



News Flash – Under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program, which became effective on January 1, 2011, beneficiaries with Original Medicare who obtain competitively bid items in Competitive Bidding Areas (CBAs) must obtain these items from a contract supplier for Medicare to pay, unless an exception applies. One exception occurs when an item of DMEPOS that a beneficiary already owns needs to be repaired. The “DMEPOS Competitive Bidding Program Repairs and Replacements” Fact Sheet contains helpful information on Competitive Bidding Program rules that apply when an item of DMEPOS that is owned by a beneficiary needs to be repaired or requires replacement parts. It includes information on which items and services non-contract suppliers may provide, and which Healthcare Common Procedure Coding System (HCPCS) codes can be considered replacement parts associated with repair of base equipment. To view the fact sheet, please visit the DMEPOS Competitive Bidding Educational Resources page at http://www.cms.gov/DMEPOSCompetitiveBid/04_Educational_Resources.asp on the Centers for Medicare & Medicaid Services (CMS) website, scroll down to “Downloads”, and select “DMEPOS Competitive Bidding Fact Sheets”.

MLN Matters® Number: MM7235 **Revised**

Related Change Request (CR) #: 7235

Related CR Release Date: January 14, 2011

Effective Date: January 4, 2011

Related CR Transmittal #: R130NCD

Implementation Date: February 15, 2011

Home Oxygen Use to Treat Cluster Headache (CH)

Note: This MLN Matters® Article was revised on July 9, 2012, was revised to add a reference to MM7820 available at <http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM7820.pdf> for a full description of the codes and modifiers required to identify home use of oxygen for cluster headache provided in a Medicare-approved clinical study.

Provider Types Affected

This article is intended for suppliers that bill Medicare Durable Medical Equipment Medicare Administrative Contractors (DME MAC) for home use of oxygen services.

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What You Need to Know

CR7235, from which this article is taken, announces that (effective for claims with dates of service on and after January 4, 2011) Medicare will allow for the coverage of home use of oxygen to treat Medicare beneficiaries diagnosed with Cluster Headaches (CH) when these beneficiaries are enrolled in clinical studies that are approved by the Centers for Medicare & Medicaid Services (CMS) for the purpose of gaining further evidence.

Background

Medicare has a National Coverage Determination (NCD) on the home use of oxygen stating that its use is reasonable and necessary for patients with significant hypoxemia, as evidenced by a blood gas study or a measurement of arterial oxygen saturation. (Please refer to the "Medicare NCD Manual, Chapter 1, Part 4 ((Sections 200 – 310.1) Coverage Determinations), Section 240.2 (Home Use of Oxygen), which you can find at http://www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf on the CMS website.

In March 2006, an internally generated NCD led to coverage of beneficiaries who were participating in clinical studies that did not qualify for coverage based on the initial criteria for hypoxemia established in the earlier NCD. (Please refer to MLN Matters® article MM4389 -- MMA - Coverage for Home Use of Oxygen Included in Clinical Trials, released on May 26, 2006 which you can find at <http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM4389.pdf> on the CMS website.) This expansion in coverage requires that beneficiaries be enrolled subjects in National Heart, Lung, and Blood Institute-sponsored clinical trials; and the current national policy states that the home use of oxygen is reasonable and necessary for only those patients diagnosed with significant hypoxemia in conjunction with certain health conditions.

Effective for claims with dates of service on and after January 4, 2011, Medicare will allow for coverage of home use of oxygen to treat Medicare beneficiaries diagnosed with CH when beneficiaries are enrolled in clinical studies that are approved by CMS for the purpose of gaining further evidence. Medicare will allow for coverage of beneficiaries with CH participating in an approved prospective clinical study comparing normobaric 100% oxygen with at least one clinically appropriate comparator for the treatment of CH. The clinical study must address whether home use of oxygen improves Medicare beneficiaries' health outcomes and is subject to the criteria as outlined in the NCD Manual, chapter 1, section 240.2.2.

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DME MACs will use existing clinical trial coding conventions to help identify on a claim that the Home use of Oxygen for CH was provided pursuant to a Medicare-approved clinical study under Coverage with Evidence Development (CED). Your claims for these services must contain:

- The ICD-9-CM diagnosis codes for CH (339.00, cluster headache syndrome unspecified, 339.01, cluster headache episodic, and 339.02, cluster headache, chronic);
- HCPCS code E1399 (durable medical equipment, miscellaneous);
- Place of Service (POS) 12 (home);
- The 8-digit clinical trial number is optional;
- The Clinical Trial ICD-9-CM diagnosis code of V70.7 (Examination of participant in clinical trial); and
- The Clinical Trial Procedure Code Modifier Q0 (Investigational clinical service provided in a clinical research study that is in an approved clinical research study).

Currently, there are no clinical trials approved or pending approval for the home use of oxygen for CH. Certificates of Medical Necessity (CMNs) are not required in the context of this clinical trial setting. This is a Part B DME benefit only.

Should your DME MAC deny your claims for home use of oxygen for the treatment of CH (effective for dates of service on and after January 4, 2011) that do not conform to all of the above coding requirements, they will use following messages:

- Claim Adjustment Reason Code (CARC) 50 - These are non-covered services because this is not deemed a 'medical necessity' by the payer. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present;
- Remittance Advice Remark Code (RARC) N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx> on the CMS website. If you do not have web access, you may contact the contractor to request a copy of the NCD; and
- Group Code - Patient Responsibility (PR) if ABN/HINN given, otherwise Contractual Obligation (CO).
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Additional Information

The official instruction, CR 7235, issued to your DME/MAC regarding this change may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R130NCD.pdf> on the CMS website. If you have any questions, please contact your DME MAC at their toll-free number, which may be found at <http://www.cms.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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