CMS Manual System

Pub 100-03 Medicare National Coverage Determinations

Transmittal 51

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. (This addition to 200.1, of Pub. 100-03 is a national coverage determination (NCD) made under section 1862(a)(1) of the Social Security Act. NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges (see 42 CFR 405.1064, effective May 1, 2005). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an administrative law judge may not review an NCD. (See 1869(f)(1)(A)(i) of the Social Security Act.)

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
R	1/Table of Contents
N	1/200.1/Nesiritide for the Treatment of Heart Failure Patients (Effective March 2, 2006)

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:

Manual Instruction

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

Medicare National Coverage Determinations Manual

Chapter 1 – Part 4, Section 200.1

Coverage Determinations

Table of Contents
(Rev.51, 04-07-06)

200.1 – Nesiritide for Treatment of Heart Failure Patients (Effective March 2, 2006)

(Rev.51, Issued: 04-07-06, Effective: 03-02-06, Implementation: 05-22-06)

A. General

Nesiritide (Natrecor®) is Food and Drug Administration (FDA) approved for the intravenous treatment of patients with acutely decompensated congestive heart failure (CHF) who have dyspnea (shortness of breath) at rest or with minimal activity. Nesiritide is not self-administered.

B. Nationally Covered Indications

N/A

C. Nationally Non-covered Indications

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.

D. Other

Effective for dates of service on or after March 2, 2006, 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.

(This NCD last reviewed March 2006.)