PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Polivy Prior Authorization Policy
- Polivy™ (polatuzumab vedotin-piiq intravenous infusion – Genentech)

REVIEW DATE: 06/29/2022

OVERVIEW

Polivy, a CD79b-directed antibody-drug conjugate, is indicated in combination with bendamustine and a rituximab product is indicated for the treatment of adult patients with relapsed or refractory **diffuse large B-cell lymphoma** (DLBCL), not otherwise specified, after at least two prior therapies.[1] Accelerated approval was granted for this indication based on complete response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on **B-Cell Lymphomas** (version 4.2022 – June 9, 2022) recommend Polivy for the second-line or subsequent treatment of DLBCL, follicular lymphoma, histologic transformation of indolent lymphoma to DLBCL, AIDS-related B-cell lymphoma, post-transplant lymphoproliferative disorders, and high-grade B-cell lymphoma.[2,3]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Polivy. 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 Polivy as well as the monitoring required for adverse events and long-term efficacy, approval requires Polivy to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Diffuse Large B-Cell 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)** Patient has been treated with at least one prior chemotherapy regimen; AND
     Note: Examples of chemotherapy regimens include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) plus rituximab.
   - **C)** Polivy is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

2. B-Cell Lymphoma. Approve for 6 months if the patient meets the following criteria (A, B, and C):
Note: Examples include follicular lymphoma, high-grade B-cell lymphoma, AIDS-related B-cell lymphoma, post-transplant lymphoproliferative disorders, histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma.
A) Patient is ≥ 18 years of age; AND
B) Patient has been treated with at least one prior chemotherapy regimen; AND
Note: Examples of chemotherapy regimens include CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) plus rituximab or Gazyva (obinutuzumab intravenous infusion), CVP (cyclophosphamide, vincristine, prednisone) plus rituximab or Gazyva, or lenalidomide plus rituximab.
C) Polivy is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Polivy 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. Polivy™ intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; September 2020.
2. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2022 – June 9, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 20, 2022.
3. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 20, 2022. Search term: polatuzumab.