BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.21.129

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	June 28, 2019
Subject:	Polivy	**Page:**	1 of 4

Last Review Date: March 7, 2025

Polivy

Description

Polivy (polatuzumab vedotin-piiq)

Background
Polivy (polatuzumab vedotin-piiq) is a CD79b-directed antibody-drug conjugate with activity against dividing B cells. Polivy binds to CD79b, a B-cell specific surface protein, which is a component of the B-cell receptor. Upon binding, Polivy is internalized and the linker is cleaved by lysosomal proteases to enable intracellular delivery of MMAE, the anti-mitotic agent. MMAE binds to microtubules and kills dividing cells by inhibiting cell division and inducing apoptosis (1).

Regulatory Status
FDA-approved indications: Polivy is a CD79b-directed antibody and microtubule inhibitor conjugate indicated: (1)

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

Patients should be premedicated with an antihistamine and antipyretic before Polivy is administered due to the risk of infusion-related reactions (1).

Polivy can cause peripheral neuropathy, myelosuppression, serious and opportunistic infections, progressive multifocal leukoencephalopathy (PML), tumor lysis syndrome, hepatotoxicity (1).

Embryo-fetal toxicity can occur when Polivy is administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment with Polivy and for at least 3 months after the last dose. Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment with Polivy and for at least 5 months after the last dose (1).

The safety and effectiveness of Polivy in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Polivy may be considered **medically necessary** if the conditions indicated below are met.

Polivy may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)
    a. Patient has received at least two prior therapies **AND** used in combination with bendamustine and a rituximab product
2. Previously untreated diffuse large B-cell lymphoma (DLBCL)

   a. International Prognostic Index score of 2 or greater **AND** used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP)
3. Previously untreated high-grade B-cell lymphoma (HGBL)
   a. International Prognostic Index score of 2 or greater **AND** used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP)

AND ALL of the following for **ALL** indications:

a. Patient will be premedicated with an antihistamine and antipyretic
b. Prescriber agrees to monitor the patient for signs and symptoms of:
   i. Peripheral neuropathy
   ii. Infusion-related reactions
   iii. Myelosuppression
   iv. Serious and opportunistic infections
c. Female patients of reproductive potential **only**: Prescriber agrees to advise patient to use effective contraception during treatment and for 3 months after the last dose
d. Male patients with female partners of reproductive potential **only**: Prescriber agrees to advise patient to use effective contraception during treatment and for 5 months after the last dose
e. Prescriber will not exceed the FDA labeled dose of 1.8 mg/kg

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

None

Rationale

Summary
Polivy (polatuzumab vedotin-piiq) is a CD79b-directed antibody-drug conjugate with activity against dividing B cells. Polivy binds to CD79b, a B-cell specific surface protein, which is a component of the B-cell receptor. Upon binding, Polivy is internalized and the linker is cleaved by lysosomal proteases to enable intracellular delivery of MMAE, the anti-mitotic agent. MMAE binds to microtubules and kills dividing cells by inhibiting cell division and inducing apoptosis. The safety and effectiveness of Polivy in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Polivy while maintaining optimal therapeutic outcomes.

References
1. Polivy [package insert]. South San Francisco, CA: Genentech, Inc.; April 2023.
2. NCCN Drugs & Biologics Compendium® Polatuzumab vedotin-piiq 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.

Policy History

Date	Action
June 2019	Addition to PA
September 2019	Annual review
June 2020	Annual review
December 2020	Annual review and reference update
September 2021	Annual review and reference update
September 2022	Annual review and reference update
March 2023	Annual review and reference update
May 2023	Per PI update, added indications of previously untreated DLBCL and previously untreated high-grade B-cell lymphoma (HGBL)
June 2023	Annual review and reference update
September 2023	Annual review and reference update
December 2023	Annual review and reference update
March 2024	Annual review and reference update
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.