

GAZYVA® (obinutuzumab) is NOW FDA APPROVED for use in combination with bendamustine followed by GAZYVA monotherapy for the treatment of patients with follicular lymphoma (FL) who relapsed after, or are refractory to, a rituximab-containing regimen.¹

IMPORTANT SAFETY INFORMATION

Boxed WARNINGS: HEPATITIS B VIRUS REACTIVATION and PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY

- **Hepatitis B Virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur in patients receiving CD20-directed cytolytic antibodies, including GAZYVA. Screen all patients for HBV infection before treatment initiation. Monitor HBV positive patients during and after treatment with GAZYVA. Discontinue GAZYVA and concomitant medications in the event of HBV reactivation**
- **Progressive Multifocal Leukoencephalopathy (PML) including fatal PML, can occur in patients receiving GAZYVA**

FDA approval of this indication was based on a Phase III, open-label, randomized study including 321 patients with follicular lymphoma (FL) who had no response to or progressed during or within 6 months of rituximab or a rituximab-containing regimen.¹ Treatment comprising six 28-day cycles of GAZYVA + bendamustine followed by GAZYVA monotherapy every 2 months for up to 2 years was compared with six 28-day cycles of bendamustine alone.*

- The trial was stopped at the preplanned interim analysis due to significant improvement in progression-free survival vs bendamustine alone²
- The trial demonstrated a 52% reduction in the risk of disease progression or death vs bendamustine alone (HR [95% CI]=0.48 [0.34, 0.68], *P*<0.0001) as determined by an independent review committee (IRC)
- The most common Grade 3-4 adverse reactions (incidence ≥ 10%) observed in patients with iNHL in the GAZYVA + bendamustine followed by GAZYVA monotherapy treated arm were neutropenia, thrombocytopenia and infusion reactions
- The most common adverse reactions (incidence ≥ 10%) observed in patients with iNHL in the GAZYVA + bendamustine followed by GAZYVA monotherapy treated arm were infusion reactions, neutropenia, nausea, fatigue, cough, diarrhea, constipation, pyrexia, thrombocytopenia, vomiting, upper respiratory tract infection, decreased appetite, arthralgia, sinusitis, anemia, asthenia and urinary tract infection

*GAZYVA was given by IV infusion as a flat dose of 1000 mg on Days 1, 8, and 15 of Cycle 1; on Day 1 of Cycles 2 to 6; and then every 2 months until disease progression for up to 2 years. Bendamustine was given intravenously on Days 1 and 2 for all treatment cycles (1 to 6) at 90 mg/m²/day when given in combination with GAZYVA or 120 mg/m²/day when given alone. Only patients in the GAZYVA + bendamustine arm who did not have disease progression (patients with a complete response [CR], partial response [PR], or stable disease [SD]) at the end of the 6 cycles continued receiving GAZYVA monotherapy for 2 years.

To learn more, please visit GAZYVA.com.

Select Codes for Your Reference^{1,3}

Type	Code	Description
NDC-10	50242-070-01	1000-mg/40-mL (25 mg/mL) single-dose vial
NDC-11	50242-0070-01	1000-mg/40-mL (25 mg/mL) single-dose vial
ICD-10-CM	C82.90-C82.99	Follicular lymphoma, unspecified
	C82.00-C82.09	Follicular lymphoma grade I
	C82.10-C82.19	Follicular lymphoma grade II
	C82.20-C82.29	Follicular lymphoma grade III, unspecified
	C82.30-C82.39	Follicular lymphoma grade IIIa
	C82.80-C82.89	Other types of follicular lymphoma

Note: This table is provided for informational purposes only. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech does not make any representation or guarantees concerning reimbursement or coverage for any service or item.

Please see the accompanying full Prescribing Information for additional Important Safety Information, including Boxed WARNINGS.

PATIENT ASSISTANCE INFORMATION

- Genentech BioOncology® Access Solutions provides reliable, effective access and reimbursement services to assist your patients and practice
- Visit Genentech-Access.com/Gazyva to learn more about our programs and services. To speak with one of our dedicated Specialists, call 1-888-249-4918

DISTRIBUTION INFORMATION

- A list of authorized distributors is available at <http://www.genentech-access.com/com/gazyva>

IMPORTANT SAFETY INFORMATION (CONTINUED)

ADDITIONAL WARNINGS AND PRECAUTIONS

- **Infusion Reactions:** GAZYVA can cause severe and life-threatening infusion reactions. Thirty-eight percent of patients experienced a reaction on Day 1 during treatment with GAZYVA in combination with bendamustine. For patients with Grade 4 infusion reactions, including but not limited to anaphylaxis, acute life-threatening respiratory symptoms, or other life-threatening infusion reaction, stop and permanently discontinue GAZYVA therapy. Premedicate patients with acetaminophen, an antihistamine, and a glucocorticoid. Closely monitor patients during the entire infusion. Infusion reactions within 24 hours of receiving GAZYVA have occurred. For Grades 1, 2, or 3 infusion reactions, interrupt or discontinue infusion for reactions
- **Tumor Lysis Syndrome (TLS):** TLS, including fatal cases, has been reported in patients receiving GAZYVA. Patients with high tumor burden, high circulating lymphocyte count ($>25 \times 10^9/L$) or renal impairment are at greater risk for TLS and should receive appropriate tumor lysis prophylaxis with antihyperuricemics and hydration prior to the infusion of GAZYVA
- **Infections:** Serious bacterial, fungal, and new or reactivated viral infections can occur during and following GAZYVA therapy. Fatal infections have been reported. Do not administer GAZYVA to patients with an active infection
- **Neutropenia:** Severe and life-threatening neutropenia can occur. Monitor patients with Grade 3 to 4 neutropenia frequently with regular laboratory tests until resolution. Neutropenia can also be of late onset and/or prolonged
- **Thrombocytopenia:** Severe and life-threatening thrombocytopenia has been reported during treatment with GAZYVA in combination with bendamustine. Monitor all patients for thrombocytopenia. In patients with Grade 3 or 4 thrombocytopenia, monitor platelet counts and bleeding frequently until resolution and consider dose delays of GAZYVA and bendamustine or dose reductions of bendamustine. Management of hemorrhage may require blood product support

ADDITIONAL IMPORTANT SAFETY INFORMATION

- The safety of GAZYVA was evaluated based on a safety population of 392 patients with indolent NHL (iNHL), of whom 81% had follicular lymphoma. In patients with follicular lymphoma, the most common adverse reactions that were seen were consistent with the overall population who had iNHL
- Grade 3/4 adverse reactions were: neutropenia (33%), infusion reactions (11%), thrombocytopenia (10%), urinary tract infection (3%), upper respiratory tract infection (2%), pyrexia (1%), asthenia (1%), sinusitis (1%), and pain in extremity (1%)
- The most common adverse reactions (incidence $\geq 10\%$) were: infusion reactions (69%), neutropenia (35%), nausea (54%), fatigue (39%), cough (26%), diarrhea (27%), constipation (19%), pyrexia (18%), thrombocytopenia (15%), vomiting (22%), upper respiratory tract infection (13%), decreased appetite (18%), arthralgia (12%), sinusitis (12%), anemia (12%), asthenia (11%), and urinary tract infection (10%)
- During the monotherapy period with GAZYVA, the most common Grade 3-4 adverse reactions were neutropenia (10%), and anemia, febrile neutropenia, thrombocytopenia, sepsis, upper respiratory tract infection, and urinary tract infection (all at 1%)
- During the monotherapy period with GAZYVA, the most common adverse reactions were cough (15%), upper respiratory tract infections (12%), neutropenia (11%), sinusitis (10%), diarrhea (8%), infusion related reactions (8%), nausea (8%), fatigue (8%), bronchitis (7%), arthralgia (7%), pyrexia (6%), nasopharyngitis (6%), and urinary tract infections (6%)

You are encouraged to report side effects to Genentech and the FDA. You may contact Genentech by calling 1-888-835-2555. You may contact the FDA by visiting www.fda.gov/medwatch, or calling 1-800-FDA-1088.

Please see the accompanying full Prescribing Information for additional Important Safety Information, including Boxed WARNINGS.

References: 1. GAZYVA [package insert]. South San Francisco, CA: Genentech USA, Inc.; 2016. 2. Data on file. Genentech, Inc. 3. ICD10Data.com.



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