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Clinical Research Division

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The Honorable Maria Cantwell
U.S. Senator
511 Senate Dirksen Building
Washington, D.C. 20510

Dear Senator Cantwell,

I am the Director of Clinical Research for Hematology and Hematologic Malignancies at the Seattle Cancer Care Alliance and the Chairman of the Scientific Advisory Board of the Lymphoma Research Foundation and am writing to express my grave concerns about the payment levels established by CMS for the calendar year 2008 hospital outpatient prospective payment system (HOPPS) for radioimmunotherapy of patients with non-Hodgkin's Lymphoma. Unless extraordinary action is taken to address these reimbursement rates before they go into effect on January 1, 2008, I fear that patient access to these therapies may be significantly limited, if not eliminated.

Radioimmunotherapies – tositumomab (Bexxar) and ibritumomab tiuxetan (Zevalin) – represent an important treatment option for individuals with non-Hodgkin lymphoma, including patients who have undergone other treatment that is no longer providing a therapeutic benefit. For some of these patients, the radioimmunotherapies may truly be life-prolonging. It is also important to note that these therapies are only given to patients for a single course of therapy and are not given in successive cycles of treatment.

Administration of the radioimmunotherapies is somewhat complex and must be undertaken in facilities that are equipped for their administration. This fact presents an initial challenge to patient access, but the proposed payment rates for 2008 represent a much more serious barrier to access. It is our understanding that the payment rates for 2008 will be significantly less than the cost of acquisition, preparation, and handling of radioimmunotherapies. If this payment situation is not addressed, hospital outpatient departments will be unable to stock these therapies, and this treatment option will be effectively eliminated for non-Hodgkin lymphoma patients.

We recommend that several specific steps be taken to address this situation:

- The Centers for Medicare & Medicaid Services (CMS) should consider the radioimmunotherapy regimen a specified covered outpatient drug, or SCOD. In the CY 2008 rule, the agency improperly splits the radioimmunotherapy regimen into separate elements and considers the first dose a diagnostic dose rather than a therapeutic dose. This is at odds with the Food and Drug Administration labeling of the products and current practice.
- CMS should cover the cost of compounding radioimmunotherapies. Elimination of the compounding fee creates another obstacle to the willingness of institutions to make this

therapy available to their patients, because these institutions find the payment inadequate to meet their costs.

- The agency should consider setting payment for radioimmunotherapies on the basis of 106 percent of average sales price (ASP) or a composite ambulatory payment classification (APC) that would reflect the entire cost of the radioimmunotherapy regimen. We understand that the APC Advisory Panel reviewed these options at a recent meeting, and we urge CMS to consider these proposals. Because the effective date of the payment system is imminent, an ASP-based system may represent the most feasible alternative.

At the fund-raising event I attended in north Seattle at Dr. Douglas Lee's home before your last election as Senator you spoke convincingly of your support for medical oncology services. I believe this is an opportunity for you to intervene personally and make a major difference for the half million Americans living with lymphoma. I fear that these products will simply not be available for treatment of non-Hodgkin lymphoma after the new year since the providers will lose money with every administration of the drugs and companies making them will cease production. The payment structure proposed for 2008 will not produce savings to the Medicare program in the long run, and it will certainly not ensure access to quality health care.

Sincerely,

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