DESCRIPTION: Obinutuzumab is a monoclonal antibody that targets the CD20 antigen expressed on the surface of pre B- and mature B-lymphocytes. Upon binding to CD20, obinutuzumab mediates B-cell lysis through (1) engagement of immune effector cells, (2) by directly activating intracellular death signaling pathways and/or (3) activation of the complement cascade. The immune effector cell mechanisms include antibody-dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis.

INDICATION(S): GAZYVA™, in combination with chlorambucil, is indicated for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL) 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.

CLL-Recommended dose for 6 cycles (28 day cycles): • 100 mg on day 1 Cycle 1; • 900 mg on day 2 Cycle 1; • 1000 mg on day 8 & 15 of Cycle 1; • 1000 mg on day 1 of Cycles 2–6

The dose for follicular lymphoma is 1000 mg on day 1, 8 and 15 of Cycle 1, and 1000 mg on day 1 of Cycles 2-6, and then every 2 months for 2 years.

REASONS FOR PA:
- Cost
- Potential for misuse
- Toxicity

CRITERIA for APPROVAL:
1. Patient has been diagnosed with previously untreated chronic lymphocytic leukemia (CLL), Medication will be used in combination with Chlorambucil
2. Patient has been diagnosed with follicular lymphoma and will be used in combination with bendamustine followed by GAZYVA monotherapy, who relapsed after, or are refractory to, a rituximab-containing regimen.
3. A screening for HBV infection by measuring HBsAg and anti-HBc was performed
4. Patient is an Adult, 18 years of age or greater
5. CLL - Dosing is dose for 6 cycles (28 day cycles): 100 mg on day 1 Cycle 1, 900 mg on day 2 Cycle 1; 1000 mg on day 8 and 15 of Cycle 1; 1000 mg on day 1 of Cycles 2–6
6. FL - dose for follicular lymphoma is 1000 mg on day 1, 8 and 15 of Cycle 1, and 1000 mg on day 1 of Cycles 2-6, and then every 2 months for 2 years.

REASONS for DENIAL of BENEFIT:
1. Patient has a hypersensitivity to obinutuzumab or any of its components
2. Patient does not meet above criteria

RENEWAL CRITERIA:
1. Patient has demonstrated a response to therapy

BENEFIT APPROVAL: Initial approval for a period of 3 months Renewal approval period: 24 months
Members may only obtain a 30 days’ supply at a time.