PERMANENT J-CODE FOR **GAZYVA**: **J9301**

Use the permanent J-code for services on or after January 1, 2015

J-code	Descriptor	Billable units	Effective date
J9301	Injection, obinutuzumab, 10 mg	10 mg = 1 billable unit	**January 1, 2015**

Indication

GAZYVA® (obinutuzumab), in combination with chlorambucil, is indicated for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL).

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**

Additional Warnings and Precautions

- **Infusion Reactions**: GAZYVA can cause severe and life-threatening infusion reactions. 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, 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 can occur within 12-24 hours after the first infusion. Patients with high tumor burden and/or high circulating lymphocyte count (>25 x 10^9/L) are at greater risk for TLS and should receive appropriate tumor lysis prophylaxis with anti-hyperuricemics and hydration beginning 12-24 hours prior to the infusion of GAZYVA
- **Infections**: Serious bacterial, fungal, and new or reactivated viral infections can occur during and following GAZYVA therapy. Do not administer GAZYVA to patients with an active infection
- **Neutropenia**: Severe 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

Please see reverse side for additional Important Safety Information.

Genentech
A Member of the Roche Group

GAZYVA®
obinutuzumab injection

GAZYVA ACCESS SOLUTIONS

Your resource for access and reimbursement support services

Contact GAZYVA Access Solutions if you have any questions about coverage and reimbursement.

Other billing and coding resources	
Centers for Medicare & Medicaid Services (CMS)	www.cms.gov
American Academy of Professional Coders (AAPC)	www.aapc.com
American Medical Association (AMA)	www.ama-assn.org
Centers for Disease Control and Prevention (CDC)	www.cdc.gov

While GAZYVA Access Solutions offers billing and coding information, it does not provide billing services or coding advice. Correct coding is the responsibility of the provider submitting a claim for the item or service. Please check with individual payers to verify codes and specialty billing requirements. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

Additional Warnings and Precautions (cont)

- **Thrombocytopenia**: Fatal hemorrhagic events have been reported. Severe thrombocytopenia occurred in 11% of trial patients. 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 chlorambucil or dose reductions of chlorambucil. Management of hemorrhage may require blood product support.

Additional Important Safety Information

- The most common adverse reactions (incidence ≥10%) were: infusion reactions (69%), neutropenia (40%), thrombocytopenia (15%), anemia (12%), pyrexia (10%), cough (10%), and musculoskeletal disorders (17%)
- Grade 3/4 adverse reactions were: infusion reactions (21%), neutropenia (34%), thrombocytopenia (11%), anemia (4%), leukopenia (5%), and pyrexia (<1%)

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.

For additional information on coding for GAZYVA, visit **Genentech-Access.com/GAZYVA** or call **(888) 249-4918** to speak with one of our dedicated Specialists.

Genentech
A Member of the Roche Group

GAZYVA® obinutuzumab injection

 ACS/092314/0037 Printed in USA