

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 79</b>	<b>Date: DECEMBER 21, 2007</b>
	<b>Change Request 5820</b>

**SUBJECT: Nebulized Beta Adrenergic Agonist Therapy for Lung Diseases**

**I. SUMMARY OF CHANGES:** On September 10, 2007, CMS posted a National Coverage Determination (NCD) for nebulized beta adrenergic agonist therapy for lung diseases. After examining the available medical evidence, CMS determined that no NCD is appropriate at this time. and that section 1862(a)(1)(A) reasonable and necessary decisions should continue to be made by local Medicare contractors through the local coverage determination process or case-by-case adjudication.

**NEW / REVISED MATERIAL**

**EFFECTIVE DATE: SEPTEMBER 10, 2007**

**IMPLEMENTATION DATE: January 22, 2008**

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

**II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)**

**R=REVISED, N=NEW, D=DELETED**

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
<b>R</b>	1/Table of Contents
<b>N</b>	1/200.2/Nebulized Beta Adrenergic Agonist Therapy for Lung Diseases (Effective September 10, 2007)

**III. FUNDING:**

**SECTION A: For Fiscal Intermediaries and Carriers:**

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

**SECTION B: For Medicare Administrative Contractors (MACs):**

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

**IV. ATTACHMENTS:**

**Business Requirements  
Manual Instruction**

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

# Attachment - Business Requirements

Pub. 100-03	Transmittal: 79	Date: December 21, 2007	Change Request: 5820
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**SUBJECT: Nebulized Beta Adrenergic Agonist Therapy for Lung Diseases**

**Effective Date: September 10, 2007**

**Implementation Date: January 22, 2008**

## I. GENERAL INFORMATION

**A. Background:** Lung diseases such as chronic obstructive pulmonary disease (COPD) and asthma are characterized by airflow limitation that may be partially or completely reversible. Pharmacologic treatment with bronchodilators is used to prevent and/or control daily symptoms that may cause disability for persons with these diseases. These medications are intended to improve the movement of air into and from the lungs by relaxing and dilating the bronchial passageways. Beta adrenergic agonists are a commonly prescribed class of bronchodilator drug. They can be administered via nebulizer, metered dose inhaler, orally, or dry powdered inhaler.

Nebulized beta adrenergic agonist with racemic albuterol has been used for many years. More recently, levalbuterol, the (R) enantiomer of racemic albuterol, has been used in some patient populations. There are concerns regarding the appropriate use of nebulized beta adrenergic agonist therapy for lung disease. Because of those concerns, the Centers for Medicare & Medicaid Services (CMS) internally generated a formal request for a national coverage determination (NCD) to determine when treatment with a nebulized beta adrenergic agonist is reasonable and necessary for Medicare beneficiaries with COPD.

**B. Policy:** After examining the available medical evidence, CMS determines that no NCD is appropriate at this time. Section 1862(a)(1)(A) of the Social Security Act decisions should be made by local contractors through a local coverage determination (LCD) process or case-by-case adjudication. See *Heckler v. Ringer*, 466 U.S. 602, 617 (1984) (Recognizing that the Secretary has discretion to either establish a generally applicable rule or to allow individual adjudication.). See also, 68 Fed. Reg. 63692, 63693 (November 7, 2003).

## II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A B M A C	D M M A C	F I	C A R I E R	R H R I	Shared-System Maintainers				OTH ER
						F I S S	M C S	V M S	C W F		
5820.1	Effective with dates of service on and after September 10, 2007, contractors shall continue to process nebulized beta adrenergic agonist therapy for lung disease claims through their local Medicare contractors and the LCD process or case-by-case adjudication. No changes to process or policy are being made with this instruction. See Pub 100-	X	X	X	X	X					

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTH ER
		M A C	M A C				I S S	M S	V S	C W F	
	03, NCD Manual, part 4, section 200.2, for further information.										

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTH ER
		M A C	M A C				I S S	M S	V S	C W F	
5820.2	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLN MattersArticles">http://www.cms.hhs.gov/MLN MattersArticles</a> 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 one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. 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	X	X					

### IV. SUPPORTING INFORMATION

**A. For any recommendations and supporting information associated with listed requirements, use the box below:**

*Use "Should" to denote a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

**B. For all other recommendations and supporting information, use this space:**

## **V. CONTACTS**

**Pre-Implementation Contact(s):** Francina Spencer, coverage, [francina.spencer@cms.hhs.gov](mailto:francina.spencer@cms.hhs.gov), 410-786-4614, Pat Brocato-Simons, coverage, [patricia.brocato-simons@cms.hhs.gov](mailto:patricia.brocato-simons@cms.hhs.gov)

**Post-Implementation Contact(s):** Appropriate regional office

## **VI. FUNDING**

**A. For *Fiscal Intermediaries and Carriers*, use only one of the following statements:**

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

**B. For *Medicare Administrative Contractors (MACs)*, use the following statement:**

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**Medicare National Coverage  
Determinations Manual  
Chapter 1, Part 4 (Sections 200 – 310.1)  
Coverage Determinations**

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(Rev. 79, 12-21-07)**

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(Effective September 10, 2007)*

**200.2 - Nebulized Beta Adrenergic Agonist Therapy for Lung Diseases –  
(Effective September 10, 2007)**

**(Rev. 79; Issued: 12-21-07; Effective: 09-10-07; Implementation: 01-22-08)**

**A. General**

*Lung diseases such as chronic obstructive pulmonary disease (COPD) and asthma are characterized by airflow limitation that may be partially or completely reversible. Pharmacologic treatment with bronchodilators is used to prevent and/or control daily symptoms that may cause disability for persons with these diseases. These medications are intended to improve the movement of air into and from the lungs by relaxing and dilating the bronchial passageways. Beta adrenergic agonists are a commonly prescribed class of bronchodilator drug. They can be administered via nebulizer, metered dose inhaler, orally, or dry powdered inhaler.*

*Nebulized beta adrenergic agonist with racemic albuterol has been used for many years. More recently, levalbuterol, the (R) enantiomer of racemic albuterol, has been used in some patient populations. There are concerns regarding the appropriate use of nebulized beta adrenergic agonist therapy for lung disease.*

**B. Nationally Covered Indications**

N/A

**C. Nationally Non-Covered Indications**

N/A

**D. Other**

*After examining the available medical evidence, the Centers for Medicare & Medicaid determines that no national coverage determination (NCD) is appropriate at this time. Section 1862(a)(1)(A) of the Social Security Act decisions should be made by local contractors through a local coverage determination process or case-by-case adjudication. See Heckler v. Ringer, 466 U.S. 602, 617 (1984) (Recognizing that the Secretary has discretion to either establish a generally applicable rule or to allow individual adjudication.). See also, 68 Fed. Reg. 63692, 63693 (November 7, 2003).*

*(This NCD last reviewed September 2007.)*