SmartHealth Ascension

Obinutuzumab

(Gazvya®) J9301 (10mg)

Covered with prior authorization

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

- Individual has a diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma; **AND**
- Individual is using for one of the following:
    - In combination with bendamustine for first-line treatment in individuals without del (17p)/TP53 mutation (NCCN 2A); **OR**
    - 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**
    - 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**
    - In combination with venetoclax for first-line treatment in individuals with or without del (17p)/TP53 mutation (NCCN 2A); **OR**
    - In combination with acalabrutinib for first-line treatment in individuals with or without del (17p)/TP53 mutation; **OR**
    - As a single agent for first-line treatment in individuals who are frail or with del (17p)/TP53 mutation (NCCN 2A); **OR**
    - As a single agent for treatment of relapsed/refractory disease without del (17p)/TP53 mutation (NCCN 2A).

  OR
- Individual has a diagnosis of follicular lymphoma; **AND**
- 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:
    - Cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP regimen); **OR**
    - Cyclophosphamide, vincristine, and prednisone (CVP regimen); **OR**
    - Bendamustine.

Requests for Gazvya® (obinutuzumab) may **not** be approved if the above criteria are not met and for all other indications not included above.

Initial authorization and reauthorization are up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Exclusion criteria:

- Treatment of diffuse large B-cell lymphoma and mantle-cell lymphoma.
- Requests for Gazvya® (obinutuzumab) may **not** be approved if the above criteria are not met and for all other indications not included above.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
- Individuals with significant known risk factors, unless the record provides an assessment of clinical benefit that outweighs the risk.

NOTE: Gazyva® 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®.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage. Gazyva® is a monoclonal antibody directed against the surface antigen CD20 and is used to treat chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) and follicular lymphoma (FL). Gazyva® is FDA-approved in combination with chlorambucil for previously untreated CLL. CLL and SLL are different manifestations of the same disease and are managed in much the same way. The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the use of Gazyva®. NCCN recommends it to be used as first-line treatment for patients without del (17p) mutation, in combination with either chlorambucil or bendamustine. NCCN also recommends Gazyva® first-line as a single agent for those with del (17p) mutation (2A recommendation) and for frail patients without del (17p) mutation (2B recommendation). It is also recommended as a single agent in patients without del (17p) mutation in relapsed or refractory disease. Venetoclax was recently granted FDA approval for treatment of CLL/SLL based on a study of Gazyva® in combination with venetoclax as first-line therapy in those with CLL/SLL with or without del (17p) mutation. Similarly, acalabrutinib (Calquence) and ibrutinib (Imbruvica) have FDA approval in combination with Gazyva® for first line therapy of CLL/SLL. Gazyva® is also FDA-approved to treat follicular lymphoma (FL), a type of B-cell lymphoma. It is indicated in combination with bendamustine followed by monotherapy for up to 2 years for treatment of FL which has relapsed after or is refractory to a rituximab-containing regimen. It is also approved in combination with bendamustine, CHOP regimen, or CVP regimen followed by monotherapy for up to 2 years for previously untreated FL.

Key References Accessed 8/2022:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. 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. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. 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. V5.2021. Revised September 22, 2021.
    b. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. V1.2022. Revised September 8, 2021.
6. 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.
7. 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, randomized, open-label, phase 3 trial [published correction appears in Lancet Oncol. Lancet Oncol. 2019; 20: 43-56.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.