CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 961 **Date: MAY 26, 2006**

CHANGE REQUEST 4389

SUBJECT: Home Use of Oxygen in Approved Clinical Trials

I. SUMMARY OF CHANGES: On March 20, 2006, CMS announced a National Coverage Determination (NCD) covering the home use of oxygen for Medicare beneficiaries who are enrolled in an approved clinical trial with arterial oxygen partial measurements from 56 to 65 mmHg or whose oxygen saturation is at or above 89 percent. CMS will cover the home use of oxygen in clinical trials identified by CMS and sponsored by the National Heart, Lung & Blood Institute. This decision does not change coverage for the home use of oxygen provided outside the clinical trials currently identified in section 240.2 of the CMS NCD manual. Contractor discretion continues in making local determinations of reasonable and necessary (base on existing guidance provided by the Secretary) for medically accepted home uses of oxygen not addressed in 240.2 of the NCD manual.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: March 20, 2006
IMPLEMENTATION DATE: October 3, 2006

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

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	20/Table of Contents
N	20/30.6.4/DMEPOS Clinical Trials and Demonstrations

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

X	**Business Requirements**
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification

	Recurring Update Notification

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 961	Date: May 26, 2006	Change Request 4389

SUBJECT: Home Use of Oxygen in Approved Clinical Trials

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) nationally covers home oxygen for patients with oxygen partial pressure measurements at or below 55 mmHg or oxygen saturation at or below 88%. If certain other diseases/conditions are present, an oxygen partial pressure of 56-60 mmHg, or an oxygen saturation of 89% are permitted.

B. Policy: On March 20, 2006, CMS announced a National Coverage Determination (NCD) covering the home use of oxygen for Medicare beneficiaries who do not meet the current requirements and who are enrolled in an approved clinical trial with arterial oxygen partial pressure measurements from 56 to 65 mmHg or whose oxygen saturation is at or above 89%. CMS will cover the home use of oxygen in clinical trials identified by CMS and sponsored by the National Heart, Lung & Blood Institute.

Medicare regulations require Medicare Advantage (MA) organizations to follow CMS NCDs. This NCD raises special issues that require some modification of most MA plan rules governing provision of items/services in/out of network. The items/services covered under this NCD are inextricably linked to the clinical trials with which they are associated and cannot be covered outside of the context of those clinical trials. MA plans must cover these services regardless of whether they are available through in-network providers. MA plans may have reporting requirements when enrollees participate in clinical trials in order to track and coordinate their members' care, but cannot require prior authorization or approval. MA plans shall bill on a fee-for-service basis for the oxygen equipment that would not normally be covered outside of the approved clinical trial. For additional clinical trial policy, refer to section 310, Pub. 100-03, NCD Manual. This policy remains unchanged.

This decision does not change coverage for the home use of oxygen provided outside the clinical trials currently identified in section 240.2 of the NCD Manual. Contractor discretion continues in making local determinations of reasonable and necessary (based on existing guidance provided by the Secretary) for medically accepted home uses of oxygen not addressed in section 240.2 of the NCD Manual.

II. BUSINESS REQUIREMENTS

“Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)					
		FI	RHH	Car	DME	Shared System Maintainers	Other

						FISS	MCS	VMS	CWF	
4389.1	Contractors shall recognize modifier “QR” as the appropriate modifier for reporting home use of oxygen furnished during an approved clinical trial for fee-for-service beneficiaries who have arterial oxygen partial measurements from 56 to 65 mmHg or oxygen saturation at or above 89%.				X					DME PSCs
4389.1.1	DMERCs shall recognize the QR modifier at the claim line level.				X					DME PSCs
4389.2	Contractors shall recognize condition code 30 and ICD-9-CM diagnosis code V70.7 in the second diagnosis code position for reporting home use of oxygen furnished during an approved clinical trial for fee-for-service beneficiaries who have arterial oxygen partial measurements from 56 to 65 mmHg or oxygen saturation at or above 89%.		X			X				
4389.3	Contractors shall recognize condition code 30 and ICD-9-CM diagnosis code V70.7 in the second diagnosis code position for reporting home use of oxygen furnished during an approved clinical trial for MA beneficiaries who have arterial oxygen partial measurements from 56 to 65 mmHg or oxygen saturation at or above 89%.		X			X				
4389.3.1	Contractors shall apply applicable coinsurance for MA plan beneficiaries when reporting home use of oxygen furnished during an approved clinical trial.		X			X				
4389.4	Contractors shall recognize HCPCS codes E0424, E0425, E0430, E0431 E0434, E0435, E0439, E0440, E0441, E0442, E0443, E0444, E0445, E1390, E1391, E1405, E1406, E1392, A4575, A4606, A4608, A4615, A4616, A4617, A4619, A4620, A7525, A9900, E0455, E0555, E0580, E1353, E1355 as clinical trial codes for home use of oxygen when modifier QR is attached.				X				X	DME PSCs

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
4389.5	Contractors shall recognize HCPCS codes E0424, E0425, E0430, E0431 E0434, E0435, E0439, E0440, E0441, E0442, E0443, E0444, E0445, E1390, E1391, E1405, E1406, E1392, A4575, A4606, A4608, A4615, A4616, A4617, A4619, A4620, A7525, A9900, E0455, E0555, E0580, E1353, E1355 as clinical trial codes for home use of oxygen when condition code 30 and ICD-9-CM diagnosis code V70.7 in the second diagnosis code position are used.		X			X				
4389.6	Contractors shall note that any accessory codes listed in 4389.4 and 4389.5 are included in the base oxygen fee and are not separately payable, as is current policy.		X		X	X				DME PSCs
4389.7	Contractors shall require the use of the Certificate of Medical Necessity (CMN) for initial claims submitted for approved clinical trials for home use of oxygen that contain a HCPCS code from 4389.4 and modifier QR.				X					DME PSCs
4389.7.1	Contractors shall pay subsequent claims submitted for approved clinical trials for home use of oxygen that contain a HCPCS code from 4389.4 based on the initial date and status of the initial CMN.				X					DME PSCs
4389.8	Contractors shall note that current oxygen policy at Pub. 100-03, section 240.2, NCD Manual, current clinical trials policy at Pub 100-03, section 310, NCD Manual, and current claims processing instructions at Pub. 100-04, sections 30.6.1-30.6.3, Claims Processing Manual, remain unchanged.		X		X					

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)					
		FI	RHH	Car	DME	Shared System Maintainers	Other

						FISS	MCS	VMS	CWF	
4389.9	A provider education article related to this instruction will be available at www.cms.hhs.gov/MLNMattersArticles shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.		X		X	X				
4389.10	Contractors shall educate MA plans that claims for clinical trial services will need to continue to be billed separately from non-clinical trial services.		X							

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

X-Ref Requirement #	Instructions
4389.2 and 4389.3	The ICD-9-CM code alerts the claim processing system that this is a clinical trial.

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: March 20, 2006 **Implementation Date:** October 3, 2006 **Pre-Implementation Contact(s):** Karen Rinker (coverage) 410-786-0189; Karen.rinker@cms.hhs.gov, Wilfred Gehne (Part A claims) 410-786-6148, Wilfred.gehne@cms.hhs.gov; Tracey Hemphill (DMERC claims), 410-786-7169, tracey.hemphill@cms.hhs.gov. **Post-Implementation Contact(s):** Appropriate RO	**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.**

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Medicare Claims Processing Manual

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

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(Rev. 961, 05-26-06)

30.6.4 – DMEPOS Clinical Trials and Demonstrations

(Rev. 961, Issued: 05-26-06; Effective: 03-20-06; Implementation: 10-03-06)

The definition of the QR modifier is " item or service has been provided in a Medicare specified study." When this modifier is attached to a HCPCS code, it generally means the service is part of a CMS related clinical trial, demonstration or study.

- *The DMERCs shall recognize the "QR" modifier when associated with an oxygen home therapy clinical trial identified by CMS and sponsored by the National Heart, Lung & Blood Institute. DMERCs shall pay these claims if the patient's arterial oxygen partial measurements are from 56 to 65 mmHg, or whose oxygen saturation is at or above 89%.*

The definition of condition code 30 is " qualified clinical trial." When this condition code is reported on a claim, it generally means the service is part of a CMS related clinical trial, demonstration or study.

- *The RHHIs shall recognize condition code 30, accompanied by ICD-9-CM diagnosis code V70.7 in the second diagnosis code position, when associated with an oxygen home therapy clinical trial identified by CMS and sponsored by the National Heart, Lung & Blood Institute. RHHIs shall pay these claims if the patient's arterial oxygen partial measurements are from 56 to 65 mmHg, or whose oxygen saturation is at or above 89%.*