# Gazyva (obinutuzumab)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization | 1 year |

## APPROVAL CRITERIA

Requests for Gazyva (obinutuzumab) may be approved if the following criteria are met:

I. Individual has a diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma; **AND**
II. Individual is using for one of the following:
   A. In combination with bendamustine for first-line treatment in individuals without del (17p)/TP53 mutation (NCCN 2A); **OR**
   B. In combination with chlorambucil for first-line treatment in individuals without del(17p)/TP53 mutation who have significant comorbidity or age ≥65 (Label, NCCN 2A); **OR**
   C. In combination with ibrutinib for first-line treatment in individuals without del(17p)/TP53 mutation who have significant comorbidity or age ≥65 (Ibrutinib label, NCCN 2B); **OR**
   D. In combination with venetoclax for first-line treatment in individuals with or without del(17p)/TP53 mutation (NCCN 2A); **OR**
   E. In combination with acalabrutinib for first-line treatment in individuals with or without del (17p)/TP53 mutation; **OR**
   F. As a single agent for first-line treatment in individuals who are frail or with del(17p)/TP53 mutation (NCCN 2A); **OR**
   G. As a single agent for the treatment of relapsed/refractory disease without del(17p)/TP53 mutation (NCCN 2A).

**OR**

III. Individual has a diagnosis of follicular lymphoma; **AND**
IV. Individual is using in combination with one of the following regimens *and* as monotherapy, for up to 24 months or until disease progression, following the listed combination therapy regimens:
   A. Cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP regimen); **OR**
   B. Cyclophosphamide, vincristine, and prednisone (CVP regimen); **OR**
   C. Bendamustine;

**OR**

V. Individual has a diagnosis of hairy cell leukemia (NCCN 2A); **AND**
VI. Individual is using as initial therapy who are unable to tolerate purine analogs; **AND**
VII. Individual is using in combination with vemurafenib.

Requests for Gazyva (obinutuzumab) may not be approved for the following:

I. Treatment of diffuse large B-cell lymphoma and mantle-cell lymphoma; **OR**

II. May not be approved when the above criteria are not met and for all other indications.

**Note**:
Gazyva (obinutuzumab) has a black box warning for hepatitis B (HBV) reactivation which, in some cases, results in fulminant hepatitis, hepatic failure, and death. Gazyva and concomitant medications should be discontinued in the event of HBV reactivation. Gazyva also has a black box warning for progressive multifocal leukoencephalopathy (PML), including fatal PML, which can occur in patients receiving Gazyva.

**Key References**:


1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. Cheson BD, Chua N, Mayer J, et al. Overall Survival Benefit in Patients with Rituximab-Refractory Indolent Non-Hodgkin Lymphoma Who Received Obinutuzumab plus Bendamustine Induction and Obinutuzumab Maintenance in the GADOLIN study. J Clin Oncol 2018;36:2259-2266.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. .
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp.
    a. B-Cell Lymphomas. V5.2022. Revised July 12, 2022.
    b. Chronic Lymphocytic Leukemia/small lymphocytic lymphoma. V1.2023. Revised August 5, 2022.
7. Park JH, Winer ES, Huntington SF, et al. First line chemo-free therapy with the BRAF inhibitor vemurafenib combined with obinutuzumab is effective in patients with HCL [abstract]. *Blood* 2021;138:Abstract 43.
8. Moreno C, Greil R, Demirkan F, et al. Ibrutinib plus obinutuzumab versus chlorambucil plus obinutuzumab in first-line treatment of chronic lymphocytic leukemia (iLLUMINATE): a multicentre, randomised, open-label, phase 3 trial [published correction appears in Lancet Oncol. Lancet Oncol. 2019; 20: 43-56.
9. Sehn LH, Goy A, Offner FC, et al. Randomized phase II trial comparing obinutuzumab (GA101) with Rituximab in patients with relapsed CD20+ indolent B-cell non-Hodgkin lymphoma: final analysis of the GAUSS study. J Clin Oncol. 2015; 33(30):3467-3474.