DME MAC Jurisdiction A Resource
INFORMATION FOR DME MAC SUPPLIERS in CT, DE, DC, ME, MD, MA, NH, NJ, NY, PA, RI, & VT
June 2016
Number 40

Key Dates For Jurisdiction A Transition

Effective July 1, 2016, the Jurisdiction A DME MAC will transition from NHIC to Noridian Healthcare Solutions. NHIC and Noridian are working closely together in all operational areas to ensure a smooth transition and the least amount of disruption to our Jurisdiction A suppliers and beneficiaries. Noridian will be acquiring all necessary files and pending workloads from NHIC at the time of transition cutover to continue operations of the Jurisdiction A contract. In order to transition this workload successfully, it is necessary for Noridian to impose a single system dark day on July 1. A dark day is a business day during the cutover period when the Medicare claims processing systems, customer service, and the interactive voice response (IVR) system will not be available for normal business operations. There will be no access to the Viable Medicare System (VMS) to conduct claim entry or claim correction, verify beneficiary eligibility or claim status. All of these services will resume with Noridian on July 5, 2016.

In preparation for the transition, NHIC is providing the below key dates and information relating to the termination of the services currently provided by NHIC:

This bulletin should be shared with all healthcare practitioners and managerial members of the physician/supplier staff. Bulletins are available at no cost from our web site at: http://www.medicarenhic.com/dme/

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Date Service Ending with NHIC	Function	Specific Services
6/24/2016 5:00 EDT	Written Inquiries/Correspondence/Appeals *Current NHIC phone/FAX numbers and addresses can be found at:* **http://www.medicarenhic.com/dme/contacts.aspx**	Submission of: General Written Inquiries, FOIA requests, Medicare Secondary Payor, ADMC requests, Prior Authorization Requests, Additional Documentation Responses, Reopenings, Reconsiderations, ALJ Hearing Requests, Overpayments, and Requested Refunds
6/24/2016 5:00 EDT	Outreach & Education	Fax Line (781-741-3586) and e-mail address: **outreach-education@hpe.com**
6/24/2016 5:00 EDT	Website Forms	Use and submission of any forms residing on the NHIC Website
6/24/2016 5:00 EDT	Claim Submission	Paper
6/30/2016 3:00 EDT	Claim Submission	Electronic
6/30/2016 5:00 EDT	Provider Contact Center **Effective 7/1/16:** *The same IVR and TTY/TDD toll free numbers will remain in place with Noridian. The direct CSR and Telephone Reopenings line will no longer be available. You will be prompted through the IVR line to connect directly to a CSR or the TRU.*	IVR: 866-419-9458 Direct CSR: 866-590-6731 TTY/TTD: 888-897-7539 Telephone Reopenings (TRU): 844-687-2656
6/30/2016 5:00 EDT	NHIC Website	The NHIC Website will be available, including all self-service tools, educational products and Decision Desktop
6/30/2016 5:00 EDT	NHIC CERT Coordinator	Contacting our CERT Coordinator for CERT related questions/concerns: **323-432-7840** or **alina.jimenez@hpe.com**

NHIC Provider Services Portal (PSP):

Separate notification was issued via e-mail to all NHIC portal users and placed on the NHIC website and portal home pages: http://www.medicarenhic.com/dme/psphome.aspx

VPIQ:

Separate notification was issued via e-mail to all NHIC VPIQ users.

CEDI:

JA Transition information can be found at:
https://www.ngscedi.com/ngs/portal/ngscedi/!ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOK9DS1NPP29DbwsggOdDRz9PbwDjAzdjAy8TPQLsh0VAdUVKY8!/

Additional information can be viewed on the Noridian JA Implementation Website:
https://med.noridianmedicare.com/web/jadme

Noridian's timeline article can be viewed at the following:
https://med.noridianmedicare.com/web/jadme/article-detail/-/view/4546752/timeline-for-implementation-activities

General Information

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DRU	Drugs	**O&P**	Orthotics & Prosthetics	**SPE**	Specialty Items
GEN	General	**OXY**	Oxygen	**VIS**	Vision
MOB	Mobility/Support Surfaces	**PEN**	Parenteral/Enteral Nutrition		

***MLN Matters* Disclaimer**
These articles were prepared as a service to the public and are not intended to grant rights or impose obligations. These 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.

2016 Durable Medical Equipment Prosthetics, Orthotics, and Supplies Healthcare Common Procedure Coding System (HCPCS) Code Jurisdiction List (MM9481) (GEN)

MLN Matters® Number: MM9481 Revised
Related CR Release Date: May 10, 2016
Related CR Transmittal #: R3520CP

Related Change Request (CR) #: CR9481
Effective Date: January 1, 2016
Implementation Date: February 1, 2016

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

Provider Types Affected

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

Provider Action Needed

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

Additional Information

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

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

Document History

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

Claim Status Category and Claim Status Codes Update (MM9550) (GEN)

MLN Matters® Number: MM9550
Related CR Release Date: May 20, 2016
Related CR Transmittal #: R3527CP

Related Change Request (CR) #: CR 9550
Effective Date: October 1, 2016
Implementation Date: October 3, 2016

Provider Types Affected

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

Provider Action Needed

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

Background

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

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

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

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

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

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

Additional Information

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

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

Coding Revisions to National Coverage Determinations (MM9540) (GEN)

MLN Matters® Number: MM9540
Related CR Release Date: April 29, 2016
Related CR Transmittal #: R1658OTN

Related Change Request (CR) #: CR 9540
Effective Date: July 1, 2016
Implementation Date: July 5, 2016, unless otherwise noted

Provider Types Affected

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

What You Need to Know

Change Request (CR) 9540 is the 7th maintenance update of the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) conversions and other coding updates specific to National Coverage Determinations (NCDs). Edits

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

Background

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

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

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

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

Additional Information

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

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

Coding Revisions to National Coverage Determinations (NCDs) (MM9631) (GEN)

MLN Matters® Number: MM9631 Revised
Related CR Release Date: June 3, 2016

Related CR Transmittal #: R1672OTN

Related Change Request (CR) #: CR 9631
Effective Date: October 1, 2016 - unless noted differently in CR9631
Implementation Date: October 3, 2016

Note: *This article was revised on June 6, 2016, to reflect the revised CR9631 issued on June 3, 2016. In the article, the CR release date, transmittal number, and the Web address for accessing the CR are revised. All other information remains the same.*

Provider Types Affected

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

Provider Action Needed

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

Background

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

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

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

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

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

Additional Information

The official instruction, CR 9631, issued to your MAC regarding this change is available at **https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1672OTN.pdf**.

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

Document History

- June 6, 2016 - revised due to revised CR - no substantive change to the article.
- May 17, 2016 - initial issuance.

Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP): Additional Instructions for the Implementation of Round 2 Recompete of the DMEPOS CBP Program and National Mail Order (NMO) Recompete (MM9579) (GEN)

MLN Matters® Number: MM9579
Related CR Release Date: April 28, 2016
Related CR Transmittal #: R3500CP

Related Change Request (CR) #: CR 9579
Effective Date: October 1, 2016
Implementation Date: October 3, 2016

Provider Types Affected

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

Provider Action Needed

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

Background

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

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

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

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

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

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

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

Clarification of Grandfathering instructions

Under the Medicare DMEPOS CBP, a beneficiary who obtains competitive bidding items in a designated CBA must obtain these items from a contract supplier, unless an exception applies. One exception is that a beneficiary may continue to obtain a DME rental item(s) from a non-contract supplier if the beneficiary was receiving the rented item(s) from the non-contract supplier when the CBP

took effect in the CBA. Such non-contract supplier would be considered a "grandfathered supplier" with respect to such rented item and such beneficiary for the remainder of the period during which rental payments are made (for example, for the remainder of the 13-month period of continuous use for a capped rental item). An additional exception is that a beneficiary, who continues to obtain a rented, grandfathered competitive bidding item from a non-contract, grandfathered supplier, may also obtain certain covered accessories or supplies furnished for use with such rented "grandfathered" equipment from the same non-contract, grandfathered supplier for the remainder of the period during which rental payments are made (for example, for the remainder of the 13-month period of continuous use for a capped rental item).

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

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

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

Additional Information

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

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

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

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

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

Guidance on Implementing System Edits for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (MM9371) (GEN)

MLN Matters® Number: MM9371
Related CR Release Date: May 20, 2016
Related CR Transmittal #: R1669OTN

Related Change Request (CR) #: CR 9371
Effective Date: October 3, 2016
Implementation Date: October 3, 2016

Provider Types Affected

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

Provider Action Needed

Impact to You

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

What You Need to Know

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

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

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

What You Need to Do

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

Background

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

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

The covered items and services defined in the Act include:

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

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

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

- Physicians (as defined in Section 1861(r) of the Act)
- Physical Therapists
- Occupational Therapists
- Qualified Speech-Language Pathologists
- Physician Assistants
- Nurse Practitioners
- Clinical Nurse Specialists
- Certified Registered Nurse Anesthetists
- Certified Nurse-Midwives
- Clinical Social Workers
- Clinical Psychologists
- Registered Dietitians, and
- Nutritional Professionals

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

- Orthotists
- Prosthetists
- Opticians, and
- Audiologists

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

Some Technical Details

The DME-MACs will:

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

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

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

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

Additional Information

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

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

Implementation of the Award for Jurisdiction A Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Workload (MM9546) (GEN)

MLN Matters® Number: MM9546 Revised
Related CR Release Date: April 19, 2016
Related CR Transmittal #: R1642OTN

Related Change Request (CR) #: CR 9546
Effective Date: December 16, 2015
Implementation Date: July 1, 2016

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

Provider Types Affected

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

What You Need to Know

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

Background

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

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

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

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

Additional Information

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

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

Document History

Date of Change	Description
April 22, 2016	This article was revised to correct the Noridian address in the Background Section. The transmittal number, CR release date and link to the transmittal also changed. All other information remains the same.
March 17, 2016	The article was revised to modify language regarding submission of certain claims in paragraph 3 of the Background section.
March 15, 2016	Initial issuance of article.

Implementation of the Award for Jurisdiction B Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Workload (MM9526) (GEN)

MLN Matters® Number: MM9526 Revised
Related CR Release Date: March 11, 2016
Related CR Transmittal #: R1636OTN
Related Change Request (CR) #: CR 9526
Effective Date: January 4, 2016
Implementation Date: July 1, 2016

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

Provider Types Affected

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

What You Need to Know

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

Background

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

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

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

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

Additional Information

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

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

Document History

- March 17, 2016 - The article was revised to change the implementation date and modify language regarding submission of certain claims in paragraph 2 of the Background section.
- March 15, 2016 - Initial issuance of article.

Intravenous Immune Globulin (IVIG) Demonstration - Implementation (SE1424) (SPE)

MLN Matters® Number: SE1424 Revised
Related CR Release Date: N/A
Related CR Transmittal N/A
Related Change Request (CR) #: N/A
Effective Date: N/A
Implementation: N/A

Note: *This article was revised on June 2, 2016, to make suppliers aware that a new contractor is administering this demonstration. See article SE1610 at* **https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1610.pdf** for more information.

Provider Types Affected

This MLN Matters® Article is intended for suppliers submitting claims to Durable Medical Equipment Medicare Administrative Contractors (DME MACs) for Intravenous Immune Globulin (IVIG) drugs and services to Medicare beneficiaries.

Suppliers do not need to apply to participate in the demonstration as long as they meet all Medicare as well as other national, state, and local standards and regulations applicable to the provision of demonstration covered services.

Provider Action Needed

In this article, the Centers for Medicare & Medicaid Services (CMS) alerts providers to a three year demonstration to evaluate the benefits of providing payment for items and services needed for the in-home administration of IVIG for the treatment of Primary Immune Deficiency Disease (PIDD). CMS has designed the IVIG demonstration to pay a bundled payment for items and services needed for the in-home administration of intravenous immune globulin for the treatment of PIDD. The demonstration will begin paying for services as of October 1, 2014, and will continue for three years, as long as funding remains available.

Background

Depending on the circumstances, traditional fee-for-service (FFS) Medicare covers some, or all, components of home infusion services. By special statutory provision, Medicare Part B covers IVIG for persons with PIDD who wish to receive the drug at home. Medicare does not separately pay for any services or supplies to administer the drug if the person is not homebound, and is otherwise receiving services under a Medicare Home Health episode of care. As a result, many beneficiaries have chosen to receive the drug at their doctor's office, in an outpatient hospital setting, or to self-administer the drug subcutaneously. Beneficiaries may also alternate between settings or drug formulations, if necessary, to accommodate travel or other personal situations.

IVIG Demonstration

The "*Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012*" authorized the demonstration under Part B of Title XVIII of the *Social Security Act*. The demonstration is limited to no more than 4,000 beneficiaries, and the $45 million budget covers benefit costs, as well as administrative expenses for implementation and evaluation. Participation is voluntary and may be terminated by the beneficiary at any time.

Under this demonstration, Medicare will issue under Part B a bundled payment for all items and services that are necessary to administer IVIG in the home to enrolled beneficiaries who are not otherwise homebound and receiving home health care benefits. In processing all services and supplies needed for the administration of IVIG, CMS is not making any changes to existing coverage

determinations to receive the IVIG drug in the home or for services and supplies that are otherwise not covered under the traditional FFS Medicare Part B benefit.

The demonstration only applies to situations where the beneficiary requires IVIG for the treatment of PIDD, or is currently receiving subcutaneous immune globulin to treat PIDD and wishes to switch to IVIG. This demonstration does not apply if the immune globulin is intended to be administered subcutaneously. Only those beneficiaries with PIDD who are eligible to receive IVIG under the current Medicare benefit (have Part B, and have traditional FFS Medicare) will be eligible to enroll in the demonstration and have the services paid under the new demonstration.

This demonstration will not change how subcutaneous administration of immune globulin (SCIG) is covered and paid for under the traditional Medicare FFS program. Also, nothing in this demonstration will impact how IVIG is paid by Medicare for beneficiaries who are covered under a home health episode of care.

Beneficiaries participating in the demonstration shall not be restricted in any way from receiving Medicare covered IVIG, and non-demonstration Medicare covered related services from different providers at different times should they so choose. For example, a beneficiary receiving services under the demonstration at home may choose to switch and receive them at a doctor's office or outpatient department at any time. The beneficiary may switch back to receiving services under the demonstration as long as they are otherwise still eligible, and funding remains available.

Beneficiaries under hospice shall not be excluded from this demonstration, and their demonstration claims shall be processed in the same manner as other Medicare (non-demonstration) claims for hospice patients.

Beneficiaries covered under a home health episode of care may apply to participate in the demonstration but will not be eligible to have services paid for under the demonstration until after the home health episode of care has ended. Similarly, beneficiaries who are participating in the demonstration and subsequently become eligible to receive services under a home health episode of care will not be eligible to have services paid for under the demonstration for the period of time they are covered under such episodes.

Providers/suppliers billing for the services and supplies covered under the demonstration must meet all Medicare as well as other national, state, and local standards and regulations applicable to the provision of services related to home infusion of IVIG.

Beneficiary Eligibility

In order to pay for the new demonstration covered services, the following requirements must be met:

1. The beneficiary must be enrolled in the demonstration on the eligibility file provided by NHIC, Corp., the implementation support contractor (as of July 1, 2016, Noridian Healthcare Solutions, LLC is the support contractor);
2. The beneficiary must be eligible to have the IVIG drug paid for at home (has a diagnosis of PIDD) under the traditional Medicare benefit;
3. The beneficiary must be enrolled in Medicare Part B and not be enrolled in a Medicare Advantage plan (i.e. have traditional FFS Medicare coverage);
4. The beneficiary must not be covered on the date of service in a home health episode (In such circumstances, the services are covered under the home health episode payment.)
5. The place of service must be the beneficiary's home or a setting that is "home like".

Billing Details

A new "Q" code has been established for services, supplies, and accessories used in the home under the Medicare Intravenous Immune Globulin (IVIG) Demonstration:

Q2052 - (Long Description) - Services, supplies, and accessories used in the home under Medicare Intravenous immune globulin (IVIG) demonstration.

Q2052- (Short Description) - IVIG demo, services/supplies.

The code is for use with the IVIG demo only and the jurisdiction for this code is DME MAC.

The new demonstration service code (Q2052) must be billed as a separate claim line on the same claim for the IVIG drug itself.

Specialty pharmacies will bill for the IVIG drug itself when intended for home administration by beneficiaries who are not homebound and not covered under a home health benefit episode. For those beneficiaries participating in the demonstration, specialty pharmacies shall bill for the demonstration covered services on the same claim as the drug itself. Claims for the demonstration bundled service (Q2052) billed in the absence of the "J" code for the IVIG drug will not be payable. The new demonstration covered services will be paid as a bundle and will be subject to coinsurance and deductible in the same manner as other Part B services.

For 2014, the nationwide Medicare allowable for Q2052 will be $300 each time the IVIG is administered. (The 2016 payment rate for Q2052 is $336.05.) While this is expected to be approximately monthly, it can be more or less frequent depending upon a patient's medical need.

As with all DMEPOS claims, specialty pharmacies will bill these claims to the appropriate DME MAC jurisdiction based on the beneficiary's state.

The following "J" codes (as updated by CR 8724) represent immune globulin drugs that are administered intravenously and payable in 2014 under Medicare Part B for services rendered in the home (or home-like setting) for beneficiaries with PIDD: Privigen, (J1459), Bivigam (J1556), Gammaplex (J1557), Gamunex (J1561), Immune Globulin Not Otherwise Specified (J1566 and J1599), Octagam (J1568), Gammagard liquid (J1569), and Flebogamma (J1572). Immune globulin drugs covered under Medicare Part B for administration in the home for patients with PIDD are subject to change; coverage of any drugs under the demonstration shall not differ from drugs that are eligible for payment under Part B for beneficiaries not enrolled in the demonstration.

Note: If the claim for IVIG is not otherwise payable under Medicare Part B, the Q2052 claim line is not payable under the demonstration. The claim for Q2052 must have the same place of service code on the claim line as the IVIG (J code) for which it is applicable. In cases where the drug is mailed or delivered to the patient prior to administration, the date of service for the administration of the drug (the "Q2052" claim line) may be no more than 30 calendar days after the date of service on the drug claim line.

If multiple administrations of IVIG are submitted on a single claim, each date of service for the administration of the drug (Q2052) must be on a separate claim line. If these requirements are not met, the claim will not be processed and Medicare will return a Group Code of CO (Contractual Obligation), a Remittance Advice Remarks Code (RARC) of M51 (Missing/incomplete/invalid procedure code(s)) and a Claim Adjustment Remarks Code (CARC) of B15 (This service/procedure requires that a qualifying service/procedure be received and covered. The qualifying other service/procedure has not been received/adjudicated).

If a claim is submitted with the HCPCS Q2052 code and the beneficiary is not enrolled in the demonstration on the date of service, the claim will be denied with a RARC of M138 (Patient identified as a demonstration participant but the patient was not enrolled in the demonstration at the time services were rendered. Coverage is limited to demonstration participants.), a CARC of 96 (Non-covered charge(s)), and a Group Code of CO.

Coverage of demonstration services shall be subject to the usual coordination of benefit process and the usual Medicare Secondary Payer process as well.

Questions and Answers Relating to Supplier Eligibility

Question: Is the DMEPOS (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies) Supplier required to be certified to bill the A/B MACs in order to provide the nursing component of the Q2052 - Services, Supplies and Accessories Used in the Home under the Medicare Intravenous Immune Globulin (IVIG) Demonstration?

Answer: No. The DMEPOS supplier must currently be able to bill the DME MACs (enrolled and current with the National Supplier Clearinghouse) and meet all regulatory and statutory requirements. If a state requires licensure to furnish certain items or services, a DMEPOS supplier: Must be licensed to provide the item or service; and may contract with a licensed individual or other entity to provide the licensed services unless expressly prohibited by State law. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs or from any other federal procurement or non-procurement programs.

Question: Can the supplier/pharmacy contract or subcontract nursing services for the administration of the IVIG to bill the Q2052 - Services, Supplies and Accessories Used in the Home under the Medicare Intravenous Immune Globulin (IVIG) Demonstration?

Answer: Yes. If a state requires licensure to furnish certain items or services, a supplier/pharmacy: Must be licensed to provide the item or service; and may contract with a licensed individual or other entity to provide the licensed services unless expressly prohibited by State law.

A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other federal procurement or non-procurement programs.

How Beneficiaries can apply for the IVIG Demonstration

To participate in this demonstration the beneficiary must complete and submit an application form. All applications must be signed by the beneficiary as well as his or her physician. **Submission of an application does not guarantee that a beneficiary will be accepted to participate in the demonstration.**

CMS has contracted with NHIC, Corp., DME MAC Jurisdiction A, (NHIC is being replaced by Noridian as of July 1, 2016) to help administer the demonstration. NHIC (Noridian, effective July 1, 2016) will review all applications for eligibility and will create and upload an enrollment file to be used by CMS' claims processing systems.

CMS conducted an initial enrollment period from 8/08/2014 - 9/12/2014. Since the number of beneficiaries and funds available to implement this demonstration are limited, not all beneficiaries who are eligible may be accepted if more eligible beneficiaries apply than can be served with the funds available. If the number of eligible beneficiaries that apply during the initial enrollment period is below the statutory limits, then additional applications will continue to be accepted after the 9/12/2014 deadline on a rolling basis until enrollment and/or funding limits are reached. As of June 2016, Medicare is continuing to accept applications from beneficiaries on a rolling basis. This will continue as long as the funding or enrollment limitations are not reached or until the demonstration ends, whichever occurs sooner. The last date to submit an application for coverage prior to September 30, 2017 (when the demonstration is scheduled to end) is August 15, 2017.

Until June 24, 2016, the enrollment application and the application completion guide are available at:
http://www.medicarenhic.com or through the IVIG Demo Hot Line at: (844)-625-6284.

As of June 24, 2016, the enrollment application and the application completion guide will be available at
http://med.noridianmedicare.com/web/ivig.

Until June 23, 2016, completed applications may be submitted by fax or mail to NHIC, Corp. at the following address:

Applications may be mailed to:
NHIC, Corp.
IVIG Demo
P.O. Box 9140
Hingham, MA. 02043-9140

For overnight mailings:
NHIC, Corp
IVIG Demo
75 William Terry Dr.
Hingham, MA. 02043

Applications may be faxed to:
Fax 781-741-3533

As of June 24, 2016, completed applications may be submitted by fax or mail to Noridian.

Applications may be mailed to:
Noridian Healthcare Solutions, LLC
IVIG Demo
PO Box 6788
Fargo ND 58108-6788

For overnight mailings:

Noridian Healthcare Solutions, LLC
IVIG Demo
900 42nd Street South
Fargo ND 58103

Applications may be faxed to:

Fax 701-277-2428

Additional Information

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

MLN Matters article SE1610 at **https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1610.pdf** contains details on submitting applications to Noridian, the new support contractor, as of July 1, 2016.

Document History

- July 31, 2014 - Initial issuance.
- August 28, 2014 - revised to amend some of the billing instructions, particularly with regard to date of service on the Q2052 claim line. Also, some questions and answers related to supplier eligibility are added to the article.
- June 2, 2016 - Revised to add a link to SE1610, which announces a new contractor administering the demonstration, and to update the article to reflect the new contractor's information.

JW Modifier: Drug Amount Discarded/Not Administered to any Patient (MM9603) (DRU)

MLN Matters® Number: MM9603 Revised
Related CR Release Date: May 24, 2016
Related CR Transmittal #: R3530CP

Related Change Request (CR) #: CR 9603
Effective Date: July 1, 2016
Implementation Date: July 5, 2016

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

Provider Types Affected

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

Provider Action Needed

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

Effective July 1, 2016, providers are required to:

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

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

Background

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

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

Additional Information

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

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

Document History

Document History	Description
May 25, 2016	The article was revised to reflect an updated CR. That CR updated the X-Ref Requirement number in the CR's Supporting Information Section. In the article, the CR release date, transmittal number and link to the CR was changed. All other information remains the same.

Limiting the Scope of Review on Redeterminations and Reconsiderations of Certain Claims (SE1521) (GEN)

MLN Matters® Number: SE1521 Revised
Related CR Release Date: N/A
Related CR Transmittal #: N/A
Related Change Request (CR) #: N/A
Effective Date: N/A
Implementation Date: N/A

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

Provider Types Affected

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

What You Need to Know

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

Background

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

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

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

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

Additional Information

You can find out more about appealing claims decisions in the "*Medicare Claims Processing Manual*" (Publication 100-04, Chapter 29 (Appeals of Claims Decisions), Section 310.4.C.1. (Conducting the Redetermination (Overview)) at **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c29.pdf** on the CMS website. You can also find out more about 1) conducting a redeterminations in 42 CFR 405.948, at **http://www.ecfr.gov/cgi-bin/text-idx?SID=06584dd6a5fc15094e7633ff5f6cb359&mc=true&node=pt42.2.405&rgn=div5#se42.2.405_1948**; and 2) conducting a reconsideration in 42 CFR 405.968 at **http://www.ecfr.gov/cgi-bin/text-idx?SID=06584dd6a5fc15094e7633ff5f6cb359&mc=true&node=pt42.2.405&rgn=div5#se42.2.405_1968** on the Internet.

Medicare Policy Clarified for Prolonged Drug and Biological Infusions Started Incident to a Physician's Service Using an External Pump (SE1609) (DRU)

MLN Matters® Number: SE1609
Related CR Release Date: N/A
Related CR Transmittal #: N/A
Related Change Request (CR) #: N/A
Effective Date: N/A
Implementation Date: N/A

Provider Types Affected

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

What You Need to Know

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

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

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

Background

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

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

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

Additional Information

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

Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - July 2016 Update (MM9636) (DRU)

MLN Matters® Number: MM9636
Related CR Release Date: May 6, 2016
Related CR Transmittal #: R3518CP

Related Change Request (CR) #: CR 9636
Effective Date: July 1, 2016
Implementation Date: July 5, 2016

Provider Types Affected

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

Provider Action Needed

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

Background

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

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

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

Additional Information

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

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

Don't forget to review the:

Key Dates For Jurisdiction A Transition

Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - July 2016 (MM9572) (GEN)

MLN Matters® Number: MM9572
Related CR Release Date: April 1, 2016
Related CR Transmittal #: R3488CP

Related Change Request (CR) #: CR 9572
Effective Date: July 1, 2016
Implementation Date: July 5, 2016

Provider Types Affected

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

What You Need to Know

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

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

Background

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

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

Additional Information

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

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

The **DMEPOS Competitive Bidding Program** site includes information on all rounds of the CBP, including product categories and single payment amounts for the Round One Re-compete, Round Two, and the national mail-order program for diabetic testing supplies; and the ZIP codes of areas included in the CBP.

Reclassification of Certain Durable Medical Equipment HCPCS Codes Included in Competitive Bidding Programs (CBP) from the Inexpensive and Routinely Purchased Payment Category to the Capped Rental Payment Category (MM8822) (GEN)

MLN Matters® Number: MM8822 Revised
Related CR Release Date: April 26, 2016

Related CR Transmittal #: R1644OTN

Related Change Request (CR) #: CR 8822
Effective Date: July 1, 2016 - except in Round 1 Re-compete CBP areas where effective date is January 1, 2017
Implementation Date: July 5, 2016 - except for A/B and HHH MACs where implementation is 10/3/2016

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

Provider Types Affected

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

What You Need to Know

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

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

Background

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

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

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

HCPCS Codes for Items Reclassified to Capped Rental DME Category

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

Further Details from CR8822:

1. In Round 1 Re-compete CBAs, payment for HCPCS codes shown in the above table will be made under the inexpensive and routinely purchased (IN) payment category for dates of service July 1, 2016 through December 31, 2016. Your MAC will recognize that the capped payment category requires payment of 10 percent of the purchase price for the first three months and 7.5 percent for each of the remaining rental months 4 through 13. You should also be aware that payment amounts will be based on the lower of the supplier's actual charge and the fee schedule amount. Your MAC will return as unprocessable claims for the inexpensive and routinely purchased codes described above that are billed with the KH, KI and KJ modifiers. Such unprocessable claims will be returned with Claim Adjustment Reason Code (CARC) 4 (The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.), Remittance Advice Remark Code (RARC) N519 (Invalid combination of HCPCS modifiers) and Group Code CO (Contractual Obligation).

2. Effective for claims with dates of service on or after July 1, 2016, for items furnished in Round 2 CBAs, your MAC will cease any IN category rental payments for the codes in the above table and start payment under the Capped Rental (CR) payment category; applying a determination of the number of rental months paid (which cannot exceed 13 rental months combined from dates of service before and after the effective date (July 1, 2016)).

3. Effective for claims with dates of service on or after January 1, 2017, for items furnished in Round 1 Re-compete CBAs, your MAC will cease any IN rental payments for these codes, and start payment under the Capped Rental (CR) payment category; applying a determination of the number of rental months paid (which cannot exceed 13 rental months combined from dates of service before and after the effective date (January 1, 2017)).

4. Effective July 1, 2016, in all areas except the nine Round 1 CBAs, your MACs will process and pay claims for wheelchair base codes K0835 - K0864): E1020, E1028, E2368, E2369, E2370, E2375, K0015, and E0955 (when applicable) on a lump sum purchase basis when used with complex rehabilitative power wheelchairs.

5. Effective January 1, 2017 in all areas including the Round 1 Re-compete CBAs, your MACs will process and pay claims for the codes K0835 - K0864): E1020, E1028, E2368, E2369, E2370, E2375, K0015, and E0955 (when applicable) on a lump sum purchase basis when used with complex rehabilitative power wheelchairs.

6. When Home Health/Hospice (HHHs) providers bill codes E0197, E0140, E0149, E0985, E1020, E1028, E2228, E2368, E2369, E2370, E2375, K0015, K0070 and E0955 for services outside a competitive bid area on or after July 1, 2016, payment will be made on a capped rental basis.

7. When HHHs bill E1020, E1028, E2368, E2369, E2370, E2375, K0015, and E0955 for services outside a competitive bid area on or after July 1, 2016, MACs will process such claims on a lump sum purchase basis, where applicable, when used with a complex rehabilitative wheelchair base (K0835-K0864). **Note that for this requirement, MACs will calculate the fee for the lump sum purchase basis (NU modifier - Purchase of new equipment) for these items as the rental price times ten. The fee for a used item lump sum purchase basis (UE modifier - Purchase of used equipment) will be 75 percent of the purchase fee.**

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

Additional Information

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

If you have any questions, please contact your MAC at their toll-free number, which is available at **http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html**

Document History

Date of Change	Description
April 29, 2016	The article was changed due to a revised CR8822. Only the CR release date, transmittal number, and the Web address for the CR were changed in the article. All other information remains the same.
March 24, 2016	The article was revised due to a revised Change Request. The revised CR adds business requirements 8822.6.2, 8822.6.3 and 8822.7 (bottom of page 7 and top of page 8 of this article), which provides instructions to the MACs for calculating the lump sum purchases. In the article, the transmittal number, CR issue date, and the Web address for accessing CR8822 are revised. All other information is unchanged.

Remittance Advice Remark and Claims Adjustment Reason Code and Medicare Remit Easy Print and PC Print Update (MM9466) (GEN)

MLN Matters® Number: MM9466
Related CR Release Date: April 1, 2016
Related CR Transmittal #: R3489CP
Related Change Request (CR) #: CR 9466
Effective Date: July 1, 2016
Implementation Date: July 5, 2016

Provider Types Affected

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

Provider Action Needed

CR9466 updates the Claim Adjustment Reason Code (CARC) and Remittance Advice Remark Code (RARC) lists. It also instructs Medicare system maintainers to update Medicare Remit Easy Print (MREP) and PC Print. Make sure that your billing staffs are aware of these changes and obtain the updated MREP or PC Print software if they use that software.

Background

The *Health Insurance Portability and Accountability Act (HIPAA)* of 1996, instructs health plans to be able to conduct standard electronic transactions adopted under HIPAA using valid standard codes. Medicare policy states that CARCs and RARCs, as appropriate, that provide either supplemental explanation for a monetary adjustment or policy information that generally applies to the monetary adjustment of a claim or service, are required in the remittance advice and coordination of benefits transactions.

The Centers for Medicare & Medicaid Services (CMS) instructs MACs and Shared Systems, if appropriate, to conduct updates based on the code update schedule that results in publication of updated code lists three times a year (around March 1, July 1, and November 1).

Medicare's Shared System Maintainers (SSMs) are responsible for implementing appropriate code deactivation, making sure that any deactivated code is not used in original business messages, but the deactivated code in derivative messages is allowed. SSMs must make sure that Medicare does not report any deactivated code on or before the effective date for deactivation as posted on the Washington Publishing Company (WPC) website. If any new or modified code has an effective date past the implementation date specified in CR9466, MACs will implement on the date specified on the WPC website. The WPC website is available at **http://www.wpc-edi.com/Reference** on the Internet.

In case of any discrepancy in the code text as posted on WPC website and as reported in any CR, the WPC version should be implemented.

CR9466 advises the SSMs and MACs to perform the updates posted on the WPC based on the March 1, 2016 CARC and RARC code change lists.

Additional Information

The official instruction, CR9466, issued to your MAC regarding this change, is available at **https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3489CP.pdf** on the CMS website.

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

Updated Information on the Intravenous Immune Globulin (IVIG) Demonstration (SE1610) (SPE)

MLN Matters® Number: SE1610
Related CR Release Date: N/A
Related CR Transmittal #: N/A
Related Change Request (CR) #: N/A
Effective Date: N/A
Implementation Date: N/A

Provider Types Affected

This MLN Matters® Article is intended for suppliers submitting claims to Durable Medical Equipment Medicare Administrative Contractors (DME MACs) for Intravenous Immune Globulin (IVIG) drugs and services for Medicare beneficiaries.

As mentioned in MLN Matters Article **SE1424**, suppliers do not need to apply to participate in the demonstration as long as they meet all Medicare as well as other national, state, and local standards and regulations applicable to the provision of demonstration covered services.

Provider Action Needed

In this article, the Centers for Medicare & Medicaid Services (CMS) informs providers that a new Medicare contractor, Noridian Healthcare Solutions, LLC, will replace NHIC as the implementation support contractor for the IVIG demonstration as of July 1, 2016. This article also reminds suppliers of the 2016 payment rate for demonstration service code Q2052. The 2016 payment rate is $336.05. As of June 2016, Medicare is continuing to accept applications from beneficiaries on a rolling basis. This will continue as long as the funding or enrollment limitations are not reached or until the demonstration ends, whichever occurs sooner. As of June 24th, applications should no longer be submitted to NHIC. The last date to submit an application for coverage prior to September 30, 2017 (when the demonstration is scheduled to end) is August 15, 2017.

Make sure your staff is aware of this information.

Background

In MLN Matters Article **SE1424**, CMS provides a complete overview of the IVIG demonstration. Part of the overview includes a discussion of how beneficiaries need to submit an application in order to participate in the demonstration. As of June 24, 2016, such applications must be submitted to Noridian Healthcare Solutions, LLC.

The enrollment application and the application completion guide will be available at **https://med.noridianmedicare.com/web/ivig** or through the IVIG Call Center at (844)-625-6284. You can also sign up to receive IVIG Demonstration ListServe updates from the new Implementation Support Contractor.

As of June 24, 2016, completed applications may be submitted by fax or mail to Noridian.

Applications may be mailed to:

Noridian Healthcare Solutions, LLC
IVIG Demo
PO Box 6788
Fargo ND 58108-6788

For overnight mailings:
Noridian Healthcare Solutions, LLC
IVIG Demo
900 42nd Street South
Fargo ND 58103

Applications may be faxed to:
Fax 701-277-2428

Additional Information

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

MLN Matters Article SE1424 has more details and is available at **https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1424.pdf**.

Updates to Pub. 100-04, Chapters 1 and 16 to Correct Remittance Advice Messages (MM9578) (GEN)

MLN Matters® Number: MM9578
Related CR Release Date: April 29, 2016
Related CR Transmittal #: R3510CP
Related Change Request (CR) #: CR 9578
Effective Date: October 1, 2016
Implementation Date: October 3, 2016

Provider Types Affected

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

Provider Action Needed

If Change Request (CR) 9578 updates Chapter 1 and Chapter 16 of the "*Medicare Claims Processing Manual*" to reflect the standard format and to correct any non-compliant remittance advice code combinations. Make sure that your billing staffs are aware of the corrected code combinations.

Background

Section 1171 of the *Social Security Act* requires a standard set of operating rules to regulate the health insurance industry's use of Electronic Data Interchange (EDI) transactions. Operating Rule 360: Uniform Use of CARCs and RARCs, regulates the way in which group codes, Claims Adjustment Reason Codes (CARCs), and Remittance Advice Remark Codes (RARCs) may be used. The rule requires specific codes which are to be used in combination with one another if one of the named business scenarios applies. This rule is authored by the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE).

Medicare and all other payers must comply with the CAQH CORE-developed code combinations. The business scenario for each payment adjustment must be defined, if applicable, and a valid code combination selected for all remittance advice messages.

CR9578 makes the following code revisions:

1. When a MAC rejects an out of jurisdiction professional claim as unprocessable, the following codes are used:
    - Group Code of CO
    - CARC 109, and
    - RARC N104

2. When a MAC rejects misdirected Railroad Retirement Board claims as unprocessable, the following codes are used:
   - Group Code of CO
   - CARC 109, and
   - RARC N105

3. When a MAC rejects misdirected United Mine Workers Association claims as unprocessable, the following codes are used:
   - Group Code CO
   - CARC 109, and
   - RARC N127

4. In the above 3 situations, RARC MA130 was used previously, but will no longer be used in these situations.

Additional Information

The official instruction, CR9578 issued to your MAC regarding this change is available at **http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3510CP.pdf**.
The revised manual Chapters 1 and 16 are attached to CR9578.

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

Updates to Pub. 100-04, Chapters 3, 6, 7 and 15 to Correct Remittance Advice Messages (MM9562) (GEN)

MLN Matters® Number: MM9562
Related CR Release Date: March 18, 2016
Related CR Transmittal #: R3481CP
Related Change Request (CR) #: CR 9562
Effective Date: June 20, 2016
Implementation Date: June 20, 2016

Provider Types Affected

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

What You Need to Know

Change Request (CR) 9562 informs MACs about revisions to Chapters 3, 6, 7 and 15 of the "*Medicare Claims Processing Manual*" to ensure that all remittance advice coding is consistent with nationally standard operating rules. It also provides a format for consistently showing remittance advice coding throughout the manual. CR9562 does not reflect any change in Medicare policy.

Background

Section 1171 of the *Social Security Act* requires a standard set of operating rules to regulate the health insurance industry's use of Electronic Data Interchange (EDI) transactions. Operating Rule 360: Uniform Use of CARCs and RARCs, regulates the way in which group codes, Claims Adjustment Reason Codes (CARCs) and Remittance Advice Remark Codes (RARCs) may be used. The rule requires specific codes which are to be used in combination with one another if one of the named business scenarios applies. This rule is authored by the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE).

Medicare and all other payers must comply with the CAQH CORE-developed code combinations. CR8424 established a standard format for presenting these code combinations in the "*Medicare Claims Processing Manual*." CR9562 updates Chapters 3, 6, 7 and 15 of the manual to reflect the standard format and to correct any non-compliant code combinations. CR9562 does not reflect any change in Medicare policy.

Additional Information

The official instruction, CR9562, issued to your MAC regarding this change is available at **https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3481CP.pdf** on the CMS website. The revised manual chapters are included in CR9562.

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

Fee Schedule Updates (GEN)

The 2016 fee schedules and subsequent updates are available via the "Fee Schedules" section of the Jurisdiction A Durable Medical Equipment Medicare Administrative Contractor (DME MAC JA) Website, **http://www.medicarenhic.com/dme/dmfees.aspx**. This quarter the following notices have been posted:

- There are no updates to the 2nd Quarter 2016 Jurisdiction A DME MAC Fee Schedule
- 2nd Quarter 2016 Average Sales Price Medicare Part B Drug Pricing File
- 2nd Quarter 2016 Oral Anticancer Drug Fees

Note: The January 1 fees for the current calendar year are posted as the "*Jurisdiction A DME MAC Fee Schedule*" for that particular year, and these files are not changed throughout the year. Rather, separate notices are posted as fee revisions/updates become available. Please be sure you are viewing the appropriate file/notice for the item and date of service.

Inclusion or exclusion of a fee schedule amount for an item or service does not imply any health insurance coverage.

MLN Connects® Provider eNews (GEN)

Note: *Links to each edition of the eNews can be found on the MLN Connects® Provider eNews Archive at:*
https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Provider-Partnership-Email-Archive.html

MLN Connects® Provider eNews for March 10, 2016

MLN Connects® Events

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

Medicare Learning Network® Publications and Multimedia

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

Announcements

- CMS Proposes to Test New Medicare Part B Prescription Drug Models
- HHS Reaches Goal of Tying 30 Percent of Medicare Payments to Quality Ahead of Schedule
- 2016 Value Modifier Results and Upward Payment Adjustment Factor
- Open Payments System Registration for Physicians and Teaching Hospitals
- 2015 PQRS Data Submission Deadlines

- EHR Incentive Programs: Attest to 2015 Program Requirements by March 11
- Hospice, IRF, LTCH, SNF, HHA: QIES System Downtime from March 16 through 21
- Quality of Patient Care Star Ratings TEP Call for Nominations through March 18
- Home Health Agencies: Register for HHCAHPS before April 1
- Next Generation ACO Model Second Application Cycle: Letter of Intent due May 2
- New ST PEPPER Available
- Five Ways Patients Can Become Informed Medicare Consumers
- March is Colorectal Cancer Awareness Month

Claims, Pricers, and Codes

- April 2016 Average Sales Price Files Available

MLN Connects® Provider eNews for March 17, 2016

MLN Connects® Events

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

Other CMS Events

- Comparative Billing Report on Modifier 25: Internal Medicine Webinar
- Comparative Billing Report on Non-invasive Vascular Studies Webinar

Medicare Learning Network® Publications and Multimedia

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

Announcements

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

MLN Connects® Provider eNews for March 24, 2016

MLN Connects® Events

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

Other CMS Events

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

Medicare Learning Network® Publications and Multimedia

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

Announcements

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

Claims, Pricers, and Codes

- Update to the RHC Qualifying Visit List

MLN Connects® Provider eNews for March 31, 2016

MLN Connects® Events

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

Medicare Learning Network® Publications and Multimedia

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

Announcements

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

Claims, Pricers, and Codes

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

MLN Connects® Provider eNews for April 07, 2016

MLN Connects® Events

- Open Payments 2016: Prepare to Review Reported Data Call - Last Chance to Register
- IMPACT Act: Data Element Library Call - Last Chance to Register

- Medicare Shared Savings Program ACO Application Process Call - Register Now
- 2016 PQRS Reporting: Avoiding 2018 Negative Payment Adjustments Call - Register Now
- National Partnership to Improve Dementia Care and QAPI Call - Register Now

Other CMS Events

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

Medicare Learning Network® Publications and Multimedia

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

Announcements

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

Claims, Pricers, and Codes

- April 2016 Outpatient PPS Pricer File Available

MLN Connects® Provider eNews for April 14, 2016

MLN Connects® Events

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

Other CMS Events

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

Medicare Learning Network® Publications and Multimedia

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

- Infection Control: Injection Safety Web-Based Training Course - Revised

Announcements

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

Claims, Pricers, and Codes

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

MLN Connects® Provider eNews for April 21, 2016

MLN Connects® Events

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

Other CMS Events

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

Medicare Learning Network® Publications and Multimedia

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

Announcements

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

Claims, Pricers, and Codes

- Rural Health Clinic Claims Processing Incorrectly

MLN Connects® Provider eNews for April 28, 2016

MLN Connects® Events

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

Other CMS Events

- Comparative Billing Report on Subsequent Nursing Facility E/M Services Webinar
- Comparative Billing Report on Modifiers 24 and 25: General Surgeons Webinar
- Medicare Learning Network® Publications and Multimedia
- Acute Care Hospital Inpatient Prospective Payment System Booklet - Revised
- New Educational Web Guides Fast Fact

Announcements

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

Claims, Pricers, and Codes

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

MLN Connects® Provider eNews for May 05, 2016

MLN Connects® Events

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

Medicare Learning Network® Publications and Multimedia

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

Announcements

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

Claims, Pricers, and Codes

- Reprocessing of Selected Dialysis Claims

MLN Connects® Provider eNews for May 12, 2016

MLN Connects® Events

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

Medicare Learning Network® Publications and Multimedia

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

Announcements

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

Claims, Pricers, and Codes

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

MLN Connects® Provider eNews for May 19, 2016

MLN Connects® Events

- New Audio Recordings and Transcripts Available

Other CMS Events

- Comparative Billing Report on Psychotherapy and E/M Services Webinar

Medicare Learning Network® Publications and Multimedia

- Part C Appeals: Organization Determinations, Appeals, and Grievances WBT - Revised
- Part D Coverage Determinations, Appeals, and Grievances WBT - Revised
- Resources for Medicare Beneficiaries Booklet - Revised
- How to Use the Searchable Medicare Physician Fee Schedule Booklet - Revised
- Updated MLN Matters® Search Indices

Announcements

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

MLN Connects® Provider eNews for May 26, 2016

MLN Connects® Events

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

Other CMS Events

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

Medicare Learning Network® Publications and Multimedia

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

Announcements

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

MLN Connects® Provider eNews for June 2, 2016

MLN Connects® Events

- Physician Compare Initiative Call - Register Now
- Quality Measures and the IMPACT Act Call - Registration Now Open
- New Audio Recording and Transcript Available

Other CMS Events

- SNF Quality Reporting Program Provider Training: Reserve Your Hotel Room by June 8

Medicare Learning Network® Publications and Multimedia

- CMS Provider Minute Videos for Part A and Part B Providers and DMEPOS Suppliers

Announcements

- Medicare's "Big Data" Tools Fight and Prevent Fraud to Yield Over $1.5 Billion in Savings
- Integrated Efforts to Improve Patient Safety and Reduce Hospital Readmissions
- DMEPOS Competitive Bidding Program Round 2 Recompete and National Mail-Order Recompete: List of Contract Suppliers Available
- ICD-10 Resources: Clinical Concepts Series
- June is National Safety Month

Claims, Pricers, and Codes

- July 2016 Average Sales Price Files Available

MLN Connects® Provider eNews for June 9, 2016

News & Announcements

- Medicare Makes Enhancements to the Shared Savings Program to Strengthen Incentives for Quality Care
- TEP on Refinement of NQF #0678: Nominations due June 10
- New PEPPER for Short-term Acute Care Hospitals and June 21 Webinar
- 2016 PQRS GPRO Registration Open through June 30
- Long-Term Care Facilities: Mandatory Submission of Staffing Data via PBJ Begins July 1
- Antipsychotic Drug use in Nursing Homes: Trend Update
- Home Health Quality of Patient Care Star Ratings TEP Summary Available

Claims, Pricers & Codes

- 2017 ICD-10-PCS Updates Available

Upcoming Events

- Physician Compare Initiative Call - June 16

- IRF Tier Comorbidity Updates: Soliciting Stakeholder Input Call - June 16
- Quality Measures and the IMPACT Act Call - July 7

Medicare Learning Network® Publications & Multimedia

- Updated Information on the IVIG Demonstration MLN Matters® Article - New
- June 2016 Catalog Available
- Medicaid Program Integrity: What Is a Prescriber's Role in Preventing the Diversion of Prescription Drugs? Fact Sheet - Revised
- Vaccine and Vaccine Administration Payments under Medicare Part D Fact Sheet - Revised
- Reading the Institutional Remittance Advice Booklet - Reminder
- Medicare Enrollment Guidelines for Ordering/Referring Providers Fact Sheet - Reminder

Don't forget to review the:

Key Dates For Jurisdiction A Transition

DME MAC Jurisdiction A Local Coverage Determinations (GEN)

The LCDs can be found on the DME MAC JA Web site at:
http://www.medicarenhic.com/dme/mrlcdcurrent.aspx

LCDs can also be found on the CMS Web site within the Medicare Coverage Database (MCD), which is accessible by going to: **http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx**

Billing Guidance - Billing for External Infusion Pumps and Drugs When Treatment Was Initiated Somewhere Other Than the Beneficiary Home - DME MAC Joint Publication (SPE)

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

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

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

- purchase a drug for a medically reasonable and necessary prolonged drug infusion; and,
- begin the drug infusion in the physician's office or hospital outpatient setting using an external pump; and,
- send the patient home for a portion of the infusion; and,
- have the patient return at the end of the infusion period.

In these scenarios, claims must be submitted to the appropriate A/B MAC for the drug or biological, the administration, and the external infusion pump. Additional information is available in MLN Matters® Special Edition Article # 1609, available at:
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html

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

Infusions Started in the Beneficiary's Home

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

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

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

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

Correct Coding - JW Modifier Use - Revised - Effective for Claims with Dates of Service On or After July 1, 2016 -Joint DME MAC Publication (GEN)

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

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

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

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

Scenario 1

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

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

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

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

Scenario 2

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

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

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

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

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

Correct Coding - LIM innovations Infinite Socket™ - Revised - DME MAC Joint Publication (O&P)

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

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

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

Base code

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

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

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

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

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

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

Addition codes

Use on all claims in addition to the base code:

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

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

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

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

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

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

L5651 ADDITION TO LOWER EXTREMITY, ABOVE KNEE, FLEXIBLE INNER SOCKET, EXTERNAL FRAME
L5920 ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE OR HIP DISARTICULATION, ALIGNABLE SYSTEM

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

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

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

For questions about correct coding, contact the Pricing, Data Analysis and Coding (PDAC) contractor Contact Center at (877) 735-1326 during the hours of 8:30 a.m. to 4:00 p.m. CT, Monday through Friday, or e-mail the PDAC by completing the **DME PDAC Contact Form.**

Correct Coding - Martin Bionics Socket-less Socket™ - Revised - Effective June 1, 2016 - DME MAC Joint Publication (O&P)

This article revises the Correct Coding article published March 10, 2016 to provide specific HCPCS codes for Medicare billing. HCPCS code L5999 (LOWER EXTREMITY PROSTHESIS, NOT OTHERWISE SPECIFIED), which is currently used for billing purposes, is being replaced with specific L-codes. The revised coding requirements are effective for claims with dates of service on or after June 1, 2016

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

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

Base code:

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

L5321 SOCKET ABOVE KNEE, MOLDED SOCKET, OPEN END, SACH FOOT, ENDOSKELETAL SYSTEM, SINGLE AXIS KNEE.
L5590 PREPARATORY, ABOVE KNEE - KNEE DISARTICULATION ISCHIAL LEVEL SOCKET, NON-ALIGNABLE SYSTEM, PYLON NO COVER, SACH FOOT, LAMINATED SOCKET, MOLDED TO MODEL

The addition codes discussed below (L5631, L5649, L5950) and choice of suspension must be included on the same claim for the complete prosthesis i.e., the claim that includes one of the above codes.

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

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

Do not use L5321 or L5590 for billing a replacement socket for an existing prosthesis.

Addition codes:

Use these codes on all claims in addition to the base code:

L5631 ADDITION TO LOWER EXTREMITY, ABOVE KNEE OR KNEE DISARTICULATION, ACRYLIC SOCKET.
L5649 ADDITION TO LOWER EXTREMITY, ISCHIAL CONTAINMENT/NARROW M-L SOCKET.
L5950 ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE, ULTRALIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL).

The combination of base and addition codes listed above include all the features and functions of the Socket-less Socket™. HCPCS code L5999 must not be used to bill for features or functions included in the socket. Use of L5999 in this manner will be rejected as incorrect coding (unbundling).

Suspension:

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

Other Additions:

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

L5651 ADDITION TO LOWER EXTREMITY, ABOVE KNEE, FLEXIBLE INNER SOCKET, EXTERNAL FRAME
L5920 ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE OR HIP DISARTICULATION, ALIGNABLE SYSTEM

NOTE: The Socket-less Socket™ includes an option to use a combination of "flower distal cup technology with special NASA-based mesh fabric" as a functional alternative to a flexible inner socket. This combination of materials is not considered to be a flexible inner socket and must not be coded using L5651. L5999 must not be used for these items as payment for these materials is considered included in the payment for the base code. Separate claims for these materials will be denied as incorrect coding (unbundling).

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

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

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

For questions about correct coding, contact the Pricing, Data Analysis and Coding (PDAC) contractor Contact Center at (877) 735-1326 during the hours of 8:30 a.m. to 4:00 p.m. CT, Monday through Friday, or e-mail the PDAC by completing the **DME PDAC Contact Form**.

Correct Coding and Coverage of Ventilators - Revised May 2016 - DME MAC Joint Publication (SPE)

This article has been revised to reflect clarifications on coding and coverage requirements for ventilators in the Frequent and Substantial Servicing (FSS) payment category and to remove ventilator codes that were retired effective January 1, 2016.

Ventilator technology has evolved to the point where it is possible to have a single device capable of operating in numerous modes, from basic continuous positive pressure (CPAP and bi-level PAP) to traditional pressure and volume ventilator modes. This creates the possibility that one piece of equipment may be able to replace numerous and different pieces of equipment. Equipment with multifunction capability creates the possibility of errors in claims submitted for these items. This article will discuss the application of Medicare proper coding and payment rules for ventilators.

HCPCS CODING

Effective for claims with DOS on or after January 1, 2016, all products classified as ventilators must be billed using one of the following HCPCS codes:

E0465 HOME VENTILATOR, ANY TYPE, USED WITH INVASIVE INTERFACE, (E.G., TRACHEOSTOMY TUBE)
E0466 HOME VENTILATOR, ANY TYPE, USED WITH NON-INVASIVE INTERFACE, (E.G., MASK, CHEST SHELL)

Products previously assigned to HCPCS codes E0450 and E0463 must use HCPCS code E0465. Products previously assigned to HCPCS codes E0460, E0461 and E0464 must use HCPCS code E0466. The PDAC will update the product classification listing in a future update.

Suppliers are reminded that the payment policy requirements for the FSS payment category prohibits FSS payment for devices used to deliver continuous and/or intermittent positive airway pressure, regardless of the illness treated by the device. (*Social Security Act* 1834(a)(3)(A)) This means that products currently classified as HCPCS code E0465 or E0466 when used to provide CPAP or bi-level PAP (with or without backup rate) therapy, regardless of the underlying medical condition, may not be paid in the FSS payment category. General principles of correct coding require that products assigned to a specific HCPCS code only be billed using the assigned code. Thus, using the HCPCS codes for CPAP (E0601) or bi-level PAP (E0470, E0471) devices for a ventilator (E0465, E0466) used to provide CPAP or bi-level PAP therapy is incorrect coding. Claims for ventilators billed using the CPAP or bi-level PAP device HCPCS codes will be denied as incorrect coding.

Suppliers are encouraged to be sure that the correct category of product is provided and billed to avoid errors in HCPCS coding.

COVERAGE

Items may only be covered based upon the reasonable and necessary (R&N) criteria applicable to the product. The Centers for Medicare & Medicaid Services (CMS) *National Coverage Determination Manual* (Internet-Only Manual, 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.

These ventilator-related disease groups overlap conditions described in the Respiratory Assist Devices LCD used to determine coverage for bi-level PAP devices. Each of these disease categories are conditions where the specific presentation of the disease can vary from patient to patient. For conditions such as these, the specific treatment plan for any individual patient will vary as well. Choice of an appropriate treatment plan, including the determination to use a ventilator vs. a bi-level PAP device, is made based upon the specifics of each individual beneficiary's medical condition. In the event of a claim review, there must be sufficient detailed information in the medical record to justify the treatment selected.

UPGRADES

An upgrade is defined as an item that goes beyond what is medically necessary under Medicare's coverage requirements. In some cases, CMS policy that allows for billing of upgrade modifiers can be used when providing an item or service that is considered beyond what is medically necessary. This is NOT applicable to ventilators in the situations described above.

Although the use of a ventilator to treat any of the conditions contained in the PAP or RAD LCDs is considered "more than is medically necessary", the upgrade billing provisions may not be used to provide a ventilator for conditions described in the PAP or RAD LCDs. CPAP and bi-level PAP items are in the Capped Rental payment category while ventilators are in the FSS payment category. Upgrade billing across different payment categories is not possible. Claims for items billed for upgrade across different payment categories will be rejected as unprocessable.

PAYMENT CATEGORY

Ventilators are classified in the FSS payment category. FSS items are those for which there must be frequent and substantial servicing in order to avoid risk to the patient's health (*Social Security Act* §1834(a)(3) (A)). The monthly rental payment for items in this pricing category is all-inclusive meaning there is no separate payment by Medicare for any options, accessories or supplies used with a ventilator. In addition, all necessary maintenance, servicing, repairs and replacement are also included in the monthly rental. Claims for these items and/or services will be denied as unbundling.

COVERAGE OF SECOND VENTILATOR

Medicare does not cover spare or back-up equipment. Claims for backup equipment will be denied as not reasonable and necessary - same/similar equipment.

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

The following are examples of situations in which a beneficiary would qualify for both a primary ventilator and a secondary ventilator:

- A beneficiary requires one type of ventilator (e.g. a negative pressure ventilator with a chest shell) for part of the day and needs a different type of ventilator (e.g. positive pressure ventilator with a nasal mask) during the rest of the day.
- A beneficiary who is confined to a wheelchair requires a ventilator mounted on the wheelchair for use during the day and needs another ventilator of the same type for use while in bed. Without two pieces of equipment, the beneficiary may be prone to certain medical complications, may not be able to achieve certain appropriate medical outcomes, or may not be able to use the medical equipment effectively.

Refer to the PAP and RAD LCDs and related Policy Articles and to the *DME MAC Supplier Manuals* for additional information on coverage, coding and documentation of these items.

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

Coverage and Coding - New Oral Antiemetic Drug Varubi® - Revised - Effective Date July 1, 2016 - Joint DME MAC Publication (DRU)

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

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

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

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

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

Q9981 - ROLAPITANT, ORAL, 1 MG

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

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

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

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

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

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

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

Hand-Finger Orthoses - Use of CG Modifier - Revised - Joint DME MAC Publication (O&P)

This replaces a previous version published April 8, 2010

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

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

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

For questions about correct coding, contact the Pricing, Data Analysis, and Coding contractor (PDAC) at (877) 735-1326 during the hours of 8:30 a.m. to 4:00 p.m. CT, Monday through Friday, or e-mail the PDAC by completing the **DME PDAC Contact Form**.

Correct Coding - Manual Wheelchair Bases - Revised - DME MAC Joint Publication (MOB)

This is a revision to a previous version published February 13, 2014

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

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

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

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

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

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

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

Correct Coding Reminder - Duopa® (AbbVie) - Joint DME MAC Publication (DRU)

On January 09, 2015, Duopa® (AbbVie) was approved by the FDA. Duopa® is an enteral-suspension combination of levodopa and carbidopa, and is indicated for the treatment of Parkinson's disease (PD). Duopa® is administered as a continuous 16-hour infusion into the jejunum through a percutaneous endoscopic gastrostomy-jejunal tube (PEG-J), using a CADD®-Legacy 1400 portable infusion pump. Duopa® enteral suspension is supplied as a single-use cassette. Each cassette contains 20 mg levodopa and 4.63 mg carbidopa (as 5 mg of the monohydrate) per mL of enteral suspension. Each cassette contains approximately 100 mL of suspension. Per the manufacturer, the maximum recommended daily dose of Duopa® is 2000 mg of the levodopa component (i.e., one cassette per day) administered over 16 hours. At the end of the daily 16-hour infusion, patients will disconnect the pump from the PEG-J and take their night-time dose of oral immediate-release carbidopa-levodopa tablets.

The DME MACs have received questions about the proper unit of service (UOS) to bill for Duopa®. For dates of service on or after January 09, 2015 through December 31, 2015, claims for Duopa® must be submitted using the DME miscellaneous code J7799 (NOC DRUGS, OTHER THAN INHALATION DRUGS, ADMINISTERED THROUGH DME). **When billing J7799, one (1) unit of service (UOS) is one cassette.**

A unique HCPCS code was created for Duopa® with claims for dates of service on or after January 01, 2016. The new code is:

J7340 CARBIDOPA 5 MG/LEVODOPA 20 MG ENTERAL SUSPENSION

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

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

For questions about correct coding, contact the Pricing, Data Analysis and Coding (PDAC) contractor Contact Center at (877) 735-1326 during the hours of 8:30 a.m. to 4:00 p.m. CT, Monday through Friday, or e-mail the PDAC by completing the **DME PDAC Contact Form**.

Affordable Care Act (ACA) 6407 - Supplier Frequently Asked Questions - Revised - DME MAC Joint Publication (GEN)

This FAQ is revised to update the criteria associated with the written order prior to delivery and face-to-face examination. While this document makes reference to "ACA 6407 requirements", technically these requirements are found in the Social Security Act Section 1834(a)(11)(B) and it's implementing regulation at 42 CFR 410.38. The CMS regulation contains the details for the face-to-face examination, written order prior to delivery and the list of items subject to these requirements.

ACA 6407

Q1: What is ACA 6407?

A1: "ACA" refers to the *Affordable Care Act of 2012* and "6407" is the specific section of the *Affordable Care Act* which requires a face-to-face (F2F) encounter with a physician and a valid written order prior to delivery. Suppliers should review the DME MAC Joint Publication titled "*Face-to-Face Examination and Prescription Requirements Prior to the Delivery of Certain DME Items Specified in the Affordable Care Act - Revised*" for a complete list of affected HCPCS codes.

Q2: When will CMS enforce the F2F requirements and 5EO?

A2: Section 6407 of the ACA was implemented on 7/1/2013 and the DME MAC contractors began enforcement of the 5EO and NPI requirements for dates of services on or after 1/1/2014. Enforcement of the F2F requirements by the DME MACs has been postponed by CMS until a future date.

Q3: What is the difference between "implementation" and "enforcement" regarding ACA 6407?

A3: Implementation is the date that the provisions of ACA 6407 became effective (7/1/2013). Enforcement is when DME MACs begin auditing claims to determine that suppliers are following the provisions of ACA 6407.

Q4: Is the Comprehensive Error Rate Testing (CERT) contractor following the DME MAC delay in enforcement of the F2F requirements?

A4: No. CERT has been instructed by CMS not to delay the enforcement of the F2F requirements. The CERT contractor operates under the rules of the *Improper Payments Elimination and Recovery Act* (IPERA) and must enforce all coverage and payment rules mandated by CMS regulations. Consequently, claims reviewed by the CERT contractor that are not compliant with the F2F requirements may result in denial or recoupment. If the CERT contractor denies for this reason, suppliers may submit a request for a redetermination.

Face-to-Face Encounter

Q5: Do suppliers need to obtain a new F2F encounter every six months?

A5: No, there is no requirement under ACA 6407 that a supplier obtain documentation of a new F2F encounter on a periodic basis. A F2F encounter within 6 months prior to the 5EO date is required for any order obtained on or after 7/1/2013.

Q6: What if the policy has a requirement for a F2F encounter within 30-days for an item that is also on the ACA list? Must the F2F encounter be performed within the 30-days or within six months?

A6: There is no 30-day F2F requirement. There are existing LCD requirements that require a physician encounter that must be performed for certification. The ACA F2F requirement does not replace any existing patient/physician encounters. Suppliers must meet both the ACA requirements and any certification requirements outlined in the applicable LCD. By meeting the LCD requirement, the ACA requirement is automatically met.

Q7: Does the ACA F2F requirement apply to orthotics and prosthetics?

A7: Not at this time. ACA 6407 (SSA Section 1834(a)(11)(B)) and the implementing regulation at 42 CFR 410.38 gives the Secretary the authority to specify to which HCPCS codes the face-to-face requirement and written order prior to delivery apply. CMS did not include orthotics or prosthetic codes on the list of applicable HCPCS codes. Suppliers should review the DME MAC Joint Publication titled "*Face-to-Face Examination and Prescription Requirements Prior to the Delivery of Certain DME Items Specified in the Affordable Care Act - Revised*" for a complete list of affected HCPCS codes.

Q8: Must the F2F encounter specifically mention the DME item being ordered?

A8: No. However, in order for the ACA requirements to be met, the F2F encounter must address a medical condition that supports the item ordered.

Q9: Does the F2F encounter with the treating practitioner (Medical Doctor (MD), Doctor of Osteopathic Medicine (DO) or Doctor of Podiatric Medicine (DPM), physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS)) need to specifically state the beneficiary was there for a F2F encounter for the specific DME item, or can the beneficiary have a visit and the physician's notes show physical limitations that justify the specific DME item?

A9: In contrast to power mobility devices, items subject to the ACA 6407 requirements do not require that the F2F encounter specify that the visit was expressly for the purpose of documenting the need for the specific item of DME. However, as noted above, there must be sufficient documentation in the medical records to support the need for the item ordered.

Q10: Can the F2F documentation be electronically signed by the treating practitioner?

A10: CMS has published instructions to contractors allowing electronic signatures (see *CMS Program Integrity Manual*, Chapter 3, Section 3.3.2.4). CMS has not provided detailed guidance defining the format or contents of an electronic signature. CMS does allow contractors to authenticate electronic signatures. We recommend that when suppliers obtain electronic records that the electronic signatures are clearly identifiable as electronic and meet the same date and credential standards as outlined in Chapter 3, Section 3.3.2.4. that are also required for a non-electronic signature for the same document type. Refer to each LCD and the *Supplier Manual* for additional information regarding signatures.

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

Q11: What elements must be included on the 5EO for items associated with ACA 6407 HCPCS code list?

A11: ACA 6407 requires 5 specific elements that must be included on the order:

- Beneficiary's name
- Item of DME ordered - this may be general - e.g., "hospital bed"- or may be more specific.
- Signature of the prescribing practitioner
- Prescribing practitioner's National Practitioner Identifier (NPI)
- The date of the order

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

Q12: What date should be used for the "date of the order" on the 5EO?

A12: Use the date the supplier is contacted by the treating practitioner (for verbal orders) or the date entered by the treating practitioner (for written dispensing orders).

Q13: What if the treating practitioner wants to specify additional elements on the 5EO?

A13: Nothing prohibits the treating practitioner (or the supplier) from including additional elements on the 5EO. The 5 elements listed above are the minimum elements required.

Q14: Some treating practitioners indicate a future date on which to start therapy. How is this handled?

A14: In some cases, the treating practitioner may specify a future start date for therapy that is different from the date of the order. This start date does not impact the date of the order, date of service (DOS) entered on the claim, Medicare-required forms

(e.g., CMN, DIF) or refill/delivery timelines. As long as the supplier has a properly completed 5EO with a correctly determined prescription date, an item may be shipped or delivered on or after the date of the order.

Q15: May the treating practitioner use a signature or date stamp on the 5EO?
A15: Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

Q16: The ACA 6407 does not apply to all DMEPOS and does not apply to various supplies and accessories. How should suppliers handle those items?
A16: For non-ACA items and items that do not require a written order prior to delivery, a standard dispensing order and detailed written order are sufficient. For ACA 6407 items that are provided based on a 5EO, the supplier must obtain a detailed written order before submitting a claim for any associated options, accessories and/or supplies that are separately billed. Suppliers should review the DME MAC Joint Publication titled "*Face-to-Face Examination and Prescription Requirements Prior to the Delivery of Certain DME Items Specified in the Affordable Care Act - Revised*" for a complete list of affected HCPCS codes.

Q17: Can the 5EO and the F2F encounter be on the same document as long as it is in the medical record?
A17: No. The F2F encounter and 5EO must be two separate documents. The face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans or other information as it may be appropriate).

Q18: If the beneficiary is in the hospital, can the attending physician conduct the F2F encounter and the beneficiary's primary care physician complete the 5EO?
A18: Yes. The treating practitioner that conducted the face-to-face examination does not need to be the prescriber for the DME item. However the prescriber must:

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

Q19: Can the F2F encounter, 5EO and the delivery of the DME item all be completed in the same day?
A19: Yes. However, the date stamp (or equivalent) indicating the date of receipt must clearly reflect that the 5EO was received prior to delivery of the item.

Documenting a Receipt Date

Q20: Must the 5EO be date stamped by the supplier upon receipt?
A20: A date stamp (or equivalent) is required which clearly indicates the supplier's date of receipt of the completed 5EO.

Q21: What methods are acceptable for documenting a receipt date?
A21: The DME MACs do not specify what method may be used to indicate date of receipt; however, there must be some indicator or notation on the documents that they were received by the supplier within the required time period. Some commonly accepted methods are:

- Hardcopy date stamps
- Hand-written dates
- Facsimile headers and electronic receipt dates (*see question 22 for additional information*)

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

Q22: Can a fax header be used to document receipt of the 5EO prior to delivery, or must we use a date stamp?
A22: We highly recommend the use of a date stamp to document receipt of the 5EO. If a fax date or equivalent is used, the information must be legible, it must be clear that the supplier is the one that received the 5EO on the date listed. Possible ways to document this would be to also submit a copy of the fax cover sheet or the header listing the "to" and "from" sender names.

5EO - Corrections to Document

Q23: What happens if there is an error on the 5EO document and it is not noticed until after the equipment is delivered to the beneficiary?

A23: Written order prior to delivery (WOPD) is a long-standing statutory requirement for certain items of DME. The list of items subject to WOPD (termed a 5EO for ACA 6407 items) was expanded by the *Affordable Care Act* Section 6407. Medicare policy stipulates that a 5EO that is missing an element is not "curable" by a provider (i.e., a provider cannot make corrections to a 5EO) except as outlined below:

I. If errors in the 5EO are found prior to delivery, the supplier has two options:
   A. The 5EO may be properly amended following the guidance in the *Medicare Program Integrity Manual* (Internet-Only Manual, Publication 100-08), Chapter 3, Section 3.3.2.5; or,
   B. A new 5EO may be created and sent to the physician for signature and date.

II. If errors in the 5EO are found after delivery of the item, the supplier has two options:
   A. If the error is discovered prior to claim submission, the original supplier may recover the delivered item(s), obtain a compliant, complete 5EO and then may redeliver the item(s) to the beneficiary; or,
   B. If the error is discovered after submitting a claim, the original supplier can recover their items and a new supplier must complete the transaction after complying with all requirements.

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

Q24: Does Medicare consider a different location (with a different NPI or PTAN) another supplier?

A24: Yes. A different location of the same company is considered a "new" supplier as that location operates and bills the Medicare program under a separate NPI/PTAN.

TABLE A: DME List of Specified Covered Items

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

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

The full table can be found starting on **page 58**

Face-to-Face and Written Order Requirements for Certain Types of DME - Revised April 2016 (GEN)

This letter is revised to update the criteria associated with the five-element written order prior to delivery (5EO) and face-to-face examination. While this document makes reference to "ACA 6407 requirements", technically these requirements are found in the Social Security Act Section 1843(a)(11)(B) and its implementing regulation at 42 CFR 410.38. The CMS regulation contains the details for the face-to-face examination, written order prior to delivery and the list of items subject to these requirements.

Dear Physician,

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

1. An in-person, face-to-face examination with the treating practitioner (Medical Doctor (MD), Doctor of Osteopathic Medicine (DO) or Doctor of Podiatric Medicine (DPM), physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS))* and,
2. The treating practitioner must document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered; and,

3. The face-to-face examination must have occurred sometime during the six (6) months prior to the date of the order for the item.

*The *Medicare Access and SCHIP Reauthorization Act of 2015* eliminated the ACA requirement that the NP, PA or CNS face-to-face examination documentation be co-signed by an MD or DO.

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

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

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

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

Prescription (order) Requirements

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

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

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

Face-to-face Examination Requirements

For Medicare beneficiaries, the treating practitioner must have a face-to-face examination with the beneficiary in the six (6) months prior to the date of the written order for the specified items of DME.

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

For the treating practitioner prescribing a specified DME item:

- The face-to-face examination with the beneficiary must be conducted within the six (6) months prior to the date of the prescription.
- The face-to-face examination must document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered.
- Remember that all Medicare coverage and documentation requirements for DMEPOS also apply. There must be sufficient medical information included in the medical record to demonstrate that the applicable coverage criteria are met. Refer to the applicable Local Coverage Determination for information about the medical necessity criteria for the item(s) being ordered.

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

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

Date and Timing Requirements

There are specific date and timing issues:

- The date of the face-to-face examination must be on or before the date of the 5EO and may be no older than 6 months prior to the 5EO date.
- The date of the face-to-face examination must be on or before the date of delivery for the item(s) prescribed.
- The date of the 5EO (prescription) must be on or before the date of delivery or Date of Service (DOS).
- ALL DMEPOS suppliers must have the completed 5EO in their file BEFORE the delivery of these items.

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

Upon request by the contractor, all DMEPOS suppliers must provide documentation from the qualifying face-to-face examination and the completed 5EO.

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

Sincerely,

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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 **http://www.dmepdac.com**

The full table can be found starting on **page 58**

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 (GEN)

This article has been revised to update the criteria associated with the five-element written order prior to delivery (5EO) and face-to-face examination. While this document makes reference to "ACA 6407 requirements", technically these requirements are found in the Social Security Act Section 1843(a)(11)(B) and its implementing regulation at 42 CFR 410.38. The CMS regulation contains the details for the face-to-face examination, written order prior to delivery and the list of items subject to these requirements.

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

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

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

Prescription (order) Requirements

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

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

The first bullet above, claims for purchases or initial rentals, includes all claims for payment of purchases and initial rentals for items not originally covered (reimbursed) by Medicare Part B. Claims for items obtained outside of Medicare Part B, e.g. from another payer prior to Medicare participation (including Medicare Advantage plans), are considered to be new initial claims for Medicare payment purposes. This means that all Medicare payment requirements must be met, the same as any other item initially covered by Medicare.

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

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

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

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

The 5EO must be available upon request.

For any of the specified items affected by the ACA 6407 requirements to be covered by Medicare, a written, signed and dated order (5EO) must be received by the supplier prior to delivery of the item. If the supplier delivers the item prior to receipt of a written order, it will be denied as statutorily noncovered. If the written order is not obtained prior to delivery, payment will not be made for that item

even if a written order is subsequently obtained. If a similar item is subsequently provided by an unrelated supplier who has obtained a written order prior to delivery, it will be eligible for coverage.

Note that the 5EO for these specified DME items require the National Provider Identifier (NPI) of the prescribing practitioner. Prescriptions for other DME items do not have this NPI requirement. Suppliers should pay particular attention to orders that include a mix of items, some of which are subject to these new order requirements. For example, oxygen concentrators (E1390) are often ordered in conjunction with portable oxygen (E0431). Orders for code E0431 require inclusion of the NPI while orders for E1390 do not.

Face-To-Face Examination Requirements

The treating practitioner must have a face-to-face examination with the beneficiary in the six (6) months prior to the date of the written order for the specified items of DME.

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

For the treat practitioner prescribing a specified DME item:

- The face-to-face examination with the beneficiary must be conducted within the six (6) months prior to the date of the prescription.
- The face-to-face examination must document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered.
- Remember that all Medicare coverage and documentation requirements for DMEPOS also apply. There must be sufficient medical information included in the medical record to demonstrate that the applicable coverage criteria are met. Refer to the applicable Local Coverage Determination for information about the medical necessity criteria for the item(s) being ordered.
- The treating practitioner that conducted the face-to-face examination does not need to be the prescriber for the DME item; however, the prescriber must:
    - Verify that the qualifying in-person visit occurred within the 6-months prior to the date of their prescription; and,
    - Have documentation of the qualifying face-to-face examination that was conducted.
- The prescriber must provide a copy of the 5EO for the item(s) to the DMEPOS supplier before the item can be delivered.

Date and Timing Requirements

There are specific date and timing requirements:

- The date of the face-to-face examination must be on or before the date of the 5EO and may be no older than 6 months prior to the 5EO date.
- The date of the face-to-face examination must be on or before the date of delivery for the item(s) prescribed.
- The date of the 5EO must be on or before the date of delivery.
- The DMEPOS supplier must have documentation of the completed 5EO in their file prior to the delivery of these items.

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

Upon request by the contractor, all DMEPOS suppliers must provide documentation from the qualifying face-to-face examination and the completed 5EO.

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

Claim Denial

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

Local Coverage Determinations (LCD)

LCDs that contain items subject to these requirements are:

- Automatic External Defibrillators
- Cervical Traction Devices

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

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

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

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

TABLE A: DME List of Specified Covered Items

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

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

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

HCPCS Code	Description
E0294	Hospital bed semi-electric (head and foot adjustment) without rail with mattress
E0295	Hospital bed semi-electric (head and foot adjustment) without rail without mattress
E0296	Hospital bed total electric (head, foot and height adjustments) without rail with mattress
E0297	Hospital bed total electric (head, foot and height adjustments) without rail without mattress
E0300	Pediatric crib, hospital grade, fully enclosed
E0301	Hospital bed Heavy Duty extra wide, with weight capacity 350-600 lbs with any type of rail, without mattress
E0302	Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, without mattress
E0303	Hospital bed Heavy Duty extra wide, with weight capacity 350-600 lbs with any type of rail, with mattress
E0304	Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, with mattress
E0424	Stationary compressed gas Oxygen System rental; includes contents, regulator, nebulizer, cannula or mask and tubing
E0431	Portable gaseous oxygen system rental includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
E0433	Portable liquid oxygen system
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, content gauge, cannula or mask, and tubing
E0439	Stationary liquid oxygen system rental, includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0441	Oxygen contents, gaseous (1 months supply)
E0442	Oxygen contents, liquid (1 months supply)
E0443	Portable Oxygen contents, gas (1 months supply)
E0444	Portable oxygen contents, liquid (1 months supply)
E0450*	Volume control ventilator without pressure support used with invasive interface
E0460*	Negative pressure ventilator portable or stationary
E0461*	Volume control ventilator without pressure support node for a noninvasive interface
E0462	Rocking bed with or without side rail
E0463*	Pressure support ventilator with volume control mode used for invasive surfaces
E0464*	Pressure support vent with volume control mode used for noninvasive surfaces
E0470	Respiratory Assist Device, bi-level pressure capability, without backup rate used non-invasive interface
E0471	Respiratory Assist Device, bi-level pressure capability, with backup rate for a non-invasive interface
E0472	Respiratory Assist Device, bi-level pressure capability, with backup rate for invasive interface
E0480	Percussor electric/pneumatic home model
E0482	Cough stimulating device, alternating positive and negative airway pressure
E0483	High Frequency chest wall oscillation air pulse generator system
E0484	Oscillatory positive expiratory device, non-electric
E0570	Nebulizer with compressor
E0575	Nebulizer, ultrasonic, large volume
E0580	Nebulizer, durable, glass or autoclavable plastic, bottle type for use with regulator or flowmeter
E0585	Nebulizer with compressor & heater
E0601	Continuous airway pressure device
E0607	Home blood glucose monitor
E0627	Seat lift mechanism incorporated lift-chair
E0628	Separate Seat lift mechanism for patient owned furniture electric
E0629	Separate seat lift mechanism for patient owned furniture non-electric
E0636	Multi positional patient support system, with integrated lift, patient accessible controls
E0650	Pneumatic compressor non-segmental home model
E0651	Pneumatic compressor segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor segmental home model with calibrated gradient pressure
E0655	Non- segmental pneumatic appliance for use with pneumatic compressor on half arm
E0656	Non- segmental pneumatic appliance for use with pneumatic compressor on trunk
E0657	Non- segmental pneumatic appliance for use with pneumatic compressor chest
E0660	Non- segmental pneumatic appliance for use with pneumatic compressor on full leg
E0665	Non- segmental pneumatic appliance for use with pneumatic compressor on full arm
E0666	Non- segmental pneumatic appliance for use with pneumatic compressor on half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor on full-leg
E0668	Segmental pneumatic appliance for use with pneumatic compressor on full arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor on half leg
E0671	Segmental gradient pressure pneumatic appliance full leg
E0672	Segmental gradient pressure pneumatic appliance full arm
E0673	Segmental gradient pressure pneumatic appliance half leg
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency
E0692	Ultraviolet light therapy system panel treatment 4 foot panel

HCPCS Code	Description
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

HCPCS Code	Description
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

Standard Documentation Language for Local Coverage Determinations and Related Policy Articles - Joint DME MAC Publication (GEN)

Note: *This is a revision to the previous article published in November 2015. This version updates the requirements for orders and face-to-face examinations, in compliance with the Affordable Care Act (ACA) Section 6407. While the Standard Documentation language makes reference to "ACA 6407 requirements", technically these requirements are found in the Social Security Act Section 1843(a)(11)(B) and its implementing regulation at 42 CFR 410.38. The CMS regulation contains the details for the face-to-face examination, written order prior to delivery and the list of items subject to these requirements.*

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

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

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

*****IMPORTANT*****

Many policies contain coverage and documentation requirements that are unique to that specific policy. Such unique information is not included in this article. It is important that suppliers review the actual LCD to be sure to have all of the relevant information necessary applicable to the item(s) provided.
In several places you will see "placeholders" like "XXX" or "###". Information specific to the policy will be inserted in these spots. Occasionally you may also see "Editor Note" comments. These notes are used to indicate where optional sections may be inserted, when applicable and formatting information.

Standard Language

LCD

COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on *Social Security Act* §1862(a)(1)(A) provisions, are defined by the following indications and limitations of coverage and/or medical necessity.

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

While this Standard Documentation language makes reference to "ACA 6407 requirements", technically these requirements are found in the *Social Security Act* Section 1843(a)(11)(B) and its implementing regulation at 42 CFR 410.38. The CMS regulation contains the details for the face-to-face examination, written order prior to delivery and the list of items subject to these requirements.

DWO VERBIAGE

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

ACA 5EO or WOPD

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

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

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

REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. (CMS *Program Integrity Manual*, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.8-9).

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

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

DOCUMENTATION REQUIREMENTS

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

PRESCRIPTION (ORDER) REQUIREMENTS

GENERAL (PIM 5.2.1)

All items billed to Medicare require a prescription. An order for each item billed must be signed and dated by the prescribing practitioner, kept on file by the supplier, and made available upon request. Items dispensed and/or billed that do not meet these prescription requirements and those below must be submitted with an EY modifier added to each affected HCPCS code.

DISPENSING ORDERS (PIM 5.2.2)

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

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

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

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

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

The dispensing order must be available upon request.

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

ACA 6407 PRESCRIPTION REQUIREMENTS

ACA 6407 requires a specific written order prior to delivery for the HCPCS codes specified in the table contained in the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section below. This ACA 6407-required prescription has five (5) mandatory elements. For the purposes of this policy, the ACA 6407- required order is referred to as a 5-element order (5EO). The 5EO must meet all of the requirements below:

- The 5EO must include all of the following elements:
    - Beneficiary's name

  - Item of DME ordered - this may be general - e.g., "hospital bed"- or may be more specific.
  - Signature of the prescribing practitioner
  - Prescribing practitioner's National Practitioner Identifier (NPI)
  - The date of the order
- The 5EO must be completed within six (6) months after the required ACA 6407 face-to-face examination; and,
- The 5EO must be received by the supplier before delivery of the listed item(s); and,
- A date stamp or equivalent must be used to document the 5EO receipt date by the supplier.

Note that 5EO for these specified DME items require the National Provider Identifier to be included on the prescription. Prescriptions for other DME items do not have this NPI requirement. Suppliers should pay particular attention to orders that include a mix of items, some of which are subject to these new order requirements. For example, oxygen concentrators (E1390) are often ordered in conjunction with portable oxygen (E0431). Orders for code E0431 require inclusion of the NPI while orders for E1390 do not.

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

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

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

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

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

The 5EO must be available upon request.

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

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

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

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

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

Additional order date instructions:

- If the prescriber creates a complete and compliant DWO, only a single date - the "order date" - is required. This order date may be the date that the prescriber signs the document (either wet signature or electronic signature).

- If someone other than the prescriber (e.g., DME supplier) creates the DWO then the prescription must be reviewed and, "…personally signed and dated…" by the prescriber. In this scenario, two (2) dates are required: an "order date" and a prescriber-entered "signature date".

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

Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state "PRN" or "as needed" utilization estimates for replacement frequency, use, or consumption are not acceptable. (PIM 5.9)

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

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

The DWO must be available upon request.

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

WRITTEN ORDERS PRIOR TO DELIVERY (PIM 5.2.4)
A written order prior to delivery (WOPD) is required for XXX. The supplier must have received a WOPD that has been both signed and dated by the prescribing practitioner and meets the requirements above for a DWO before dispensing the item.

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

NEW ORDER REQUIREMENTS (PIM 5.2.7)
A new prescription is required when:

- There is a change in the order for the accessory, supply, drug, etc.;
- On a regular basis (even if there is no change in the order) only if it so specified in the documentation section of a particular medical policy;
- When an item is replaced; and
- When there is a change in the supplier.

MEDICAL RECORD INFORMATION

GENERAL (PIM 5.7 -5.9)
The COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY section of this LCD contains numerous reasonable and necessary (R&N) requirements. The NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the related Policy Article contains numerous non-reasonable and necessary, benefit category and statutory requirements that must be met in order for payment to be justified. Suppliers are reminded that:

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

Information contained directly in the contemporaneous medical record is the source required to justify payment except as noted elsewhere for prescriptions and CMNs. The medical record is not limited to treating practitioner's office records but may include records from hospitals, nursing facilities, home health agencies, other healthcare professionals, etc. (not all-inclusive). Records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that an item is reasonable and necessary.

CONTINUED MEDICAL NEED

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

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

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

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

CONTINUED USE

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

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

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

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

REFILL DOCUMENTATION (PIM 5.2.7-8)

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

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

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

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

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

PROOF OF DELIVERY (PIM 4.26, 5.8)
Proof of delivery (POD) is a Supplier Standard. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers are required to maintain POD documentation in their files. Regardless of the method of delivery, the contractor must be able to determine that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are received by a specific Medicare beneficiary.

Suppliers, their employees, or anyone else having a financial interest in the delivery of the item are prohibited from signing and accepting an item on behalf of a beneficiary (i.e., acting as a designee on behalf of the beneficiary). The signature and date the beneficiary or designee accepted delivery must be legible.

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

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

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

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

Method 1-Direct Delivery to the Beneficiary by the Supplier
Suppliers may deliver directly to the beneficiary or the designee. In this case, POD to a beneficiary must be a signed and dated delivery document. The POD document must include:

- Beneficiary's name
- Delivery address
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Beneficiary (or designee) signature

The date delivered on the POD must be the date that the DMEPOS item was received by the beneficiary or designee. The date of delivery may be entered by the beneficiary, designee, or the supplier. When the supplier's delivery documents have both a supplier-entered date and a beneficiary or beneficiary's designee signature date on the POD document, the beneficiary or beneficiary's designee-entered date is the date of service.

In instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS supply must be the date of service on the claim.

Method 2-Delivery via Shipping or Delivery Service Directly to a Beneficiary
If the supplier utilizes a shipping service or mail order, the POD documentation must be a complete record tracking the item(s) from the DMEPOS supplier to the beneficiary. An example of acceptable proof of delivery would include both the supplier's own detailed shipping invoice and the delivery service's tracking information. The supplier's record must be linked to the delivery service record by some clear method like the delivery service's package identification number or supplier's invoice number for the package sent to the beneficiary. The POD record must include:

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

- Quantity delivered
- Date delivered
- Evidence of delivery

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

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

Method 3-Delivery to Nursing Facility on Behalf of a Beneficiary
For items directly delivered by the supplier to a nursing facility or when a delivery service or mail order is used to deliver the item(s) to a nursing facility, the supplier must have:

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

This information must be available upon request.

CORRECT CODING (PIM 3.3)
Correct coding is a determination that the item(s) provided to the beneficiary are billed using the appropriate HCPCS code for the item. Suppliers are required to correctly code for the items billed. An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, or MAC articles. Information that is sufficiently detailed to unambiguously identify the specific product delivered to the beneficiary and the HCPCS code used to bill for that item must be maintained by the supplier and be available upon request.

For LCDs that use ICD-10 diagnosis codes, correct coding of the ICD-10 code is required. A diagnosis is correctly coded when it meets all the coding guidelines listed in International Classification of Diseases Guidelines (ICD), CMS ICD policy or guideline requirements, LCDs, or MAC articles. Information that is sufficiently detailed to unambiguously justify the ICD-10 code used to bill for DMEPOS items must be contained in the beneficiary's medical record and be available upon request.

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

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

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

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

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS
AFFORDABLE CARE ACT (ACA) 6407 REQUIREMENTS
ACA 6407 contains provisions that are applicable to certain specified items in this policy. In this policy the specified items are:

{Insert code table}

These items require an in-person, face-to-face interaction between the beneficiary and their treating practitioner prior to prescribing the item. This face-to-face evaluation must specifically document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered. A dispensing order is not sufficient to provide these items. A 5EO (see ACA 5EO

section above) must be received prior to delivery. Refer to the related Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information about these statutory requirements.

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

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

GENERAL
CERTIFICATE OF MEDICAL NECESSITY (PIM 5.3) (**Editor Note:** *Only for items requiring CMN*)
A Certificate of Medical Necessity (CMN), which has been completed, signed, and dated by the treating practitioner, must be kept on file by the supplier and made available upon request. The CMN may act as a substitute for the detailed written order if it contains the same information as required in a detailed written order. The CMN for XXX is CMS Form ### (DME form ###). In addition to the order information that the treating practitioner enters in Section B, the supplier can use the space in Section C for a written confirmation of other details of the order or the treating practitioner can enter the other details directly.

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

DME INFORMATION FORM (PIM 5.3)

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

REPAIR/REPLACEMENT (BPM Ch. 15, §110.2)
A new Certificate of Medical Necessity (CMN) and/or treating practitioner's order is not needed for repairs.

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

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

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

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

REPAIR/REPLACEMENT (BPM Ch. 15, §120)
Adjustments and repairs of prostheses and prosthetic components are covered under the original order for the prosthetic device.

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

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

The prosthetist must retain documentation of the prosthesis or prosthetic component replaced, the reason for replacement, and a description of the labor involved irrespective of the time since the prosthesis was provided to the beneficiary. This information must

be available upon request. It is recognized that there are situations where the reason for replacement includes but is not limited to changes in the residual limb; functional need changes; or irreparable damage or wear/tear due to excessive beneficiary weight or prosthetic demands of very active amputees.

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

APPENDICIES
PIM citations above denote references to CMS *Program Integrity Manual*, Internet Only Manual 100-8

Utilization Guidelines
Refer to Coverage Indications, Limitations and/or Medical Necessity

POLICY ARTICLE

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on *Social Security Act* §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

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

Or

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

STATUTORY PRESCRIPTION (ORDER) REQUIREMENTS
Many DMEPOS items have statutory prescription requirements. Items with statutory order requirements are:

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

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

AFFORDABLE CARE ACT (ACA) 6407 REQUIREMENTS
ACA 6407 contains provisions that are applicable to specified items in this policy. In this policy the specified items are:

{Select codes from table below}

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

The treating practitioner must have a face-to-face examination with the beneficiary in the six (6) months prior to the date of the written order for the specified items of DME.

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

For the treating practitioner prescribing a specified DME item:

- The face-to-face examination with the beneficiary must be conducted within the six (6) months prior to the date of the prescription.
- The face-to-face examination must document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered.
- Remember that all Medicare coverage and documentation requirements for DMEPOS also apply. There must be sufficient medical information included in the medical record to demonstrate that the applicable coverage criteria are met. Refer to the applicable Local Coverage Determination for information about the medical necessity criteria for the item(s) being ordered.

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

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

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

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

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

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

ACA 6407 Prescription Requirements:

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

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

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

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

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

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

Date and Timing Requirements
There are specific date and timing requirements:

- The date of the face-to-face examination must be on or before the date of 5EO 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 5EO must be on or before the date of delivery.
- The DMEPOS supplier must have the completed 5EO in their file prior to the delivery of these items.

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

Upon request by the contractor, all DMEPOS suppliers must provide documentation from the treating practitioner face-to-face examination and the completed 5EO.

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

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

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

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

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

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

LCD and Policy Article Revisions Summary for March 17, 2016 (GEN)

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

Urological Supplies

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

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

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

LCD and Policy Article Revisions Summary for May 19, 2016 (GEN)

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

Knee Orthoses

LCD

Revision Effective Date: 06/02/2016

ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY:

- Added: HCPCS Codes L1832 and L1833 to Group 2 Diagnoses
- Added: Initial, Subsequent, and Sequela ICD-10s to Group 2 and Group 4
- Removed: ICD-10 Non-specific femur codes S72.426B & S72.426C - entered in error

DOCUMENTATION REQUIREMENTS:

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

DOCUMENTATION REQUIREMENTS:

- Revised: Standard Documentation language (Effective 04/28/2016)

Policy Article

Revision Effective Date: 06/02/2016

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

- Added: Definitions from CMS DMEPOS Quality Standards (42 CFR 424.57) and 42 CFR 414.402

CODING GUIDELINES:

- Added: Custom fabricated orthosis definitions
- Added: Definition of K0672

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

Results of Widespread Prepayment Review of Claims (Continuous Positive Airway Pressure Devices) HCPCS Code E0601 (SPE)

Historical Review Results

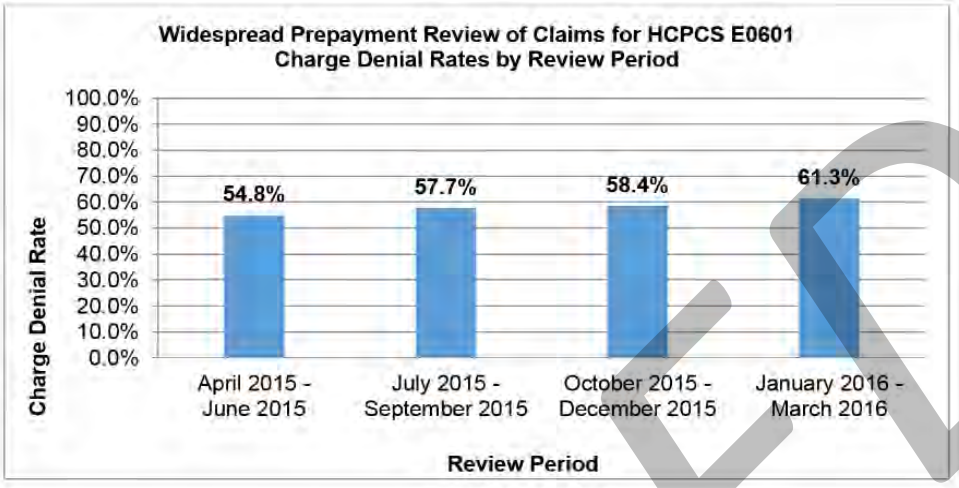
This review was initiated due to errors identified by the Comprehensive Error Rate Testing (CERT) Contractor. The overall Charge Denial Rate (CDR) is the total denied allowance amount (dollar amount of services determined to be billed in error) divided by the total allowance amount (dollar amount of services medically reviewed). The previous quarterly findings covered claims reviewed from October 2015 through December 2015, and reported a CDR of 58.4%.

Current Review Results

The DME MAC JA has completed the widespread prepayment review of claims for Continuous Positive Airway Pressure Devices (HCPCS E0601). These findings include claims processed from January 2016 through March 2016. This review involved prepayment complex medical review of 1805 claims submitted by 369 suppliers. Responses to the Additional Documentation Request (ADR) were not received for 254 (14%) of the claims. Of the 1551 claims for which responses were received, 502 claims were allowed and 1049 were denied/partially denied. This resulted in a claim denial rate of 68%. The overall CDR was 61.3%.

Charge Denial Rate Historical Data

The following graph depicts the Charge Denial rate from previous periods to current:



Primary Reasons for Denial

Based on the review of the documentation received, the following are the primary reasons for denial. Note that the percentages below reflect the fact that a claim could have more than one missing/incomplete item:

Face-to-Face Clinical Evaluation Documentation Issues

- 17% of the denied claims had insufficient Face-to-Face clinical documentation to support medical necessity and consequently did not meet the coverage criteria outlined in the PAP LCD. The insufficient clinical documentation included:
  - Missing Face-to-Face
  - Untimely Face-to-Face
  - Face-to-Face does not meet criteria based documentation submitted. Clinical documentation provided did not reflect the need for the care provided or no detailed narrative in the clinical documentation describing symptoms of sleep disordered breathing, daytime sleepiness/fatigue, observed apneas, and/or choking/gasping during sleep; duration of symptoms; or Epworth Sleepiness Scale scores.
  - Face-to-Face is illegible due to poor fax quality or illegible handwriting
  - Medical documentation not authenticated by the author.

  Scenarios included:
  A. Beneficiaries seeking initial coverage of a PAP device
  B. Beneficiaries seeking PAP replacement following the 5 year Reasonable Useful Lifetime (RUL)
  C. Beneficiaries seeking PAP replacement upon entering Fee-for-Service (FFS) Medicare

Detailed Written Order/Written Order Prior to Delivery Issues

- 30% of the denied claims had an incomplete Written Order Prior to Delivery (WOPD) for PAP device E0601.
  Included in these results for incomplete WOPD were orders which were missing either:
  A. Beneficiary's name
  B. The description of the E0601 PAP device ordered
  C. The prescribing practitioner's National Provider Identification (NPI)
  D. The signature of the prescribing practitioner
  E. The date of the order
  F. Signature date
  G. A date of receipt demonstrating supplier received the Detailed Written Order (DWO) on or before delivery
  H. DWO not submitted, illegible or is written before the Face-to-Face

- 85% of the claims had an incomplete DWO for PAP accessories.
  Included in these for incomplete DWO were orders which were missing either:
  A. Beneficiary's name
  B. Physician's name

C. Date of the order
D. Detailed description of item(s) ordered
E. Items to be dispensed
F. Physician signature and signature date

Also included in this calculation are orders which contain incompatible combinations: An example of this would be when the DWO lists multiple items that have the same purpose such as heated tubing and non heated tubing, or several different masks.

Sleep Study Documentation Issues

- 19% of the denied claims had insufficient Sleep Study documentation to support medical necessity and consequently did not meet the coverage criteria outlined in the PAP LCD. The insufficient clinical documentation included:
  A. No Sleep Study submitted
  B. Sleep test results did not meet Medicare coverage criteria
  C. Sleep Study interpretation per the PAP LCD

Training Documentation Issues

- 6% of the denied claims did not include evidence of training on the PAP device.
- 23% of the denied claims did not include evidence of beneficiary training (by entity conducting the test) on how to properly apply a portable sleep monitoring device prior to the home sleep test (HST). Per the PAP LCD, this can be accomplished either by a Face-to-Face demonstration, via video, or telephonic instruction and noted in the record.

Delivery Issues

- 3.2% of the denied claims were missing proof of delivery.
- 7% of the denied claims had proof of delivery which were missing either the beneficiary's name, delivery address, a sufficient description of the item(s) being delivered, quantity delivered, date delivered, or beneficiary's signature.

*Refer to Article: Proof of Delivery Reminder.

Claim Examples

As an additional educational effort, the following are actual examples of claim denials. NHIC expects that these examples will assist suppliers in understanding the medical review process and the common documentation errors that may occur with PAP claims:

Example 1:

Received: A DWO/WOPD, a Sleep Test that meets the Medicare coverage criteria, evidence of training on the PAP device, proof of delivery containing replacement items, and Face-to-Face clinical evaluation by the treating physician.
Insufficient: DWO lists incompatible combinations. Some suppliers use preprinted forms for their DWOs that include a listing of many different items, not all of which may be needed by an individual beneficiary. The final document that is signed and dated by the physician must clearly identify the specific items that are being ordered for the beneficiary. *Refer to article Detailed Written Orders posted 4/8/10.

Example 2: (Initial coverage of PAP)

Received: Face-to-Face clinical evaluation, a DWO/WOPD, evidence of training on the PAP device and a diagnostic Sleep Test.
Incomplete/Insufficient: Proof of Delivery is missing a sufficient description of item(s) delivered.

Example 3:

Received: A DWO/WOPD, a Face-to-Face clinical evaluation by treating physician, Home Sleep Study, proof of delivery, and evidence of Training on the PAP device
Missing: Documentation submitted did not include information to support that the beneficiary received instruction for the application and use of a portable sleep monitoring device for a home sleep study either by Face-to-Face, video or telephonic instruction.

Next Step

Based on the results of this prepayment review, DME MAC JA will continue to review claims billed for Continuous Airway Pressure Devices (E0601).

Suppliers are reminded that repeated failure to respond to ADR requests could result in a referral to the Jurisdiction A Program Safeguard Contractor/Zone Program Integrity Contractor.

DME MAC JA performs ongoing assessment of the effectiveness of its prepayment widespread reviews. Questions and comments can be sent to the DME MAC JA Provider Compliance mailbox at:
dme_mac_jurisdiction_a_provider_compliance@hpe.com

NHIC offers a self-service tool, Decision Desktop, which allows suppliers direct access to specific details about a claim decision for claims which have been selected for Complex Medical Review. This tool enables the direct access to comprehensive information relating to the reason for denial along with saving time since it is no longer necessary to contact Customer Service for this information.

Decision Desktop can be accessed through the following link: **http://www.medicarenhic.com/dme/mr.aspx**

Educational References

NHIC provides extensive educational offerings related to the proper documentation requirements for E0601 claims. Please ensure that the responsible supplier staff is aware of and references this educational material so that supporting documentation for your claims is compliant with all requirements:

- **Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718)**
- **Results of Widespread Prepayment Review of Claims for HCPCS E0601 (Continuous Positive Airway Pressure Devices)** (posted 2/25/16, 11/25/15, 8/27/15, and 5/29/15)
- **DME MAC Jurisdiction A Supplier Manual** - Chapter 10 - Durable (Chapter 10 - Durable Medical Equipment) for additional information regarding general coverage and documentation requirements.
- **Items Provided on a Recurring Basis and Refill Requirements - Joint DMC MAC Publication**
- **Live Line Chat** - Online chat sessions to ask billing, policy, documentation and other general questions

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Results of Widespread Prepayment Complex Review for Lower Limb Prostheses (O&P)

Historical Review Results

This review was initiated due to errors identified by the Comprehensive Error Rate Testing (CERT) Contractor. The overall Charge Denial Rate (CDR) is the total denied allowance amount (dollar amount of services determined to be billed in error) divided by the total allowance amount (dollar amount of services medically reviewed). The previous quarterly findings resulted in a CDR of 34.6%. A summary of findings was published on the NHIC, Corp. Website on January 28, 2016. Based on this result, a widespread prepayment review was continued.

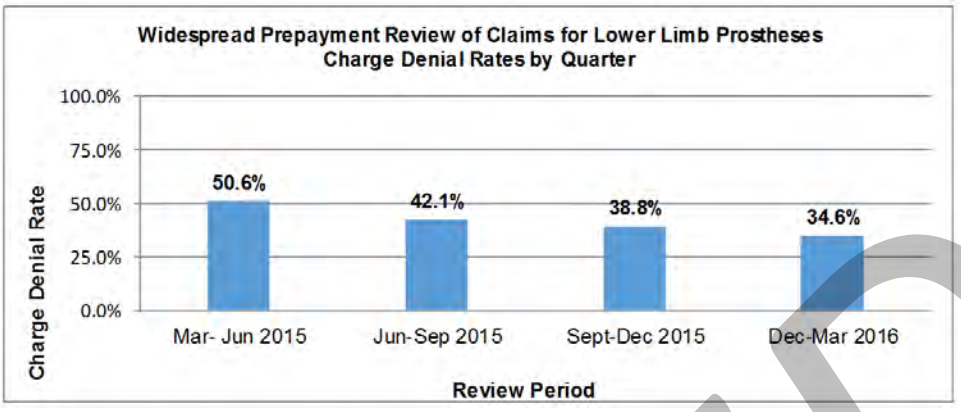
Current Review Results

DME MAC JA has completed a widespread prepayment complex review of claims for Lower Limb Prostheses HCPCS codes billed with a K3 functional level modifier.

The review involved prepayment complex medical review of 178 claims submitted by 123 suppliers for claims processed December 06, 2015 to March 01, 2016. Responses to the Additional Documentation Request (ADR) were not received for 13 (7%) of the claims. For the remaining 165 claims, 85 claims were allowed and 80 were denied resulting in a claim denial rate of 49%. The overall Charge Denial Rate was 34.6%.

Charge Denial Rate Historical Data

The following chart depicts the Charge Denial Rate from previous quarters to current:



Reasons for Denial

Based on review of the documentation received, the following are the reasons for denial. Note that the percentages noted below reflect the fact that a claim could have more than one missing/incomplete item.

Lack of Medical Record Documentation

- 26% of the denied claims had no medical record information submitted.

Clinical documentation did not support the functional level of the Lower Limb Prosthesis

- 20% of the denied claims had medical records submitted but the records did not support the functional level of the billed item(s).

Proof of Delivery

- 6% of the denied claims were missing a valid Proof of Delivery.

Reason for Replacement

- 36% of the denied claims had no statement or reason for replacement either on the physician's order or in the medical documentation.

Claim Examples

As an additional educational measure, the following are actual examples of claim denials. NHIC, Corp. expects these examples will assist suppliers in understanding the medical review process and the common documentation errors that occur with Lower Limb Prostheses claims.

Example 1:

Received: The supplier submitted a Detailed Written Order, which includes the beneficiary's name, specific items or components to be dispensed, treating physician's signature, date of clinician's signature and date of the order; An invoice of items that were billed, which includes the manufacturer, model numbers and cost of each item; and the prosthetist's evaluation/assessment documentation detailing the functional level of the items billed.

Missing: Clinical documentation to support functional level of the device and to corroborate the prosthetist's records. Proof of Delivery verifying that the beneficiary received the items that were billed.

Example 2:

Received: The supplier submitted a Detailed Written Order, which includes the beneficiary's name, specific items or components to be dispensed, treating physician's signature, date of clinician's signature and date of the order; Proof of Delivery that includes the manufacturer, model numbers, verifying that the beneficiary received the items that were billed; The prosthetist's evaluation/assessment detailing the functional level of the items billed; Clinical documentation to support functional level of the device and to corroborate the prosthetist's records.

Missing: Information by the ordering physician, either on the Detailed Written Order or in the medical record, demonstrating the reason for replacement.

Example 3:

Received: The supplier submitted a Detailed Written Order, which includes the beneficiary's name, specific items dispensed, treating physician's signature and date, and date of the order; Proof of Delivery that includes the manufacturer, model numbers, verifying that the beneficiary received the items that were billed; and the prosthetist's evaluation/assessment documentation detailing the functional level of the items billed.

Missing: The submitted clinical documentation did not support the functional level of the device and did not corroborate the prosthetist's records. Since the prosthetist is a supplier, the prosthetist's records must be corroborated by the information in the medical record.

Next Step

Based on the results of this prepayment review, DME MAC JA will continue to review claims for Lower Limb Prostheses HCPCS codes billed with a K3 functional level modifier and components/additions provided.

Suppliers are reminded that repeated failure to respond to ADR requests could result in a referral to the Jurisdiction A Program Safeguard Contractor/Zone Program Integrity Contractor.

Questions and comments can be sent to the DME MAC Jurisdiction A Provider Compliance mailbox at:
dme_mac_jurisdiction_a_provider_compliance@hpe.com

NHIC offers a self-service tool, Decision Desktop, which allows suppliers direct access to specific details about a claim decision for claims which have been selected for Complex Medical Review. This tool enables direct access to comprehensive information relating to the reason for denial along with saving time since it is no longer necessary to contact Customer Service for this information.

Decision Desktop can be accessed through the following link: **http://www.medicarenhic.com/dme/mr.aspx**

Educational References

NHIC provides extensive educational offerings related to the proper documentation requirements for Lower Limb Prostheses claims. Please ensure that the responsible supplier staff is aware of and references this educational material so that supporting documentation for your claims is compliant with all requirements:

- **LCD for Lower Limb Prostheses (L33787) and related Policy Article (A52496)**
- **DME MAC Jurisdiction A Supplier Manual** (Chapter 10 - Durable Medical Equipment) for additional information regarding coverage and documentation requirements
- **Dear Physician Letter** - Documentation of Artificial Limbs
- **CERT Errors Articles**
- **Lower Limb Prostheses Documentation Reminder for Physicians**
- **Results of Widespread Prepayment Complex Review for Lower Limb Prostheses** (posted 04/23/15, 07/30/15, 10/29/15, 01/28/16)
- **Live Line** - Online chat sessions to ask billing, policy, documentation, and other general questions

Results of Widespread Prepayment Review for Enteral Nutrition Infusion Pump-Without Alarm (B9000) and Enteral Nutrition Infusion Pump-With Alarm (B9002) (PEN)

Historical Review Results

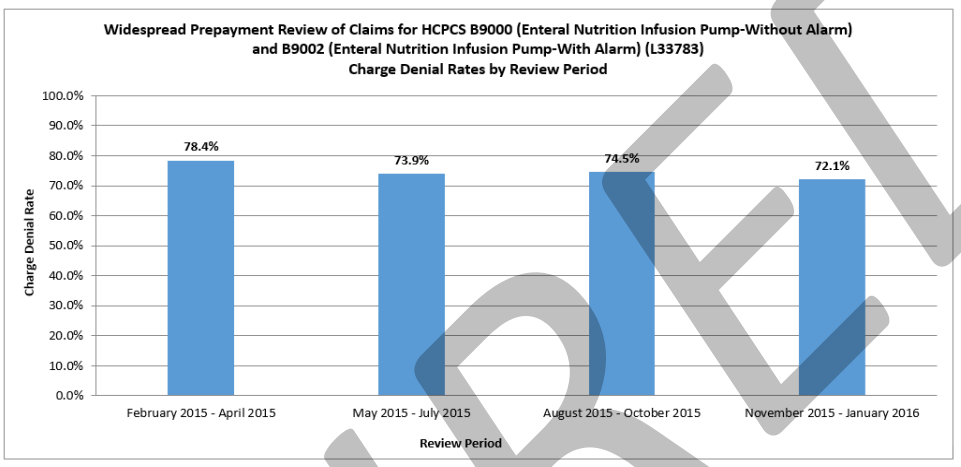
DME MAC JA Medical Review continues to review Enteral Nutrition Infusion Pump-Without Alarm (B9000) and Enteral Nutrition Infusion Pump-With Alarm (B9002, based on the results of the previous prepayment widespread review. The result of the total denied allowance amount (dollar amount of allowable charges for services determined to be billed in error) divided by the total allowance amount of services medically reviewed is the Charge Denial Rate (CDR). The previous review included claims reviewed August 01, 2015 - October 31, 2015, which resulted in 74.5% CDR.

Current Review Results

DME MAC JA has completed the widespread prepayment review of claims for B9002. These findings include claims processed primarily from November 1, 2015 thru January 31, 2016. The review involved prepayment complex medical review of 480 claims submitted by 93 suppliers. Responses to the Additional Documentation Request (ADR) were not received for 81 (17%) of the claims. For the remaining claims, 96 claims were allowed, and 303 were denied/partially denied resulting in a claim denial rate of 76% and a Charge Denial Rate of 72.1%.

Charge Denial Rate Historical Data

The following data depicts the Charge Denial Rate from previous quarters to current:



Reasons for Denial

Based on review of the documentation received, the following are the primary reasons for denial. Note that the percentages noted below reflect the fact that a claim could have more than one missing/incomplete item. Also note that claims can be denied for multiple reasons therefore the percentages of reviews may not add up to 100%:

Clinical Documentation Issues (67%)

- 7% of the claims denied statutorily - did not meet prosthetic benefit requirement
- 3% of the denied claims did not have any medical record documentation submitted
- 20% of the denied claims did not have documentation to support specialty formula billed.
- 37% of the denied claims did not have documentation to support reasonable and necessary use of the enteral pump

Note: *The criteria for enteral nutrition must first be met in order to allow consideration for payment of an enteral nutrition infusion pump.*

Proof of Delivery Issues (43%)

- 16% of the denied claims had no Proof of Delivery (POD)
- 22% shipped either before or after the date of service of the claim when the item(s) is shipped via a shipping service or delivery service (Method II) directly to a beneficiary
- 5% of the denied claims were missing beneficiary (or designee) signature when item(s) are delivered directly by the supplier to the beneficiary

Detailed Written Order (DWO) Issues (38%)

- 4% The DWO did not include a detailed description of Detailed written order was missing a detailed description of the DME item(s) ordered B9002
- 15% The DWO was missing a physician signature and date of signature
- 6% The claim was missing a DWO
- 5% The claim was missing a detailed written order
- 8% The detailed written order was illegible

DME Information Form (DIF) (8%)

- 4% of the denied claims did not include a DME Informational Form
- 4% of the denied claims included a DIF that did not list the Enteral Pump HCPCS code

Claim Examples

As an additional educational measure, the following are actual examples of claim denials. NHIC expects these examples will assist suppliers in understanding the medical review process and the common documentation errors that occur with Enteral Nutrition Infusion Pump claims.

Example 1:

Received: Detailed written order, DME Information Form, Proof of Delivery
Missing: Illegible clinical documentation. Unable to determine reasonable and necessary for the specialty formula

Example 2:

Received: Detailed written order, Proof of Delivery
Missing: DME Information Form, clinical documentation to support the prosthetic benefit

Example 3:

Received: POD, clinical documentation establishing reasonable and necessary and coverage criteria
Missing: DME Information Form, Detailed written order

Next Step

Based on the results of this prepayment review, DME MAC JA will continue to review claims for B9000 and B9002.

DME MAC Jurisdiction A performs ongoing assessment of the effectiveness of its prepayment widespread reviews. One assessment is the Compliance Improvement Program (CIP), which measures suppliers' performance with providing complete and accurate supporting documentation and their response rate to Additional Documentation Requests (ADRs).

When a supplier achieves and maintains high quality accuracy and ADR response rate over three (3) quarterly periods, the supplier will be temporarily removed from that particular widespread review. The supplier's authorized official will be notified and provided details of this decision.

Questions and comments can be sent to the DME MAC Jurisdiction A Provider Compliance mailbox at:
dme_mac_jurisdiction_a_provider_compliance@hpe.com

Educational References

NHIC provides extensive educational offerings related to the proper documentation requirements for enteral nutrition infusion pump claims. Please ensure that the responsible supplier staff is aware of and references this educational material so that supporting documentation for your claims is compliant with all requirements:

- **Enteral Nutrition (L33783) LCD and related Policy Article (A52493)**
- **Results of Widespread Prepayment Review for B9000 (Enteral Nutrition Infusion Pump-Without Alarm) and B9002 (Enteral Nutrition Infusion Pump-With Alarm) (L33783)** (posted 06/26/2014, 09/25/2014, 12/18/2014, 03/26/2015, 06/26/2015,9/29/2015)
- **DME MAC Jurisdiction A Supplier Manual** (Chapter 10 - Durable Medical Equipment) for additional information regarding coverage and documentation requirements.
- **CERT Physician Letter Enteral Nutrition**
- **Enteral Nutrition Units of Service Calculator**

Results of Widespread Prepayment Review for HCPCS Code L1940 (Ankle-Foot Orthosis) (O&P)

Historical Review Results

This is the first DME MAC JA medical review for Ankle-Foot Orthosis, (HCPCS L1940). This medical review was initiated due to errors identified by a DME MAC JA Medical Review Probe. The overall Charge Denial Rate (CDR) is the total denied allowance amount (dollar amount of services determined to be billed in error) divided by the total allowance amount (dollar amount of services medically reviewed). The Ankle-Foot Orthosis probe had a charge denial rate of 78.5%, which was noted in the article published November 25, 2015.

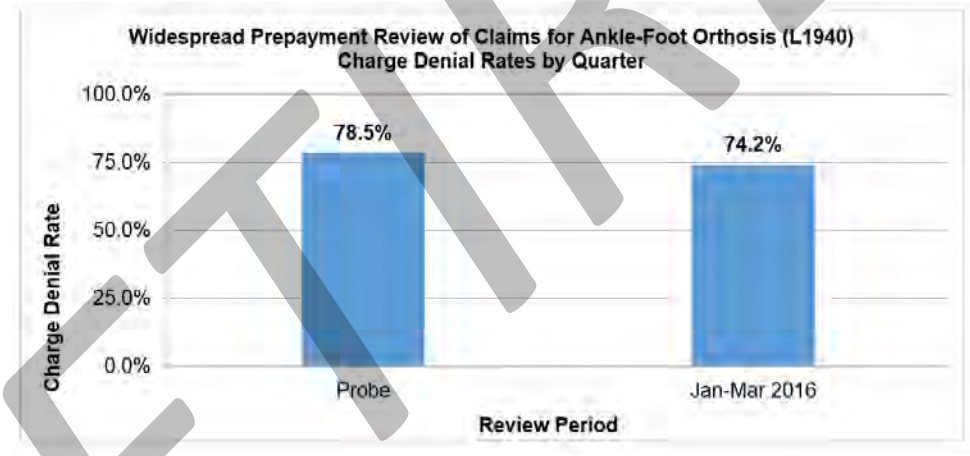
Current Review Results

DME MAC JA has completed the prepayment review of claims for Ankle-Foot Orthosis, (HCPCS L1940). These findings include claims with dates processed from January 1, 2016 through March 31, 2016.

The review involved prepayment complex medical review of 256 claims submitted by 184 suppliers. Responses to the Additional Documentation Request (ADR) were not received for 36 (14%) of the claims. For the remaining 220 claims, 62 of the claims were allowed (28%) and 158 of the claims were denied/partially denied. This resulted in a claim denial rate of 72%. The total denied allowance amount (dollar amount of allowable charges for services determined to be billed in error divided by the total allowance amount of services medically reviewed) resulted in an overall Charge Denial Rate (CDR) of 74.2%.

Charge Denial Rate Historical Data

The following data depicts the Charge Denial Rate from previous quarters to current:



Primary Reasons for Denial

Based on review of the documentation received, the following are the primary reasons for denial. Note that the percentages detailed below reflect the fact that a claim could have more than one missing/incomplete item. Also note that claims can be denied for multiple reasons, therefore the percentages of reviews may not add up to 100%.

Clinical Documentation (74%)

- 22% of denied claims did not support that the orthosis was custom fabricated.
- 18% of the denied claims did not provide documentation to support the medical necessity of a custom fabricated orthosis, rather than a prefabricated orthosis.
- 9% of the denied claims were missing medical records from the treating physician to corroborate the information in submitted orthotist records.
- 9% of the denied claims did not meet the basic coverage criteria for beneficiaries with weakness or deformity of the foot and ankle, who:
    1. Require stabilization for medical reasons, and,
    2. Have the potential to benefit functionally.
- 7% of the denied claims included medical records that were not authenticated by the author.

- 3% of the denied claims did not include clinical documentation.

Detailed Written Order (46%)

- 16% of the denied claims included a supplier created detailed written order that was missing an order start date.
- 12% of the denied claims did not include a sufficiently detailed description of item(s).
- 9% of the denied claims were missing a detailed written order.
- 2% of the denied claims included a detailed written order that was missing the physician's printed name.
- 3% of the denied claims included a detailed written order that was illegible.

Proof of Delivery (48%)

- 16% of the denied claims were missing a proof of delivery.
- 12% of the denied claims were missing the delivery address.
- 8% of the denied claims included a proof of delivery that did not include a narrative description or a brand name/model number of the item being dispensed.
- 7% of the denied claims did not include the quantity delivered.
- 4% of the denied claims showed the item(s) were delivered either before or after the date of service (method I).

Claim Examples

As an additional educational measure, the following are actual examples of claim denials. NHIC expects these examples will assist suppliers in understanding the medical review process and the common documentation errors that occur with L1940 Ankle-Foot Orthoses claims:

Example 1

Received:

- A detailed written order which included the beneficiary's name, date of the order, physician's name, detailed description of the item(s), and physician signature and signature date;
- Clinical documentation consisting of only orthotist notes that demonstrated a positive model was used to create the custom fabricated orthosis.
- Proof of delivery which included the beneficiary's name, delivery address, quantity delivered, date delivered and beneficiary (or designee) signature that validates that the beneficiary received the items that were billed.

Missing:

- Medical records from the treating physician to corroborate the information in submitted orthotist records.

Example 2

Received:

- Proof of delivery which included the beneficiary's name, quantity delivered, date delivered and beneficiary (or designee) signature that validates that the beneficiary received the items that were billed.

Missing:

- A detailed written order which included: the beneficiary's name, date of the order, physician's name, detailed description of the item(s), and physician signature and signature date;
- Clinical documentation consisting of: orthotist notes and physician's medical records to provide information the beneficiary meets all coverage criteria;
- Proof of delivery that included a delivery address.

Example 3

Received:

- A detailed written order which included the beneficiary's name, date of the order, physician's name, description of only base item ordered, and physician signature and signature date;
- Clinical documentation consisting of orthotist notes and physician's medical records, which included information that the beneficiary met the basic coverage criteria and a positive model was used to create the custom fabricated orthosis.

Missing:

- A detailed written order which included the additions to the base code being ordered;
- Proof of delivery.

Next Step

Based on the results of this prepayment review, DME MAC JA will continue to review claims for Ankle-Foot Orthosis, HCPCS L1940. Suppliers are reminded that repeated failure to respond to ADR requests could result in a referral to the Jurisdiction A Program Safeguard Contractor/Zone Program Integrity Contractor.

Educational References

NHIC provides extensive educational offerings related to the proper documentation requirements for L1940 Ankle-Foot Orthoses claims. Please ensure that the responsible supplier staff is aware of, and references this educational material so that supporting documentation for your claims is compliant with all requirements:

- **Ankle-Foot/Knee-Ankle Foot Orthosis LCD**
- **Supplier Self Audits**
- **Results of Widespread Prepayment Review for HCPCS Code L1940 (Ankle-Foot Orthosis)** (Posted 11/25/2015)

Results of Widespread Prepayment Review for HCPCS Code L4360 (Pneumatic Walking Boot) (O&P)

Historical Review Results

This is the first DME MAC JA medical review for the Pneumatic Walking Boot, (HCPCS L4360). This medical review was initiated due to errors identified by a DME MAC JA medical review probe. The overall Charge Denial Rate (CDR) is the total denied allowance amount (dollar amount of services determined to be billed in error) divided by the total allowance amount (dollar amount of services medically reviewed). The Pneumatic Walking Boot probe had a CDR of 96.7%, which was noted in the article published on November 25, 2015.

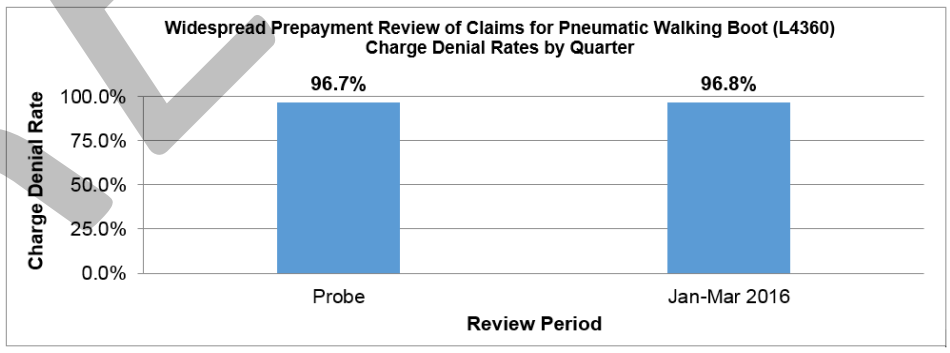
Current Review Results

DME MAC JA has completed the widespread prepayment review of claims for Pneumatic Walking Boot, (HCPCS L4360). These findings include claims with dates processed from January 1, 2016 through March 31, 2016.

The review involved prepayment complex medical review of 255 claims submitted by 167 suppliers. Responses to the Additional Documentation Request (ADR) were not received for 91 (36%) of the claims. For the remaining 164 claims, 4 of the claims were allowed (2%) and 160 of the claims were denied, resulting in a claim denial rate of 98%. The overall CDR was 96.8%.

Charge Denial Rate Historical Data

The following data depicts the Charge Denial Rate from previous quarters to current:



Primary Reasons for Denial

Based on review of the documentation received, the following are the primary reasons for denial. Note that the percentages detailed below reflect the fact that a claim could have more than one missing/incomplete item. Also note that claims can be denied for multiple reasons, therefore the percentages of reviews may not add up to 100%.

Clinical Documentation (116%)

- 90% of the denied claims did not meet the coverage criteria for a custom fitted item.
- 9% of the denied claims did not include clinical documentation.
- 9% of the denied claims did not contain clinical documentation that demonstrated the beneficiary required the item requested.
- 7% of the denied claims included medical records that were not authenticated by the author.

Detailed Written Order (75%)

- 53% of the denied claims were missing a detailed written order (DWO).
- 7% of the denied claims included a supplier created detailed written order that was missing an order date/start date.
- 4% of the denied claims included a detailed written order that did not include a narrative description or a brand name/model number of the item being ordered.

Proof of Delivery (110%)

- 69% of the denied claims were missing a proof of delivery.
- 13% of the denied claims did not include a sufficiently detailed description to identify if the item(s) billed were delivered
- 15% of the denied claims included a proof of delivery that was missing the delivery address.
- 9% of the denied claims did not include quantity delivered.

Claim Examples

As an additional educational measure, the following are actual examples of claim denials. NHIC expects these examples will assist suppliers in understanding the medical review process and the common documentation errors that occur with L4360 Pneumatic Walking Boot claims:

Example 1

Received:

- A detailed written order which includes the beneficiary's name, date of the order, physician's name, detailed description of the item(s), and physician signature and signature date;
- Clinical documentation consisting of orthotist notes and physician's medical records, which included information that the beneficiary met the basic coverage criteria.
- Proof of delivery which includes the beneficiary's name, quantity delivered, date delivered and beneficiary (or designee) signature that validates that the beneficiary received the items that were billed.

Missing:

- Clinical documentation consisting of orthotist notes, which included information that the item was custom fitted.
- Proof of delivery which includes a delivery address.

Example 2

Received:

- A detailed written order which includes the beneficiary's name, date of the order, physician's name, detailed description of the item(s), and physician signature and signature date;
- Clinical documentation consisting of orthotist notes and physician's medical records, which included information that the beneficiary met the basic coverage criteria.
- Proof of delivery which includes the beneficiary's name, delivery address, quantity delivered, date delivered and beneficiary (or designee) signature that validates that the beneficiary received the items that were billed.

Missing:

- Clinical documentation consisting of orthotist notes, which included information that the item was custom fitted.

Example 3

Received:

- Clinical documentation consisting of orthotist notes and physician's medical records, which included information that the beneficiary met the basic coverage criteria.

Missing:

- A detailed written order which includes the beneficiary's name, date of the order, physician's name, base code of item ordered, and physician signature and signature date;
- Clinical documentation consisting of orthotist notes, which included information that the item was custom fitted.

- Proof of delivery.

Next Step

Based on the results of this prepayment review, DME MAC JA will continue to review claims for the Pneumatic Walking Boot, HCPCS L4360. Suppliers are reminded that repeated failure to respond to ADR requests could result in a referral to the Jurisdiction A Program Safeguard Contractor/Zone Program Integrity Contractor.

Educational References

NHIC provides extensive educational offerings related to the proper documentation requirements for L4360 Pneumatic Walking Boot claims. Please ensure that the responsible supplier staff is aware of, and references this educational material so that supporting documentation for your claims is compliant with all requirements:

- **Ankle-Foot/Knee-Ankle Foot Orthosis LCD**
- **Correct Coding - Definitions Used for Off-the-Shelf versus Custom Fitted Prefabricated Orthotics (Braces) - Correction**
- **Supplier Self Audits**
- **Results of Widespread Prepayment Review for HCPCS Code L4360 (Pneumatic Walking Boot) (Posted 11/25/15)**

Results of Widespread Prepayment Review for Nebulizers (HCPCS Code E0570) (SPE)

Historical Review Results

This review was initiated due to errors identified by the Comprehensive Error Rate Testing (CERT) Contractor. The overall Charge Denial Rate (CDR) is the total denied allowance amount (dollar amount of services determined to be billed in error) divided by the total allowance amount (dollar amount of services medically reviewed). The previous quarterly findings covered the period of August 2015 through October 2015, and reported a CDR of 67.7%.

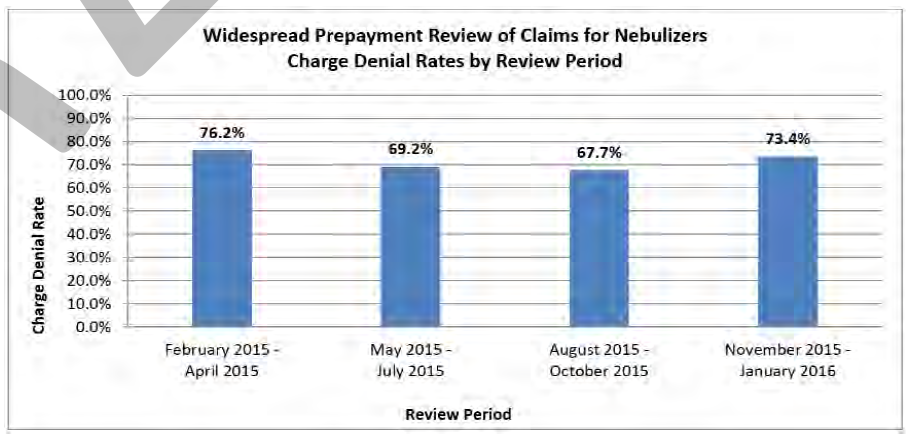
Current Review Results

The DME MAC Jurisdiction A has recently completed a widespread prepayment review of claims for E0570 (Nebulizer, with Compressor). These findings include claims processed primarily from November 2015 through January 2016.

The review involved prepayment complex medical review of 1,645 claims submitted by 532 suppliers. Responses to the Additional Documentation Request (ADR) were not received for 359 (22%) of the claims. For the remaining 1,286 claims, 318 claims were allowed (25%) and 968 were denied/partially denied resulting in a claim denial rate of 75%. The overall CDR was 73.4%.

Charge Denial Rate Historical Data

The following data depicts the Charge Denial Rate from previous quarters to current:



Reasons for Denial

Based on review of the documentation received, the following are the reasons for denial. Note that the percentages detailed below reflect the fact that a claim could have more than one missing/incomplete item. Also note that claims can be denied for multiple reasons therefore the percentages of reviews may not add up to 100%:

Clinical Documentation Issues (51% of the total claims reviewed)

- 19% of claims were denied because no medical records were submitted
- 32% of the denied claims had insufficient or incomplete clinical documentation. The following are common issues identified with clinical documentation:
  - Clinical documentation did not support reasonable and necessary use of a nebulizer, per LCD guidelines (25%)
  - Illegible copy of documentation submitted (2%)
  - Physician signature did not meet signature requirements including:
  - Missing physician's handwritten or electronic signature or unsigned typed note with physician's typed name only (5%)

Written Order Prior to Delivery (WOPD) (36% of the total claims reviewed)

- 1% of the denied claims did not include a WOPD.
- 35% of the denied claims had an incomplete or invalid WOPD. The following are common issues identified:
  - Missing the prescribing practitioner's National Provider Identifier (NPI) (3%)
  - Ordering practitioner's signature date was after the item(s) were delivered (5%)
  - Insufficient evidence (i.e. date stamp, fax date, etc.) within the documentation to show that the supplier received the written order prior to delivering the item(s) (25%)
  - The WOPD contained corrections and or changes that did not comply with accepted record keeping principles (2%)

Proof of Delivery Issues (12% of the total claims reviewed)

- 2% of the denied claims were missing proof of delivery.
- 10% of the denied claims had an incomplete or invalid proof of delivery. The following are common issues identified:
  - Illegible copy of proof of delivery (1%)
  - Missing the delivery address (2%)
  - Missing beneficiary (or designee) signature when item(s) are delivered directly by the supplier to the beneficiary (Method I)(1%)
  - Nebulizer (first month rental) delivered to the beneficiary either before or after the date of service of the claim when delivered directly by the supplier (Method I) (5%)
  - Nebulizer (first month rental) shipped either before or after the date of service of the claim when the item(s) is shipped via a shipping service or delivery service (Method II) directly to a beneficiary (1%)

Claim Examples

As an additional educational measure, the following are actual examples of claim denials. NHIC expects these examples will assist suppliers in understanding the medical review process and the common documentation errors that occur with nebulizer claims:

Example 1:

Received: WOPD with: beneficiary name, order date, description of item(s) to be dispensed, physician's signature, date of signature, physician's NPI number, clinical notes and proof of delivery

Reason for Denial: The physician's signature date on the WOPD is after the item(s) were delivered. Insufficient evidence (i.e. date stamp or similar) within the documentation submitted to show that the supplier received the WOPD prior to delivering the item(s). The proof of delivery submitted shows that the item(s) were delivered before the date of service on the submitted claim.

Example 2:

Received: WOPD with: beneficiary name, order date, description of item to be dispensed, physician's signature, date of signature, physician's NPI number, evidence of supplier receipt of the detailed written order prior to delivery and clinical notes.

Reason for Denial: Clinical notes submitted did not demonstrate the reasonable and necessary use of a small volume nebulizer, with compressor, for the administration of albuterol for the management of a diagnosis supported by the Local Coverage Determination (LCD). Missing proof of delivery.

Example 3:

Received: WOPD with: beneficiary name, order date, description of item to be dispensed, physician's signature, date of signature, physician's NPI number, clinical notes and proof of delivery

Reason for Denial: Invalid alteration to the physician's NPI number on the WOPD. Insufficient evidence (i.e. Date stamp or similar) within the documentation submitted to show that the supplier received the WOPD prior to delivering the item(s). Proof of delivery missing the delivery address.

Next Step

Based on the results of this prepayment review, DME MAC A will continue to review claims for E0570 (Nebulizer, with Compressor).

Suppliers are reminded that repeated failure to respond to ADR requests could result in a referral to the Jurisdiction A Program Safeguard Contractor/Zone Program Integrity Contractor.

DME MAC Jurisdiction A performs ongoing assessment of the effectiveness of its prepayment widespread reviews. One assessment is the Compliance Improvement Program (CIP), which measures suppliers' performance with providing complete and accurate supporting documentation and their response rate to Additional Documentation Requests (ADRs). When a supplier achieves and maintains high quality accuracy and ADR response rate over three (3) quarterly periods, the supplier will be temporarily removed from that particular widespread review. The supplier's authorized official will be notified and provided details of this decision.

Questions and comments can be sent to the DME MAC Jurisdiction A Provider Compliance mailbox at:
dme_mac_jurisdiction_a_provider_compliance@hpe.com

NHIC offers a self-service tool, Decision Desktop, which allows suppliers direct access to specific details about a claim decision for claims which have been selected for Complex Medical Review. This tool enables direct access to comprehensive information relating to the reason for denial along with saving time since it is no longer necessary to contact Customer Service for this information.

Decision Desktop can be accessed through the following link: **http://www.medicarenhic.com/dme/mr.aspx**

Educational References

NHIC provides extensive educational offerings related to the proper documentation requirements for nebulizer claims. Please ensure that the responsible supplier staff is aware of and references this educational material so that supporting documentation for your claims is compliant with all requirements:

- **Nebulizers (L33370) LCD Nebulizers - Policy Article - Effective October 2015 (A52466)**
- **Results of Widespread Prepayment Review of Claims for E0570** (posted 3/26/2015, 6/25/2015, 9/24/2015, 12/23/2015)
- **DME MAC Jurisdiction A Supplier Manual** (Chapter 10 - Durable Medical Equipment) for additional information regarding coverage and documentation requirements.
- **CERT Error Articles**
- **Frequently Asked Questions** (search word "nebulizer")
- **Face-to-Face and Written Order Requirements for High Cost DME** - Dear Physician Letter
- **Live Line Chat** - Online chat sessions to ask billing, policy, documentation and other general questions
- **Nebulizer Checklist**

Results of Widespread Prepayment Review of Claims for Lumbar-Sacral Orthoses (HCPCS Codes L0631/L0637) (O&P)

Historical Review Results

This review was initiated due to errors identified by the Comprehensive Error Rate Testing (CERT) Contractor. The overall Charge Denial Rate (CDR) is the total denied allowance amount (dollar amount of services determined to be billed in error) divided by the total allowance amount (dollar amount of services medically reviewed). The previous quarterly findings covered the period of September 2015 through November 2015 and resulted in a CDR of 96.3%.

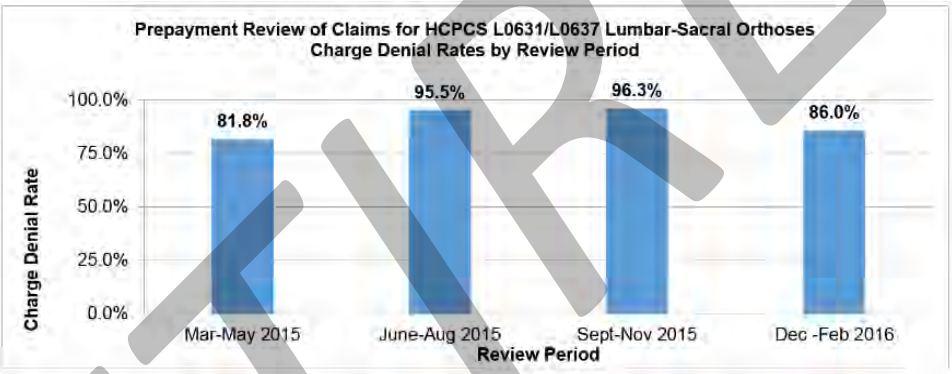
Current Review Results

DME MAC JA has completed the widespread prepayment review of claims for Lumbar-Sacral Orthoses (HCPCS Codes L0631/L0637). These findings include claims processed primarily from December 2015 through February 2016.

The review involved prepayment complex medical review of 974 claims submitted by 314 suppliers. Responses to the Additional Documentation Request (ADR) were not received for 283 (29%) of the claims. For the remaining 691 claims, 88 claims were allowed (13%) and 603 claims were denied resulting in a claim denial rate of 87%. The overall CDR was 86%.

Charge Denial Rate Historical Data

The following graph depicts the Charge Denial Rate from previous review periods to current:



Primary Reasons for Denial

Based on review of the documentation received, the following are the reasons for denial. Note that the percentages noted below reflect the fact that a claim could have more than one missing/incomplete item. Also note that claims can be denied for multiple reasons therefore the percentages of reviews may not add up to 100%:

Detailed Written Orders Issues

- Missing a Detailed Written Order (DWO) (17%)
- Incomplete DWO (28%)
  - DWOs submitted were not legible and/or did not list beneficiary name (7%)
  - DWOs missing date of the order and/or signature date (11%)
  - DWOs were missing a detailed description of the requested Lumbar Sacral Orthotic (s). The detailed description on the written order may be either a narrative description or a brand name/model number (10%)

Clinical Documentation Issues

- Missing clinical documentation to support medical necessity (3%)
- Incomplete/Invalid clinical documentation (85%)
  - Medical documentation was not authenticated by the clinician conducting the exam (1%)
  - The documentation submitted did not meet the coverage criteria for a custom fitted orthosis (84%)

Proof of Delivery Issues

- Missing Proof of Delivery (POD) (16%)
- Incomplete Proof of Delivery (POD) (11%)

- Delivery documentation (Method 1) did not include signature of beneficiary or designee (1%)
- Date(s) of service do not match shipping/receipt dates for items, as defined within LCD (L33790) (1%)
- Delivery documentation does not include delivery address (1%)
- Delivery documentation does not specify the requested Lumbar-Sacral-Orthosis, and it is unclear from the description which orthotic is being delivered. 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. (8%)

Claim Examples

As an additional educational measure, the following are actual examples of claim denials. NHIC expects these examples will assist suppliers in understanding the medical review process and the common documentation errors that occur with Lumbar-Sacral Orthoses claims:

Example 1:

Received: The supplier submitted clinical documentation, fitter notes, and a POD.
Missing: The DWO. The fitter notes state "The brace was fitted to the beneficiary". This does not give enough information to determine that the orthotic was modified by a person with expertise, prior to delivery.

Example 2:

Received: The supplier submitted a completed DWO, clinical documentation, and a POD.
Missing: The documentation does not meet the coverage criteria for a custom fitted orthosis. There must be documentation from the supplier/fitter, which demonstrates modifications by a qualified provider were made to the orthotic prior to delivery.

Example 3:

Received: The supplier submitted a completed DWO, POD, clinical documentation and supplier notes.
Missing: The medical documentation submitted is dated after the date of service. It is unclear if the item requested was necessary at the time the orthotic was ordered. Entries in the beneficiary's medical record must have been created prior to, or at the time of, the initial date of service (DOS) to establish whether the initial reimbursement was justified based upon the applicable coverage policy.

Next Step

Based upon the results of initial prepayment review, DME MAC JA will continue to review claims for Lumbar-Sacral Orthoses, HCPCS codes L0631/L0637.

Suppliers are reminded that repeated failure to respond to ADR requests could result in a referral to the JA Program Safeguard Contractor/Zone Program Integrity Contractor. NHIC offers a self-service tool, Decision Desktop, which allows suppliers direct access to specific details about a claim decision for claims which have been selected for Complex Medical Review. This tool enables direct access to comprehensive information relating to the reason for denial along with saving time since it is no longer necessary to contact Customer Service for this information.

Decision Desktop can be accessed through the following link: **http://www.medicarenhic.com/dme/mr.aspx**

Educational References

NHIC provides extensive educational offerings related to the proper documentation requirements for Lumbar-Sacral Orthoses claims. Please ensure that the responsible supplier staff is aware of and references this educational material so that supporting documentation for your claims is compliant with all requirements:

- **LCD for Spinal Orthoses: TLSO and LSO (L33790)**
- **DME MAC Jurisdiction A Supplier Manual** (Chapter 10 - Durable Medical Equipment) for additional information regarding coverage and documentation requirements
- **Widespread Prepayment Review of Claims for L0631/L0637** (posted 10/29/15 and 01/28/16)
- **Supplier Self Audits**

Quarterly Provider Update (GEN)

The Quarterly Provider Update (QPU) is a comprehensive resource published by the Centers for Medicare & Medicaid Services (CMS) on the first business day of each quarter. It is a listing of all non-regulatory changes to Medicare including program memoranda, manual changes, and any other instructions that could affect providers. Regulations and instructions published in the previous quarter are also included in the update. The QPU can be accessed at **http://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/index.html**. CMS encourages you to bookmark this website and visit it often for this valuable information.

Supplier Manual News (GEN)

The Jurisdiction A Durable Medical Equipment Medicare Administrative Contractor (DME MAC JA) *Supplier Manual* is available via the "*Publications*" section of our website at **http://www.medicarenhic.com/dme/publications.aspx**. After accepting the CPT License Agreement, suppliers can access the entire *DME MAC JA Supplier Manual*, including revised chapters and archived revisions.

Updates/Corrections Made:

In March of 2016 chapter 10 of the *DME MAC JA Supplier Manual* was updated. Suppliers who maintain hard copy manuals at their place of business need to discard the previously published pages and replace them with the revised ones.

Updating Supplier Records (GEN)

If you have moved, or are planning to move, and have not yet sent in a "*Change of Information*" form (CMS-855S), be sure to notify the National Supplier Clearinghouse (NSC) of your new address immediately. Any changes or updates to supplier addresses, telephone numbers (including area code changes), or tax information must be reported in writing to the NSC within 30 days after such changes have taken place.

If you wait, your payments can be suspended. When an item is sent to a supplier's "Pay To" address and is returned by the U.S. Postal Service noting "Do Not Forward" (DNF), the Jurisdiction A Durable Medical Equipment Medicare Administrative Contractor (DME MAC JA) places a DNF code on the supplier's file. The DNF code suspends payments for that supplier number. The supplier must then verify their address with the NSC in writing.

Note: *A request to change your address should not be sent to DME MAC JA since we cannot change supplier files.*

For instructions on the completion and mailing of CMS-855S, visit the CMS Forms web site at **http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/index.html** to download the Form.

Failure to provide the updated information is grounds for denial or revocation of a Medicare billing number.


Medicare
Learning
Network®
Official Information Health Care
Professionals Can Trust
http://go.cms.gov/MLNGenInfo

Helpful Contacts

Customer Service Telephone

Interactive Voice Response (IVR) System: 866-419-9458
Customer Service Representatives: 866-590-6731
TTY-TDD: 888-897-7539

Outreach & Education

outreach-education@hpe.com

Claims Submissions

DME Jurisdiction A Claims
P.O. Box 9165
Hingham, MA 02043-9165

DME - ADS
P.O. Box 9170
Hingham, MA 02043-9170

Written Inquiries

DME - Written Inquiries
P.O. Box 9146
Hingham, MA 02043-9146
Written Inquiry FAX: 781-741-3118

DME - MSP Correspondence
P.O. Box 9175
Hingham, MA 02043-9175

Overpayments

Refund Checks:
NHIC, Corp.
P.O. Box 809252
Chicago, IL 60680-9252

Payment Offset Fax Requests: 781-741-3916

Note: *Include both the demand letter or the remittance indicating the overpayment, and the Offset Request Form*

Appeals and Reopenings

Telephone Reopenings: 844-687-2656

Redetermination Requests Fax:

Redeterminations:
DME - Redeterminations
P.O. Box 9150
Hingham, MA 02043-9150

Reconsiderations:
C2C Solutions, Inc.
Attn: QIC DME
P.O. Box 44013
Jacksonville, FL 32231-4013

Faxed Reopenings: 781-741-3914 **or** 781-741-3842

781-741-3118 **or** 781-741-3840

Redetermination for Overnight Mailings:
NHIC, Corp. DME MAC Jurisdiction A
Appeals
75 William Terry Drive
Hingham, MA 02044

Reconsideration Street Address for Overnight Mailings:
C2C Solutions, Inc.
Attn: QIC DME
532 Riverside Avenue 6 Tower
Jacksonville, FL 32202

Administrative Law Judge (ALJ) Hearings:
HHS OMHA Mid-West Field Office
BP Tower, Suite 1300
200 Public Square
Cleveland, OH 44114-2316

Local Coverage Determinations (LCDs)

Draft LCDs Comments Mailing Address:
Wilfred Mamuya, MD PhD
Medical Director
DME MAC Jurisdiction A
75 Sgt. William Terry Dr.
Hingham, MA 02043

LCD Reconsiderations Mailing Address:
Same as Draft LCDs Comments

Draft LCDs Comments Email Address:
NHICDMEDraftLCDFeedback@hpe.com

LCD Reconsiderations Email Address:
NHICDMELCDRecon@hpe.com

LCD Reconsiderations Fax: 781-741-3991

ADMC Requests

Mailing Address:
NHIC, Corp.
Attention: ADMC
P.O. Box 9170
Hingham, MA 02043-9170

ADMC Requests Fax:
Attention: ADMC
781-741-3991

Common Electronic Data Interchange (CEDI)

Help Desk: 866-311-9184

Email Address: ngs.CEDIHelpdesk@wellpoint.com

DME MAC Jurisdiction A Resource

INFORMATION for DME MAC SUPPLIERS in CT, DE, DC, ME, MD, MA, NH, NJ, NY, PA, RI & VT

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Publication Information

NHIC, Corp. is the contractor for the Jurisdiction A DME MAC serving all of Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island and Vermont.

Visit the following websites for more information:

NHIC, Corp.: **http://www.medicarenhic.com/dme**

TriCenturion: **http://www.tricenturion.com**

CMS: **http://www.cms.gov**

The *DME MAC Jurisdiction A Resource*, together with occasional special releases, serves as legal notice to physicians and suppliers concerning responsibilities and requirements imposed upon them by Medicare law, regulations, and guidelines.

If you have any comments about the *DME MAC Jurisdiction A Resource* or would like to make suggestions, please write to:

DME MAC Jurisdiction A Resource Coordinator
Outreach & Education Publications
NHIC, Corp.
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Hingham, MA 02043

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A CMS Contractor

75 Sgt. William B. Terry Drive
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