Patients Against Lymphoma

Non-Profit | Independent | Evidence-based

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Founded in 2002

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Centers for Medicare and Medicare Services
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P. O. Box 8013
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RE: CMS-1414-P, Proposed Changes to the Hospital Outpatient Prospective Payment System and CY2010 Payment Rates For Radiopharmaceuticals

Dear Sir or Madam:

Patients Against Lymphoma (PAL) is a non-profit organization representing the concerns of lymphoma patients, survivors and their families. Our mission is funded *independent of health industry funding*.

Background: To the detriment of patients, both Bexxar® and Zevalin® have been sorely underutilized, and reimbursement has been cited as a major cause.

> *(Berenson, Alex. "2 Lymphoma Drugs Go Unused, And Backers Cite Market Forces." New York Times. July 14, 2007 and Garber, Ken, "Users Fear That Lymphoma Drugs Will Disappear." Journal of the National Cancer Institute, Vol. 99, Issue 7, pp. 498-501.)*

The proposed **Average Sales Price** (ASP) payment method for 2010 takes a big step toward solving a serious reimbursement issue, and we applaud CMS for its effort to find a long term solution that will improve patient access to these life-saving treatments. However, we are concerned that payment would default to CY2008 **mean unit cost** if the manufacturers are unable to submit sales data to CMS by November 1, 2009.

As we understand CY2008, the reimbursement rates for Bexxar® and Zevalin® were derived from 2006 hospital claims data. CMS acknowledged that many claims were incorrectly submitted and some represented unusually low costs. In fact, the mean unit cost, as reported in the 2006 Outpatient Department Prospective Payment System (OPPS) claims data, started at $16.57 (dx) and $4.34 (rx) for Bexxar® and $37.27 (dx) and $4.77 (rx) for Zevalin®, which are **unrealistically low estimates of cost**.

CMS acknowledged that some claims were "incorrectly coded" and thus "unlikely to represent claims for treatment with the products described as A9543 (Zevalin®) and A9545 (Bexxar®)," but nonetheless set rates for 2008 that were **approximately one half the cost of**

these drugs. If this claims methodology had been implemented in 2008, hospitals would not have been able to subsidize these drugs, undermining patient access.

This led to an *unprecedented* Congressional intervention: In the Medicare, Medicaid and SCHIP Extension Act of 2007 and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Congress mandated that CMS pay for therapeutic radiopharmaceuticals on a cost-to-charge basis through January 1, 2010. This allowed continued patient access to these very important treatment options.

Going forward: It's our understanding that if the manufacturers cannot submit the necessary data by November 1 2009 and payment defaults to claims in 2010:

> the payment for Bexxar® (A9545, classified by CMS as Iodine I-131 tositumomab, therapeutic) would be $9,401.95 and;
>
> the payment for Zevalin® (A9543, classified by CMS as Y90 ibritumomab, therapeutic) would be $15,802.70.

It's our understanding that these rates are *substantially below cost* and would again result in denied access to these vital drugs, which are highly effective, even when other agents are not, and also cost effective (price per year in remission). [1]

While PAL supports the Proposed Rule policy of using ASP methodology, we respectfully request that claims default to cost-to-charge per MIPPA rather than hospital claims. This would give patients the "safety net" we need for continued access to these lifesaving drugs should a default claims procedure be necessary.

We truly appreciate the efforts that CMS has made in developing and implementing payment methodologies that will ensure continued patient access to Bexxar® and Zevalin®, and we fully support and encourage the use of ASP for CY2010 and beyond.

Respectfully,

Karl Schwartz

President and co-founder, 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

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1 IMPLICATIONS FOR PATIENTS WITH LYMPHOMA AS A RESULT OF CMS-1392-FC AS IT RELATES TO BEXXAR® Therapeutic Regimen (Tositumomab + Iodine 131 Tositumomab) and ZEVALIN® Therapeutic Regimen (Ibritumomab Tiuxetan) www.lymphomation.org/cms-rep.pdf