MEDICARE
Part A Intermediary
Part B Carrier

May 17, 2005

Steve Phurrough, M.D., M.P.A.
Director, Coverage and Analysis Group
Mail Stop C-109-06
7500 Security Boulevard
Baltimore, Maryland 21244

Re: National Coverage Determination Request - Nesiritide, J2324

Dear Dr. Phurrough:

This letter, along with the enclosed binder of supporting documentation, is a formal request for a National Coverage Determination (NCD) on Natrecor® (Nesiritide).

Acute heart failure is the single most common cause of hospitalization in the U.S. for patients older than 65 years of age, resulting in approximately one million hospitalizations each year. Nesiritide has been granted FDA approval 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. Tab A includes background descriptive information on this agent, and Tab B provides a compendium of pertinent randomized clinical trial publications, with respect to the current FDA labeling along with the Follow-Up Serial Infusions of Natrecor® (FUSION) Trial results.

More recently, two reports have indicated that there are serious adverse consequences associated with Nesiritide usage that some reputable researchers in the field believe is inadequately evaluated (Tab C).

Nesiritide was first billed to the Medicare Program during the first quarter of 2003. Tab D includes representative utilization data for this new therapeutic agent. These data show a rapid and steady increase during the past two years in both the number of services allowed and the dollars paid by Medicare Part B contractors. Local data from HGSA closely follows the national trend data. In TrailBlazer Texas Part A data, allowed amounts have increased from about $824,000 for 83 patients in April-June 2003 to $3,557,000 for 398 patients in January-March 2005.

The major contributing factor to this above increased utilization pertains to the use of intravenous Nesiritide in chronic CHF and maintenance therapy, especially in the outpatient setting. Thus, the specific reason for our NCD request focuses on the "off-label" use of intravenous Nesiritide.

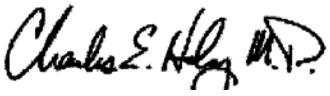
FUSION I was "designed to evaluate the safety and tolerability of weekly infusions of Natrecor® (Nesiritide) when administered in an outpatient setting to patients with advanced chronic CHF who are at high risk for hospitalization," but it did not evaluate the clinical efficacy and long-term outcomes of Nesiritide in this patient population. Scios' senior vice president of clinical research and medical affairs was quoted in the FUSION I press release (see **Tab** B) as follows: "The FUSION I trial provides compelling data to support the further study of Natrecor® in the outpatient setting for the treatment of patients with advanced CHF." It appears, however, that the results of the FUSION I Trial have been extrapolated to expand the utilization of Nesiritide to chronic CHF and maintenance therapy in the outpatient setting.

Consequently, this NCD request presents an opportunity for CMS, in support of its key stakeholders (including, but not restricted to, beneficiaries, contractors and the cardiology/provider communities), to engage in a deliberative, evidence-based process for determining the "reasonable and necessary" applications of Nesiritide as a therapeutic modality in CHF patients.

We respectfully request that CMS develop a National Coverage Determination that requires that "off-label" use of Nesiritide is covered by Medicare only if it is a service performed as a part of a randomized controlled clinical trial of sufficient size to adequately assess the safety and long-term efficacy of this therapy, and/or an appropriately designed clinical registry. For example, such evidence-based coverage might be directly linked to the ongoing FUSION II trial regarding Nesiritide use in the outpatient setting (refer to **Tab E** for brief protocol description).

For further assistance, please feel free to contact Dr. Charles Haley at (469) 372-2660.

Sincerely,



Charles Haley, MD
Contractor Medical Director
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AB/agr
Enclosure: Binder