

POLICY: Oncology (Injectable) – Polivy Utilization Management Medical Policy

- Polivy® (polatuzumab vedotin-piiq intravenous infusion – Genentech)

EFFECTIVE DATE: 1/1/2021

LAST REVISION DATE: 06/18/2025; selected revision 01/28/2026

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

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

- **Diffuse large B-cell lymphoma (DLBCL), not otherwise specified**, treatment of relapsed or refractory disease, in combination with bendamustine and a rituximab product in adults after at least two prior therapies.
- **DLBCL, previously untreated, 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 1.2026 – December 22, 2025) recommend Polivy for the second-line or subsequent treatment of DLBCL, follicular lymphoma, histologic transformation of indolent lymphomas to DLBCL, HIV-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 . It also recommended Polivy for the treatment of mantle cell lymphoma for subsequent therapy in combination with Lunsumio (mosunetuzumab intravenous infusion) (category 2A). Polivy is also recommended for the treatment of Burkitt lymphoma for subsequent therapy, in combination with Columvi (glotitamab intravenous infusion), as a bridge to transplant for allogeneic hematopoietic cell transplant (category 2A).

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 ALL of the following (A, B, and C):

Note: Includes histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma.

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) The medication 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) The medication is prescribed by or in consultation with an oncologist.

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

- 2. High-Grade B-Cell Lymphoma.** Approve for 6 months if the patient meets BOTH 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.

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

Other Uses with Supportive Evidence

- 3. B-Cell Lymphoma.** Approve for 6 months if the patient meets ALL of the following (A, B, and C):

Note: Examples include HIV-related B-cell lymphoma and post-transplant lymphoproliferative disorders.

A) Patient is ≥ 18 years of age; AND

B) Patient meets ONE of the following (i or ii):

a. Patient has an International Prognostic Index score of ≥ 2 ; OR

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) The medication 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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- 4. Burkitt Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D and E):
- A) Patient is \geq 18 years of age; AND
 - B) The medication is used as subsequent therapy; AND
 - C) The medication is used in combination with Columvi (glotitamab intravenous infusion); AND
 - D) The medication is used as a bridge for allogeneic hematopoietic cell transplant; AND
 - E) The medication 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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- 5. Mantle Cell Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- A) Patient is \geq 18 years of age; AND
 - B) Patient has received at least one covalent Bruton tyrosine kinase inhibitor; AND
Note: Examples of a covalent Bruton tyrosine kinase inhibitors include Brukinsa (zanubrutinib capsules and tablets), Calquence (acalabrutinib tablets), and Imbruvica (ibrutinib capsules, oral suspension, and tablets).
 - C) The medication will be used in combination with Lunsumio Velo (mosunetuzumab-axgb subcutaneous injection); AND
 - D) The medication 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:

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 1.2026 – December 22, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 22, 2026.
3. The NCCN Drugs & Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 22, 2026. Search term: polatuzumab.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Diffuse Large B-Cell Lymphoma: Patient has an International Prognostic Index score of \geq 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

Annual Revision	<p>Diffuse Large B-Cell Lymphoma: Added Note that diffuse large B-cell lymphoma includes histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma.</p> <p>B-Cell Lymphoma: Removed follicular lymphoma and histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma from the Note. Revised AIDS to HIV in the Note.</p>	06/26/2024
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024
Annual Revision	<p>High-Grade B-Cell Lymphoma: Removed the requirements that patient has an International Prognostic Index score of ≥ 2, Polivy is used first-line, and patient has been treated with at least one prior chemotherapy regimen.</p> <p>B-Cell Lymphoma: Added patient has an International Prognostic Index score of ≥ 2 as an option for approval.</p>	06/18/2025
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/15/2025
Selected Revision	<p>Burkitt Lymphoma: Burkitt lymphoma was added as a new condition for approval.</p> <p>Mantle Cell Lymphoma: Mantle cell lymphoma was added as a new condition for approval.</p>	01/28/2026