, TWO BATTERIES AND ONE CHARGER, SWITCH CONTROL OF TERMINAL DEVICE
L6955	ABOVE ELBOW, EXTERNAL POWER, MOLDED INNER SOCKET, REMOVABLE HUMERAL SHELL, INTERNAL LOCKING ELBOW, FOREARM, OTTO BOCK OR EQUAL ELECTRODES, CABLES, TWO BATTERIES AND ONE CHARGER, MYOELECTRONIC CONTROL OF TERMINAL DEVICE
L6960	SHOULDER DISARTICULATION, EXTERNAL POWER, MOLDED INNER SOCKET, REMOVABLE SHOULDER SHELL, SHOULDER BULKHEAD, HUMERAL SECTION, MECHANICAL ELBOW, FOREARM, OTTO BOCK OR EQUAL SWITCH, CABLES, TWO BATTERIES AND ONE CHARGER, SWITCH CONTROL OF TERMINAL DEVICE
L6965	SHOULDER DISARTICULATION, EXTERNAL POWER, MOLDED INNER SOCKET, REMOVABLE SHOULDER SHELL, SHOULDER BULKHEAD, HUMERAL SECTION, MECHANICAL ELBOW, FOREARM, OTTO BOCK OR EQUAL ELECTRODES, CABLES, TWO BATTERIES AND ONE CHARGER, MYOELECTRONIC CONTROL OF TERMINAL DEVICE
L6970	INTERSCAPULAR-THORACIC, EXTERNAL POWER, MOLDED INNER SOCKET, REMOVABLE SHOULDER SHELL, SHOULDER BULKHEAD, HUMERAL SECTION, MECHANICAL ELBOW, FOREARM, OTTO BOCK OR EQUAL SWITCH, CABLES, TWO BATTERIES AND ONE CHARGER, SWITCH CONTROL OF TERMINAL DEVICE
L6975	INTERSCAPULAR-THORACIC, EXTERNAL POWER, MOLDED INNER SOCKET, REMOVABLE SHOULDER SHELL, SHOULDER BULKHEAD, HUMERAL SECTION, MECHANICAL ELBOW, FOREARM, OTTO BOCK OR EQUAL ELECTRODES, CABLES, TWO BATTERIES AND ONE CHARGER, MYOELECTRONIC CONTROL OF TERMINAL DEVICE
L7007	ELECTRIC HAND, SWITCH OR MYOELECTRIC CONTROLLED, ADULT
L7008	ELECTRIC HAND, SWITCH OR MYOELECTRIC CONTROLLED, PEDIATRIC
L7009	ELECTRIC HOOK, SWITCH OR MYOELECTRIC CONTROLLED, ADULT
L7010	ELECTRONIC HAND, OTTO BOCK, STEEPER OR EQUAL, SWITCH CONTROLLED
L7015	ELECTRONIC HAND, SYSTEM TEKNIK, VARIETY VILLAGE OR EQUAL, SWITCH CONTROLLED
L7020	ELECTRONIC GREIFER, OTTO BOCK OR EQUAL, SWITCH CONTROLLED

L7025	ELECTRONIC HAND, OTTO BOCK OR EQUAL, MYOELECTRONICALLY CONTROLLED
L7030	ELECTRONIC HAND, SYSTEM TEKNIK, VARIETY VILLAGE OR EQUAL, MYOELECTRONICALLY CONTROLLED
L7035	ELECTRONIC GREIFER, OTTO BOCK OR EQUAL, MYOELECTRONICALLY CONTROLLED
L7040	PREHENSILE ACTUATOR, SWITCH CONTROLLED
L7045	ELECTRONIC HOOK, SWITCH OR MYOELECTRIC CONTROLLED, PEDIATRIC
L7170	ELECTRONIC ELBOW, HOSMER OR EQUAL, SWITCH CONTROLLED
L7180	ELECTRONIC ELBOW, MICROPROCESSOR SEQUENTIAL CONTROL OF ELBOW AND TERMINAL DEVICE
L7181	ELECTRONIC ELBOW, MICROPROCESSOR SIMULTANEOUS CONTROL OF ELBOW AND TERMINAL DEVICE
L7185	ELECTRONIC ELBOW, ADOLESCENT, VARIETY VILLAGE OR EQUAL, SWITCH CONTROLLED
L7186	ELECTRONIC ELBOW, CHILD, VARIETY VILLAGE OR EQUAL, SWITCH CONTROLLED
L7190	ELECTRONIC ELBOW, ADOLESCENT, VARIETY VILLAGE OR EQUAL, MYOELECTRONICALLY CONTROLLED
L7191	ELECTRONIC ELBOW, CHILD, VARIETY VILLAGE OR EQUAL, MYOELECTRONICALLY CONTROLLED
L7260	ELECTRONIC WRIST ROTATOR, OTTO BOCK OR EQUAL
L7261	ELECTRONIC WRIST ROTATOR, FOR UTAH ARM
L7360	SIX VOLT BATTERY, EACH
L7362	BATTERY CHARGER, SIX VOLT, EACH
L7364	TWELVE VOLT BATTERY, EACH
L7366	BATTERY CHARGER, TWELVE VOLT, EACH
L7367	LITHIUM ION BATTERY, REPLACEMENT
L7368	LITHIUM ION BATTERY CHARGER, REPLACEMENT ONLY
L8500	ARTIFICIAL LARYNX, ANY TYPE
L8505	ARTIFICIAL LARYNX REPLACEMENT BATTERY / ACCESSORY, ANY TYPE
L8510	VOICE AMPLIFIER

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 the DME PDAC Contact Form located on the PDAC website.

Correct Coding – Definitions Used for Off-the-Shelf versus Custom Fitted Prefabricated Orthotics (Braces) - Revised

Joint DME MAC Publication

As part of the 2014 HCPCS update codes were created describing certain off-the-shelf (OTS) orthotics. Some of these codes parallel codes for custom fitted versions of the same items. Refer to the appropriate Local Coverage Determination (LCD) for a list of codes.

When providing these items suppliers must:

- Provide the product that is specified by the ordering physician, i.e. (1) type of orthosis and (2) method of fitting (OTS or custom fitted)
- Be sure that the medical record justifies the need for the type of product and method of fitting

- Be sure only to use the code that accurately reflects both the type of orthosis and the appropriate level of fitting
- Have detailed documentation that justifies the code selected for custom fitted versus OTS codes)

The following definitions will be used for correct coding of these items.

Off-the-shelf (OTS) orthotics are:

- Items that are prefabricated
- They may or may not be supplied as a kit that requires some assembly. Assembly of the item and/or installation of add-on components and/or the use of some basic materials in preparation of the item does not change classification from OTS to custom fitted
- OTS items require minimal self-adjustment for fitting at the time of delivery for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit an individual
- This fitting does not require expertise of a certified orthotist or an individual who has equivalent specialized training in the provision of orthoses to fit the item to the individual beneficiary

The term "minimal self-adjustment" is defined at 42 CFR §414.402 as an adjustment the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and that does not require the services of a certified orthotist (that is, an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training. For example, adjustment of straps and closures, bending or trimming for final fit or comfort (not all-inclusive) fall into this category.

Fabrication of an orthosis using CAD/CAM or similar technology without the creation of a positive model with minimal self-adjustment at delivery is considered as OTS.

Custom fitted orthotics are:

- Devices that are prefabricated
- They may or may not be supplied as a kit that requires some assembly. Assembly of the item and/or installation of add-on components and/or the use of some basic materials in preparation of the item does not change classification from OTS to custom fitted
- Classification as custom fitted requires substantial modification for fitting at the time of delivery in order to provide an individualized fit, i.e., the item must be trimmed, bent, molded (with or without heat), or otherwise modified resulting in alterations beyond minimal self-adjustment
- This fitting at delivery does require expertise of a certified orthotist or an individual who has equivalent specialized training in the provision of orthosis to fit the item to the individual beneficiary

Substantial modification is defined as changes made to achieve an individualized fit of the item that requires the expertise of a certified orthotist or an individual who has equivalent specialized training in the provision of orthotics such as a physician, treating practitioner, an occupational therapist, or physical therapist in compliance with all applicable Federal and State licensure and regulatory requirements. A certified orthotist is defined as an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification.

Use of CAD/CAM or similar technology to create an orthosis without a positive model of the patient may be considered as custom fitted if the final fitting upon delivery to the patient requires substantial modification requiring expertise as described in this section.

A certified orthotist is defined as an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification.

Kits are:

- A collection of components, materials and parts that require further assembly before delivery of the final product
- The elements of a kit may be packaged and complete from a single source or may be an assemblage of separate components from multiple sources by the supplier

A summary classification algorithm is included at the end of this document to assist in determinations about the type of product and correct code selection.

Refer to the Contractor Supplier Manual, applicable Local Coverage Determination and related Policy Article for additional information about other coverage, coding and documentation requirements.

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 the DME PDAC Contact Form located on the PDAC website: https://www.dmepdac.com/

Classification Algorithm – Overview of Criteria

Determining Proper Coding of Prefabricated Orthotics

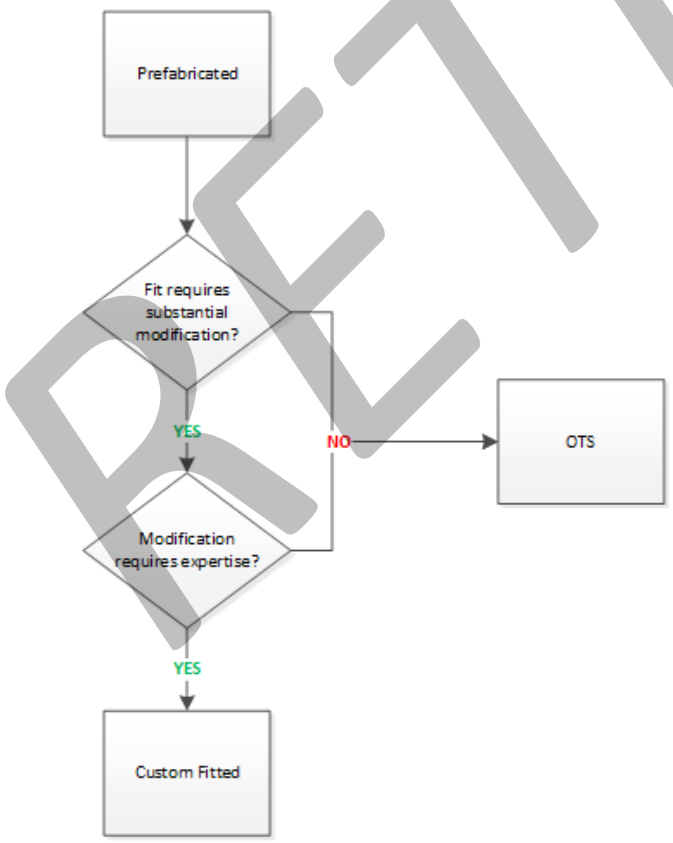
The following question and answer relates to whether a prefabricated orthotic is properly billed using a code for a custom fitted orthotic versus one furnished off-the-shelf and does not address medical necessity for the item. The descriptors for the HCPCS codes for custom fitted orthotics include the following nomenclature:

- Off-the-shelf (OTS) - Prefabricated item that requires minimal self-adjustment such as being trimmed, bent, molded, assembled, or otherwise adjusted to fit the beneficiary. Minimal self-adjustment does not require the expertise of a certified orthotist or an individual with equivalent expertise.
- Custom fitted - Prefabricated item that requires substantial modification e.g., has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by certified orthotist or an individual with equivalent expertise.

Question: Is the prefabricated orthotic furnished with custom fitting that is and can only be provided by an individual with expertise or furnished off-the-shelf (OTS)?

Answer: Classification depends on (1) what must be done at final fitting and (2) who must do it. Expertise of a qualified practitioner and substantial modification at the time of delivery qualify the items for classification as custom fitted. Fail either one of these criteria and the item is classified as off-the-shelf.

How to Decide What Code Type for Prefabricated Orthotic



Lower Limb Prostheses (HCPCS L5980) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D DME MAC Medical Review Department is conducting a service specific review of HCPCS code L5980. The quarterly edit effectiveness results from November 2013 through February 2014 are as follows:

The L5980 review involved 33 claims of which 28 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 80%.

Top Denial Reasons

- Documentation does not support the functional level billed on the claim.
- Documentation did not support the beneficiary will reach or maintain a defined functional state within a reasonable period of time.
- Documentation does not support medical need for replacement.
- Records submitted are from a prosthetist/orthotist, documentation was not submitted from physician.

Going Forward

Based on the results of this review, Noridian will continue with the Prepayment Service Specific Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Lower Limb Prostheses Local Coverage Determination (LCD) L11453 and Policy Article A25367.

Suppliers can also review a specific policy Documentation Checklist for Lower Limb Prostheses on the Noridian website.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM) [PDF], Chapter 3.

Documentation does not support the functional level billed on the claim.
A determination of the medical necessity for certain components/additions to the prosthesis is based on the beneficiary's potential functional abilities. Potential functional ability is based on the reasonable expectations of the prosthetist, and treating physician, considering factors including, but not limited to:

- The beneficiary's past history (including prior prosthetic use if applicable)
- The beneficiary's current condition including the status of the residual limb and the nature of other medical problems
- The beneficiary's desire to ambulate.

The records must document the beneficiary's current functional capabilities and his/her expected functional potential, including an explanation for the difference, if that is the case. It is recognized, within the functional classification hierarchy, that bilateral amputees often cannot be strictly bound by functional level classifications.

Documentation did not support the beneficiary will reach or maintain a defined functional state within a reasonable period of time.
Lower limb prosthesis is covered when the beneficiary:

- Will reach or maintain a defined functional state within a reasonable period of time;
- Is motivated to ambulate.

Documentation does not support medical need for replacement.
Replacement of a prosthesis or prosthetic component is covered if the treating physician orders a replacement device or part because of any of the following:

- A change in the physiological condition of the beneficiary
- Irreparable wear of the device or a part of the device
- The condition of the device, or part of the device, requires repairs and the cost of such repairs would be more than 60% of the cost of a replacement device, or of the part being replaced.

Records submitted are from a prosthetist/orthotist, documentation was not submitted from physician.
Information contained directly in the contemporaneous medical record is the source required to justify payment except as noted elsewhere for prescriptions and Certificates of Medical Necessity (CMNs). The medical record is not limited to physician'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.

Lower Limb Prostheses (HCPCS L5981) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D DME MAC Medical Review Department is conducting a service specific review of HCPCS code L5981. The quarterly edit effectiveness results from December 2013 through March 2014 are as follows:

The L5981 review involved 28 claims, of which 26 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 93%.

Top Denial Reasons

- Documentation does not support the functional level billed on the claim
- Documentation did not support the beneficiary will reach or maintain a defined functional state within a reasonable period of time.
- Documentation does not support the medical necessity for the items requested
- Records submitted are from a prosthetist/orthotist, documentation was not submitted from a physician

Going Forward

Based on the results of this review, Noridian will continue with the Prepayment Service Specific Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Lower Limb Prostheses Local Coverage Determination (LCD) L11453 and Policy Article A25367.

Suppliers can also review a specific policy Documentation Checklist for Lower Limb Prostheses on the Noridian website.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations.

Information about probe/error validation reviews may be found in chapter 3 of CMS Publication 100-8 Program Integrity Manual (PIM).

Policy Education

Documentation does not support the functional level billed on the claim.
A determination of the medical necessity for certain components/additions to the prosthesis is based on the beneficiary's potential functional abilities. Potential functional ability is based on the reasonable expectations of the prosthetist, and treating physician, considering factors including, but not limited to the following

- The beneficiary's past history (including prior prosthetic use if applicable); and
- The beneficiary's current condition including the status of the residual limb and the nature of other medical problems; and
- The beneficiary's desire to ambulate.

The records must document the beneficiary's current functional capabilities and his/her expected functional potential, including an explanation for the difference, if that is the case. It is recognized, within the functional classification hierarchy, that bilateral amputees often cannot be strictly bound by functional level classifications.

Documentation did not support the beneficiary will reach or maintain a defined functional state within a reasonable period of time.
Lower limb prosthesis is covered when the beneficiary:

- Will reach or maintain a defined functional state within a reasonable period of time
- Is motivated to ambulate.

Documentation does not support the medical necessity for the items requested.
For any item to be covered by Medicare, it must:

- Be eligible for a defined Medicare benefit category
- Be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and
- Meet all other applicable Medicare statutory and regulatory requirements.

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

Records submitted are from a Prosthetist/Orthotist, documentation was not submitted from a physician.
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 physician'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.

Orthotics & Prosthetics Month: July 2014

Join Noridian for a month dedicated to Orthotics and Prosthetics education. In addition to a variety of O & P policy-specific web-based workshops scheduled throughout the month of July, we will also be hosting some special O & P events. To register for these events, go to the Schedule of Events page under Training/Events.

O & P Month Events

- Spinal Orthosis web-based workshop: Tuesday, July 1 at 3 p.m. CT
- AFO/KAFO Online Q & A Session: Monday, July 7 @ 3 p.m. CT
- External Breast Prosthesis web-based workshop: Wednesday, July 9 at 1 p.m. CT
- O & P ACT: Tuesday, July 15 at 3 p.m. CT

- Lower Limb Prosthesis web-based workshop: Wednesday, July 23 at 11 a.m. CT
- & P Live Online Q & A Session: Monday, July 28 @ 3 p.m. CT
- Therapeutic Shoes for Persons with Diabetes web-based workshop: Tuesday, July 29 at 3 p.m. CT

Noridian looks forward to your participation.

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 2013 through March 2014 are as follows:

The L0631 review involved 965 claims, of which 833 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 87%.

The L0637 review involved 668 claims, of which 588 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 87%.

Top Denial Reasons

- No documentation was received in response to the additional documentation request (ADR)
- Coverage criteria indicated in Spinal Orthoses Local Coverage Determination (LCD) (L11459) was not met
- Proof of delivery provided was invalid
- DME item does not have the required coding verification or it is not listed in the Product Classification List of the Pricing, Data Analysis, and Coding (PDAC) website

Going Forward

Based on the results of this review, Noridian will continue with the Prepayment Service Specific Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Spinal Orthoses LCD L11459 and Policy Article A23846.

Suppliers can also review a specific policy Documentation Checklist for Spinal Orthoses on the Noridian website.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations.

Information about probe/error validation reviews may be found in Chapter three of CMS Publication 100-8, Program Integrity Manual (PIM).

Policy Education

No documentation was received in response to the additional documentation request (ADR). Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R §424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide records may not only be a claim denial but also referral to the National Supplier Clearinghouse (NSC).

Please also remember documentation must be submitted to our office within 45 days from the date on the ADR letter. Failure to provide the requested documentation within 45 days may result in a partial or complete denial of the claim. Submission information can be found on the ADR letters or under the claims section on our website.

Coverage criteria indicated in Spinal Orthoses LCD (L11459) was not met.
A thoracic-lumbar-sacral orthosis (L0628-L0640) is covered when it is ordered for one of the following indications:

- To reduce pain by restricting mobility of the trunk; or
- To facilitate healing following an injury to the spine or related soft tissues; or
- To facilitate healing following a surgical procedure on the spine or related soft tissue; or
- To otherwise support weak spinal muscles and/or a deformed spine.

Proof of delivery (POD) provided was invalid.
Suppliers are required to maintain POD documentation in their files. (PIM 4.26, 5.8) 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 slip. The POD record 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 and date of signature

The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. In instances where the item is delivered directly by the supplier, the date the beneficiary received the DMEPOS item 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 record must contain the information specified above.

Method 3–Delivery to Nursing Facility on Behalf of a Beneficiary
When a supplier delivers items directly to a nursing facility, the documentation described for Method 1 (see above) is required.

When a delivery service or mail order is used to deliver the item to a nursing facility, the documentation described for Method 2 (see above) is required.

Regardless the methods of delivery, for those beneficiaries that are residents of a nursing facility, information from the nursing facility showing that the item(s) delivered for the beneficiary's use were actually provided to and used by the beneficiary must be available upon request.

DME item does not have the required coding verification or it is not listed in the Product Classification List of the Pricing, Data Analysis, and Coding (PDAC) website.
Manufacturers and suppliers are reminded that a number of items require coding verification review by the PDAC contractor. As noted in the LCD and related Policy Articles that include these codes, claims for these HCPCS codes will be denied if the products requiring coding verification review are not listed on the PDAC Product Classification List. Coding decisions are updated frequently. Suppliers should refer to the Product Classification List often to ensure DMEPOS items billed have been coded by the PDAC. The Product Classification List is located on Durable Medical Equipment Coding System (DMECS) which is located on the PDAC website.

Effective for claims with dates of service on or after July 1, 2010, the only products that may be billed using codes, L0450, L0454-L0472, L0488-L0492, L0625-L0628, L0630, L0631, L0633, L0635, L0637, and L0639 for prefabricated orthoses are those that are specified in the PDAC contractor website.

Effective for claims with dates of service on or after July 1, 2010, prefabricated spinal orthoses and spinal orthoses that are custom fabricated by a manufacturer/central fabrication facility which has not received coding verification review from the PDAC must be billed with code A9270.

Suppliers should contact the PDAC for guidance on the correct coding of these items.

OXYGEN

Dear Physician – Home Oxygen Initial Qualification Testing

April 2014

Dear Physician,

Home use of oxygen and oxygen equipment is eligible for Medicare reimbursement only when beneficiary meets all of the requirements set out in the Oxygen and Oxygen Equipment Local Coverage Determination (LCD) and related Policy Article (PA). This article reviews the blood oxygen testing requirements. Refer to the LCD and PA for information on additional payment criteria.

Timing of Physician Visit and Testing

For initial qualification testing scenarios, the beneficiary must be seen and evaluated by the treating physician within 30 days prior to the date of Initial Certification. In addition, the qualification testing must be performed within the 30 days before the initial date of service. As described earlier, for oxygen initially prescribed at the time of hospital discharge, testing must be performed within the 2 days prior to discharge. This 2-day prior to discharge rule does not apply to discharges from nursing facilities.

Qualifying Test Results

The results of a blood oxygen study that has been ordered and evaluated by the attending physician are used as one of the criteria for determining Medicare reimbursement.

Medicare classifies qualification results into three groups, regardless the test methodology used. The following table summarizes the qualifying results for each group.

	ABG (mm HG)	Oximetry (% Sat)	Notes
Group I	=55	=88	-
Group II	56-59	89	+ Additional disease criteria
Group III	>59	>89	Presumed noncovered

Qualification Tests

Blood oxygen levels are used to assess the beneficiary's degree of hypoxemia. Blood oxygen levels may be determined by either of two different test methods:

- Arterial blood gas (ABG) measurement; or,
- Pulse oximetry.

Arterial blood gas measurements are more accurate and therefore are the preferred measurement method. When both ABGs and oximetry are performed on the same day, the ABG value must be used for reimbursement qualification.

Blood oxygen values may be obtained using a variety of techniques. The LCD describes the following as acceptable oximetry testing methods:

- At rest and awake - often referred to as "spot" oximetry
- During exercise – requires a series of 3 tests done during a single testing session:
  - At rest, off oxygen - showing a non-qualifying result
  - Exercising, off oxygen – showing a qualifying result
  - Exercising, on oxygen – showing improvement in test results obtained while exercising off of oxygen
- During sleep
  - Overnight sleep oximetry
    - May be done in hospital or at home. Refer to the LCD for detailed information about home overnight sleep oximetry.
  - Titration Polysomnogram
    - Must be used for beneficiaries with concurrent (OSA) in order to establish that the beneficiary is in the "chronic stable state"
    - Refer to the Positive Airway Pressure Devices LCD for information about testing for OSA

Note: The overnight sleep oximetry and the titration polysomnogram referenced above are not the same test as home sleep testing used for the diagnosis of Obstructive Sleep Apnea.

Chronic Stable State (CSS)

All qualification testing must be performed while the beneficiary is in the CSS. CSS requires that all of the following be met:

- [O]ther forms of treatment (e.g., medical and physical therapy directed at secretions, bronchospasm and infection) have been tried, have not been sufficiently successful, and oxygen therapy is still required.
- Each patient must receive optimum therapy before long-term home oxygen therapy is ordered.
- It is expected that virtually all patients who qualify for home oxygen coverage for the first time under these guidelines have recently been discharged from a hospital where they submitted to arterial blood gas tests. If more than one arterial blood gas test is performed during the patient's hospital stay, the test result obtained closest to, but no earlier than two days prior to the hospital discharge date, is required as evidence of the need for home oxygen therapy. (Note: this is the only exception to the CSS requirement.)
- For those patients whose initial oxygen prescription did not originate during a hospital stay, blood gas studies should be done while the patient is in the chronic stable state, i.e., not during a period of an acute illness or an exacerbation of their underlying disease.

Please refer to the Local Coverage Determination (LCD) on Oxygen, the related Policy Article and the Supplier Manual for additional information about coverage, billing and documentation requirements. Thank you for your assistance in reducing the CERT error rate.

Sincerely,

Paul J. Hughes, M.D.
Medical Director, DME MAC, Jurisdiction A
NHIC, Corp.

Stacey V. Brennan, M.D., FAAFP
Medical Director, DME MAC, Jurisdiction B
National Government Services

Robert D. Hoover, Jr., MD, MPH, FACP
Medical Director, DME MAC, Jurisdiction C
CGS Administrators, LLC

Eileen M. Moynihan, MD, FACP, FACR
Medical Director, DME MAC, Jurisdiction D
Noridian Healthcare Solutions

Oxygen (HCPCS E1390) Quarterly Results of Documentation Compliance Review Results

The Jurisdiction D DME MAC Medical Review Department is conducting a documentation compliance review of HCPCS code E1390, oxygen concentrator. A documentation compliance review is a nonclinical, technical review verifying that submitted documentation meets payment requirements according to Local Coverage Determinations (LCD) for that DMEPOS item. The quarterly edit effectiveness, from December 1, 2013, through February 28, 2014, resulted in an overall error rate of 30%.

Top Denial Reasons

Requested documentation was not received by the contractor within the allotted timeframe.

- There was no proof of delivery (POD) submitted or the POD was invalid.
- There was no documentation to support the beneficiary had been seen and evaluated by the treating physician within 30 days prior to the date of the initial Certificate of Medical Necessity (CMN).
- The documentation provided did not contain the beneficiary's most recent arterial blood gas P02 and/or oxygen saturation test.

Going Forward

Based on the results of this review, Noridian will continue with the Documentation Compliance Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Oxygen Local Coverage Determination (LCD) L11457 and Policy Article A33677.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations. Educational training and events are located at https://www.noridianmedicare.com/dme/train/.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM), Chapter 3 located at http://www.cms.gov/manuals/downloads/pim83c03.pdf.

Policy Education

Documentation not received within the correct time frame.
Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R §424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide records may not only be a claim denial but also referral to the NSC. 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 patient's medical records will reflect the need for the care provided. The patient's medical records include the physician'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.

There was no proof of delivery (POD) submitted or the POD was invalid.
CMS Manual System, Pub. 100-08, Medicare Program Integrity Manual, Chapter 4 and 5, Section 4.26 and 5.8 states that

> Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and 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 durable medical equipment 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 OIG for imposition of Civil Monetary Penalties or other administrative sanctions.

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

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 slip. The POD record 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 and date of signature

The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. 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 record must contain the information specified above.

Method 3 – Delivery to Nursing Facility on Behalf of a Beneficiary
When a supplier delivers items directly to a nursing facility, the documentation described for Method 1 (see above) is required. When a delivery service or mail order is used to deliver the item to a nursing facility, the documentation described for Method 2 (see above) is required.

Regardless the method of delivery, for those beneficiaries that are residents of a nursing facility, information from the nursing facility showing that the item(s) delivered for the beneficiary's use were actually provided to and used by the beneficiary must be available upon request.

There was no documentation to support the beneficiary had been seen and evaluated by the treating physician within 30 days prior to the date of the initial Certificate of Medical Necessity (CMN).
LCD L11457 Testing and Visit Requirements states that an evaluation by the treating physician, within 30 days prior to initial certification, is required when the CMN is initiated in the following instances:

- With the first claim for home oxygen, (even if the beneficiary was on oxygen prior to Medicare eligibility or oxygen was initially covered by a Medicare HMO.)
- During the first 36 months of the rental period, when there has been a change in the beneficiary's condition that has caused a break in medical necessity of at least 60 days plus whatever days remain in the rental month during which the need for oxygen ended. (Please refer to the Policy Article NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES for additional information.)

The documentation provided did not contain the beneficiary's most recent arterial blood gas P02 and/or oxygen saturation test.
LCD L11457 indicates the qualifying blood gas study must be one that complies with the Fiscal Intermediary, Local Carrier, or A/B Medicare Administrative Contractor (MAC) policy on the standards for conducting the test and is covered under Medicare Part A or Part B. This includes a requirement that the test be performed by a provider who is qualified to bill Medicare for the test – i.e., a Part A provider, a laboratory, an Independent Diagnostic Testing Facility (IDTF), or a physician. A supplier is not considered a qualified provider or a qualified laboratory for purposes of this policy. Blood gas studies performed by a supplier are not acceptable. In addition, the qualifying blood gas study may not be paid for by any supplier. These prohibitions do not extend to blood gas studies performed by a hospital certified to do such tests.

The qualifying blood gas study may be performed while the beneficiary is on oxygen as long as the reported blood gas values meet the Group I or Group II criteria.

When both arterial blood gas (ABG) and oximetry tests have been performed on the same day under the same conditions (i.e., at rest/awake, during exercise, or during sleep), the ABG result will be used to determine if the coverage criteria were met. If an ABG test done at rest and awake is nonqualifying, but either an exercise or sleep oximetry test on the same day is qualifying, the exercise or oximetry test result will determine coverage.

All oxygen qualification testing must be performed in-person by a physician or other medical professional qualified to conduct oximetry testing. With the exception of overnight oximetry (see below), unsupervised or remotely supervised home testing does not qualify as a valid test for purposes of Medicare reimbursement of home oxygen and oxygen equipment.

Claims for oxygen equipment and supplies for beneficiaries who do not meet the coverage requirements for home oxygen therapy will be denied as not reasonable and necessary.

Oxygen and Oxygen Equipment (HCPCS E0439 and E0434) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D DME MAC Medical Review Department is conducting a service specific review of HCPCS code E0439 and E0434. The quarterly edit effectiveness results from January 2014 through April 2014 are as follows:

- The E0439 review involved 267 claims, of which 185 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 68%.
- The E0434 review involved 93 claims, of which 76 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 74%.

Top Denial Reasons

- The Proof of Delivery (POD) submitted is invalid
- No documentation was received in response to the Additional Documentation Request (ADR) letter
- The date of the physician's signature on the CMN/order is after the date of service on the claim and a dispensing order was not provided
- A blood gas study was not provided
- The Certificate of Medical Necessity submitted is incomplete or invalid

Going Forward

Based on the results of this review, Noridian will continue with the Prepayment Service Specific Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Oxygen and Oxygen Equipment Local Coverage Determination (LCD) L11457 and Policy Article A33677

Suppliers can also review specific policy resources for Oxygen and Oxygen Equipment on the Noridian website. There, you will find information related to proper documentation requirements including a physician letter, documentation checklists, FAQs, and a presentation used during web-based workshops.

Suppliers can also review a specific policy Documentation Checklist for Oxygen and Oxygen Equipment on the Noridian website.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM), Chapter 3.

Policy Education

The Proof of Delivery (POD) submitted is invalid.

PROOF OF DELIVERY (PIM 4.26, 5.8)

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and 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 OIG for imposition of Civil Monetary Penalties or other administrative sanctions.

Suppliers are required to maintain POD documentation in their files. There are two methods of delivery:

- Delivery directly to the beneficiary or authorized representative
- Delivery via shipping or delivery service

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 slip. The POD record 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 and date of signature

The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. 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 record must contain the information specified above.

No documentation was received in response to the Additional Documentation Request (ADR) letter.
Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R 424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide records may not only be a claim denial but also referral to the NSC. The supplier standards can be found in 424 CFR Section 424.57(c).

The date of the physician's signature on the CMN/order is after the date of service on the claim and a dispensing order was not provided.
All items billed to Medicare require a prescription. An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request.

Dispensing Orders (PIM 5.2.2)
Equipment and supplies may be delivered upon receipt of a dispensing order except for those items that require a written order prior to delivery. 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 Physician's name
- Date of the order and the start date, if the start date is different from the date of the order
- Physician 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 physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

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

The dispensing order must be available upon request.

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

A blood gas study was not provided.
The blood gas study refers to either an oximetry test or an arterial blood gas test.

Home oxygen will be considered reasonable and necessary if the beneficiary had a qualifying blood gas study which meets criteria stated below, and

The qualifying blood gas study was performed by a physician or by a qualified provider or supplier of laboratory services, and

The qualifying blood gas study was obtained under the following conditions:

- If the qualifying blood gas study is performed during an inpatient hospital stay, the reported test must be the one obtained closest to, but no earlier than 2 days prior to the hospital discharge date, or
- If the qualifying blood gas study is not performed during an inpatient hospital stay, the reported test must be performed while the beneficiary is in a chronic stable state – i.e., not during a period of acute illness or an exacerbation of their underlying disease

Group I criteria include any of the following:

- An arterial PO 2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent taken at rest (awake), or
- An arterial PO 2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, for at least 5 minutes taken during sleep for a beneficiary who demonstrates an arterial PO 2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent while awake, or
- A decrease in arterial PO 2 more than 10 mm Hg, or a decrease in arterial oxygen saturation more than 5 percent from baseline saturation, for at least 5 minutes taken during sleep associated with symptoms (e.g., impairment of cognitive processes and [nocturnal restlessness or insomnia]) or signs (e.g., cor pulmonale, "P" pulmonale on EKG, documented pulmonary hypertension and erythrocytosis) reasonably attributable to hypoxemia, or
- An arterial PO 2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken during exercise for a beneficiary who demonstrates an arterial PO 2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent during the day while at rest. In this case, oxygen is provided for during exercise if it is documented that the use of oxygen improves the hypoxemia that was demonstrated during exercise when the beneficiary was breathing room air.

Initial coverage for beneficiaries meeting Group I criteria is limited to 12 months or the physician-specified length of need, whichever is shorter. (Refer to the Certification section for information on recertification.)

Group II criteria include the presence of

- An arterial PO 2 of 56-59 mm Hg or an arterial blood oxygen saturation of 89 percent at rest (awake), during sleep for at least 5 minutes, or during exercise (as described under Group I criteria), and
- Any of the following:

- Dependent edema suggesting congestive heart failure, or
- Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF), or
- Erythrocythemia with a hematocrit greater than 56 percent.

Initial coverage for beneficiaries meeting Group II criteria is limited to 3 months or the physician specified length of need, whichever is shorter. (Refer to the Certification section for information on recertification.)

Group III includes beneficiaries with arterial PO 2 levels at or above 60 mm Hg or arterial blood oxygen saturations at or above 90 percent. For these beneficiaries there is a rebuttable presumption of non-coverage.

The Certificate of Medical Necessity submitted is incomplete or invalid.
A Certificate of Medical Necessity (CMN) or a DME Information Form (DIF) is a form required to help document the medical necessity and other coverage criteria for selected durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items. CMNs contain sections A through D. Sections A and C are completed by the supplier and Sections B and D are completed by the physician.

For certain items or services billed to a DME MAC, the supplier must receive a signed CMN from the treating physician or a signed DIF from the supplier. A supplier must have a faxed, photocopied, original signed order, or an electronic CMN or DIF in their records before they can submit a claim for payment to Medicare. CMNs or DIFs have a DME MAC form number, e.g., 01, 02, 03 and a revision number, e.g., .01, .02. Some forms also have an alpha suffix, e.g., A, B, C.

All CMNs and DIFs have a CMS form number in addition to the DME MAC form number. The CMS form number is in the bottom left corner of the form. CMNs and DIFs are referred to by their CMS form numbers. DME MAC form numbers identify the CMN on electronic claims submitted to the DME MAC. For example, CMS Form 484 serves as the CMN for oxygen.

A completed CMN or DIF must be maintained by the supplier and be available to the DME MAC on request. When hardcopy CMNs or DIFs are submitted to the DME MAC, the supplier must include a copy of only the front side. When CMNs are submitted electronically, information from sections A and B are required.

The "Initial Date" found in Section A of the CMN should be either the specific date that the physician gives as the start of the medical necessity or if the physician does not give a specific start date, the "Initial Date" would be the date of the order.

The "Signature Date" is the date the physician signed and dated Section D of the CMN. This date might not be the same as the "Initial Date", since the "Signature Date" must indicate when the physician signed Section D of the CMN. Medicare requires a legible identifier for services provided/ordered. The method used, e.g., hand written or electronic, to sign an order or other medical record documentation for medical review purposes in determining coverage is not a relevant factor. Rather, an indication of a signature in some form needs to be present.

Signature and date stamps are not acceptable for use on CMNs and DIFs. Hand written, facsimiles of original written and electronic signatures and dates will only be accepted by the DME MACs.

The "Delivery Date/Date of Service" on the claim must not precede the "Initial Date" on the CMN or DIF or the start date on the written order. To ensure that an item is still medically necessary, the delivery date/date of service must be within three months from the "Initial Date" of the CMN or DIF or three months from the date of the physician's signature.

The supplier must be able to produce the CMN or DIF and if requested by the DME MACs and ZPICs, produce information to substantiate the information on the CMN or DIF.

Dear Physician Letter – PECOS

March 2014

Dear Physician:

The Centers for Medicare and Medicaid Services (CMS) is expanding claim edits for ordering/referring providers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). Effective January 1, 2014, specific edits were implemented that will prevent DMEPOS suppliers from receiving payment from Medicare for items that you have prescribed if you do not have a current enrollment in the Medicare Provider Enrollment, Chain and Ownership System (PECOS). Please help your Medicare patients to continue to be able to receive services you order by promptly enrolling in PECOS, or by updating your existing Medicare enrollment information if you have not done so recently.

For any DMEPOS item to qualify for coverage by Medicare it must be ordered by a physician or a practitioner who is eligible to order such item. To be eligible:

- Physicians or practitioners must be enrolled in PECOS and
- Must be registered in the system and
- Have a specialty that is eligible to order DMEPOS items for Medicare beneficiaries.

The provider specialties who can order DMEPOS items include:

- Doctor of Medicine or Osteopathy
- Doctor of Dental Medicine or Dental Surgery
- Doctor of Podiatric Medicine
- Physician Assistant
- Certified Clinical Nurse Specialist
- Nurse Practitioner
- Doctor of Optometry

In order to continue to order DMEPOS for Medicare beneficiaries, you will have to enroll in the Medicare program or "revalidate" your Medicare enrollment information. You may do so by:

- Using Internet-based PECOS, or
- By filling out the appropriate Medicare provider enrollment application(s) and mailing it, along with any required information, to the local Medicare carrier or A/B MAC, who will enter your information into PECOS and process your enrollment application.

To confirm if you have a current enrollment record in Medicare, contact your designated enrollment contractor or you can go on-line, using Internet-based PECOS, to view your enrollment record. While viewing your PECOS record, take time to ensure that your NPI and name are listed correctly. Update your enrollment record with any necessary corrections.

We remind you that your enrollment in PECOS is required for your patients to receive their Medicare covered benefits for DMEPOS items. For additional information, consult with your Local A/B Medicare Administrative Contractor.

Sincerely,

Paul J. Hughes, M.D.
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NHIC, Corp.

Stacey V. Brennan, M.D., FAAFP
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Group One Pressure Reducing Support Surfaces (HCPCS E0181 and E0185) Quarterly Results of Service Specific Prepayment Review of Claims

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 2013 through January 2014 are as follows:

The E0181 review involved 353 claims, of which 234 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 68%.

The E0185 review involved 265 claims, of which 184 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 66%.

Top Denial Reasons

- No documentation was received in response to Additional Documentation Letters (ADR).
- Medical records did not support coverage criteria.
- Detailed written order was signed and dated after the date of delivery.
- The proof of delivery (POD) was invalid for HCPCS Code E0181.
- Medical records did not support coverage criteria for HCPCS code E0185.

Going Forward

Based on the results of this review, Noridian will continue with the Prepayment Widespread Review.

Education Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Group 1 Pressure Reducing Support Surfaces Local Coverage Determination (LCD) L11587 and Policy Article A33678.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations. Educational training and events are located at https://www.noridianmedicare.com/dme/train/.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM), Chapter 3 located at http://www.cms.gov/manuals/downloads/pim83c03.pdf.

Policy Education

No documentation was received in response to Additional Documentation Letters (ADR).
Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R §424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide records may not only be a claim denial but also referral to the NSC. 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 patient's medical records will reflect the need for the care provided. The patient's medical records include the physician'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.

Medical records did not support coverage criteria.
A group 1 mattress overlay or mattress is covered if one of the following three criteria are met:

- The patient is completely immobile-i.e., patient cannot make changes in body position without assistance, or
- The patient has limited mobility- i.e., patient cannot independently make changes in body position significant enough to alleviate pressure and at least one of conditions A-D below, or
- The patient has any stage pressure ulcer on the trunk or pelvis and at least one of the conditions A-D.

Detailed written order was signed and dated after the date of delivery.
A detailed written order prior to delivery (WOPD) is required for support surfaces. The supplier must have received a WOPD that has been both signed and dated by the treating physician and meets the requirements for a DWO before dispensing the item.

The proof of delivery (POD) was invalid for HCPCS code E0181.
Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and 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 durable medical equipment 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 OIG for imposition of Civil Monetary Penalties or other administrative sanctions.

Suppliers are required to maintain 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

Medical records did not support coverage criteria for HCPCS code E0185.

Conditions for criteria 2 and 3 (in each case the medical record must document the severity of the condition sufficiently to demonstrate the medical necessity for a pressure reducing support surface):

- Impaired nutritional status.
- Fecal or urinary incontinence
- Altered sensory perception
- Compromised circulatory status

Pressure Reducing Support Surfaces Group Two (HCPCS E0277) Quarterly Results of Widespread Prepayment Review Results

The Jurisdiction D, DME MAC, Medical Review Department is conducting a widespread complex review of HCPCS code E0277. The quarterly edit effectiveness results from October 2013 through January 2014 are as follows:

The E0277 review involved 106 claims, of which 74 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 73%.

Top Denial Reasons

- Documentation was not received within the allotted time frame.
- Medical records did not support coverage criteria.
- Detailed written order was signed and dated after the date of delivery.
- The proof of delivery was invalid.

Going Forward

Based on the results of this review, Noridian will continue with the Prepayment Widespread Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Group 2 Pressure Reducing Support Surfaces Local Coverage Determination (LCD) L11579 and Policy Article A35422.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations. Educational training and events are located at https://www.noridianmedicare.com/dme/train/.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM), Chapter 3 located at http://www.cms.gov/manuals/downloads/pim83c03.pdf.

Policy Education

Documentation not received within the allotted time frame.
Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R §424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide records may not only be a claim denial but also referral to the NSC. 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 patient's medical records will reflect the need for the care provided. The patient's medical records include the physician'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.

Medical records did not support coverage criteria.
A group 2 support surface is covered if the beneficiary meets at least one of the following:

- The beneficiary has multiple stage II pressure ulcers located on the trunk or pelvis (ICD-9 707.02-707.05) which have failed to improve over the past month, during which time the beneficiary has been on a comprehensive ulcer treatment program including each of the following:
  - Use of an appropriate group 1 support surface, and
  - Regular assessment by a nurse, physician, or other licensed healthcare practitioner, and
  - Appropriate turning and positioning, and
  - Appropriate wound care, and
  - Appropriate management of moisture/incontinence, and
  - Nutritional assessment and intervention consistent with the overall plan of care
- The beneficiary has large or multiple stage III or IV pressure ulcer(s) on the trunk or pelvis (ICD-9 707.02-707.05): The beneficiary had a myocutaneous flap or skin graft for a pressure ulcer on the trunk or pelvis within the past 60 days (ICD-9 707.02 -707.05), and has been on a group 2 or 3 support surface immediately prior to discharge from a hospital or nursing facility within the past 30 days.

Detailed written order was signed and dated after the date of delivery.
A detailed written order prior to delivery (WOPD) is required for support surfaces. The supplier must have received a WOPD that has been both signed and dated by the treating physician and meets the requirements for a DWO before dispensing the item.

The proof of delivery (POD) was invalid.
Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and 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 durable medical equipment 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 OIG for imposition of Civil Monetary Penalties or other administrative sanctions. Suppliers are required to maintain 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

REFILLS

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

REIMBURSEMENT

DMEPOS Fee Schedule – 2014 April Update

MLN Matters® Number: MM8645
Related Change Request (CR) #: CR 8645
Related CR Release Date: March 11, 2014
Effective Date: April 1, 2014
Related CR Transmittal #: R2902CP
Implementation: April 7, 2014

Provider Types Affected

This MLN Matters® Article is intended for physicians, providers, and suppliers submitting claims to Part A/B Medicare Administrative Contractors (MACs), Hospice and Home Health (HHHMACs), and Durable Medical Equipment MACs (DME MACs) for DMEPOS items or services paid under the DMEPOS fee schedule.

Provider Action Needed

The Centers for Medicare & Medicaid Services (CMS) issued Change Request (CR) 8645 that alerts providers and suppliers that CMS issued instructions updating the DMEPOS fee schedule payment amounts. Be sure your billing personnel are aware of these changes.

Background

CMS updates DMEPOS fee schedules on a quarterly basis, when necessary, in order to implement fee schedule amounts for new and existing codes, as applicable, and apply changes in payment policies. The quarterly update process for the DMEPOS fee schedule is located in the "Medicare Claims Processing Manual", Chapter 23, Section 60, which is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf on the CMS website.

Key Points of CR8645

Splints, Casts and Certain Intraocular Lenses (IOLs)

The following are the HCPCS codes for splints, casts, and certain IOLs added to the DMEPOS fee schedule file:

- A4565, Q4001, Q4002, Q4003, Q4004, Q4005, Q4006, Q4007, Q4008, Q4009, Q4010, Q4011, Q4012, Q4013, Q4014, Q4015, Q4016, Q4017, Q4018, Q4019, Q4020, Q4021, Q4022, Q4023, Q4024, Q4025, Q4026, Q4027, Q4028, Q4029, Q4030, Q4031, Q4032, Q4033, Q4034, Q4035, Q4036, Q4037, Q4038, Q4039, Q4040, Q4041, Q4042, Q4043, Q4044, Q4045, Q4046, Q4047, Q4048, Q4049, V2630, V2631, V2632.

As written in the MLN Matters® Article MM8523 (*Change to the Reasonable Charge Update for 2014 for Splints, Casts, and Certain Intraocular Lenses*) at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8523.pdf, for dates of service on or after April 1, 2014, payment for splints, casts and IOLs inserted in a physician's office will be made using national fee schedule amounts.

For splints and casts, codes A4565 and Q4001-Q4049 are used when supplies are indicated for cast and splint purposes and:

- Payment is in addition to the payment made under the physician fee schedule for the procedure for applying the splint or cast. Per the regulations at 42 CFR Section 414.106, national fee schedule amounts for 2014 for these items were developed using 2013 reasonable charges updated by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June 2013, which is 1.8 percent; and
- For each year subsequent to 2014, the fee schedule amounts will be updated by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year, reduced by the productivity adjustment as described in Section 1886(b)(3)(B)(xi)(II) of the Social Security Act.

For intraocular lenses (codes V2630, V2631 and V2632), payment under the DMEPOS fee schedule is only made for lenses implanted in a physician's office:

- For payment of IOLs inserted in a physician's office furnished from April 1, 2014, through December 31, 2014, regulations at 42 CFR Section 414.108 require national fee schedules be established based on the Calendar Year (CY) 2012 national average allowed charges updated by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 24-month period ending with June 2013, which is 3.5 percent;
- For each year subsequent to 2014, the fee schedule amounts will be updated by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year, adjusted by the productivity adjustment as described in Section 1886(b)(3)(B)(xi)(II) of the Act; and
- For IOL codes V2630 and V2631, national fee schedules amounts have been established using the fee schedule amounts for comparable code V2632 since there is insufficient allowed charge data for use in calculating the fee schedule amounts.

Subject to coinsurance and deductible rules, Medicare payment for these items is to be equal to the lower of the actual charge for the item or the amount determined under the applicable fee schedule payment methodology.

Payment Category Reclassification of Certain DME

Effective for dates of service on or after April 1, 2014, certain HCPCS codes for DME are reclassified from the payment category for inexpensive or other routinely purchased DME to the payment category for capped rental items, to align with the regulatory definition of routinely purchased equipment found at 42 CFR Section 414.220(a)(2).

These changes were determined through rulemaking (CMS-1526-F) and as written in the MLN Matters® Article MM8566 titled Rescind/Replace Reclassification of Certain Durable Medical Equipment from the Inexpensive and Routinely Purchased Payment Category to the Capped Rental Payment Category, available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network MLN/MLNMattersArticles/Downloads/MM8566.pdf on the CMS website.

As part of the April 2014 update to the DMEPOS fee schedule, the methodology used to calculate fee schedule amounts for capped rental items has been used to establish new fee schedule amounts for the following HCPCS codes:

- A4639, A7025, E0117, E0144, E0198, E0300, E0620, E0656, E0657, E0740, E0762, E0764, E0849, E0855, E0856, E0984, E0986, E1002, E1003, E1004, E1005, E1006, E1007, E1008, E1010, E1014, E1029, E1030, E1161, E1232, E1233, E1234, E1235, E1236, E1237, E1238, E1700, E2227, E2310, E2311, E2312, E2313, E2321, E2322, E2325, E2326, E2327, E2328, E2329, E2330, E2351, E2373, E2374, E2376, E2377, E2378, E2500, E2502, E2504, E2506, E2508, E2510, K0607, K0730.

Consistent with the capped rental payment methodology, only Rental Amounts (RR) will appear on the fee schedule file for the above codes, effective April 1, 2014, and:

- The HCPCS codes transitioning to the capped rental payment category with corresponding KC, KF or KE modifiers will continue to have rental amounts associated with these modifiers on the fee schedule file;
- The capped rental fee schedule amount is calculated based on ten percent of the base year purchase price increased by the covered item update;
- This is the fee schedule amount for rental months one through three. Beginning with the fourth month, the fee schedule amount is equal to 75 percent of the fee schedule amount paid in each of the first three rental months; and
- All of the payment rules for capped rental items, including guidelines regarding continuous use and transfer of title to the beneficiary following 13 months of continuous use, apply to these codes, effective for claims with dates of service on or after April 1, 2014.

Also effective April 1, 2014, MACs will process and pay claims for capped rental wheelchair accessories on a lump sum purchase basis when used with complex rehabilitative power wheelchairs (wheelchair base codes K0835 – K0864). In this case, the supplier must give the beneficiary the option of purchasing these accessories at the time they are furnished. The purchase fee schedule amount for capped rental accessories furnished in this manner is equal to the rental fee (for months one through three) multiplied by ten. If the beneficiary declines the purchase option, the supplier must furnish the accessory on a rental basis and payment will be made in accordance with the capped rental payment rules.

Specific Coding and Pricing Issues

As part of this update, effective April 1, 2014, HCPCS code L8680 is not included on the 2014 DMEPOS fee schedule file and the coverage indicator is revised to "I" to show it is not payable by Medicare. Note that:

- For neurostimulator devices, HCPCS code L8680 is no longer separately billable for Medicare because payment for electrodes has been incorporated in CPT code 63650 *Percutaneous implantation of neurostimulator electrode array, epidural.*
- CMS established non-facility practice expense inputs for CPT code 63650 in the Medicare Physician Fee Schedule Final Rule (published November 27, 2013). As a result, practitioners should not report electrode(s) using code L8680 in conjunction with a lead implantation procedure furnished in any setting for Medicare.

- Also, this change for code L8680 will be available on the HCPCS Quarterly Update website at http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS_Quarterly_Update.html on the CMS website.

Additional Information

The official instruction, CR8645, issued to your MAC regarding this change is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2902CP.pdf on the CMS website.

NACHA Operating Rules Implementation for Health Care EFT – Revised

MLN Matters® Number: MM8629 Revised
Related CR Release Date: April 9, 2014
Related CR Transmittal #: R13670TN
Related Change Request (CR) #: CR 8629
Effective Date: July 1, 2014
Implementation Date: July 7, 2014

This article was revised on April 10, 2014, to reflect changes made to CR8629 on April 9. In the article, the transmittal number, CR release date, and the Web address for the CR are revised. All other information is unchanged.

Provider Types Affected

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

What You Need to Know

This article is based on CR8629 which informs MACs that they must comply with National Automated Clearinghouse Association (NACHA) Operating Rules that are applicable to initiators of health care payments. CR8629 requires MACs to modify or change data elements currently inputted into payment information that is transmitted through the Automated Clearinghouse (ACH) Electronic Funds Transfer (EFT) Network with electronic health care payments.

Physicians, other providers, and suppliers should be aware that, consequently, the payment information that a provider receives or that is transmitted from a provider's financial institution regarding the health care EFT payment may change as per these requirements. Specifically, the Company Entry Description that is reported or transmitted to a provider from its financial institution may change in terms of content or length.

Providers are urged to contact their financial institutions directly in order to understand the form in which payment information will be transmitted or reported on a per payment basis as a result of CR8629. We suggest that providers should subsequently take steps to assure that the payment information that is changed as a result of CR8629 can be accommodated by your accounting processes and systems.

Background

In support of Health Insurance Portability & Accountability Act of 1996 (HIPAA) Operating Rules for health care EFT and remittance advice transactions adopted by HHS, NACHA – The Electronic Payments Association has adopted its own operating rules that apply to ACH transactions that are health care payments from health plans to providers. NACHA manages the development, administration, and governance of the ACH Network used by all types of financial networks and represents more than 10,000 financial institutions.

The new NACHA standard that applies to health care payments took effect on September 20, 2013. Some of the NACHA Operating Rules that apply to health care payments apply to "Originators" of those payments, which include the health plans, payers, or their business associates.

A specific NACHA Operating Rule that applies to Originators – and is distinct from related HIPAA requirements – is the requirement to clearly identify CCD (Cash Concentration or Disbursement) Entries that are Healthcare EFT Transactions using a specific identifier.

The Healthcare EFT Standard requires that the Company Entry Description field contains "HCCLAIMPMT" to identify the payment as healthcare.

Additional Information

For information on the NACHA Operating Rules that apply to health care payments, particularly with regard to requirements for originators, see https://healthcare.nacha.org/healthcarerules on the Internet.

The official instruction, CR8629 issued to your MAC regarding this change may be viewed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1367OTN.pdf on the CMS website.

You may also want to view article MM8619 at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8619.pdf on the CMS website.

Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files – July 2014 Quarterly ASP

MLN Matters® Number: MM8748
Related CR Release Date: April 25, 2014
Related CR Transmittal #: R2936CP
Related Change Request (CR) #: CR 8748
Effective Date: July 1, 2014
Implementation Date: July 7, 2014

Provider Types Affected

This MLN Matters® Article is intended for physicians, providers, and suppliers who submit claims to Medicare Administrative Contractors (MACs), including Durable Medical Equipment Medicare Administrative Contractors (DME MACs), and/or Home Health and Hospices (HH&H) MACs for services provided to Medicare beneficiaries.

Provider Action Needed

MACs will use the July 2014 Average Sales Price (ASP) and not otherwise classified (NOC) drug pricing files to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after July 1, 2014, with dates of service July 1, 2014, through September 30, 2014.

Change Request (CR) 8748, from which this article is taken, instructs MACs to implement the July 2014 ASP Medicare Part B drug pricing file for Medicate Part B drugs, and if they are released by the Centers for Medicare & Medicaid Services (CMS), to also implement the revised April 2014, January 2014, October 2013, and July 2013 ASP drug pricing files. Make sure your billing personnel are aware of these changes.

Background

The ASP methodology is based on quarterly data submitted to the Centers for Medicare & Medicaid Services (CMS) by manufacturers. CMS supplies the MACs with the ASP and NOC drug pricing files for Medicare Part B drugs on a quarterly basis. Payment allowance limits under the Outpatient Prospective Payment System (OPPS) are incorporated into the Outpatient Code Editor (OCE) through separate instructions that can be located in the "Medicare Claims Processing Manual" (Chapter 4, Section 50 (Outpatient PRICER)) at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf on the CMS website.

The following table shows how the quarterly payment files will be applied:

Files	Effective for Dates of Service
July 2014 ASP and ASP NOC	July 1, 2014, through September 30, 2014
April 2014 ASP and ASP NOC	April 1, 2014, through June 30, 2014
January 2014 ASP and ASP NOC	January 1, 2014, through March 31, 2014
October 2013 ASP and ASP NOC	October 1, 2013, through December 31, 2013
July 2013 ASP and ASP NOC	July 1, 2013, through September 30, 2013

Additional Information

The official instruction, CR 8748 issued to your MAC regarding this change may be viewed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2936CP.pdf on the CMS website.

Rescind/Replace Reclassification of Certain DME from Inexpensive and Routinely Purchased Payment Category to Capped Rental Payment Category

MLN Matters® Number: MM8566 Revised
Related Change Request (CR) #: CR 8566
Related CR Release Date: March 25, 2014
Related CR Transmittal #: R13620TN
Effective Date: April 1, 2014
Implementation: April 7, 2014

Note: This article was revised on April 8, 2014, to add a note on page 4 that states Medicare policy for DME items needed during a covered Part A stay in a skilled nursing facility (SNF). The note is a clarification and does not change existing policies. The effective date for the Power Wheelchair Accessories on page 3 was corrected to April 1, 2014. In addition, further clarification of affected providers was added below (bold). All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for suppliers 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. In addition, this MLN Matters® Article is intended to clarify the interaction between these Part B coding changes and the bundled Part A payment that SNFs receive for a resident's Medicare-covered stay.

Provider Action Needed

The Centers for Medicare & Medicaid Services (CMS) issued Change Request (CR) 8566 as a one-time notification that provides instructions regarding the reclassification of certain DME from the inexpensive and routinely purchased (IN) DME payment category to the capped rental (CR) DME payment category for the Healthcare Common Procedure Coding System (HCPCS) odes listed in 'Attachment A' of CR8566. Be sure your billing personnel are aware of these changes.

Background

DME and accessories used in conjunction with DME are paid for under the DME benefit and in accordance with the rules at section 1834(a) of the Social Security Act (the Act). The Medicare definition of routinely purchased durable medical equipment (DME) set forth at 42 CFR 414.220(a)(2) specifies that routinely purchased equipment means 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. CMS-1526-F is available at http://www.gpo.gov/fdsys/pkg/FR-201312-02/pdf/2013-28451.pdf on the Internet.

Also in the rule, 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) are payable under the lump sum purchase method. The complex rehabilitative power wheelchair base codes and options/accessories are payable under the lump sum purchase method set forth at 42 CFR 414.229(a)(5) and section 1834(a)(7)(A)(iii) of the Act.

In order to align the payment category with the required regulatory definition, certain HCPCS codes listed in Attachment A will reclassify from the inexpensive and routinely purchased (IN) DME payment category to the capped rental (CR) DME payment category. Instructions for billing capped rental items can be found at "Medicare Claims Processing Manual" (Pub. 100-04), Chapter 20, Section 130.9 at http://www.cms.gov/Regulationsand-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf along with other sources listed on the CMS and contractor websites.

Be aware the effective date is April 1, 2014 for HCPCS codes not included in a Competitive Bidding Program (CBP) as shown in Attachment A of CR8566. A forthcoming CR will address the codes that are reclassifying to the capped rental payment category effective July 1, 2016, and January 1, 2017.

As shown in the table below, HCPCS codes for items included under the Round 2 and/or Round 1 Recompete DMEPOS CBPs will transition to the capped rental payment category in stages.

Payment Category Transition Effective Dates	
April 1, 2014	HCPCS codes not included in a CBP are reclassified from IN DME to CR DME in all areas
July 1, 2016	HCPCS codes included in a CBP are reclassified from IN DME to CR DME in all areas except the 9 Round 1 Recompete CBAs, where items furnished to beneficiaries residing in these areas will remain in, IN DME through December 31, 2016
January 1, 2017	HCPCS codes included in a CBP are reclassified from IN DME to CR DME in the 9 Round 1 Recompete CBAs

When the HCPCS codes listed below are furnished in CBAs in accordance with contracts entered into as part of the Round 1 Recompete CBP, the payment category transition from inexpensive and routinely purchased to capped rental DME is effective January 1, 2017.

HCPCS for Items Reclassified to Capped Rental DME Category Effective July 1, 2016*	
Support Surfaces	E0197
Walkers	E0140 & E0149
Wheelchairs Options/Accessories	E0985, E1020, E1028, E2228, E2368, E2369, E2370, E2375, K0015, K0070
Wheelchair Seating	E0955

* Items furnished in accordance with Round 1 Recompete contracts reclassify effective January 1, 2017

Complex Rehabilitative Power Wheelchair Accessories
Effective April 1, 2014, for wheelchair accessory codes classified under the capped rental DME payment category and furnished for use with a complex rehabilitative power wheelchair (that is, furnished to be used as part of the complex rehabilitative power wheelchair), the supplier must give the beneficiary the option of purchasing these accessories at the time they are furnished. These accessory items would be considered as part of the complex rehabilitative power wheelchair (codes K0835 – K0864) and associated lump sum purchase option set forth at 42 CFR 414.229(a)(5).

If the beneficiary declines the purchase option, the supplier must furnish the items on a rental basis and payment will be made on a monthly rental basis in accordance with the capped rental payment rules.

Note: Items Needed During a Covered Part A Stay in a SNF
For an SNF resident whose stay is covered by Part A of Medicare, the extended care benefit provides comprehensive coverage for the overall package of institutional care that the SNF furnishes. This coverage includes any medically necessary durable medical equipment (DME) under the heading of ". . . drugs, biologicals, supplies, appliances, and equipment . . ." (section 1861(h)(5) of the Social Security Act (the Act)).

Accordingly, in cases where such a resident has a medical need for DME during the course of the Part A stay, the SNF is obligated to furnish it, since the SNF's global per diem payment for the covered stay itself already includes any medically necessary DME. Prior to April 1, 2014, and the change in Medicare Part B payment rules addressed in this article, Medicare beneficiaries may have brought this equipment purchased under Part B with them for use during a covered Part A stay in a SNF. This may still be the case for beneficiaries who take over ownership of the equipment after 13 months of continuous Part B rental payments.

However, in those cases where the beneficiary enters a SNF under a covered Part A stay and is in the middle of the 13-month capped rental period under Part B for the item, it is the responsibility of the SNF to ensure that the beneficiary has access to this equipment if it is medically necessary while the beneficiary is in the SNF during the Part A stay.

Additional Information
The official instruction, CR 8566 along with Attachment A, issued to your MAC regarding this change may be viewed at http://www.cms.gov/Regulations-andGuidance/Guidance/Transmittals/Downloads/R1362OTN.pdf on the CMS website.

Claim Status Category and Claim Status Codes Update

MLN Matters® Number: MM8684
Related CR Release Date: May 23, 2014
Related CR Transmittal #: R2967CP
Related Change Request (CR) #: CR 8684
Effective Date: October 1, 2014
Implementation Date: October 6, 2014

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 Medicare Administrative Contractors (DME MACs) and Home Health & Hospice MACs (HH&H MACs), for services to Medicare beneficiaries.

Provider Action Needed
This article is based on Change Request (CR) 8684 which informs the MACs of the changes to Claim Status Category Codes and Claim Status Codes. Make sure that your billing personnel are aware of these changes.

Background
The Health Insurance Portability and Accountability Act (HIPAA) requires all health care benefit payers to use only Claim Status Category Codes and Claim Status Codes approved by the national Code Maintenance Committee in the X12 276/277 Health Care Claim Status Request and Response format adopted as the standard for national use (e.g. previous HIPAAN Matters® named versions included 004010X093A1, more recent HIPAA named versions). These codes explain the status of submitted claim(s). Proprietary codes may not be used in the X12 276/277 to report claim status. The National Code Maintenance Committee meets at the beginning of each X12 trimester meeting (February, June, and October) and makes decisions about additions, modifications, and retirement of existing codes. The codes sets are available at

http://www.wpc-edi.com/reference/codelists/healthcare/claim-status-category-codes/ and http://www.wpc-edi.com/reference/codelists/healthcare/claim-status-codes/ on the Internet.

All code changes approved during the June 2014 committee meeting will be posted on these sites on or about July 1, 2014. Included in the code lists are specific details, including the date when a code was added, changed, or deleted.

These code changes will be used in the editing of all X12 276 transactions processed on or after the date of implementation and are to be reflected in X12 277 transactions issued on and after the date of implementation of CR8684.

Additional Information

The official instruction, CR8684 issued to your MAC regarding this change is available at http://www.cms.gov/Regulations-and- Guidance/Guidance/Transmittals/Downloads/R2967CP.pdf on the CMS website.

Implement Operating Rules – Phase III ERA EFT: CORE 360 Uniform Use of CARC and RARC Rule – Update from CAQH CORE – February 1, 2014 version 3.0.4

MLN Matters® Number: MM8651 Revised
Related Change Request (CR) #: CR 8651
Related CR Release Date: April 10, 2014
Related CR Transmittal #: R1370OTN
Effective Date: May 27, 2014 for DME MACs
Implementation Date: May 27, 2014 for DME MACs

Note: This article was revised on April 11, 2014, to reflect the revised CR8651 issued on April 10. The effective and implementation dates for the DME MACs are revised. Also the CR release date, transmittal number, and the Web address for accessing the CR are changed. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for suppliers submitting claims to Durable Medical Equipment Medicare Administrative Contractors (DME/MACs) for services to Medicare beneficiaries.

Provider Action Needed

This article is based on Change Request (CR) 8651 which informs MACs to update the CORE 360 Uniform Use of Claim Adjustment Reason Codes (CARC) and Remittance Advice Remark Codes (RARC) Rule per the spreadsheets attached to CR8651.

Background

The Department of Health and Human Services (HHS) adopted the Phase III Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) Electronic Funds Transfer (EFT) & Electronic Remittance Advice (ERA) Operating Rule Set that was implemented January 1, 2014, under the Affordable Care Act. The Health Insurance Portability and Accountability Act (HIPAA) amended the Social Security Act by adding Part C—Administrative Simplification—to Title XI of the Social Security Act, requiring the Secretary of the HHS to adopt standards for certain transactions to enable health information to be exchanged more efficiently and to achieve greater uniformity in the transmission of health information. Through the Affordable Care Act, Congress sought to promote implementation of electronic transactions and achieve cost reduction and efficiency improvements by creating more uniformity in the implementation of standard transactions. This was done by mandating the adoption of a set of operating rules for each of the HIPAA transactions. The Affordable Care Act defines operating rules and specifies the role of operating rules in relation to the standards.

CR 8651 deals with the regular update in CAQH CORE defined code combinations per Operating Rule 360 - Uniform Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes (835) Rule. For more detailed information on the codes, see the attachment to CR8651, which contains a number of

spreadsheets detailing the changes for July, 2014. CR8651 is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1370OTN.pdf on the Centers for Medicare & Medicaid Services (CMS) website.

CAQH CORE has published Code Combination version 3.0.4 on February 1, 2014. This update is based on the November 1, 2013 CARC and RARC updates as posted at the WPC website. Visit http://www.wpc-edi.com/reference for CARC and RARC updates and http://www.caqh.org/CORECodeCombinations.php for CAQH CORE defined code combination updates.

Note: Per ACA mandate, all health plans including Medicare must comply with CORE 360 Uniform Use of CARCs and RARCs (835) rule or CORE developed maximum set of CARC/RARC/Group Code for a minimum set of four Business Scenarios. Medicare can use any code combination if the business scenario is not one of the four CORE defined business scenarios but for the four CORE defined business scenarios, Medicare must use the code combinations from the lists published by CAQH CORE.

Additional Information

The official instruction, CR 8651 issued to your DME MAC regarding this change may be viewed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1370OTN.pdf on the CMS website.

RARC, CARC, MREP and PC Print Update

MLN Matters® Number: MM8703
Related CR Release Date: April 4, 2014
Related CR Transmittal #: R2920CP
Related Change Request (CR) #: CR 8703
Effective Date: July 1, 2014
Implementation Date: July 7, 2014

Provider Types Affected

This MLN Matters® Article is for physicians, providers, and suppliers sending claims to Medicare Administrative Contractors (MACs) for services to Medicare beneficiaries.

Provider Action Needed

This article is based on Change Request (CR) 8703, which updates the Claims Adjustment Reason Code (CARC) and Remittance Advice Remark Code (RARC) lists and also instructs Medicare systems maintainers to update the Medicare Remit Easy Print (MREP) and PC Print by July 1, 2014. Make sure that your billing staffs are aware of these updates and that they obtain the updated MREP or PC Print software if you 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. Accordingly, Medicare policy states that CARCs and appropriate RARCs must be used for:

- Transaction 835 (Health Care Claim Payment/Advice) and standard paper remittance advice, along with Group Code to report payment adjustments and Informational RARCs to report appeal rights, and other adjudication related information; and
- Transaction 837 (coordination of benefits).

The CARC and RARC changes that affect Medicare are usually requested by the Centers for Medicare & Medicaid Services (CMS) staff in conjunction with a policy change. If a modification has been initiated by an entity other than CMS for a code currently used by Medicare, MACs must either use the modified code or use another code if the modification makes the modified code inappropriate to explain the specific reason for adjustment. CARC and RARC code sets are updated three times a year on a regular basis. CR 8703 lists only the changes that have been approved since the last code update (CR 8561, Transmittal 2855, issued

on January 10, 2014, with the related MLN Matters® article available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLN MattersArticles/Downloads/MM8561.pdf on the CMS website), and does not provide a complete list of codes for these two code sets.

Changes in CARC List since CR 8561

The following tables list the changes in the CARC database since the last code update in CR8561. The full CARC list is available from the Washington Publishing Company (WPC) website at http://wpc-edi.com/Reference on the Internet.

New Codes – CARC

Code	Narrative	Effective Date
259	Additional payment for Dental/Vision service utilization.	01/26/2014
260	Processed under Medicaid ACA Enhanced Fee Schedule.	01/26/2014

Modified Codes – CARC

Code	Modified Narrative	Effective Date
257	The disposition of the claim/service is undetermined during the premium payment grace period, per Health Insurance Exchange requirements. This claim/service will be reversed and corrected when the grace period ends (due to premium payment or lack of premium payment). (Use only with Group Code OA) Notes: To be used for months 2 and 3 in the grace period.	01/26/2014

Deactivated Codes – CARC

Code	Current Narrative	Effective Date
A7	Presumptive Payment Adjustment	07/01/2015

Changes in RARC List since CR 8561

The following tables list the changes in the RARC database since the last code update in CR8561. The full RARC list is available from the WPC website at http://wpc-edi.com/ Reference on the Internet.

New Codes – RARC

Code	Narrative	Effective Date
N699	Payment adjusted based on the Physician Quality Reporting System (PQRS) Incentive Program.	3/1/2014
N700	Payment adjusted based on the Electronic Health Records (EHR) Incentive Program.	3/1/2014
N701	Payment adjusted based on the Value-based Payment Modifier.	3/1/2014
N702	Decision based on review of previously adjudicated claims or for claims in process for the same/similar type of services	3/1/2014
N703	This service is incompatible with previously adjudicated claims or claims in process.	3/1/2014
N704	Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted.	3/1/2014

N705	Incomplete/invalid documentation.	3/1/2014
N706	Missing documentation.	3/1/2014
N707	Incomplete/invalid orders.	3/1/2014
N708	Missing orders.	3/1/2014
N709	Incomplete/invalid notes.	3/1/2014
N710	Missing notes.	3/1/2014
N711	Incomplete/invalid summary.	3/1/2014
N712	Missing summary.	3/1/2014
N713	Incomplete/invalid report.	3/1/2014
N714	Missing report.	3/1/2014
N715	Incomplete/invalid chart	3/1/2014
N716	Missing chart.	3/1/2014
N717	Incomplete/Invalid documentation of face-to-face examination	3/1/2014
N718	Missing documentation of face-to-face examination.	3/1/2014
N719	Penalty applied based on plan requirements not being met.	3/1/2014
N720	Alert: The patient overpaid you. You may need to issue the patient a refund for the difference between the patient's payment and the amount shown as patient responsibility on this notice.	3/1/2014
N721	This service is only covered when performed as part of a clinical trial.	3/1/2014
N722	Patient must use Workers' Compensation Set-Aside (WCSA) funds to pay for the medical service or item.	3/1/2014
N723	Patient must use Liability set-aside (LSA) funds to pay for the medical service or item.	3/1/2014
N724	Patient must use No-Fault set-aside (NFSA) funds to pay for the medical service or item.	3/1/2014
N725	A liability insurer has reported having ongoing responsibility for medical services (ORM) for this diagnosis.	3/1/2014
N726	A conditional payment is not allowed.	3/1/2014
N727	A no-fault insurer has reported having ongoing responsibility for medical services (ORM) for this diagnosis.	3/1/2014
N728	A workers' compensation insurer has reported having ongoing responsibility for medical services (ORM) for this diagnosis.	3/1/2014

Modified Codes - RARC

Code	Modified Narrative	Effective Date
MA50	Missing/incomplete/invalid Investigational Device Exemption number or Clinical Trial number. Start: 01/01/1997. Last modified: 03/01/2014. Notes: (Modified 2/28/03, 3/1/2014)	3/1/2014
M77	Missing/incomplete/invalid/inappropriate place of service. Start: 01/01/1997. Last Modified: 03/01/2014. Notes: (Modified 2/28/03, 3/1/2014)	3/1/2014

Code	Modified Narrative	Effective Date
N29	Missing documentation/orders/notes/summary/report/chart. Start: 01/01/2000 | Stop: 03/01/2016 | Last Modified: 03/01/2014. Notes: (Modified 2/28/03, 8/1/05, 3/1/2014) Related to N225, Explicit RARCs have been approved, this non-specific RARC will be deactivated in March 2016.	3/1/2014
N225	Incomplete/invalid documentation/orders/ notes/summary/ report/ chart Start: 08/01/2004 | Stop: 03/01/2016 | Last Modified: 03/01/2014. Notes: (Modified 8/1/05, 3/1/2014) Explicit RARCs have been approved, this non-specific RARC will be deactivated in March 2016.	3/1/2014

Deactivated Codes – RARC (There are no deactivated codes.)

Additional Information

The official instruction, CR 8703, issued to your MAC regarding this change, is available at http://www.cms.gov/Regulations-and- Guidance/Guidance/Transmittals/Downloads/R2920CP.pdf on the CMS website.

Uniform Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes Rule – Revised

MLN Matters® Number: MM8518 Revised
Related CR Release Date: March 18, 2014
Related CR Transmittal #: R1360OTN
Related Change Request (CR) #: CR 8518
Effective Date: January 1, 2014
Implementation Date: April 7, 2014 (See Note Below)

This article was revised on March 19, 2014, to reflect a new Change Request (CR). The CR was revised to include two attachments for V3.0.3 and V 3.0.4 of the Council for Affordable Quality Health Care (CAQH) Committee on Operating Rules for Information Exchange (CORE), Mandated CARC/RARC Code Combination List. Version 3.0.4, published January 31, 2014, must be implemented no later than May 1, 2014. The attachment of document V 3.0.3 shows the changes made between Version 3.0.2 and 3.0.3. The attachment of document V 3.0.4 shows the changes made between V 3.0.3 to V 3.0.4. Additionally, the implementation date for V 3.0.4 for Part A and Part B MACs has been delayed to May 5, 2014. The CR release date, transmittal number and link to the CR were also change. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for physicians, providers, and suppliers submitting claims to Medicare contractors (carriers, A/B Medicare Administrative Contractors (MACs), Home Health & Hospice Medicare Administrative Contractors (HH&H), Durable Medical Equipment MACs (DME MACs), Fiscal Intermediaries (FIs), and Regional Home Health Intermediaries (RHHIs)) for services to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 8518, from which this article is taken, instructs Medicare contractors to report only the code combinations that are listed in the current version of the Committee on Operating Rules for Information Exchange (CORE) 360 Uniform Use of CARC and RARC Rule. The spreadsheet attached to CR8518 (which is available also at http://www.caqh.org/CORECodeCombinations.php) shows the change log for CORE Code Combination Version 3.0.3 updates published on October 1, 2013.

Background

The Department of Health and Human Services (HHS) adopted the Phase III Council for Affordable Quality Healthcare (CAQH) CORE Electronic Funds Transfer (EFT) & Electronic Remittance Advice (ERA) Operating Rule Set that must be implemented by January 1, 2014, under the Affordable Care Act. The Health Insurance Portability and Accountability Act (HIPAA) amended the Act by adding Part C—Administrative Simplification—to Title XI of the Social Security Act, requiring the Secretary of HHS (the Secretary) to adopt standards for certain transactions to enable health information to be exchanged more efficiently, and to achieve greater uniformity in the transmission of health information.

More recently, the National Committee on Vital and Health Statistics (NCVHS) reported to the Congress that the transition to Electronic Data Interchange (EDI) from paper has been slow and disappointing. Through the Affordable Care Act, Congress sought to promote implementation of electronic transactions and achieve cost reduction and efficiency improvements by creating more uniformity in the implementation of standard transactions. This was done by mandating the adoption of a set of operating rules for each of the HIPAA transactions. The Affordable Care Act defines operating rules and specifies the role of operating rules in relation to the standards.

CAQH CORE published Code Combination Version 3.0.3 on October 1, 2013. This update is based on July, 2013 CARC and RARC updates as posted at the WPC website. You may review these updates at: http://www.wpc-edi.com/reference for CARC and RARC updates and http://www.caqh.org/CORECodeCombinations.php for CAQH CORE defined code combination updates.

Additional Information

The official instruction, CR 8518 issued to your Medicare contractor regarding this change may be viewed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1360OTN.pdf on the Centers for Medicare & Medicaid Services (CMS) website.

In CR8365, released on August 16, 2013, CMS instructed Medicare contractors to implement this updated rule set by January 6, 2014. You can find the associated MLN Matters® Article, MM8365 "Implement Operating Rules - Phase III ERA EFT: CORE 360 Uniform Use of Claim Adjustment Reason Codes (CARC) and Remittance Advice Remark Codes (RARC) Rule - Update from CAQH CORE" at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8365.pdf on the CMS website.

SURGICAL DRESSINGS

Medical Grade Honey as a Surgical Dressing Component – Request for Information

DME MAC Joint Publication

Surgical Dressings are covered by the DME MACs when used on a qualifying wound. Medical grade honey has been a component in many dressings. Recently the DME MACs were called upon to evaluate the generally accepted medical uses of honey in wounds. As part of our evaluation, we are soliciting information from interested parties. We are requesting that interested parties provide relevant clinical evidence discussing the accepted uses of medical grade honey in wound care.

We make these determinations using an evidence-based medical standard in a review of the published clinical literature. The Medicare standard for clinical evidence is described in the Program Integrity Manual (Internet-Only Manual, Pub. 100-08, Chapter 13, §13.7.1):

[S]hall be based on the strongest evidence available. The extent and quality of supporting evidence is key… The initial action in gathering evidence…shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question. In order of preference:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
  - Scientific data or research studies published in peer-reviewed medical journals;
  - Consensus of expert medical opinion (i.e., recognized authorities in the field); or
  - Medical opinion derived from consultations with medical associations or other health care experts.

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Interested parties choosing to provide information are encouraged to use this standard as well.

We request that all information be submitted electronically to: NHICdmedraftlcdfeedback@hp.com

Deadline for Submission of Information: August 1, 2014.

TENS

Conductive Garment for Delivery of TENS or NMES (HCPCS E0731) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D DME MAC Medical Review Department is conducting a service specific review of HCPCS code E0731. The quarterly edit effectiveness results from January 2014 through April 2014 are as follows:

> The E0731 review involved 33 claims, of which 32 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 97%.

Top Denial Reasons

- There was no documentation submitted in response to the Additional Documentation Request (ADR) letter.
- The proof of delivery (POD) provided was invalid.
- The documentation provided does not support coverage of a garment purchase.
- The documentation provided does not support indication for garment during trial period.

Going Forward

Based on the results of this review, Noridian will continue with the Prepayment Service Specific Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Transcutaneous Electrical Nerve Stimulators (TENS) Local Coverage Determination (LCD) L11495 and Policy Article A37074.

Suppliers can also review a specific policy Documentation Checklist for Transcutaneous Electrical Nerve Stimulators on the Noridian website.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM) Chapter 3.

Policy Education

There was no documentation submitted in response to the Additional Documentation Request (ADR) letter.

Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R §424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide records may not only be a claim denial but also referral to the National Supplier Clearinghouse (NSC).

Please also remember, the documentation must be submitted to our office within 45 days from the date on the ADR letter. Failure to provide the requested documentation within 45 days may result in a partial or complete denial of the claim. Submission information can be found on the ADR letters or under the claims section on our website.

The proof of delivery (POD) provided was invalid.

Suppliers are required to maintain POD documentation in their files. There are two methods of delivery:

1. Delivery directly to the beneficiary or authorized representative
2. Delivery via shipping or delivery service

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 slip. The POD record 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 and date of signature

The delivery address is the location where the item was actually delivered e.g., the beneficiary home for items directly delivered to the beneficiary or the retail location if the beneficiary picked the item up from the supplier location.

The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. In instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS item 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 record must contain the information specified above.

The documentation provided does not support coverage of a garment purchase.
A conductive garment (E0731) used with a TENS unit is rarely reasonable and necessary, but is covered only if all of the following conditions are met:

- It has been prescribed by the treating physician for use in delivering covered TENS treatment
- One of the medical indications outlined below is met:
  - The beneficiary cannot manage without the conductive garment because
    - There is such a large area or so many sites to be stimulated and
    - The stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes, and lead wires
  - The beneficiary cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes, and lead wires
  - The beneficiary has a documented medical condition, such as skin problems, that preclude the application of conventional electrodes, adhesive tapes, and lead wires
  - The beneficiary requires electrical stimulation beneath a cast to treat chronic intractable pain.

The documentation provided does not support indication for garment during trial period.
A conductive garment is not covered for use with a TENS device during the trial period unless:

- The beneficiary has a documented skin problem prior to the start of the trial period; and
- The TENS is reasonable and necessary for the beneficiary.

If the criteria above are not met for E0731, it will be denied as not reasonable and necessary.

TENS Device (HCPCS E0730) Quarterly Results of Service Specific Prepayment Review

The Jurisdiction D DME MAC Medical Review Department is conducting a service specific review of HCPCS code E0730. The quarterly edit effectiveness results from January 2014 through April 2014 are as follows:

> The E0730 review involved 74 claims, of which 70 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 95%.

Top Denial Reasons

- There was no documentation submitted in response to the Additional Documentation Request (ADR) letter.
- The documentation provided does not support usage and frequency.
- The documentation provided does not support other treatments were tried and failed. Additionally, the documentation provided does not support pain was present for three months.

Going Forward

Based on the results of this review, Noridian will continue with the Prepayment Service Specific Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Transcutaneous Electrical Nerve Stimulators (TENS) Local Coverage Determination (LCD) L11495 and Policy Article A37074.

Suppliers can also review a specific policy Documentation Checklist for Transcutaneous Electrical Nerve Stimulators on the Noridian website.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM) Chapter 3.

Policy Education

There was no documentation submitted in response to the Additional Documentation Request (ADR) letter.
Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R §424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide records may not only be a claim denial but also referral to the National Supplier Clearinghouse (NSC).

Please also remember, the documentation must be submitted to our office within 45 days from the date on the ADR letter. Failure to provide the requested documentation within 45 days may result in a partial or complete denial of the claim. Submission information can be found on the ADR letters or under the claims section on our website.

The documentation provided does not support usage and frequency.
For chronic pain covered under criterion II, there must be information in the medical record describing:

- the location of the pain
- the severity of the pain
- the duration of time the beneficiary has had the pain
- the presumed etiology of the pain
- prior treatment and results of that treatment
- reevaluation of the beneficiary at the end of the trial period, must indicate:

- how often the beneficiary used the TENS unit
- the typical duration of use each time
- the results (effectiveness of therapy)

The documentation provided does not support other treatments were tried and failed. Additionally, the documentation provided does not support pain was present for three months.
Per LCD L11495, Criterion II Chronic Pain Other than Low Back Pain, TENS is covered for chronic, intractable pain other than chronic low back pain when all of the following criteria must be met:

- The presumed etiology of the pain must be a type that is accepted as responding to TENS therapy. Examples of conditions for which TENS therapy is not considered to be reasonable and necessary are (not all-inclusive):
  - headache
  - visceral abdominal pain
  - pelvic pain
  - temporomandibular joint (TMJ) pain
- The pain must have been present for at least three months
- Other appropriate treatment modalities must have been tried and failed

TENS therapy for chronic pain that does not meet these criteria will be denied as not reasonable and necessary.

Transcutaneous Electrical Joint Stimulation Devices (TEJSD) – Response to Comment Summary

June 2014

Summary
Comments fell broadly into three groups as described below. Since there was significant business overlap among the responding entities this is not unexpected.

Coverage – General
All commenters presented reasons to allow coverage primarily centered on review of published evidence available as of the date of their comment and/or their empirical experience of the effectiveness of the therapy.

Response:
CMS Program Integrity Manual (PIM) sets out specific standards to be met when making a determination that an item or service is reasonable and necessary (PIM 13.5.1) and the quality of the evidence required for that assessment (PIM 13.7.1). The quality of the evidence submitted is insufficient to conclude that reimbursement for TEJSD is reasonable and necessary.

Coverage – Specific Criteria
Several commenters proposed specific coverage criteria.

- Consider requiring a face-to-face visit with a specialist in the OA field prior to ordering and placement of the device.
- This device should not be considered for first line of treatment.
- Patient selection by qualified professionals should be limited to those patients with Grade 2 or higher radiological evidence of OA, plus moderate to early-severe impairment on a suitable clinical evaluation scale (5 out of 10 on the Physicians' Global or equivalent), and failure of at least 3 months of conservative therapy including non-narcotic pharmaceuticals and physical therapy.

Response:

We agree that clear and specific criteria would be appropriate were the item to be covered. In the absence of an affirmative coverage determination, the recommendations are moot.

Coding
Some commenters noted that the coding guidelines were too broad and would allow devices to be included in the code that were too dissimilar to the predicate product for E0762. It was also suggested that some of the alternatives might be less effective than the predicate or ineffective. Suggestions were made for coding criteria.

Proposed E0762 requirements for medical devices granted an E0762 code.

1. Medical device must be indicated to treat a full range of symptoms of a joint disease such as osteoarthritis of the knee – not just pain,
    a. Improvement of pain
    b. Improvement of associated symptoms (e.g. morning stiffness and range of motion) of the joint disease being treated, such as osteoarthritis of the knee
    c. Overall improvement of the joint as assessed by Physicians Global Evaluation
2. Clinical efficacy must be demonstrated with two or more published short-term randomized, double-blind, prospective, placebo device controlled clinical studies producing statistically significant outcomes using standard, validated outcome measures used by the FDA or recognized professional organizations such as the American College of Rheumatology (ACR), including Physicians Global Evaluation.
3. Clinical safety must be demonstrated by two or more long-term clinical studies of at least a year or longer producing statistically significant outcomes demonstrating continued benefit and no long-term harm resulting from the treatment.
4. Scientific papers of these studies must be published in professionally-recognized peer reviewed medical journals.
5. Medical device must produce clinical and functional results similar to the predicate.
6. Electrical device applicant must provide evidence of efficacy and safety of every electrical signal used by the device in the treatment of osteoarthritis, including broad frequency ranging signal generators.
7. Devices must successfully undergo Pricing, Data Analysis and Coding (PDAC) review.

Response:
We agree that code verification review is appropriate for this code.

Testimonials/Letters of Support
Numerous letters and e-mails were received encouraging coverage.

Response:

CMS Program Integrity Manual (PIM) sets out specific standards to be met when making a determination that an item or service is reasonable and necessary (PIM 13.5.1) and the quality of the evidence required for that assessment (PIM 13.7.1). Testimonials etc. are not deemed sufficient evidence to justify coverage.

Transcutaneous Electrical Nerve Stimulators Device, Two Lead (HCPCS E0720) Quarterly Service Specific Prepayment Review Results

The Jurisdiction D DME MAC Medical Review Department is conducting a service specific complex review of HCPCS code E0720. The quarterly edit effectiveness results from November 2013 through February 2014 are as follows:

The E0720 review involved 20 claims, of which 19 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 94%.

Top Denial Reasons

- Documentation was not received within the allotted time frame.
- Documentation provided did not support usage and frequency.
- The order submitted was invalid or incomplete.
- There was no proof of delivery (POD) submitted.

Going Forward

Based on the results of this review, Noridian will continue with the prepayment service specific review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Transcutaneous Electrical Nerve Stimulators (TENS) Local Coverage Determination (LCD) L11495and Policy Article A37074.

Suppliers can also review specific policy resources for Transcutaneous Electrical Nerve Stimulators (TENS) on the Noridian website located at https://www.noridianmedicare.com/dme/coverage/docs/checklists/transcutaneous_electrical_nerve_stimulators_tens.html. There, you will find information related to proper documentation requirements including a physician letter, documentation checklists, FAQs, and a presentation used during Web-based workshops.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations. Educational training and events are located at https://www.noridianmedicare.com/dme/train/.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM), Chapter 3 located at http://www.cms.gov/manuals/downloads/pim83c03.pdf.

Policy Education

Documentation was not received within the allotted time frame.
Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R §424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide recordsmay not only be a claim denial but also referral to the NSC.

Please also remember, the documentation must be submitted to our office within 45 days from the date on the ADR letter. Failure to provide the requested documentation within 45 days may result in a partial or complete denial of the claim. Submission information can be found on the ADR letters or under the claims section on our website at https://www.noridianmedicare.com/dme/claims/edi.html.

Documentation provided did not support usage and frequency.
For chronic pain covered under criterion II, there must be information in the medical record describing:

- The location of the pain
- The severity of the pain
- The duration of time the beneficiary has had the pain
- The presumed etiology of the pain
- Prior treatment and results of that treatment
- Reevaluation of the beneficiary at the end of the trial period, must indicate
  - How often the beneficiary used the TENS unit
  - The typical duration of use each time
- The results (effectiveness of therapy)

The order submitted was invalid or incomplete.
All items billed to Medicare require a prescription. An order for each item billed must be signed and dated by the treating physician, 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. Program Integrity manual (PIM 5.2.4) stipulates a detailed written order that is received by the supplier prior to delivery (WOPD) is required for TENS. The supplier must have received a WOPD that has been both signed and dated by the treating physician and meets the requirements for a detailed written order before dispensing the item. Someone other than the ordering physician may produce the WOPD. However, the ordering physician must review the content and sign and date the document. It must contain:

- Beneficiary's name
- Physician's name
- Date of the order and the start date, if the start date is different from the date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Prescribing physician's National Provider Identifier (NPI) (*Note that only individual NPI numbers must be used. Institutional or group NPI numbers are not acceptable)
- Physician signature and signature date

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 WOPD 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.

There was no proof of delivery (POD) submitted.
Per PIM 4.26, 5.8, Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and received by, a specific Medicare beneficiary.

THERAPEUTIC SHOES

Dear Physician – CERT/Therapeutic Shoes for Persons with Diabetes

April 2014

Dear Physician:

The Comprehensive Error Rate Testing (CERT) Contractor, under contract with the Centers for Medicare & Medicaid Services (CMS), performs medical review audits for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) provided to Medicare beneficiaries to determine the paid claims error rate for Medicare contractors and providers.

Medicare covers therapeutic shoes and inserts for persons with diabetes as established by the Social Security Act §1861(s) (12). You may access the Therapeutic Shoes for Persons with Diabetes (TSPD) LCD and Related Policy Article on the CMS website under the Medicare Coverage Database. In order for your patient to qualify for these shoes and inserts, Medicare statute mandates specific coverage and documentation requirements that must be met.

The most common CERT errors center on missing documentation from the certifying physician of the patient having diabetes, the existence of one or more of the conditions for coverage and the therapeutic plan of care. Three criteria are critical to coverage and form the majority of physician-related CERT errors:

1. Documenting your management of the beneficiary's diabetes. You are considered the "Certifying Physician" and there is no substitute for this documentation requirement. The Certifying Physician, by statute, must be an M.D. or D.O. and not a nurse practitioner, physician assistant or clinical nurse specialist;
2. Documenting a qualifying foot condition. As opposed to the criteria above regarding documentation of the beneficiary's diabetes management, the documentation of the qualifying foot condition may come from your records or by your indication of agreement (signified by initialing and dating) with information from the medical records of an in-person visit with a podiatrist, another M.D or D.O., physician assistant, nurse practitioner, or clinical nurse specialist that is within 6 months prior to delivery of the shoes/inserts.

3. Failure of the records to substantiate that an in-person visit occurred within 6 months prior to the delivery of the shoes or inserts.

It is important to note that even though you may complete and sign a form attesting that all of the coverage requirements from the policy have been met, there also must be documentation in your records to indicate that you are managing the patient's diabetes and records from either your chart or that of another practitioner documenting a qualifying foot condition.

Please refer to the Local Coverage Determination (LCD) on Therapeutic Shoes for Persons with Diabetes (TSPD), the related Policy Article and the Supplier Manual for additional information about coverage, billing and documentation requirements. Thank you for your assistance in reducing the CERT error rate.

Sincerely,

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NHIC, Corp.

Stacey V. Brennan, M.D., FAAFP
Medical Director, DME MAC, Jurisdiction B
National Government Services

Robert D. Hoover, Jr., MD, MPH, FACP
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Medical Director, DME MAC, Jurisdiction D
Noridian Healthcare Solutions

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 2013 through March 2014 are as follows:

The A5500 review involved 2,924 claims, of which 2,404 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 82%.

Top Denial Reasons

- Documentation of foot abnormalities by certifying physician not met
- Documentation of diabetes management by certifying physician not met
- No documentation was received
- Documentation of in-person visit prior to selection of items not met

Going Forward

Based on the results of this review, Noridian will continue with the Prepayment Service Specific Review.

Educational Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Therapeutic Shoes for Persons with Diabetes Local Coverage Determination (LCD) L157 and Policy Article A37076.

Suppliers can also review specific policy resources for Therapeutic Shoes for Persons with Diabetes on the Noridian website. There, you will find information related to proper documentation requirements including a physician letter, documentation checklists, FAQs, and a presentation used during web-based workshops.

Suppliers can also review a specific policy Documentation Checklist for Therapeutic Shoes for Persons with Diabetes on the Noridian website.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM) Chapter 3.

Policy Education

Documentation of foot abnormalities by certifying physician not met.
There must be documentation to support that the certifying physician has documented in the patient's medical record one or more of the following conditions:

- Previous amputation of the other foot, or part of either foot, or
- History of previous foot ulceration of either foot, or
- History of pre-ulcerative calluses of either foot, or
- Peripheral neuropathy with evidence of callus formation of either foot, or
- Foot deformity of either foot, or
- Poor circulation in either foot.

In order to meet criterion 2, the certifying physician must either:

- Personally document one or more of criteria a – f in the medical record of an in-person visit within 6 months prior to delivery of the shoes/inserts and prior to or on the same day as signing the certification statement; or
- Obtain, initial/sign, date (prior to or on the same day as signing the certification statement), and indicate agreement with information from the medical records of an in-person visit with a podiatrist, other M.D. or D.O., physician assistant, nurse practitioner, or clinical nurse specialist that is within 6 months prior to delivery of the shoes/inserts, and that documents one of more of criteria above.

Note: The certification statement is not sufficient to meet the requirement for documentation in the medical record.

Documentation of diabetes management by certifying physician not met.
There must be documentation to support that the certifying physician has certified that indications (1) and (2) are met and that he/she is treating the patient under a comprehensive plan of care for his/her diabetes and that the patient needs diabetic shoes. For claims with dates of service on or after 1/1/2011, the certifying physician must:

- Have an in-person visit with the patient during which diabetes management is addressed within 6 months prior to delivery of the shoes/inserts; and
- Sign the certification statement (refer to the Documentation Requirements section of the related Local Coverage Determination) on or after the date of the in-person visit and within 3 months prior to delivery of the shoes/inserts.

Note: Per Policy Article A37076 the Certifying Physician is defined as a doctor of medicine (M.D.) or a doctor of osteopathy (D.O.) who is responsible for diagnosing and treating the patient's diabetic systemic condition through a comprehensive plan of care. The certifying physician may not be a podiatrist, physician assistant, nurse practitioner, or clinical nurse specialist.

No documentation was received.
Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R §424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide records may not only be a claim denial but also referral to the NSC.

Please also remember, the documentation must be submitted to our office within 45 days from the date on the ADR letter. Failure to provide the requested documentation within 45 days may result in a partial or complete denial of the claim. Submission information can be found on the ADR letters or under the claims section on our website.

Documentation of in-person visit prior to selection of items not met.
There must be documentation from the supplier to support an in-person visit prior to selection of the item billed. Prior to selecting the specific items that will be provided the supplier must conduct and document an in-person evaluation of the patient. The in-person evaluation of the patient by the supplier at the time of selecting the items that will be provided must include at least the following:

- An examination of the patient's feet with a description of the abnormalities that will need to be accommodated by the shoes/inserts/modifications.
- For all shoes, taking measurements of the patient's feet.

For custom molded shoes (A5501) and inserts (A5513), taking impressions, making casts, or obtaining CAD-CAM images of the patient's feet that will be used in creating positive models of the feet.

Tumor Treatment Field Therapy (TTFT) – Response to Comment Summary

June 2014

1. Commenter noted that the FDA approved the device on the basis of results from a multi-center randomized controlled phase III clinical trial. The FDA PMA approval followed a positive vote from the FDA's independent Medical Device Advisory Committee's Neurological Devices Panel with a majority in favor of both device efficacy and safety; therefore, it should be covered by Medicare.

Response: The Medical Directors disagree. While the FDA did give final approval of the PMA application through a "positive vote", the FDA's Medical Device Advisory Committee's Neurological Devices Panel decision was split (six "yes" and six "no") on the question of efficacy ("Is there a reasonable assurance that the NovoTTF-100A is effective for use in patients who meet the criteria specified in the proposed indication?"). The deciding tie-breaker vote was cast by the panel chairperson. A review of the FDA panel's meeting transcript details numerous examples of doubt expressed by panel members over the effectiveness of this therapy for recurrent GBM.

2. Several commenters emphasized that the NovoTTF-100A should be covered because it was "standard of care" as evidenced by the National Comprehensive Cancer Network's (NCCN®) designation of a 2B level of evidence.

Response: The Medical Directors disagree. As a reminder, the NCCN® Categories of Evidence and Consensus are:

Category 1: Based upon high-level evidence, there is uniform NCCN® consensus that the intervention is appropriate.

Category 2A: Based upon lower-level evidence, there is uniform NCCN® consensus that the intervention is appropriate.

Category 2B: Based upon lower-level evidence, there is NCCN® consensus that the intervention is appropriate.

Category 3: Based upon any level of evidence, there is major NCCN® disagreement that the intervention is appropriate.

Although Centers for Medicare & Medicaid Services (CMS) does not address NCCN® guidelines specifically as it relates to medical devices used to treat cancer, it does provides guidance to contractors in the acceptance of evidence from NCCN® for off-label use of drugs and biologicals in an anti-chemotherapeutic regimen. Found in the Medicare Benefit Policy Manual (Internet- Only Manual 100-02, Chapter 15, Section 50.4.5, the interpretive manual guidance states:

The listed compendia employ various rating and recommendation systems that may not be readily cross-walked from compendium to compendium. In general, a use is identified by a compendium as medically accepted if the:

1. Indication is a Category 1 or 2A in NCCN, or Class 1, Class IIa, or Class IIb in DrugDex; or,
2. Narrative text in AHFS-DI or Clinical Pharmacology is supportive.

A use is not medically accepted by a compendium if the:

1. Indication is a Category 3 in NCCN or a Class III in DrugDex; or,
2. Narrative text in AHFS or Clinical Pharmacology is "not supportive."

The complete absence of narrative text on a use is considered neither supportive nor nonsupportive.

The DME MAC medical directors note the absence of explicit instructions for a "2B" recommendation; however, it is clear that CMS intends that the contractors use the highest level of evidence possible in making coverage determinations. The NovoTTF-100A, with a 2B rating by NCCN®, clear does not fall within the "generally medically accepted" category as envisioned by CMS.

3. A commenter was critical of several references cited in the draft LCD bibliography, noting that they were published either prior to the pivotal trial, referenced coverage policies from other countries or failed to cite a single publication that calls into question the quality of the EF-11 (pivotal trial) trial design or results.

Response: The Medical Directors partially agree. The bibliography for an LCD is not intended to be a complete compendium of all studies reviewed during the development of the policy but rather key articles and information that reflects a more global understanding of a technology or service. During the comment period, the manufacturer provided the medical directors with additional information and clinical literature. This updated information was reviewed; however, it was not persuasive in changing the final policy position.

With respect to the commenter's last point about published studies that "call into question the quality of the EF-11 trial design or results", articles are rarely published that specifically attack the quality or results of a clinical trial except when appearing in publications widely read by the entire medical community or the results impact a significant portion of the population in general. The pivotal trial results were published in the European Journal of Oncology about a treatment modality that, by the manufacturer's data, impacts fewer than 7,000 patients world-wide. This is not meant as a criticism of the quality of the journal or the subscribers; it simply makes the point that there is not likely to be peer-reviewed publications critical of this specific study.

Although not published in any medical journal, the FDA's Medical Device Advisory Committee's Neurological Devices Panel public meeting was quite critical of the trial design and conclusions reached in the pivotal trial submitted as evidence for the Pre-Market Approval (PMA) application. As noted above, the panel expressed serious doubts about the efficacy of the NovoTTF-100A device and was only able to reach a positive "reasonable assurance" vote on effectiveness through the chairperson's tiebreaker.

Male Vacuum Erection System (HCPCS L7900) Quarterly Results of Service Specific Prepayment Review of Claims

The Jurisdiction D DME MAC Medical Review Department is conducting a service specific review of HCPCS code L7900. The quarterly edit effectiveness results from November 2013 through January 2014 are as follows:

The L7900 review involved 661 claims, of which 447 were denied. Based on dollars, this resulted in an overall potential improper payment rate of 67%.

Top Denial Reasons

- Documentation submitted did not support medical necessity of the item ordered.
- An invalid Proof of Delivery (POD) was submitted.
- No office notes or medical records were submitted to support coverage criteria.
- No documentation was received in response to Additional Documentation Letters (ADR).

Going Forward

Based on the results of this review, Noridian will continue with the Prepayment Widespread Review.

Education Resources

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the National Coverage Determination for Diagnosis and Treatment of Impotence NCD 230.4, CMS Publication 100-8, Program Integrity Manual (PIM) Chapter 5 and the Supplier Manual Chapter 3.

Noridian provides educational offerings by scheduling supplier workshops, training opportunities, and presentations. Educational training and events are located at https://www.noridianmedicare.com/dme/train/.

Information about probe/error validation reviews may be found in CMS Publication 100-8, Program Integrity Manual (PIM), Chapter 3 located at http://www.cms.gov/manuals/downloads/pim83c03.pdf.

Policy Education

Documentation submitted did not support medical necessity of the item ordered.
The Program Integrity Manual Chapter 5 Section 5.7 states, "For any DMEPOS item to be covered by Medicare, the beneficiary's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the beneficiary's diagnosis and other pertinent information including, but not limited to, duration of the beneficiary's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc. There must be information in the beneficiary's medical record that supports the medical necessity for the item and substantiates the answers on the CMN (if applicable) or DIF (if applicable) or information on a supplier prepared statement or physician attestation (if applicable)."

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

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 slip. The POD record 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 and date of signature

The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. 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 record must contain the information specified above.

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

When a supplier delivers items directly to a nursing facility, the documentation described for Method 1 (see above) is required.

When a delivery service or mail order is used to deliver the item to a nursing facility, the documentation described for Method 2 (see above) is required.

No office notes or medical records were submitted to support coverage criteria.
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 physician'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.

No documentation was received in response to Additional Documentation Letters (ADR).

Suppliers are in violation of Supplier Standard #28 when, upon request, they fail to provide requested documentation to a Medicare contractor. Medicare regulations (42 C.F.R §424.516[f]) stipulate that a supplier is required to maintain documentation for seven years from the date of service and, upon the request of CMS or a Medicare contractor, provide access to that documentation. Therefore, the consequences of failure to provide records may not only be a claim denial but also referral to the NSC. 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 patient's medical records will reflect the need for the care provided. The patient's medical records include the physician'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.

Please also remember, the documentation must be submitted to our office within 45 days from the date on the ADR letter. Failure to provide the requested documentation within 45 days may result in a partial or complete denial of the claim. Submission information can be found on the ADR letters or under the claims section on our website at https://www.noridianmedicare.com/dme/news/docs/2012/01_jan/additional_documentation_request_submission_60_day_time-frame_effective_january_2012.html.

Vacuum Erection Device – Coding Verification Review Requirement

Recently the Durable Medical Equipment Medicare Administrative Contractors (DME MAC) published a new Local Coverage Determination (LCD) for Vacuum Erection Devices effective for dates of service on or after August 1, 2014. The Vacuum Erection Devices LCD related Policy Article Coding Guidelines section contains additional guidance on the proper coding of products coded L7900 and L7902.

All products currently listed on the Pricing, Data Analysis, and Coding (PDAC) contractor web site with HCPCS codes L7900 or L7902 will be end dated effective October 31, 2014.

Manufacturers will be required to submit a new coding verification application to the PDAC for review and assignment of the correct code for products currently coded as L7900 or L7902.

Effective for claims with dates of service on or after November 1, 2014, the only products which may be billed to Medicare using code L7900 or L7902 are those for which a written coding verification has been made by the PDAC contractor and are listed on the Product Classification List in the Durable Medical Equipment Coding System (DMECS) maintained on the PDAC web site, https://www.dmepdac.com/dmecsapp/do/search. Products which have not received coding verification review from the PDAC must be billed with code A9270. The PDAC coding verification application required for these products is the DME and Supplies application. This application is located on the PDAC website, https://www.dmepdac.com/review/apps_check.html.

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 the DME PDAC Contact Form located on the PDAC website: https://www.dmepdac.com/.

Vacuum Erection Device – Response to Comment Summary

June 2014

Clinical Comments

1. Commenter agrees with criteria: 1) The beneficiary has an in-person clinical evaluation with their treating physician within six (6) months prior to ordering the Vacuum Erection Device (VED) and 3) Other treatment options have been tried or considered and ruled out, and the result (if tried) or contraindication (if considered) must be clearly documented in the beneficiary's medical record.

Commenter believes that criteria [sic] 2) that states "the beneficiary has no evidence of hypogonadism or hyperprolactinemia" is not a reason to exclude a patient from being treated for erectile dysfunction (ED) because correction of hormonal status is not a prerequisite to the return of erectile function.

Response: While criterion 2 was taken directly from the AUA guidelines, we agree that correction of hormonal status is not a prerequisite to the return of erectile function. We will revise the criterion in the final draft to read:

The patient has no evidence of symptomatic or untreated hypogonadism or hyperprolactinemia

2. There is no criterion 4. The Policy Specific Documentation Requirements state: For criterion 4 in the Coverage Indications, Limitations, and/or Medical Necessity section, the medical record must address the following alternative treatment options:

Response: This was a typographical error and should read "Criterion 3." It will be corrected in the final draft.

3. If providers can identify within the prescription that they have seen and evaluated the patient within the last 6 months with documentation of erectile dysfunction (607.84) related to medical conditions such as coronary artery disease, prostate cancer, hyperlipidemia, and or neurologic impairment, Commenter believes that should be sufficient.

Response: Disagree. CMS guidance to contractors (Program Integrity Manual, Internet- Only Manual 100-08, Chapter 5, Section 5.7) stipulates (in part):

> The patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient's diagnosis and other pertinent information including, but not limited to, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc.

4. According to the AUA guidelines, VEDs are first-line treatment.

Response: This comment is incorrect. The AUA Guidelines (2011) detail the following standard and recommendation:

> Standard: Oral phosphodiesterase type 5 inhibitors, unless contraindicated, should be offered as a first-line of therapy for erectile dysfunction.
>
> Recommendation: Patients who have failed a trial with phosphodiesterase type 5 (PDE5) inhibitor therapy should be informed of the benefits and risks of other therapies, including the use of a different PDE5 inhibitor, alprostadil intra-urethral suppositories, intracavernous drug injection, vacuum constriction devices, and penile prostheses.

The LCD does not relegate the VED to a second or third-line therapy; however, it does recognize the AUA standard outlined above and requires justifying a reasonable and necessary indication for variance from this standard.

5. Commenter treats many patients that have hypogonadism and ED. These patients also have other co-morbidities that lead to ED that may be separate from hypogonadism. Commenter believes that requiring documentation that the patient has no evidence of hypogonadism would exclude the majority of patients from coverage and asks that this language be removed from the policy.

Response: The medical directors disagree. The AUA Guidelines are based on the following "Index Patient":

> The recommendations and findings of the Panel were based upon the management of an Index Patient that represents the most prevalent presentation of this disorder since management may vary in atypical patients. ***The Index Patient for this document is defined as a man with no evidence of hypogonadism or hyperprolactinemia who develops, after a well-established period of normal erectile function, ED that is primarily organic in nature.*** [Emphasis Added]

Moreover, the AUA guidelines also state:

> Using a consensus-based approach, the Panel concluded that (1) informed patient decision making should remain the standard; (2) no new evidence has suggested that the guideline statements on the diagnostic evaluation should be changed; (3) a psychologic overlay frequently exists in patients with ED; and ***(4) endocrine disorders are an important consideration in the etiology of ED.*** [Emphasis Added]

The guideline and associated recommendations and standards are predicated on the absence of evidence of hypogonadism or hyperprolactinemia as contributing factors to ED.

6. Asking a patient to stop their anti-hypertensives, anti-depressants, etc is dangerous for some patient's health and could pose unnecessary harm just to determine if it is a cause of ED. It is an unreasonable request to ask a physician to make this documentation.

Response: The medical directors agree that asking patients to stop other necessary medications for co-morbid conditions is not appropriate; however, the LCD does not require that other medications be discontinued to determine if they are the cause of ED. The LCD, like many clinical guidelines, is following a standard approach that asks practitioners to consider other complicating factors in the treatment of ED. We will modify the documentation criteria in the Policy Specific Documentation Requirements section to make this clear:

> If clinically indicated, modification or discontinuation of medications contributing to ED (e.g., anti-hypertensives, anti-depressants, anxiolytics, etc.)

7. A rectal exam is not routinely recommended for ED evaluation. According to the AUA Guidelines, "A focused physical examination evaluating the abdomen, penis, testicles, secondary sexual characteristics and lower extremity pulses is usually performed." If prostate cancer screening is the issue, the U.S. Preventive Services Task Force (USPSTF) recommendations have brought this issue into question.

Response: Disagree. This LCD is tailored to a male Medicare population, made up predominately of men over the age of 65. Prostate hypertrophy and prostate cancer are more prevalent in this older population. Moreover, prostate issues are a recognized cause of ED and should be part of any focused physical examination for the evaluation of ED.

8. Testosterone assessment for evaluation of ED has not been accepted as a standard of care for every ED patient. According to the AUA Guidelines, "Additional testing, such as testosterone level measurement, vascular and/or neurological assessment, and monitoring of nocturnal erections, may be indicated in select patients."

Response: Agree with the commenter's statement; however, the LCD does not mandate measurement of testosterone levels. Testing of hormonal levels should be guided by the practitioner's history and physical findings.

9. Commonly the in-person clinical evaluation is no more than a reported history of ED, usually without even a description in the patient's words how ED presented, duration, prior therapy tried, or endocrine history. The evaluation needs to include more than simply a "Reported history of" or "The patient said or claims that". A verbal report or statement isn't an evaluation.

Response: Agree; however, the medical directors believe there are sufficient criteria for documentation of both a detailed history and physical evaluation to address this commenter's concerns.

10. Recommend that the LCD include the use of VED in treating ED 2nd to Radical Prostatectomy. There are emerging treatment protocols for ED where a VED is prescribed for those men who have undergone or who are about to undergo Robotic/Radical prostatectomy.

Response: The medical directors agree that this is an emerging treatment; however, the medical literature does not indicate that penile rehabilitation is a standard of medical care for patients who have undergone radical prostatectomy. Coverage will not be added for this indication.

11. Criterion 2 includes the statement "…developed ED after a well-established period of normal erectile function." Commenter asks for the definition of "well-established"?

Response: Vacuum erection devices are covered under the Medicare prosthetic benefit category. One of the prerequisites for coverage under this benefit is that the beneficiary must have a permanent impairment. Permanence does not require a determination that there is no possibility that the beneficiary's condition may improve sometime in the future. If the judgment of the treating physician, substantiated in the medical record, is that the condition is of long and indefinite duration (ordinarily at least 3 months), the test of permanence is considered met. Given Medicare's benefit category definition, the DME MAC medical directors would consider "well-established" to be defined as normal erectile function for a period of at least 3 months.

12. Commenter expressed concern that coverage requires that "[o]ther treatment options have been tried or considered and ruled out, and the result (if tried) or contraindication (if considered) must be clearly documented in the beneficiary's medical records." This should not be included because it is clinically incorrect and would be hard to administer. It will also reduce access to medically necessary treatments and therefore harm the health of Medicare beneficiaries who suffer from Erectile Dysfunction (ED).

Response: Disagree. As noted in a previous response, CMS guidance to contractors in the Program Integrity Manual, Chapter 5, Section 5.7 specifically states that medical documentation should include… "other therapeutic interventions and results". The commenter's assertion that this is clinically incorrect is also an erroneous statement. This policy criterion is not a strict prerequisite requirement (i.e., must try X therapy before receiving Y therapy). It simply asks the practitioner to document other treatment options that have been either tried OR considered and ruled out. For example, it would be acceptable to document in a patient with cardiovascular disease "Coronary artery disease on nitrate therapy precludes use of 5-PGE inhibitor. Order VED."

13. The draft LCD indirectly limits the types of physicians or other qualified healthcare practitioners who can prescribe the device. The draft LCD provides that a beneficiary must have no evidence of hypogonadism or hyperprolactinemia in order to be afforded coverage for a VED. Based on information provided to me, the tests associated with ruling out these conditions are typically only performed by a urologist.

Response: The Centers for Medicare & Medicaid Services (CMS) do not prohibit contractor policies from restricting the prescription of items or services to specific types of healthcare practitioners; however, the draft VED does not contain such restrictions. The ordering of hormonal testing (when necessary) is not limited to urologists; therefore, there is no restriction in the LCD.

14. The current requirements provide coverage for beneficiaries who have been diagnosed with vascular disorders of the penis (ICD-9 Code 607.82), psychosexual dysfunction with inhibited sexual excitement (302.72), injury to other specified blood vessels or abdomen of pelvis (902.89) and organic impotence (607.84).

Response: This comment is unclear with respect to the statement "current requirements". The VED LCD was developed because there were no requirements for the coverage, coding and documentation of VEDs in either Medicare national policy (i.e., National Coverage Determination) or local policy (i.e., local coverage determination).

15. The draft LCD requires other treatment methods to be attempted first and that the criterion is vague, burdensome and may increase costs.

Response: This comment is incorrect. The medical literature is quite clear that certain commonly used drugs for the treatment of ED are contraindicated in certain patient populations (e.g. PDE-5 inhibitors and patients taking nitrates). The draft LCD recognizes this point through the specific language in Criterion 3: "Other treatment options have been tried or considered and ruled out, and the result (if tried) or contraindication (if considered) must be clearly documented in the beneficiary's medical record." [Emphasis Added]

The medical directors disagree that the criterion is vague. The medical literature and guidelines from numerous clinical organizations outline a variety of treatment options for ED. The LCD criterion leaves to the discretion of the practitioner which treatment option to choose and simply requests that the practitioner document his/her rationale for the choice.

16. The Draft LCD does not indicate which or how any of the numerous available treatments for ED—PDE5 inhibitors, penile injections, penile implants, psychological counseling, lifestyle modifications, etc.—must be tried or considered before VEDs can be prescribed.

Response: As noted above, the LCD criterion leaves to the discretion of the practitioner which treatment option to choose and simply requests that the practitioner document his/her rationale for the choice. It does not mandate which or how many must be tried or considered and ruled out before selecting a VED. This approach is consistent with the current American Urological Association guidelines (2011) which state (in part):

> *The currently available therapies that should be considered for the treatment of erectile dysfunction include the following: oral phosphodiesterase type 5 [PDE5] inhibitors, intra-urethral alprostadil, intracavernous vasoactive drug injection, vacuum constriction devices, and penile prosthesis implantation. These appropriate treatment options should be applied in a stepwise fashion with increasing invasiveness and risk balanced against the likelihood of efficacy.*

Non-Clinical Comments

1. OIG audit reports are not meant to be used as a basis to attempt to reduce Medicare costs by restricting patient access to clinically appropriate treatment.

Response: Agree. The DME MACs developed the VED LCD consistent with the instructions provided by CMS to contractors in the Program Integrity Manual (Internet-only Manual, Pub. 100- 08), Chapter 13, Section 13.4 regarding the development of new LCDs. The guidance states (in part):

> The use of a LCD helps avoid situations in which claims are paid or denied without a provider having a full understanding of the basis for payment and denial.
>
> B. Contractors May Develop New/Revised LCD
> Contractors have the option to develop LCDs when any of the following occur:
>
> - A validated widespread problem demonstrates a significant risk to the Medicare trust funds (identified or potentially high dollar and/or high volume items or services). Multi-state contractors may develop uniform LCDs across all its jurisdictions even if data analysis indicates that the problem exists only in one state.
> - A LCD is needed to assure beneficiary access to care.
> - A contractor has assumed the LCD development workload of another contractor and is undertaking an initiative to create uniform LCDs across its multiple jurisdictions; or is a multi-state contractor undertaking an initiative to create uniform LCDs across its jurisdiction; or,
> - Frequent denials are issued (following routine or complex review) or frequent denials are anticipated.

The recent OIG reports simply highlight the need for a local coverage determination that outlines the coverage, coding and documentation for these devices. The DME MACs do not develop LCDs and related Policy articles for the purpose of restricting care for reasonable and necessary services.

2. Commenter states that there are potentially several different practitioners who treat patients with ED and notes that they do not have the time or resources to detail in the medical record every alternative treatment that was not the one actually recommended for the patient.

Response: The medical directors are cognizant of the multi-disciplinary approach to the diagnosis and treatment of ED. The policy criterion does not require that every practitioner involved in the care of the patient provide detailed documentation but rather anticipates that the provider ordering the VED will most likely be the individual documenting that the device is reasonable and necessary.

3. Commenter asks that medical record requirements be aligned as closely as possible with how practicing urologists generally evaluate and diagnose for organic ED. Commenter suggests that this would best be accomplished through a work group to include prescribing physicians, the American Urological Association, and suppliers.

Response: Disagree. Development of coverage policies is guided by an evidence-based approach (see Medicare Program Integrity Manual, Internet-Only Manual, Chapter 13, Section 13.7.1). CMS gives guidance in Chapter 13 as follows:

> *Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.*

For the draft LCD, there are numerous clinical guidelines and peer-reviewed articles discussing the diagnosis and treatment of ED. This level of evidence is significantly higher than opinions and working groups.

4. Commenter requests specific and clear language that suppliers might use to form a checklist when reviewing medical records – so that the presence or absence of each element in the medical record can be determined simply and accurately.

Response: Disagree. The LCD is clear in both the coverage criteria and the documentation requirements the elements necessary for supporting that a VED is reasonable and necessary. The DME MACs will not develop a form or template to use with this policy. CMS discourages the use of such templates. Claim review experience shows that that limited space templates often fail to capture sufficient detailed clinical information to demonstrate that all coverage and coding requirements are met.

Physician/LCMPs should be aware that templates designed to gather selected information focused primarily for reimbursement purposes are often insufficient to demonstrate that all coverage and coding requirements are met. This is often because these documents generally do not provide sufficient information to adequately show that the medical necessity criteria for the item/service are met.

5. Commenter feels that the sources of information that were used in the basis of decision for the changes to the current local coverage determination did not include enough information to make an informed decision.

Response: Disagree. The bibliography is comprised of guidelines from major clinical organizations whose members are involved in the care of ED patients and publications in peer-reviewed journals.

> The AUA guidelines recommend: *Only vacuum constriction devices containing a vacuum limiter should be used whether purchased over-the-counter or procured with a prescription.* [Based on Panel consensus.]

6. Commenter feels this article should not be considered in the decision to change the LCD for vacuum erection devices due to the fact that sufficient literature for vacuum erection devices were not included in this study.

Response: Disagree. The CMS instructs contractors to consider clinical evidence in a hierarchical approach in the *Program Integrity Manual* (Internet-only Manual, Pub. 100-08), Chapter 13, Section 13.7.1. While "Panel Consensus" is not the highest level of evidence in guideline development, the inclusion of this recommendation by the panel is significant enough to warrant consideration in the LCD. Moreover, this is consistent with the intent of the FDA Exemption Guidance to Manufacturers of VEDs (i.e, protecting the VED user from inappropriate vacuum levels).

7. Regarding the American College of Physician guideline: *This guideline addresses only the utility of hormonal testing and treatment of ED. Such treatments as vacuum constriction devices, intraurethral suppositories, intracavenosal injections, and psychotherapy were not included in the evidence review and are not addressed in this guideline.*

Commenter feels this article should not be considered in the decision to change the LCD for vacuum erection devices due to the fact vacuum erection devices were not included in this study.

Response: Disagree. While the ACP guideline does not specifically address VED use, this part of the guideline is discussing the appropriateness of hormonal testing in the setting of ED. The LCD is consistent with these guidelines.

8. Commenter believes the review article The Resurgence of the Vacuum Erection Devices (VED) for Treatment of Erectile Dysfunction presented at the 2013 American Urological Association meeting should be considered the gold standard for use of VEDs. The commenter then excerpts multiple citations from the article supporting patient satisfaction with VED use.

Response: We appreciate the additional clinical citation and agree that the clinical literature generally reports positive patient satisfaction with VED use. The LCD contains no contradictory position. 9. Commenter presents internal data from customers who have ordered a vacuum erection device and additional tension rings to show that one replacement ring a year is not adequate and recommends a replacement tension ring every 90 days for maximum benefit.

Response: Disagree. The DME MACs must take into consideration the requirements for refills of supplies needed on a recurring basis. Supplies are divided into consumable and non-consumable supplies. Tension rings are considered a non-consumable supply; therefore, replacement is considered reasonable and necessary when the device is no longer functional.

The LCD defines a minimum replacement frequency; however, this is not considered a timeframe for automatic or routine replacement. Replacement of non-consumable supplies is based upon documentation that the item is no longer functional for its intended use.

VENTILATORS

Correct Coding and Coverage of Ventilators

Joint DME MAC Publication

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.

Coding

Items classified as ventilators must be billed using the HCPCS codes describing ventilators. The HCPCS codes for ventilators are:

- E0450 – VOLUME CONTROL VENTILATOR, WITHOUT PRESSURE SUPPORT MODE, MAY INCLUDE PRESSURE CONTROL MODE, USED WITH INVASIVE INTERFACE (E.G., TRACHEOSTOMY TUBE)
- E0460 – NEGATIVE PRESSURE VENTILATOR; PORTABLE OR STATIONARY
- E0461 – VOLUME CONTROL VENTILATOR, WITHOUT PRESSURE SUPPORT MODE, MAY INCLUDE PRESSURE PRESSURE CONTROL MODE, USED WITH NON-INVASIVE INTERFACE (E.G. MASK)
- E0463 – PRESSURE SUPPORT VENTILATOR WITH VOLUME CONTROL MODE, MAY INCLUDE PRESSURE CONTROL MODE, USED WITH INVASIVE INTERFACE (E.G. TRACHEOSTOMY TUBE)
- E0464 – PRESSURE SUPPORT VENTILATOR WITH VOLUME CONTROL MODE, MAY INCLUDE PRESSURE CONTROL MODE, USED WITH NON-INVASIVE INTERFACE (E.G. MASK)

NOTE: Ventilators must not be billed using codes for CPAP (E0601) or bi-level PAP (E0470, E0471, E0472). Using the CPAP or bi-level PAP HCPCS codes to bill a ventilator is incorrect coding, even if the ventilator is only being used in CPAP or bi-level mode (see below). Claims for ventilators used in CPAP or bi-level PAP scenarios will be denied as incorrect coding.

Coverage

Items may only be covered based upon the applicable reasonable and necessary (R&N) criteria and based upon the classification assigned to the device. The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations Manual (Internet-Only Manual, Publ. 100-3) 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.

Each of these disease categories are comprised of conditions that can vary from severe and life-threatening to less serious forms. These disease groups may appear to overlap conditions described in the Respiratory Assist Devices LCD but they are not overlapping. Choice of an appropriate device i.e., a ventilator vs. a bi-level PAP device is made based upon the severity of the condition. CMS distinguished the use of respiratory product types in a National Coverage Analysis Decision Memo (CAG-00052N) in June 2001:

> RADs [bi-level PAP devices] provide noninvasive positive pressure respiratory assistance (NPPRA). Note that some studies in the literature refer to this as noninvasive positive pressure ventilation (NPPV).
>
> NPPRA is the administration of positive air pressure, using a nasal and/or oral mask interface which creates a seal, avoiding the use of more invasive airway access. It may sometimes be applied to assist insufficient respiratory efforts in the treatment of conditions that may involve sleep-associated hypoventilation. It is distinguished from the invasive ventilation administered via a securely intubated airway, in a patient for whom interruption or failure of respiratory support leads to death.

The conditions described in the Respiratory Assistance Devices (RAD) local coverage determination are not life-threatening conditions where interruption of respiratory support would quickly lead to serious harm or death. These policies describe clinical conditions that require intermittent and relatively short durations of respiratory support. Thus, a ventilator would not be eligible for reimbursement for any of the conditions described in the RAD LCD even though the ventilator equipment may have the capability of operating in a bi-level PAP (E0470, E0471, E0472) mode. Bi-level PAP devices (E0470, E0471) are considered as R&N in those clinical scenarios.

A ventilator would not be considered reasonable and necessary (R&N) for the treatment of obstructive sleep apnea, as described in the PAP LCD, even though the ventilator equipment may have the capability of operating in a CPAP (E0601) or bi-level PAP (E0470) mode.

Claims for ventilators used for the treatment of conditions described in the PAP or RAD LCDs will be denied as not reasonable and necessary.

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 Frequent and Substantial Servicing payment category. Upgrade billing across different payment categories is not possible.

Pricing Category

Ventilators are classified in the Frequent and Substantial Servicing (FSS) payment category. FSS item are those for which there must be frequent and substantial servicing in order to avoid risk to the patient's health. CMS designates the items which fall into this payment group. 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.

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 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 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 the DME PDAC Contact Form located on the PDAC website: https://www.dmepdac.com/.

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