Patients Against Lymphoma

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Providing support and evidence-based information on lymphomas, independent of health industry funding

12/10/2007

Re: Citizen Petition and Overview of CMS ruling that will deny or limit access to life saving treatment for lymphomas

Dear Honorable Members of Congress and Administrators:

Patients Against Lymphoma represents the concerns of lymphoma patients, survivors and their families. We are deeply concerned that the reimbursement rates for Bexxar and Zevalin, as set forth in the "final ruling" at approximately 50% of their cost, will prevent patients from receiving either of these life-saving treatments.

Overview - CMS-1392-FC, Underpaying Hospitals for Radioimmunotherapies – invaluable targeted therapeutics with curative potential

- Lymphoma is more common than leukemia; affects about 500,000 Americans; kills about 27,000 of our citizens annually
- Indolent lymphoma (approximately 50% of lymphomas) was considered unlikely to be cured until the advent of targeted immunotherapies. Radioimmunotherapies are highly active agents used to treat indolent and aggressive forms of the disease.
- Radioimmunotherapies are targeted immunotherapies that binds to a receptor on b-cell lymphomas, the most common subtype of lymphoma. RIT has multiple tumor killing mechanisms, which are specific to b-cells, normal and malignant. "Cold" and "warm" doses serve to clear normal b-cells so that subsequent radiolabeled (hot) doses are more focused on tumor cells. "Warm" doses are used to determine clearance rate of the agent to personalize dosing to improve both safety and efficacy. All doses have therapeutic effects. *(CMS has misclassified the cold and warm doses as diagnostic.)*
- RIT (Bexxar and Zevalin) are *invaluable* (irreplaceable) therapies that have curative potential and are proven to induce durable remissions, measured in years, in patients with limited or no response to prior chemotherapies:

  "Response rates of up to 95% have been reported and exciting new data are emerging from large trials again showing these drugs to be the most active single agents in lymphoma, working even when chemotherapy does not. … Patients may actually be cured with these agents.

  ~ Dr. Richard Wahl, letter to HHS Secretary Mike Leavitt

  Thus, the CMS ruling directly affects the survival of patients with b-cell lymphomas, and, as ASH has written, the ruling will have a *chilling effect on the development of future drugs* for all cancers.
- We fear the CMS ruling undermines the NIH/NCI vision. In a letter to HHS Secretary Mike Leavitt, Dr. Wahl an inventor of radioimmunotherapy, describes this effect:

"Bexxar and Zevalin were developed in part with NIH/NCI support. It is very hard to decipher the logic by which the true fruits of the NIH, science translated to practice, are not made available to the public by its sibling in the HHS family, CMS. This suggests a dysfunctional HHS family, which I am sure is neither a desired perception nor result."

- To our knowledge no prior CMS ruling has ever resulted in diminished assess to a life saving therapy until now. An eminent expert comments on the consequences of CMS-1392-FC:

  "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 healthcare."

  ~ Dr. Oliver Press, Letter to Senator Cantwell

CONCISE SUMMARY OF OUR FINDINGS:

Patients Against Lymphoma reviewed the raw CMS data and made public comment when the CMS ruling was in the proposals tage on Sept 11, 2007.
See http://www.lymphomation.org/CMS-RIT.pdf

Summary of CMS judgments and calculations in this matter:

1. **Misclassified cold and warm doses of Bexxar as diagnostic**
   Dr. Wahl writes: "classifying the dosimetry or biodistribution dose of Bexxar and Zevalin as a "diagnostic scan", like a PET scan, which they clearly are NOT (we already know the patients have lymphoma).
2. **Discriminated against RIT by not using average sales price (ASP)**
   "ASP ... that would reflect the entire cost of the radioimmunotherapy regimen." ~ Dr. Oliver Press, Letter to Senator Cantwell – Nov 2007)
3. **Used flawed claims data to calculate Mean cost** - as low as 4 dollars
   (See PAL Letter & Letter from Dr. Wahl)
4. **Includes no consumer or patient group on ruling committee**
   (based on conversation with CMS committee member)
5. **Did not follow recommendations of ASCO and ASH** ;ignored or disregarded warnings about consequences to patients. (ASH and ASCO are respected clinical associations See commentary by ASH)
   http://www.lymphomation.org/CMS-RIT-points.htm#ASH-CMS
6. **Chose not to include payments to cover costs to hospitals of compounding of these agents** (Dr. Oliver Press, Letter to Senator Cantwell)

In summary, patients are understandably upset and frightened about the loss of an invaluable, potentially curative therapy. Advocates and clinical associations are concerned about potential loss of life and the chilling effects on future research. We believe that NIH/NCI should be equally concerned about these effects and take steps to safeguard these remarkable scientific innovations – "the true fruits of the NIH, science translated to practice."

REQUESTED ACTION: We urge our elected representatives to restore the reimbursement rates for 2007 during 2008 in order to give patients continued access to these much needed drugs and allow CMS the time it needs to collect the necessary data to base reimbursement rates for 2009 on accurate data and appropriate classifications on which to set the rates for 2009.

Thank you for your time and attention to this urgent matter. We look forward to your reply and your timely actions on behalf of your constituents.

Sincerely,

Karl Schwartz

President and cofounder of Patients Against Lymphoma
Patient Consultant to the FDA/Oncologic Drug Advisory Committee (ODAC)
Participant: NCI Progress Review Group for Blood Cancers (LMPRG)
Participant: Biospecimen Access and Ethical, Legal, and Policy Issues Workshop (ELP)
Participant: Custodianship and Ownership Issues in Biospecimen Research Symposium

ATTACHED:

Attached is a list of **4,016 citizens** (as of Dec 1, 2007) who join us in our request, representing taxpayers from every state in the nation. The undersigned approved our letter to CMS dated September 11, 2007: http://www.lymphomation.org/CMS-RIT.pdf