On behalf of Genentech, I respectfully request the NCCN Non-Hodgkin’s Lymphoma Panel to review the enclosed data for Gazyva™ (obinutuzumab) in combination with chlorambucil for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL).

**Specific Changes:** Consider the available data on the use of Gazyva in the treatment of patients with previously untreated CLL.

**FDA Clearance:** On November 1, 2013, Genentech, a member of the Roche Group, received FDA approval for Gazyva in combination with chlorambucil for the treatment of patients with previously untreated CLL. Please refer to the enclosed Erivedge prescribing information for the full FDA-approved indication and safety information.

**Rationale:** The FDA approval of Gazyva is based on results from the pivotal study (CLL11) in patients with CLL and pre-existing medical conditions (comorbidities). CLL11 is a multicenter, open label, randomized, 2-stage, 3-arm, Phase III study to evaluate the efficacy and safety of Gazyva + chlorambucil, rituximab + chlorambucil or chlorambucil alone. Please refer to the enclosed Gazyva prescribing information for the full FDA-approved indication and safety information.

I have enclosed the following oral presentation and abstract of the CLL11 stage 1a study (copyright-paid where applicable), which was presented at the American Society of Clinical Oncology (ASCO) 2013 meeting in Chicago, Illinois which may include uses beyond our label. I hope this information is helpful to you.

- Goede V, Fischer K, Humphrey K, et al. Obinutuzumab (GA101) + chlorambucil (Clb) or rituximab (R) + Clb versus Clb alone in patients with chronic lymphocytic leukemia (CLL) and co-existing medical conditions (comorbidities): final stage 1 results of the CLL11 (BO21004) phase 3 trial. Presented at: American Society of Clinical Oncology; 2013; Chicago, Illinois. oral presentation The ASCO Abstract #7004 can be found in the Meeting Library section at http://www/asco.org.
- Gazyva™ Prescribing Information

**Cited References:**

1. Gazyva™ Prescribing Information