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December 4, 2007

## 2007

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## Letter to Senate Finance Committee Members

Dear Senator:

The American Society of Hematology (ASH) represents over 11,000 hematologists in the United States who are committed to the treatment of blood and blood related diseases. ASH members include hematologists and hematologist/oncologists who regularly render services to Medicare beneficiaries.

On behalf of the Society, I write to share ASH's concern with the Centers for Medicare and Medicaid Services' (CMS') recent change to the hospital outpatient payment policy for Tositumomab/Iodine I131 Tositumomab and Indium 111 Ibitumomab tiuxetan/Yttrium 90 Ibitumomab tiuxetan. The principal use of these specific radioimmunotherapy (RIT) agents is for the treatment of non-Hodgkin's Lymphoma, particularly for patients who have not responded well to a prior course of chemotherapy. The new policy will result in hospitals being paid less than half of their costs for these drugs and likely will result in severely limited patient access to this treatment and a phasing out of this important therapy.

In the final hospital outpatient rule for 2008, CMS decided to "package" all diagnostic radiopharmaceuticals into the APC payment for a related nuclear medicine procedure. As a result, RIT products classified as diagnostic radiopharmaceuticals will not be separately paid for based on their estimated cost in the manner of therapeutic radiopharmaceuticals and high cost drugs.

This CMS decision is problematic for two reasons. First is that CMS will no longer pay separately for certain doses of radioimmunotherapy agents because they are being classified as "diagnostic" as opposed to "therapeutic." Second, the proposed "packaged" payment level grossly underestimates the cost of the product.

The complete RIT treatment regimen for the non-Hodgkin's Lymphoma patient is provided over 7 to 14 days. After the initial treatment, the patient is evaluated via a nuclear medicine procedure to determine if the distribution of the agent is acceptable. If it is not, no further treatment is provided. The new CMS policy will not pay separately for the initial treatment, but packages the cost of the agent in the cost of the nuclear medicine procedure. ASH opposes the CMS policy because all doses of these RITs are intended to be therapeutic and part of a multi-day treatment regimen, even if the decision is made not to furnish any further doses. ASH believes that CMS is erroneously classifying the initial treatment as diagnostic and therefore is eliminating a separate payment.

The Society is also concerned with the proposed payment rate for the entire treatment regimen, which covers less than half of the \$30,000 cost to hospitals. This underpayment may have occurred because CMS used a methodology that led to an underestimate of costs. Unless corrected, inadequate reimbursement could prove devastating to this important therapy and patient access to the treatment may be severely limited because many hospitals will not be able to absorb losses that exceed \$15,000 per patient. If this occurs it will eliminate one of the few treatment options – in some cases the only treatment option – for some patients with non-Hodgkin’s Lymphoma who failed chemotherapy treatment. Finally, the policy could have a chilling effect on the development of future drugs and radiopharmaceuticals for treating other forms of cancer and other diseases.

A legislative remedy has been proposed that would direct CMS to continue for 2008 the payment methodology for diagnostic radiopharmaceuticals that was in place in 2007. The proposal would address the problem of drugs that utilize an imaging dose to guide therapy. A more narrow option would be to direct CMS to classify all doses of these RITs treatments as “therapeutic,” which would allow for separate payment based on estimated costs. Either modification would provide hospitals with payments that more closely approximate actual cost and would help ensure access to this invaluable treatment.

ASH notes that this change can be made in a budget neutral manner by adjusting the payment for other nuclear medicine procedures. Since the new payment rates are going into effect for services rendered on or after January 1, 2008, time is obviously of the essence; however, since CMS does quarterly updates to the hospital outpatient APC rates, the change could also be accomplished as a mid-year correction, effective April 1, 2008.

On behalf of the Society, I appreciate the opportunity to express ASH’s concerns and encourage your support for a legislative remedy to the reimbursement issue for this group of cutting edge and valuable drugs. If you have any questions or would like further information, please contact Mila Becker of the ASH staff at [mbecker@hematology.org](mailto:mbecker@hematology.org) or (202)776-0444.

Sincerely yours,



Andrew I. Schafer, MD  
President