

GAZYVA (obinutuzumab)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. CD20-positive chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)

AND ONE of the following:

- a. First-line therapy in patients without del(17p)/TP53
- b. First-line therapy in patients with del(17p)/TP53
- c. First-line therapy when used in combination with (acalabrutinib)
- d. Inadequate response or intolerance to purine analog
- e. Relapsed or refractory disease as a single agent
- 2. Follicular lymphoma (FL)

AND ONE of the following:

- a. Stage II bulky, III or IV
 - i. Used in combination with chemotherapy during the initial 6 cycles of treatment followed by use as monotherapy
- b. Patient is relapsed or refractory to a rituximab-containing regimen
 - i. Used in combination with bendamustine during the initial 6 cycles of treatment followed by use as monotherapy
- c. Patient has relapsed or refractory follicular lymphoma
 - i. Patient has received two or more lines of systemic therapy
 - ii. Used in combination with Brukinsa (zanubrutinib)
- 3. Gastric or Nongastric MALT lymphoma
 - a. Patient is relapsed or refractory to a rituximab-containing regimen
 - b. Used in combination with bendamustine during the initial 6 cycles of treatment followed by use as monotherapy
- 4. Splenic Marginal Zone lymphoma
 - a. Patient is relapsed or refractory to a rituximab-containing regimen
 - b. Used in combination with bendamustine during the initial 6 cycles of treatment followed by use as monotherapy



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- 5. Nodal Marginal Zone Lymphoma
 - a. Patient is relapsed or refractory to a rituximab-containing regimen
 - b. Used in combination with bendamustine during the initial 6 cycles of treatment followed by use as monotherapy

AND ALL of the following:

- 1. Absence of active infection
- 2. Patient has or will be screened for hepatitis B prior to initiation of therapy and will be continued to be monitored during treatment if positive
- 3. Patient will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML)

Prior - Approval Limits

Duration 12 months

Prior – Approval Renewal Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

- 1. CD20-positive chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)
- 2. Follicular lymphoma (FL)
- 3. Gastric or Nongastric MALT lymphoma
- 4. Splenic Marginal Zone lymphoma
- 5. Nodal Marginal Zone Lymphoma

AND ALL of the following:

- 1. NO disease progression or unacceptable toxicity
- 2. Absence of active infection
- 3. Patient will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML)

Prior – Approval Renewal Limits

Same as above