On behalf of the Spectrum Pharmaceuticals, Inc, I respectfully request that the NCCN Guideline Panel for treatment of non-Hodgkin’s lymphoma to review the enclosed publications for consideration of modifying the NCCN Guidelines to include Zevalin therapy for use in diffuse large B-cell lymphoma (DLBCL).

Specific Changes: To include Zevalin therapeutic regimen as an option for treating DLBCL.

The FDA approved indications for Zevalin therapeutic regimen are for the treatment of patients with:

- relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL)
- previously untreated follicular NHL who achieve a partial or complete response to first-line chemotherapy

The Zevalin therapeutic regimen is not approved for use in DLBCL. However, there have been publications in both the previously untreated and relapsed/refractory patients with DLBCL. Studies that reported response rates have cited overall response rates (ORR) of >95% in previously untreated patients. In the relapsed/refractory setting, the ORR ranged from 19% to 58%. Additionally, a group of investigators reported a duration of response of 85 months in a relapsed DLBCL patient treated with Zevalin. Grade 3 or 4 hematologic toxicity was observed both in the previously untreated and the relapsed/refractory patients.

Thank you for your review of the enclosed publications.

Sincerely,

Katherine Hsu, PharmD
References


3. Hamlin PA, Moskowitz CH, Wegner B, et al. Sequential RCHOP and yttrium-90 ibritumomab tiuxetan (RIT) is a highly effective regimen for high risk elderly patients with untreated DLBCL. Oral presentation at: International Conference on Malignant Lymphoma Meeting; June 5, 2008; Lugano, Switzerland.


