PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Gazyva Prior Authorization Policy
- Gazyva® (obinutuzumab intravenous infusion – Genentech)

REVIEW DATE: 11/16/2022

OVERVIEW

Gazyva, a CD20-directed antibody, is indicated for the treatment of:
- **Chronic lymphocytic leukemia**, in combination with chlorambucil in previously untreated patients.
- **Follicular lymphoma**, in combination with bendamustine followed by Gazyva monotherapy, for patients who relapse or are refractory to a rituximab containing regimen.
- **Follicular lymphoma, stage II bulky, III or IV**, in combination with chemotherapy, followed by Gazyva monotherapy for patients achieving at least a partial remission, in previously untreated patients.[1]

Guidelines

Gazyva is addressed in National Comprehensive Cancer Network (NCCN) guidelines:
- **B-cell lymphomas:** Guidelines (version 5.2022 – July 12, 2022) recommend Gazyva for the first-line and second-line treatment of follicular lymphoma (grade 1 or 2) in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone), CVP (cyclophosphamide, vincristine, and prednisone), bendamustine, or Revlimid (lenalidomide capsules); or as single agent maintenance treatment.[2,4] The guidelines also recommend Gazyva as second-line or maintenance therapy for gastric and nongastric mucosa-associated lymphoid tissue (MALT) lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma. Gazyva is also recommended as a substitute for rituximab products (Rituxan, biosimilars) in patients with intolerance or experiencing rare complications, regardless of histology.
- **Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL):** Guidelines (version 1.2023 – August 30, 2022) recommend Gazyva for the first-line treatment of CLL/SLL without del(17p)/TP53 mutation in patients < 65 years of age without significant comorbidities, Gazyva is recommended in combination with bendamustine, Calquence® (acalabrutinib capsules), Venclexta® (venetoclax tablets), and high-dose methylprednisolone.[2,3] For first-line treatment of CLL/SLL without del(17p)/TP53 mutation in patients ≥ 65 years of age and younger patients with significant comorbidities, Gazyva is recommended in combination with Calquence, Venclexta, high-dose methylprednisolone, chlorambucil, or Imbruvica® (ibrutinib capsules and tablets); or as a single agent. Gazyva is also recommended as a single agent or in combination with Venclexta or Calquence for the first-line treatment of CLL/SLL with del(17p)/TP53 mutation; as a single agent or in combination with high-dose methylprednisolone for relapsed or refractory CLL/SLL without del(17p)/TP53 mutation; and in combination with Venclexta for retreatment for late relapse after a period of remission in patients without del(17p)/TP53 mutations.
- **Hairy Cell Leukemia:** Guidelines (version 1.2023 – August 30, 2022) recommend Gazyva in combination with Zelboraf® (vemurafenib tablets) for initial treatment in patients who cannot tolerate purine analogs including frail patients and those with active infections.[2,5]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Gazyva. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Gazyva as well as the monitoring required for adverse events and long-term efficacy, approval requires Gazyva to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Gazyva is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma**. Approve for 6 months if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication is prescribed by or in consultation with an oncologist.

2. **Follicular Lymphoma**. Approve for 6 months if the patient meets the following criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Gazyva is used in ONE of the following situations (i, ii, or iii):
     - **i.** In combination with chemotherapy; OR
       Note: Examples include CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone), CVP (cyclophosphamide, vincristine, and prednisone), or bendamustine.
     - **ii.** For maintenance treatment following Gazyva in combination with chemotherapy; OR
     - **iii.** Patient experienced an adverse event or intolerance to a rituximab product; AND
       Note: Examples of adverse events or intolerance includes paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, toxic epidermal necrolysis. Examples of rituximab products include Rituxan and biosimilars.
   - **C)** The medication is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

3. **Hairy Cell Leukemia.** Approve for 6 months if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient is unable to tolerate purine analog therapy; AND
     Note: Examples of purine analogs include cladribine and pentostatin.
   - **C)** Gazyva is used as initial therapy; AND
   - **D)** Gazyva is used in combination with Zelboraf (vemurafenib tablets); AND
   - **E)** The medication is prescribed by or in consultation with an oncologist.

4. **Marginal Zone Lymphoma.** Approve for 6 months if the patient meets the following criteria (A, B, and C):
   Note: Includes nodal marginal zone lymphoma, splenic marginal zone lymphoma, gastric mucosa-associated lymphoid tissue (MALT) lymphoma, or nongastric MALT lymphoma.
   A) Patient is ≥ 18 years of age; AND
   B) Gazyva is used in ONE of the following situations (i, ii, or iii):
      i. First-line therapy for nodal marginal zone lymphoma only; OR
      ii. Second-line or subsequent therapy for recurrent or progressive disease; OR
      iii. Patient experienced an adverse event or intolerance to a rituximab product: AND
      Note: Examples of adverse events or intolerance includes paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, toxic epidermal necrolysis. Examples of rituximab products include Rituxan and biosimilars.
   C) The medication is prescribed by or in consultation with an oncologist.

5. **Other B-Cell Lymphoma.** Approve for 6 months if the patient meets the following criteria (A, B, and C):
   Note: Includes diffuse large B-cell lymphoma, mantle cell lymphoma, high-grade B-cell lymphoma, Burkitt lymphoma, AIDS-related B-cell lymphoma, post-transplant lymphoproliferative disorders, Castleman's disease.
   A) Patient is ≥ 18 years of age; AND
   B) Patient experienced an adverse event or intolerance to a rituximab product: AND
   Note: Examples of adverse events or intolerance includes paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, toxic epidermal necrolysis. Examples of rituximab products include Rituxan and biosimilars.
   C) The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Gazyva is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Gazyva® intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; July 2022.
2. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 14, 2022. Search term: obinutuzumab.
3. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 1.2023 – August 30, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 14, 2022.
4. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 5.2022 – July 12, 2012). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 14, 2022.
5. The NCCN Hairy Cell Leukemia Clinical Practice Guidelines in Oncology (version 1.2023 – August 30, 2022). © National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 14, 2022.