

# CMS Manual System

## Pub 100-20 One-Time Notification

Transmittal 218

Department of Health &  
Human Services (DHHS)

Centers for Medicare &  
Medicaid Services (CMS)

Date: APRIL 7, 2006

Change Request 4312

**SUBJECT: Nesiritide for Treatment of Heart Failure Patients**

**I. SUMMARY OF CHANGES:** The Centers for Medicare & Medicaid Services (CMS) has determined that there is insufficient evidence to conclude that the use of nesiritide for the treatment of chronic heart failure is reasonable and necessary for Medicare beneficiaries. Effective for dates of service on or after March 2, 2006, CMS will deny coverage of nesiritide for the treatment of chronic heart failure in Medicare beneficiaries. CMS has determined that all other indications for the use of nesiritide not otherwise indicated as non-covered above are left to local contractor discretion.

### NEW/REVISED MATERIAL

**EFFECTIVE DATE: March 2, 2006**

**IMPLEMENTATION DATE: May 22, 2006**

*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:

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	

### 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:

One-Time Notification

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

# Attachment – One-Time Notification

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**SUBJECT: Nesiritide for Treatment of Heart Failure Patients**

## I. GENERAL INFORMATION

**A. Background:** Nesiritide is Food and Drug Administration-approved for the short-term intravenous treatment of patients with acutely decompensated congestive heart failure (CHF) who have dyspnea (shortness of breath) at rest or with minimal activity. Recent studies have assessed the effectiveness of Nesiritide use for treatment of chronic heart failure in outpatient settings and a recent independent advisory panel of cardiac experts sponsored by Scios, manufacturer of Natrecor® (Nesiritide), recommends that Nesiritide be restricted to the treatment of acute decompensated heart failure in the inpatient hospital setting. In addition, recent published articles in the peer-reviewed medical literature have highlighted concerns about renal failure and mortality in persons using Nesiritide.

**B. Policy:** Effective for dates of service on or after March 2, 2006, the Centers for Medicare & Medicaid Services (CMS) has determined that there is sufficient evidence to conclude that the use of Nesiritide for the treatment of chronic heart failure is not reasonable and necessary for Medicare beneficiaries in any setting. This determination applies only to the treatment of chronic heart failure and does not change contractor discretion to cover other off-label uses of Nesiritide or use consistent with the current FDA indication for intravenous treatment of patients with acutely decompensated congestive heart failure who have dyspnea at rest or with minimal activity.

## II. BUSINESS REQUIREMENTS

*“Shall” denotes a mandatory requirement*

*“Should” denotes an optional requirement*

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
4312.1	Effective March 2, 2006, contractors shall deny claims with HCPCS code J2325 when it is submitted with ICD-9 diagnosis code 428.0 and is not accompanied by at least one of the following ICD-9 codes: 428.21; 428.23; 428.31; 428.33; 428.41; or 428.43.	X		X						

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
4312.2	Effective March 2, 2006, contractors shall deny claims with HCPCS code J2325 when it is submitted with ICD-9 diagnosis code 428.1 and is not accompanied by at least one of the following ICD-9 codes: 428.21; 428.23; 428.31; 428.33; 428.41; or 428.43.	X		X						
4312.3	Effective March 2, 2006, contractors shall deny claims with HCPCS code J2325 when it is submitted with ICD-9 diagnosis code 428.20 and is not accompanied by at least one of the following ICD-9 codes: 428.21; 428.23; 428.31; 428.33; 428.41; or 428.43.	X		X						
4312.4	Effective March 2, 2006, contractors shall deny claims with HCPCS code J2325 when it is submitted with ICD-9 diagnosis code 428.22 and is not accompanied by at least one of the following ICD-9 codes: 428.21; 428.23; 428.31; 428.33; 428.41; or 428.43.	X		X						
4312.5	Effective March 2, 2006, contractors shall deny claims with HCPCS code J2325 when it is submitted with ICD-9 diagnosis code 428.30 and is not accompanied by at least one of the following ICD-9 codes: 428.21; 428.23; 428.31; 428.33; 428.41; or 428.43	X		X						
4312.6	Effective March 2, 2006, contractors shall deny claims with HCPCS code J2325 when it is submitted with ICD-9 diagnosis code 428.32 and is not accompanied by at least one of the following ICD-9 codes: 428.21; 428.23; 428.31; 428.33; 428.41; or 428.43.	X		X						
4312.7	Effective March 2, 2006, contractors shall deny claims with HCPCS code J2325 when it is submitted with ICD-9 diagnosis code 428.40 and is not accompanied by at least one of the following ICD-9 codes: 428.21; 428.23; 428.31; 428.33; 428.41; or 428.43.	X		X						

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
4312.8	Effective March 2, 2006, contractors shall deny claims with HCPCS code J2325 when it is submitted with ICD-9 diagnosis code 428.42 and is not accompanied by at least one of the following ICD-9 codes: 428.21; 428.23; 428.31; 428.33; 428.41; or 428.43.	X		X						
4312.9	Effective March 2, 2006, contractors shall deny claims with HCPCS code J2325 when it is submitted with ICD-9 diagnosis code 428.9 and is not accompanied by at least one of the following ICD-9 codes: 428.21; 428.23; 428.31; 428.33; 428.41; or 428.43.	X		X						
4312.10	Medicare contractors shall hold the provider liable unless occurrence code 32 is present on the claim or modifier GA is present on the line on an outpatient bill.	X		X						
4312.11	Contractors shall apply the appropriate claims adjustment code as follows:  Reason Code 50: These are non-covered services because this is not deemed a ‘medical necessity’ by the payer.  Remark Code M76: Missing/incomplete/invalid diagnosis or condition.	X		X						
4312.12	Contractors shall apply the following MSN messages:  15.20 – The following policy [NCD #200.1] was used when we made this decision.  15.4 – The information provided does not support the need for this service or item.	X		X						
4312.13	Contractors shall not search for, but may adjust claims brought to their attention with dates of service March 2, 2006, through implementation.	X		X						

### III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
4312.14	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/medlearn/matters">www.cms.hhs.gov/medlearn/matters</a> shortly after the CR is released. You will receive notification of the article release via the established "Medlearn 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 Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X						

### IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

#### A. Other Instructions:

X-Ref Requirement #	Instructions
4312.15	This drug is only given in a hospital setting. For FIs, the above requirements to deny Nesiritide for chronic heart failure shall only affect 13X and 85X TOBs. 11X & 12X would be rejected by the FI.

#### B. Design Considerations:

X-Ref Requirement #	Instructions
4312.16	CMS recommends FIs create Medical Policy Parameters (MPP) to deny outpatient claims and reject inpatient claims when billed with Nesiritide for chronic heart failure.

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

<p><b>Effective Date*:</b> March 2, 2006</p> <p><b>Implementation Date:</b> May 22, 2006</p> <p><b>Pre-Implementation Contact(s):</b> Michael Lyman, 410-786-6938, <a href="mailto:Michael.lyman@cms.hhs.gov">Michael.lyman@cms.hhs.gov</a> (coverage); Bridgitte Davis, 410-786-4573, <a href="mailto:bridgitte.davis@cms.hhs.gov">bridgitte.davis@cms.hhs.gov</a> (carrier claims); Valeri Ritter, 410-786-8652, <a href="mailto:Valeri.Ritter@cms.hhs.gov">Valeri.Ritter@cms.hhs.gov</a> (FI claims).</p> <p><b>Post-Implementation Contact(s):</b> Appropriate RO</p>	<p><b>No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.</b></p>
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