
Specific Changes: Consider the recently published and presented data on the use of Rituxan maintenance for the treatment of NHL for your updating purposes.

FDA Clearance: The FDA has not approved Rituxan maintenance for the treatment of follicular NHL. Please refer to the enclosed prescribing information for the full FDA-approved indications and safety information.

Rationale: Results from the Phase III, international, multicenter, randomized PRIMA (Primary RItuximab and MAintenance) study were recently published in *The Lancet* and presented at the 52nd American Society of Hematology (ASH) meeting and exposition on December 4-7, 2010. The PRIMA study evaluated Rituxan maintenance every 8 weeks for 2 years in patients with previously untreated advanced follicular NHL who responded to initial treatment with Rituxan plus chemotherapy. At a median follow-up of 36 months, the primary endpoint, progression free survival (PFS), was 74.9% (95% CI: 70.9-78.9) in the Rituxan maintenance group compared with 57.6% (95% CI: 53.2-62.0) in the observation group (hazard ratio [HR]=0.55; 95% CI: 0.44-0.68, p<0.0001). Grade 3 and 4 adverse events were reported in 24% of patients in the Rituxan maintenance group and 17% of patients in the observation group.

Results from additional studies on Rituxan maintenance were also presented at the 2010 ASH meeting.4-11

The following enclosures are included for your review (copyright-paid where applicable):

• Foá R, Di Rocco A, van Hazel G, et al. Maintenance rituximab every 2 months for 2 years is effective and well tolerated in patients with follicular lymphoma with both standard or rapid infusion: updated results from the phase IIIb MAXIMA study. Presented at the 52nd American Society of Hematology Annual Meeting and Exposition in Orlando, Florida; December 4-7, 2010. ASH Poster #3945
• Salles GA, Catalano J, Feugier P, et al. Updated results of the PRIMA study confirms the benefit of 2-years rituximab maintenance in follicular lymphoma patients responding to immunochemotherapy. Presented at the 52nd American Society of Hematology Annual Meeting and Exposition in Orlando, Florida; December 4-7, 2010. ASH Poster #1788.
• Taverna CJ, Bassi S, Hitz F, et al. Rituximab maintenance treatment for a maximum of 5 years in follicular lymphoma: safety analysis of the randomized phase III trial SAKK 35/03. Presented at the 52nd American Society of Hematology Annual Meeting and Exposition in Orlando, Florida; December 4-7, 2010. ASH Poster #1802.
• Rituxan Prescribing Information

Cited References

5. Foá R, Di Rocco A, van Hazel G, et al. Maintenance rituximab every 2 months for 2 years is effective and well tolerated in patients with follicular lymphoma with both standard or rapid infusion: updated results from the phase IIIb MAXIMA study. Presented at the 52nd American Society of Hematology Annual Meeting and Exposition in Orlando, Florida; December 4-7, 2010. ASH Poster #3945.
7. Taverna CJ, Bassi S, Hitz F, et al. Rituximab maintenance treatment for a maximum of 5 years in follicular lymphoma: safety analysis of the randomized phase III trial SAKK 35/03. Presented at the...

