Patients Against Lymphoma

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November 19, 2007

TO: The Honorable Members of Congress
The Honorable Administrator for the Centers for Medicare and Medicaid Services (CMS)
The Honorable Administrator for Health and Human and Human Services (HHS)

RE: RE: CMS-1392-FC, Reimbursement for Radiopharmaceuticals
BEXXAR® Therapeutic Regimen (Tositumomab + Iodine 131 Tositumomab) and
ZEVALIN® Therapeutic Regimen (Ibritumomab Tiuxetan)

Dear Honorable Members of Congress and Administrators,

Patients Against Lymphoma is a non-profit organization, independent of health industry funding, which 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.

During the open comment period prior to publication of the "final rule," more than 1500 patients signed our petition to request that CMS fully reimburse for these treatments. Now, word of the "final rule" has begun to spread throughout the lymphoma population, and in just the past 72 hours, we have received 623 emails from panicked, and sometimes angry, patients in nearly every state in the nation. Their names are included on the attached list*. We fully expect that the number of emails will swell as patients begin to realize the full impact of this "final ruling."

**** The attached list contains more than 3,000 endorsements as of November 21, 2007.***

Patients who wrote to us ranged in age from a 19-year-old woman whose very future depends on these drugs to those in their 70's who cannot tolerate additional chemotherapy or a stem cell transplant. Facing recurrence of the disease and planning to use Bexxar or Zevalin as their next treatment, they are fearful that these drugs will not be available and that they will die. Many patients were literally begging for their lives with comments such as *"Please don't let my government kill me."* Likewise, families are outraged that CMS could potentially take away their mothers or fathers, brothers or sisters, grandmothers or grandfathers – and even their children.

There are more than 500,000 lymphoma patients in the United States. Bexxar and Zevalin have been proven to be the most effective single agent treatments for some forms of the disease. For many patients, Bexxar and Zevalin represent the last and only hope to arrest a disease which has historically been incurable. Some have even said that these treatments produce a cure.

Yet it has been well documented that Bexxar and Zevalin have been extremely underutilized (see Journal of the National Cancer Institute, Volume 99, Issue 7, April 4, 2007; The New York Times front page, July 14, 2007; and Newsweek's article on November 13, 2007 entitled "How Washington Is Nixing A Cancer Cure."). If allowed to take effect, this ruling will turn "underutilization" into no utilization at all. Dr. Andrew Shafer, President of the American Society of Hematology (ASH), concurs. In his letter to CMS during the open comment period, he warns, *"It (the ruling) will eliminate one of the few treatment options and perhaps the only treatment option for some patients with non-Hodgkins lymphoma who have failed chemotherapy."*

By reducing the reimbursement rates of the two drugs to below cost, hospitals will not be able to absorb the losses, making these drugs unavailable to Medicare patients - or to anyone else. The ruling states, *"(CMS) may terminate the provider agreement of any hospital that furnishes this or any other service to its patients but fails to also furnish it to Medicare patients who need it."* In other words, the agency acknowledges that the treatment is "needed," but threatens to terminate contracts if it is offered. This defies logic.

Additionally, CMS admits that its rates were based on faulty claims data, stating that some were *"incorrectly coded" and thus "unlikely to represent claims for treatment with the products described as A9543 and A9545 (Zevalin and Bexxar respectively)."* With all due respect, flawed data equals flawed results. In this case, those flaws are likely to cost dearly, with the lives of your fellow Americans.

Dr. Richard Wahl, Professor of Radiology and Oncology and Director of Nuclear Medicine and PET, Johns Hopkins University School of Medicine, agrees. In his letter to HHS Secretary Mike Leavitt, Dr. Wahl states, *"If the reimbursement rates from CMS 1392-FC remain, you will be denying lymphoma patients a very effective therapy and quite likely, their lives."* He also says, *"The prospect of their (Bexxar and Zevalin) not being available at all to lymphoma patients due to CMS recent "final rule" is criminal."*

We and the patients we represent agree with Dr. Wahl, and we respectfully request that you intervene on behalf of the thousands of patients whose very lives depend on these drugs. Specifically, we request that you restore reimbursement rates for Bexxar and Zevalin to 2007 rates during 2008. This will allow CMS the time it needs to collect the necessary data to base reimbursement rates for 2009 on accurate data.

We and the patients who need these drugs, now and in the future, urge you to act swiftly, before this ruling takes effect on January 1, 2008.

Respectfully,

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Advocacy Advisor, Patients Against Lymphoma

Karl Schwartz,
President, Patients Against Lymphoma
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Participant: NCA 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