PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 12/04/2024

OVERVIEW

Gazyva, a CD20-directed antibody, is indicated for the treatment of:[1]

- **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.

Guidelines

Gazyva is addressed in National Comprehensive Cancer Network (NCCN) guidelines:

- **B-cell lymphomas:** Guidelines (version 3.2024 – August 26, 2024) recommend Gazyva for the first-line and second-line treatment of follicular lymphoma or nodal marginal zone lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone), CVP (cyclophosphamide, vincristine, and prednisone), bendamustine, or lenalidomide; as third-line and subsequent treatment in combination with Brukinsa® (zanubrutinib capsule); or as single agent maintenance treatment.[2,4] The guidelines also recommend Gazyva as first-line treatment of nodal marginal zone lymphoma; second-line or maintenance therapy for nodal marginal zone lymphoma, extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, and splenic marginal zone lymphoma. Gazyva, in combination with Venclexta® (venetoclax tablets) and Brukinsa, is recommended for the first-line treatment of mantle cell lymphoma with TP53 mutation; and can also be substituted for rituximab in mantle cell lymphoma. Gazyva is also recommended as a substitute for rituximab products (Rituxan, biosimilars) in patients with intolerance or experiencing rare complications, regardless of histology. Finally, Gazyva is recommended as pretreatment, 7 days prior to the administration of Columvi™ (glofitamab-gxbm intravenous infusion) for the treatment of diffuse large B-cell lymphoma (DLBCL) or histologic transformation of indolent lymphomas to DLBCL, high-grade B-cell lymphoma, HIV-related B-cell lymphoma, and post-transplant lymphoproliferative disorders.
- **Castleman Disease:** Guidelines (version 1.2024 – January 18, 2024) recommend Gazyva as a substitute for rituximab products (Rituxan, biosimilars) in patients with intolerance or experiencing rare complications.[2,7]
- **Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL):** Guidelines (version 1.2025 – October 1, 2024) recommend Gazyva for the first-line treatment of CLL/SLL without del(17p)/TP53 mutation in patients with indications for treatment, Gazyva is recommended in combination with bendamustine, chlorambucil, Calquence® (acalabrutinib capsules), Venclexta, Imbruvica® (ibrutinib capsules and tablets), high-dose methylprednisolone; or as a single-agent.[2,3] Gazyva is also recommended as a single agent or in combination with Venclexta, Calquence, or high-dose methylprednisolone for the first-line treatment of CLL/SLL with del(17p)/TP53 mutation; as second-line or subsequent treatment in combination with Venclexta for CLL/SLL with or without 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; in combination with high-dose methylprednisolone for relapsed or refractory CLL/SLL with del(17p)/TP53 mutation; and in combination with Venclexta for retreatment for late relapse after a period of remission in patients with or without del(17p)/TP53 mutations.

- **Hairy Cell Leukemia:** Guidelines (version 1.2025 – September 26, 2024) 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 ALL of the following (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 ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Gazyva is used in ONE of the following situations (i, ii, iii, iv, v, or vi):
     - **i.** In combination with chemotherapy; OR
       Note: Examples include CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone), CVP (cyclophosphamide, vincristine, and prednisone), or bendamustine.
     - **ii.** In combination with lenalidomide; OR
     - **iii.** As a single agent for second-line and subsequent therapy; OR
     - **iv.** In combination with Brukinsa (zanubrutinib capsules) for third-line and subsequent therapy; OR
     - **v.** For maintenance treatment following Gazyva in combination with chemotherapy; OR
     - **vi.** 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 ALL of the following (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 ALL of the following (A, B, and C):
   Note: Includes nodal marginal zone lymphoma, splenic marginal zone lymphoma, extranodal marginal zone lymphoma of the stomach, or extranodal marginal zone lymphoma of nongastric sites (noncutaneous).
   A) Patient is ≥ 18 years of age; AND
   B) Gazyva is used in ONE of the following situations (i, ii, iii, or iv):
      i. First-line therapy for nodal marginal zone lymphoma only; OR
      ii. Second-line or subsequent therapy for recurrent or progressive disease; OR
      iii. Maintenance therapy for rituximab refractory disease; OR
      iv. 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. **Mantle Cell Lymphoma.** Approve for 6 months if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Gazyva is used in ONE of the following situations (i or ii):
      i. Induction therapy for TP53 mutated disease in combination with Venclexta (venetoclax tablets) and Brukinsa (zanubrutinib capsules); OR
      ii. Gazyva may be substituted for a rituximab product; AND
   C) The medication is prescribed by or in consultation with an oncologist.

6. **Other B-Cell Lymphoma.** Approve for 6 months if the patient meets ALL of the following (A, B, and C):
   Note: Includes diffuse large B-cell lymphoma (DLBCL), histologic transformation of indolent lymphomas to DLBCL, high-grade B-cell lymphoma, Burkitt lymphoma, HIV-related B-cell lymphoma, post-transplant lymphoproliferative disorders, Castleman's disease.
   A) Patient is ≥ 18 years of age; AND
   B) Patient meets ONE of the following (i or ii):
      i. A single dose of Gazyza is used as pretreatment before the first dose of Columvi (glofitamab-gxbm intravenous infusion); OR
      ii. 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. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 26, 2024. Search term: obinutuzumab.
3. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 1.2025 – October 1, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 26, 2024.
4. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 3.2024 – August 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 26, 2024.
5. The NCCN Hairy Cell Leukemia Clinical Practice Guidelines in Oncology (version 1.2025 – September 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 26, 2024.
6. Columvi™ intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; June 2023.
7. The NCCN Castleman Disease Clinical Practice Guidelines in Oncology (version 1.2024 – January 18, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 26, 2024.