



August 19, 2011

Donald M. Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

**Re: CMS-1525-P, Medicare Program:
Proposed Changes to the Hospital Outpatient Prospective Payment System
and CY 2012 Payment Rates - Payment System for Therapeutic
Radiopharmaceuticals**

Dear Dr. Berwick:

The Lymphoma Research Foundation (LRF) appreciates the opportunity to comment on a provision of the Proposed Rule on Hospital Outpatient Prospective Payments for calendar year 2012 that affects a large segment of the patients we represent, those with non-Hodgkin lymphoma. The payment methodology for radiopharmaceuticals recommended in the proposed rule must be clarified and simplified to ensure that those who might benefit from the therapy do not experience barriers to care as the result of the payment system.

LRF is the nation's largest non-profit organization devoted to funding innovative research and providing people with lymphoma and healthcare professionals with up-to-date information about this type of cancer. The Foundation's mission is to eradicate lymphoma and serve those touched by this disease. We fulfill this mission through our research programs, public and professional education, community-based programming and public policy and advocacy efforts. Our organization is comprised of more than 70,000 volunteers and supporters including patients, their loved ones, health care providers, researchers and clinicians.

Non-Hodgkin lymphoma (NHL) is not a single disease, but rather a group of several closely related cancers that affect the lymphatic system. The burden of NHL in the United States remains high: in 2011, it is estimated that 66,300 Americans will be diagnosed with NHL and more than 19,000 will die from the disease.¹ There are several treatments for lymphoma, and some patients may enjoy a durable remission from initial

¹ American Cancer Society. *Cancer Facts and Figures 2011*. Atlanta: American Cancer Society; 2011.

treatment. Regrettably, most patients will have a recurrence of their disease, and some will become refractory to treatment. For all of these patients, additional choices of therapy after the initial treatment are critically important. In fact, some patients may find that a series of different treatments and combinations of treatments are necessary to increase the length and enhance the quality of their lives.

Those with lymphoma and their health care providers cannot afford to lose any element of the treatment armamentarium due to reimbursement issues. However, that is the situation that exists for radiopharmaceuticals for NHL. We are writing to urge adoption of a straightforward and adequate method of payment for radiopharmaceuticals for NHL. Clarification of the payment methodology is necessary to facilitate the appropriate utilization of these treatments.

Innovative treatments like radioimmunotherapy provide an option for patients for whom other treatments for the disease may no longer provide a therapeutic benefit. It is an effective, singular course of treatment that provides long-lasting results for many patients. These drugs are administered in multiple steps, including a dosimetric step and a therapeutic step. The dosimetric step would, under the proposed rule, be reimbursed inadequately due to its classification as a diagnostic. In addition, the overall proposed rate of payment for the treatment regimen does not meet the costs borne by those institutions and practices that choose to administer it.

All components of the radiopharmaceutical treatments should be separately billable and paid as specific covered outpatient drugs (SCODs). By taking this straightforward and direct approach, the Centers for Medicare & Medicaid Services (CMS) could address the payment issues related to radiopharmaceutical treatments and remove barriers to patient access.

The matter of reimbursement for radiopharmaceuticals should not represent a great challenge. In the future, there will be additional and more vexing challenges associated with adapting the current payment system to new technologies delivered in complex ways. Resolving the reimbursement issues for the radiopharmaceuticals for NHL would be a step toward a system of payment that acknowledges and adjusts to innovation in treatment, including the method of delivery of new treatments.

LRF recognizes the significant effort CMS has made in revising the payment system for radiopharmaceuticals and we appreciate the agency's ongoing willingness to consider recommendations from the patient and medical communities. We look forward to a positive review of this recommendation.

Sincerely,



Diane Blum, MSW
Chief Executive Officer