

MLN Matters Number: MM4312

Related Change Request (CR) #: 4312

Related CR Release Date: April 7, 2006

Effective Date: March 2, 2006

Related CR Transmittal #: R218OTN and R51NCD

Implementation Date: May 22, 2006

Nesiritide for Treatment of Heart Failure Patients

Note: This article was revised on May 19, 2006, to clarify some of the language regarding the use of Nesiritide on page 2 of the article.

Provider Types Affected

Providers and physicians that submit claims to Medicare fiscal intermediaries (FIs) and carriers for Nesiritide when provided as a treatment for chronic heart failure.

Key Points

- Effective for dates of service on or after March 2, 2006, the Centers for Medicare & Medicaid Services (CMS) will deny coverage of Nesiritide for the treatment of chronic heart failure in Medicare beneficiaries. For billing guidelines about the non-covered use of Nesiritide, please refer to the *Additional Information* section of this article.
- 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 in any setting.
- This determination does not change local contractor discretion for treatment of acute(ly) decompensated heart failure consistent with the FDA labeled indication in Medicare beneficiaries who may have underlying chronic heart failure. Nor does it affect local contractor discretion for other off-label uses of Nesiritide in Medicare beneficiaries who may have underlying chronic heart failure.
- For claims submitted to FIs, the requirement to deny Nesiritide for chronic heart failure will only affect 13X and 85X Type of Bill (TOBs).
- 11X and 12X TOBs should be rejected.

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- CMS recommends that FIs create medical policy parameters to deny outpatient claims for Nesiritide for chronic heart failure in the absence of acutely decompensated heart failure.
- CMS recommends that FIs reject inpatient claims where the primary diagnosis is chronic heart failure in the absence of acutely decompensated heart failure (11X and 12X) when billed with Nesiritide for chronic heart failure.
- For inpatient claims where the beneficiary is admitted with a primary diagnosis other than heart failure and Nesiritide is administered under a DRG payment, the administration of Nesiritide should not be the sole basis for denial of the entire inpatient claim.
- The provider will be held liable unless occurrence code 32 is present on the claim, or modifier GA is present on the line on an outpatient bill when Nesiritide is used to treat chronic heart failure without documented evidence of acute decompensation.
- All other indications for the use of Nesiritide not otherwise indicated as non-covered (other off-label uses or uses consistent with the current Food and Drug Administration (FDA) indication for intravenous treatment of patients with acutely decompensated congestive heart failure (CHF) who have dyspnea at rest or with minimal activity) are left to local contractor (carrier or FI) discretion.
- This addition to Chapter 1, Section 200.1, of the *Medicare National Coverage Determinations Manual*, (Publication 100-03) is a national coverage determination (NCD) made under section 1862(a)(1) of the Social Security Act (the Act).
- NCDs are binding on all carriers, FIs, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges (ALJs) (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 ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Act.)

Background

Nesiritide is FDA-approved for the short-term intravenous treatment of patients with acutely decompensated CHF who have dyspnea (shortness of breath) at rest or with minimal activity. Recent published studies of Nesiritide have highlighted safety concerns, specifically increased mortality and decreased renal function in patients treated with Nesiritide.

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In addition, an independent advisory panel of cardiac experts sponsored by Scios, manufacturer of Natrecor® (Nesiritide), recommended that *“The use of Nesiritide should be strictly limited to patients presenting to the hospital with acutely decompensated congestive heart failure who have dyspnea at rest”*

Additional Information

Claims submitted with Healthcare Common Procedure Coding System (HCPCS) code J2325 (Injection, Nesiritide) with International Classification of Diseases (ICD-9) codes of:

- 428.0, 428.1, 428.20, 428.22, 428.30, 428.32, 428.40, 428.42, or 428.9; **and not accompanied by:**
- 428.21, 428.23, 428.31, 428.33, 428.41, or 428.43, **will be denied.**

Denied claims will be returned with the following claims adjustment codes:

- **Reason Code:** 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.

Contractors shall apply the following Medicare Summary Notice 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.

Contractors shall not search for, but may adjust, claims brought to their attention with dates of service March 2, 2006, through implementation.

Relevant Links

CR4312 is the official instruction issued to your FI or carrier, regarding changes mentioned in this article. There are two transmittals related to CR4312. One is transmittal number R51NCD, which relates to the NCD. It may be found at <http://www.cms.hhs.gov/Transmittals/downloads/R51NCD.pdf> on the CMS website.

The second transmittal, R218OTN, relates to Medicare claims processing instructions, and it can be found at <http://www.cms.hhs.gov/Transmittals/downloads/R218OTN.pdf> on the CMS website.

Please refer to your local FI or carrier if you have questions about this issue. To find the toll free phone number, go to

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<http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>
on the CMS website.

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