

Submitted by:

Janice Hashimoto, Pharm.D., Scientist
Medical Communications, Medical Affairs
Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080
Phone: (650) 467-0224
Email: mc-mc-d@gene.com
Date of request: November 1, 2013
NCCN Guidelines Panel: Non-Hodgkin's Lymphoma

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.¹ 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 alone¹. 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 (dopyright-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.³ 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
2. FDA approves GAZYVA™ (obinutuzumab) for people with previously untreated chronic lymphocytic leukemia (CLL). South San Francisco: Genentech, A Member of the Roche Group; November 1, 2013. Accessed November 1, 2013 from <http://www.gene.com/media/press-releases/14559/2013-11-01/fda-approves-gazyva-obinutuzumab-for-peo>
3. 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. ASCO Abstract #7004 and oral presentation <http://www.asco.org>