

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



News Flash – Registration is now open to all suppliers interested in participating in the Round 1 Recompete of the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program. In order to submit a bid for the Round 1 Recompete, you must first register in the Individuals Authorized Access to the CMS Computer Services (IACS) online application. Once you have registered in IACS, you will receive a user ID and password to access the online DMEPOS Bidding System (DBidS). You must register even if you registered during a previous round of competition (Round 1 Rebid, Round 2, or the national mail-order competition). Only suppliers who have a user ID and password will be able to access DBidS; suppliers that do not register will not be able to bid. Registration for the recompete will close on Friday, October 19, 2012 at 9pm prevailing Eastern Time. To register, go to the Competitive Bidding Implementation Contractor (CBIC) website, <http://www.dmecompetitivebid.com>, click on Round 1 Recompete, and then click on "REGISTRATION IS OPEN" above the Registration clock. If you have any questions about the registration process, please contact the CBIC Customer Service Center at 877-577-5331 between 9am and 9pm prevailing Eastern Time, Monday through Friday.

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Claim Modifier Did Not Prevent Medicare from Paying Millions in Unallowable Claims for Selected Durable Medical Equipment

Provider Types Affected

This MLN Matters® Special Edition (SE) Article is intended for providers and suppliers who submit claims to Durable Medical Equipment Medicare Administrative Contractors (DME MACs) for services provided to Medicare beneficiaries.

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What You Need to Know

This article highlights the April 2012 report from the Office of the Inspector General (OIG) titled "Claim Modifier Did Not Prevent Medicare from Paying Millions in Unallowable Claims for Selected Durable Medical Equipment." The article also focuses on the Medicare policy regarding the required documentation suppliers must have on file.

The objective of this OIG study was to determine whether the KX modifier was effective in ensuring that DMEPOS suppliers who submitted Medicare claims had the required supporting documentation on file. The study included individual reviews of the four contractors that processed the DMEPOS claims for Jurisdictions A through D with dates of service in 2007.

The OIG report focused on the following four categories of DMEPOS claims containing the KX modifier for Calendar Year (CY) 2007:

1. therapeutic shoes for diabetics,
2. continuous positive airway pressure systems,
3. respiratory assist devices, and
4. pressure reducing support surfaces (groups 1 and 2).

Background

Medicare providers and suppliers have a vital role in helping the Centers for Medicare & Medicaid Services (CMS) effectively manage Medicare resources. CMS acknowledges the daily challenges providers and suppliers face in serving Medicare beneficiaries and the complex process involved in obtaining and receiving the required documentation.

For certain DMEPOS, suppliers must use the KX modifier. The KX modifier indicates that the claim meets Medicare coverage criteria and the supplier has the required documentation on file. While suppliers must have a written physician's order and proof of delivery for all DMEPOS, suppliers must have additional documentation on file for items requiring the KX modifier. For example, therapeutic shoes also require that a certifying physician's statement be on file before the supplier bills Medicare.

OIG Findings

The report found that in CY 2007:

1. 60% of the sampled 400 claims, suppliers did not have the required documentation on file;
2. 37% of the claims were missing the physician orders;
3. 21% were missing proof of delivery;
4. 25% were missing use or complaint use follow-up statements; and
5. 2% were missing sleep studies.

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The Key Points section below reviews Medicare policy for coverage of therapeutic shoes for diabetics, continuous positive airway pressure systems, respiratory assist devices, and pressure reducing support surfaces (groups 1 and 2). Each DMEPOS has similar requirements that will be listed first. For additional document requirements, each DMEPOS will be listed thereafter.

Key Points

CMS reminds physicians that in order for these items to be reimbursed for their patients, the DME supplier must collect medical documentation. This includes copies of the initial evaluation and any other reports needed to comply with coverage criteria specific to:

1. therapeutic shoes for diabetics;
2. continuous positive airway pressure systems;
3. respiratory assist devices; and
4. pressure reducing support surfaces (groups 1 and 2).

Cooperation and coordination between physicians and suppliers is necessary to meet Medicare coverage documentation requirements and deliver effective and efficient healthcare to beneficiaries.

The Local Coverage Determinations (LCDs) for all four DME MACs require suppliers to have the same documentation on file for the categories of DMEPOS and dates of service included in this OIG audit. Additional coverage and payment rules for therapeutic shoes for diabetics, continuous positive airway pressure systems, respiratory assist devices, and pressure reducing support surfaces (groups 1 and 2) may be found in the LCDs for the applicable DME MAC. **See the Additional Information section below to find websites for all four contractors.**

The complete medical policy is posted on individual DME MAC websites, or in the CMS Medicare Coverage Database. The database is available at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx> on the CMS website. Each category of DMEPOS in this study requires the following documentation:

- 1) Valid written order that contains:
 - Beneficiary's name;
 - Treating physician's signature;
 - Date the treating physician signed the order, and
 - Start date of the order.
- 2) Proof of delivery.

Additional documentation requirements for each category of DMEPOS are also listed as follows:

Therapeutic Shoes

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- 1) Signed statement from the certifying physician (must be MD or DO) who is treating the patient's systemic diabetes condition;
 - Patient has diabetes mellitus; and
 - Patient has one of the following:
 - a. Previous amputation of the other foot, or part of either foot; or
 - b. History of previous foot ulceration of either foot; or
 - c. History of pre-ulcerative calluses of either foot; or
 - d. Peripheral neuropathy with evidence of callus formation of either foot; or
 - e. Foot deformity of either foot; or
 - f. Poor circulation in either foot.

Certify that the above two indications are met and that he/she is treating the patient under a comprehensive plan of care for his/her diabetes; and the patient needs diabetic shoes.

- 2) Documentation of an in-person evaluation of the patient by the certifying physician who is managing the patient's systemic diabetes condition within 6 months specifying:
 - a. The patient has diabetes mellitus;
 - b. Has one of the conditions 2a-2f listed in [Policy Article A37076](#);
 - c. Is being treated under a comprehensive plan of care for his/her diabetes, and
 - d. Requires diabetic shoes.
- 3) Documentation of an in-person evaluation of the patient by the supplier prior to selection of the items billed that included:
 - a. An examination of the patient's feet with a description of the abnormalities that will need to be accommodated by the shoes/inserts/modifications.
 - b. For all shoes, taking measurements of the patient's feet.
 - c. For custom molded shoes and inserts, taking impressions, making casts, or obtaining CAD-CAM images of the patient's feet that will be used in creating positive models of the feet.
- 4) Medical records supporting that the patient has diabetes mellitus and at least one of the conditions noted above.
- 5) Documentation of an in-person visit with the patient by the supplier at the time of delivery must be conducted with the patient wearing the shoes and inserts and must document that the shoes/inserts/modifications fit properly.

Note: Please refer to the basic coverage criteria specified in the Therapeutic Shoes LCD for your DME MAC for further guidance.

Continuous Positive Airway Pressure Systems

- 1) Documentation of a verbal order (if item is dispensed based on a verbal order) that contains:

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- a. Description of the item;
 - b. Name of the beneficiary;
 - c. Name of the physician, and
 - d. Start date of the order.
- 2) Valid written order that contains:
 - a. Beneficiary's name
 - b. Treating physician's signature
 - c. Date the treating physician signed the order
 - d. Start date of the order-if the start date differs from the signature date.
 - e. Order for PAP with pressure setting.
 - 3) Beneficiary Authorization.
 - 4) Proof of Delivery.
 - 5) Face-to-Face clinical evaluation by the physician prior to the sleep test to assess the patient for obstructive sleep apnea (OSA) containing the following elements:
 - a. Sleep history and symptoms which may be caused by OSA;
 - b. Epworth Sleepiness Scale (a standardized patient questionnaire which helps to assess the likelihood of sleep apnea) or other validated sleep inventory, and
 - c. Pertinent physical examination – e.g., body mass index, neck circumference, upper airway exam, and cardiopulmonary exam.
 - 6) Medicare-covered sleep test that meets either of the following criteria:
 - a. Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) greater than or equal to 15 events per hour with a minimum of 30 events; **OR**
 - b. AHI or RDI greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
 - i. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia, **OR**
 - ii. Hypertension, ischemic heart disease, or history of stroke.
 - 7) Documentation that the patient and/or caregiver received instruction from the supplier of the Positive Airway Pressure (PAP) device and accessories in the proper use and care of the equipment.
 - 8) To continue coverage for the PAP device (Continuous Positive Airway Pressure (CPAP) or Respiratory Assist Device (RAD)) beyond an initial 3-month trial period, there must be:
 - a. A face-to-face visit with the physician during the second or third month of the trial that documents an improvement of the beneficiary's symptoms; and

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- b. A data report from the PAP device which documents use of the PAP device for at least 4 hours per night on 70% of nights for a 30 consecutive day period during the trial.
- 9) For beneficiaries who received a PAP device prior to Fee-For-Service (FFS) Medicare enrollment and are now enrolled in Medicare and are seeking a new PAP device and/or accessories, both of the following coverage requirements must be met:
 - a. Sleep test – There must be documentation that the beneficiary had a sleep test, prior to FFS Medicare enrollment, that meets the FFS Medicare AHI/RDI coverage criteria in effect at the time that the beneficiary seeks a replacement PAP device and/or accessories, and,
 - b. Clinical Evaluation – Following enrollment in FFS Medicare, the beneficiary must have a face-to-face evaluation by their treating physician who documents in the beneficiary's medical record that:
 - i. The beneficiary has a diagnosis of obstructive sleep apnea; and,
 - ii. The beneficiary continues to use the PAP device.

Note: Please refer to the basic coverage criteria specified in the PAP LCD by your DME MAC contractor for further guidance.

Respiratory Assist Devices

- 1) Documentation of a verbal order (if item is dispensed based on a verbal order) that contains:
 - a. Description of the item;
 - b. Name of the beneficiary;
 - c. Name of the physician, and
 - d. Start date of the order.
- 2) Valid written order that contains:
 - a. Beneficiary's name
 - b. Item to be dispensed
 - c. Pressure setting with or without backup rate
 - d. Treating physician's signature
 - e. Date the treating physician signed the order
 - f. Start date of the order if the start date differs from the signature date.
- 3) Beneficiary Authorization.
- 4) Proof of Delivery.
- 5) Medical records documenting:

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- a. Symptoms characteristic of sleep-associated hypoventilation.
- b. Patient has one of the following disorders and meets all coverage criteria for that disorder:
 - i. Restrictive Thoracic Disorder, or
 - ii. Severe COPD, or
 - iii. Central Sleep or Complex Sleep Apnea, or
 - iv. Hypoventilation Syndrome.

Note: Please refer to the basic coverage criteria specified in the RAD LCD by your DME MAC contractor for further guidance.

Pressure Reducing Support Surfaces (groups 1 and 2).

- 1) Valid written order that contains:
 - a. Beneficiary's name
 - b. Treating physician's signature
 - c. Date the treating physician signed the order
 - d. Start date of the order if the start date differs from the signature date.
 - e. Clear, detailed description of the type of support surface the physician is ordering.
- 2) Beneficiary Authorization.
- 3) Signed statement from the treating physician indicating what, if any, payment criteria the patient meets.
- 4) Medical records supporting patient meets the basic coverage criteria specified in the Pressure Reducing Support Surfaces- Group 1 and 2 LCD.

Note: Please refer to the basic coverage criteria specified in the Pressure Reducing Support Surfaces- Group 1 and 2 LCDs by your DME MAC contractor for further guidance.

Additional Information

For questions about documentation requirements, please contact your DME MAC at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

The OIG report titled "Claim Modifier Did Not Prevent Medicare from Paying Millions in Unallowable Claims for Selected Durable Medical Equipment" is available at <http://oig.hhs.gov/oas/reports/region4/41004004.pdf> on the OIG website.

The Medicare Learning Network® (MLN) fact sheet titled "Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards," is available at <http://www.cms.gov/Outreach->

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[and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/DMEPOS_Qual_Stand_Booklet_ICN905709.pdf](#) on the CMS website.

The DME MAC websites are available as follows:

- [Cigna Government Services](#)
- [National Government Services](#)
- [National Heritage Insurance Company \(NHIC\)](#)
- [Noridian Administrative Services](#)

News Flash - Influenza Season is Around the Corner - As your patients age, their immune systems may weaken. This weakening can make seniors more susceptible to complications from seasonal influenza (flu). Now is the perfect time to remind your patients that seasonal influenza vaccination is the best defense against the flu. Medicare provides coverage for one flu vaccine and its administration per influenza season for seniors and other Medicare beneficiaries with no co-pay or deductible. Talk with your Medicare patients about their risk for getting the flu and start protecting your patients as soon as your 2012-2013 seasonal flu vaccine arrives. Also, don't forget to immunize yourself and your staff. *Know what to do about the flu.*

Remember – The influenza vaccine plus its administration is a covered Part B benefit. The influenza vaccine is NOT a Part D covered drug. CMS will provide information and a link to the 2012-2013 Influenza Vaccine prices when they are available.

For more information on coverage and billing of the flu vaccine and its administration, please visit the [CMS Medicare Learning Network® Preventive Services Educational Products](#) and [CMS Immunizations](#) web pages. While some providers may offer the flu vaccine, others can help their patients locate a vaccine provider within their local community. [HealthMap Vaccine Finder](#) is a free, online service where users can search for locations offering flu vaccines.

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