
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.

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

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.

