SAMPLE CODING

Relapsed/Refractory Follicular Lymphoma

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<thead>
<tr>
<th>TYPE</th>
<th>CODE</th>
<th>DESCRIPTION</th>
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<tbody>
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<td>Diagnosis: ICD-10-CM</td>
<td>C82.90–C82.99</td>
<td>Follicular lymphoma, unspecified</td>
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<td></td>
<td>C82.00–C82.09</td>
<td>Follicular lymphoma grade I</td>
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<td></td>
<td>C82.10–C82.19</td>
<td>Follicular lymphoma grade II</td>
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<td>C82.20–C82.29</td>
<td>Follicular lymphoma grade III, unspecified</td>
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<td>C82.30–C82.39</td>
<td>Follicular lymphoma grade IIIa</td>
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<td>C82.80–C82.89</td>
<td>Other types of follicular lymphoma</td>
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<td>Drug: HCPCS</td>
<td>J9301</td>
<td>Injection, obinutuzumab, 10 mg</td>
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<td>Drug: NDC</td>
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<td>Administration procedures: CPT</td>
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<td>Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug</td>
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<td></td>
<td>96415</td>
<td>Chemotherapy administration, intravenous infusion technique; each additional hour</td>
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These codes are not all-inclusive; appropriate codes can vary by patient, setting of care and payer. 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 guarantee concerning reimbursement or coverage for any service or item.

Many payers will not accept unspecified codes. If you use an unspecified code, please check with your payer.

INDICATION & IMPORTANT SAFETY INFORMATION

Indication

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

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

GAZYVA® (obinutuzumab), in combination with chemotherapy followed by GAZYVA monotherapy in patients achieving at least a partial remission, is indicated for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma (FL).

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

Contraindications

- GAzyva is contraindicated in patients with known hypersensitivity reactions (e.g., anaphylaxis) to obinutuzumab or to any of the excipients, or serum sickness with prior obinutuzumab use

Additional Warnings and Precautions

- Infusion Reactions: GAzyva can cause severe and life-threatening infusion reactions. Sixty-five percent of patients with CLL experienced a reaction to the first 1000 mg infused of GAzyva infused. Thirty-eight percent of patients with relapsed or refractory NHL and 60% of patients with previously untreated NHL experienced a reaction on Day 1 of GAzyva infusion. 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. Interrupt GAzyva for Grade 3 reactions until resolution of symptoms. Interrupt or reduce the rate of the infusion for Grade 1 or 2 reactions and manage symptoms

- Hypersensitivity Reactions Including Serum Sickness: Hypersensitivity reactions have been reported in patients treated with GAzyva. Late-onset hypersensitivity diagnosed as serum sickness has also been reported in patients treated with GAzyva. If a hypersensitivity reaction is suspected during or after an infusion, the infusion must be stopped and treatment permanently discontinued. Patients with known hypersensitivity reactions to GAzyva, including serum sickness, must not be retreated

- Tumor Lysis Syndrome (TLS): Tumor lysis syndrome, including fatal cases, has been reported in patients receiving GAzyva. Patients with high tumor burden, high circulating lymphocyte count (>25 x 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: Fatal and 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. In GALLIUM, more Grade 3 to 5 infections were reported in the recipients of GAzyva and bendamustine (117/410 patients, 29%), as compared to GAzyva plus CHOP or CVP (43/281 patients, 15%)

- 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 chemotherapy. Fatal hemorrhagic events have been reported in patients with NHL and CLL treated with GAzyva in combination with chemotherapy, including during Cycle 1. Monitor all patients for thrombocytopenia. In patients with Grade 3 or 4 thrombocytopenia, monitor platelet counts more frequently until resolution and consider subsequent dose delays of GAzyva and chemotherapy or dose reductions of chemotherapy. Transfusion of blood products (i.e., platelet transfusion) may be necessary

- Immunization: The safety and efficacy of immunization with live or attenuated viral vaccines during or following GAzyva therapy have not been studied. Immunization with live virus vaccines is not recommended during treatment and until B-cell recovery

Additional Important Safety Information

CLL

- The most common Grade 3 to 4 adverse reactions (incidence ≥10%) observed in patients with CLL in the GAzyva containing arm were neutropenia, infusion reactions, and thrombocytopenia
- The most common adverse reactions (incidence ≥10%) observed in patients with CLL in the GAzyva containing arm were infusion reactions, neutropenia, thrombocytopenia, anemia, pyrexia, cough, nausea, and diarrhea
- Adverse reactions rates and laboratory abnormalities from the Stage 2 phase are consistent with the rates in Stage 1. In addition to the adverse reactions observed in Stage 2, in Stage 1 back pain (5% vs. 2%), anemia (12% vs. 10%) and cough (10% vs. 7%) were observed at a higher incidence in the GAzyva treated patients. The incidence of Grade 3 to 4 back pain (<1% vs. 0%), cough (0% vs. <1%) and anemia (5% vs. 4%) was similar in both treatment arms. With regard to laboratory abnormalities, in Stage 1 hyperkalemia (33% vs. 18%), creatinine increased (30% vs. 20%) and alkaline phosphatase increased (18% vs. 11%) were observed at a higher incidence in patients treated with GAzyva with similar incidences of Grade 3 to 4 abnormalities between the two arms

Please see the accompanying full Prescribing Information for additional Important Safety Information, including BOXED WARNINGS.
Additional Important Safety Information (cont)

Relapsed/Refractory NHL

- The GADOLIN study evaluated safety in 392 patients with relapsed or refractory NHL, including FL (81%), small lymphocytic lymphoma (SLL) and marginal zone lymphoma (MZL) (a disease for which GAZYVA is not indicated) who did not respond to or progressed within 6 months of treatment with rituximab product or a rituximab product-containing regimen. In patients with follicular lymphoma, the profile of adverse reactions was consistent with the overall NHL population

- The most common Grade 3 to 4 adverse reactions (incidence ≥10%) observed in the GAZYVA containing arm were neutropenia, thrombocytopenia and infusion reactions

- The most common adverse reactions (incidence ≥10%) in the GAZYVA containing 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

- During the monotherapy period with GAZYVA, Grade 3 to 4 adverse reactions included 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 (incidence ≥5%) 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%)

Previously Untreated NHL

- A randomized, open-label multicenter trial (GALLIUM) evaluated the safety of GAZYVA as compared to rituximab product in 1385 patients with previously untreated follicular lymphoma (86%) or marginal zone lymphoma (14%)

- Serious adverse reactions occurred in 50% of patients on the GAZYVA arm and 43% of patients on the rituximab product arm. Fatal adverse reactions were reported during treatment in 3% in the GAZYVA arm and 2% in the rituximab product arm, most often from infections in the GAZYVA arm. During treatment and follow-up combined, fatal adverse reactions were reported in 5% of the GAZYVA arm and 4% of the rituximab product arm, with infections and second malignancies being leading causes. In the GAZYVA arm, fatal infections occurred in 2% of patients compared to <1% in the rituximab product arm

- Neutropenia, infusion related reactions, febrile neutropenia and thrombocytopenia were the most common Grade 3 to 5 adverse reactions (incidence ≥5%) observed more frequently in the GAZYVA arm

- Throughout treatment and follow-up, the most common adverse reactions (incidence ≥20%) observed at least 2% more in the GAZYVA arm were infusion related reactions, neutropenia, upper respiratory tract infection, cough, constipation and diarrhea

- During the monotherapy period, the common adverse reactions (incidence ≥10%) observed at least 2% more with GAZYVA were upper respiratory infection (40%), cough (23%), musculoskeletal pain (20%), neutropenia (19%) and herpesvirus infection (13%)

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.

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