
5.21.129

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| Section: | Prescription Drugs | Effective Date: | April 1, 2024 |
| Subsection: | Antineoplastic Agents | Original Policy Date: | June 28, 2019 |
| Subject: | Polivy | Page: | 1 of 4 |

Last Review Date: March 8, 2024

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).

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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)

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- 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

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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 2024. National Comprehensive Cancer Network, Inc. Accessed on January 22, 2024.

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 |

Keywords

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.