Utilization Review Policy 179

POLICY: Oncology – Polivy™ (polatuzumab vedotin – piiq injection for intravenous use – Genentech)

EFFECTIVE DATE: 1/1/2020
LAST REVISION DATE: 06/28/2023

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Polivy, a CD79b-directed antibody-drug conjugate, is indicated:[1]

- For the treatment of relapsed or refractory **diffuse large B-cell lymphoma** (DLBCL), not otherwise specified, in combination with bendamustine and a rituximab product in adults after at least two prior therapies.
- For previously untreated **DLBCL** not otherwise specified or **high-grade B-cell lymphoma**, in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) in adults with an International Prognostic Index (IPI) score of ≥ 2.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on **B-Cell Lymphomas** (version 4.2023 – June 2, 2023) recommend Polivy for the second-line or subsequent treatment of DLBCL, follicular lymphoma, histologic transformation of indolent lymphomas to DLBCL, AIDS-related B-cell lymphoma, post-transplant lymphoproliferative disorders, and high-grade B-cell lymphoma.[2,3] In addition, NCCN recommends Polivy for the first-line treatment of DLBCL in combination with R-CHP for patients with IPI ≥ 2.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Polivy. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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:

FDA-Approved Indications

1. **Diffuse Large B-Cell Lymphoma.** Approve for 6 months if the patient meets the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
  i. Patient meets BOTH of the following (a and b):
    a) Patient has an International Prognostic Index score of ≥ 2; AND
    b) Polivy is used as first-line therapy; OR
  ii. 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.

Dosing. Approve up to 1.8 mg/kg intravenously once every 21 days.

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2. High-Grade B-Cell Lymphoma. Approve for 6 months if the patient meets the following (A, B, and C):
A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
  i. Patient meets BOTH of the following (a and b):
    a) Patient has an International Prognostic Index score of ≥ 2; AND
    b) Polivy is used first-line; OR
  ii. 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.

Dosing. Approve up to 1.8 mg/kg intravenously once every 21 days.

Other Uses with Supportive Evidence

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3. B-Cell Lymphoma. Approve for 6 months if the patient meets the following (A, B, and C):
Note: Examples include follicular 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.

Dosing. Approve up to 1.8 mg/kg intravenously once every 21 days.

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Coverage of Polivy is not recommended in the following situations:

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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; April 2023.
2. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2023 – June 2, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 23, 2023.
3. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 23, 2023. Search term: polatuzumab.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Diffuse Large B-Cell Lymphoma:** Added Note with examples of chemotherapy regimens. **B-Cell Lymphoma:** Removed mantle cell lymphoma and changed nodal marginal zone to indolent in Note. Added Note with examples of chemotherapy regimens.	06/29/2022
Annual Revision	**Diffuse Large B-Cell Lymphoma:** Patient has an International Prognostic Index score of ≥ 2 and Polivy will be used as first-line therapy were added as a new option of approval. **High-Grade B-Cell Lymphoma:** Added new condition of approval. **B-Cell Lymphoma:** Removed high-grade B-cell lymphoma from the Note.	06/28/2023