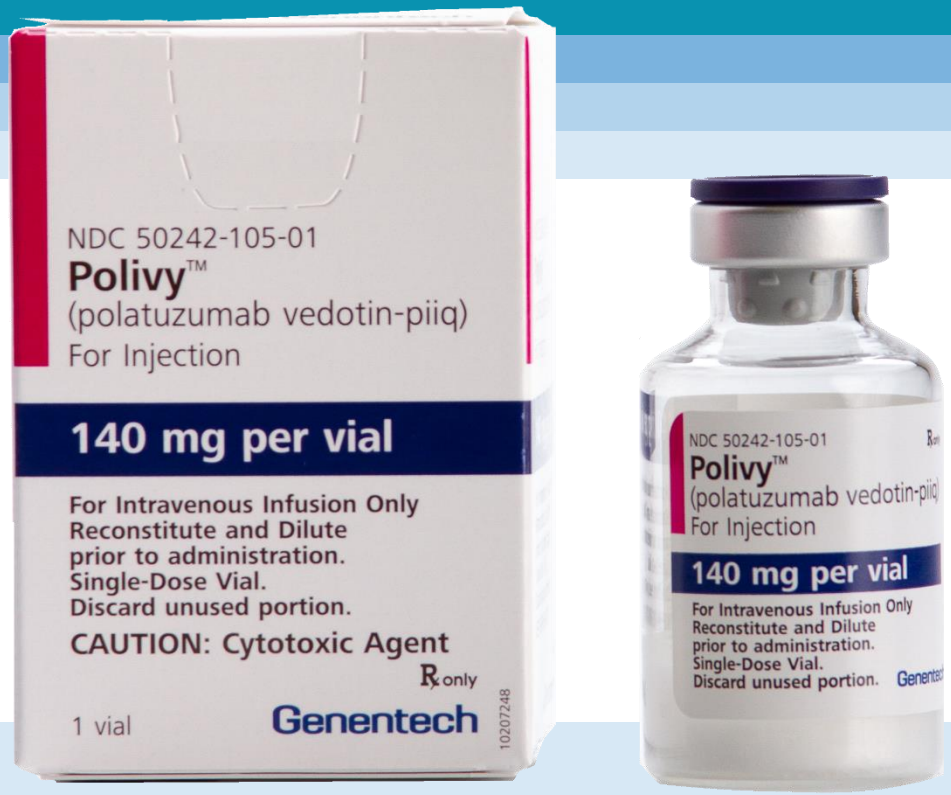
Polivy (polatuzumab vedotin-piiq)



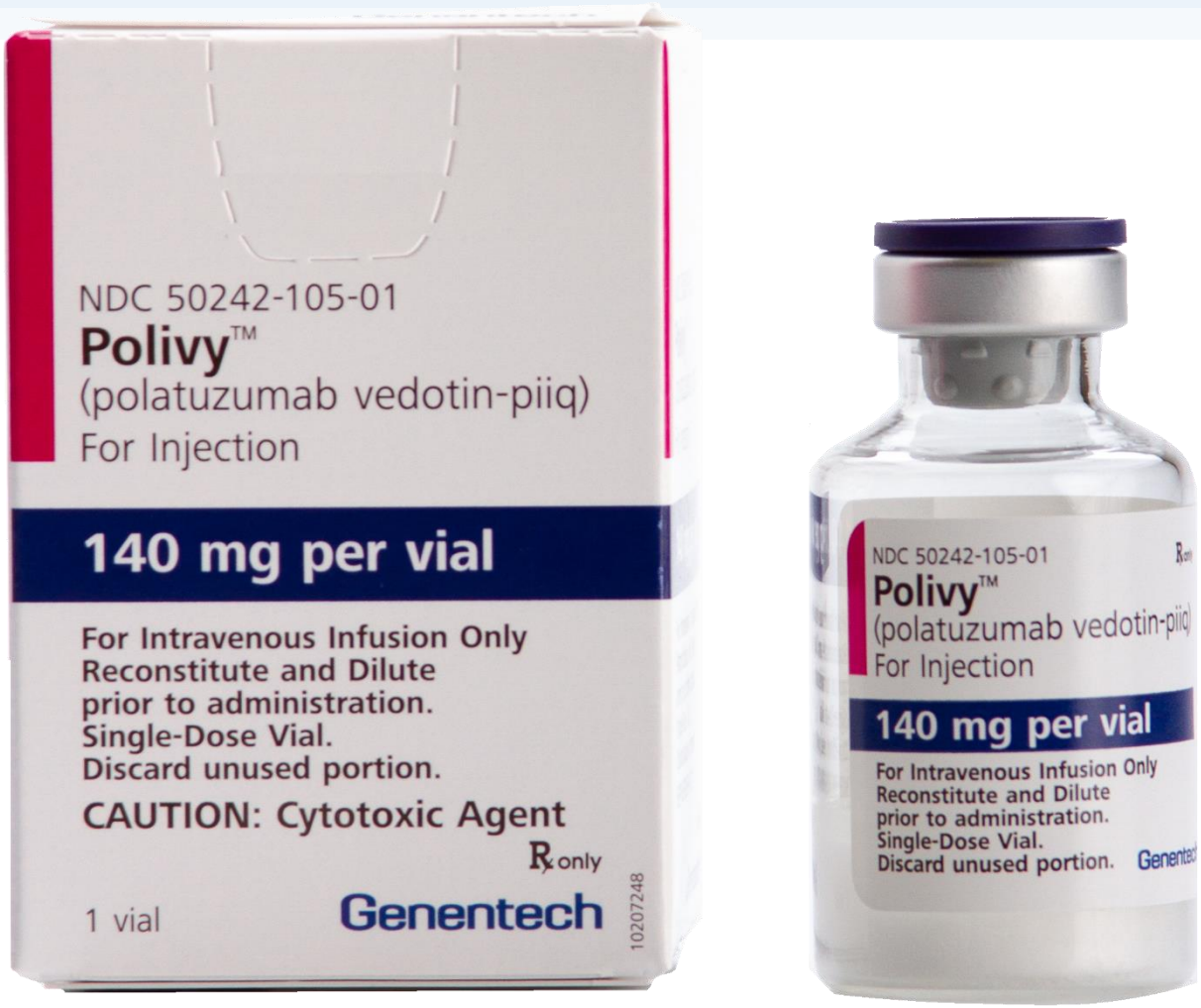
NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Polivy
- **Generic name:** Polatuzumab vedotin-piiq
- **Pharmacological class:** CD79b-directed antibody-drug conjugate
- **Strength and Formulation:** 140mg; per vial; lyophilized pwd for IV infusion after reconstitution and dilution; preservative-free
- **Manufacturer:** Genentech
- **How supplied:** Single-dose vial—1
- **Legal Classification:** Rx

Polivy


NDC 50242-105-01
Polivy™
(polatuzumab vedotin-piiq)
For Injection
140 mg per vial
For Intravenous Infusion Only
Reconstitute and Dilute
prior to administration.
Single-Dose Vial.
Discard unused portion.
CAUTION: Cytotoxic Agent
℞ only
1 vial
Genentech
10207248
NDC 50242-105-01
Polivy™
(polatuzumab vedotin-piiq)
For Injection
140 mg per vial
For Intravenous Infusion Only
Reconstitute and Dilute
prior to administration.
Single-Dose Vial.
Discard unused portion.

Indication

- In combination with bendamustine and a rituximab product for the treatment of relapsed or refractory **diffuse large B-cell lymphoma** after at least 2 prior therapies

Dosage & Administration

- **Pre-medicate** with antihistamine and antipyretic ≥30–60mins prior to dosing
- Give by **IV infusion**
- Initially 1.8mg/kg over 90mins every 21 days for 6 cycles; if tolerated, may give subsequent doses over 30mins
- Dose modifications for adverse reactions: see full labeling

Considerations for Special Populations

- **Pregnancy:** Embryo-fetal toxicity; exclude status prior to initiation
- **Nursing mothers:** Not recommended (during and for ≥2 months after last dose)
- **Pediatric:** Not established
- **Elderly:** Number of patients aged 65 years and older was not sufficient to determine whether they respond differently
- **Hepatic impairment**: Avoid administration in patients with moderate to severe impairment

Warnings/Precautions

- Monitor for **peripheral neuropathy**; interrupt, reduce dose, or discontinue based on severity if occurs
- Monitor CBCs during treatment; interrupt, reduce dose, or discontinue if **cytopenias** occur; consider granulocyte colony stimulating factor prophylaxis
- Monitor closely for **tumor lysis syndrome**, serious/fatal **infections** (eg, sepsis, pneumonia, herpes, CMV); give prophylaxis for *Pneumocystis jiroveci* pneumonia and herpes virus

Warnings/Precautions

- Monitor closely for **infusion-related reactions**; interrupt and treat if occurs; permanently discontinue based on severity
- Monitor for **progressive multifocal leukoencephalopathy** (PML); withhold if suspected and permanently discontinue if confirmed
- Risk of **hepatotoxicity**; monitor LFTs
- Advise patients on use of effective **contraception** during and for ≥3 months (females) and ≥5 months (males w. female partners) after last dose

Interactions

- May be potentiated by strong **CYP3A4 inhibitors**; monitor for toxicity
- May be antagonized by strong **CYP3A4 inducers**

Adverse Reactions

- **Most common** (≥20%): neutropenia, thrombocytopenia, anemia, peripheral neuropathy, fatigue, diarrhea, pyrexia, decreased appetite, and pneumonia
- **Also**: infusion-related reactions, infection, tumor lysis syndrome, PML, hepatotoxicity

Mechanism of Action

- Polatuzumab vedotin-piiq is a CD79b-directed antibody-drug conjugate consisting of **3 components**: 1) the humanized immunoglobulin G1 (IgG1) **monoclonal antibody** specific for human CD79b; 2) the small molecule anti-mitotic agent **MMAE**; and 3) a **protease-cleavable linker** maleimidocaproyl-valine-citrulline-p aminobenzyloxycarbonyl (mc-vc-PAB) that covalently attaches MMAE to the polatuzumab antibody

Mechanism of Action

- The monoclonal antibody binds to CD79b, a B-cell specific surface protein, which is a component of the B-cell receptor
- Upon binding CD79b, polatuzumab vedotin-piiq is internalized, and the linker is cleaved by lysosomal proteases to enable intracellular delivery of MMAE
- MMAE binds to microtubules and kills dividing cells by inhibiting cell division and inducing apoptosis

Clinical Studies

- The efficacy of Polivy was evaluated in an open-label trial that included 80 patients with relapsed or refractory DLBCL
- Patients were randomized to receive either Polivy in combination with bendamustine and a rituximab product (BR; n=40) or BR alone (n=40) for six 21-day cycles
- Efficacy was based on complete response (CR) rate at the end of treatment and duration of response (DoR), as determined by an independent review committee

Clinical Studies

- **Complete response rate**: 40% for Polivy plus BR vs 18% for BR alone (difference in CR rates: 22%)
- Of the 25 patients who achieved a partial or complete response to **Polivy plus BR**, 16 (64%) had a DoR of at least 6 months and 12 (48%) had a DoR of at least 12 months
- In the **BR arm**, of the 10 patients who achieved a partial or complete response, 3 (30%) had a DoR of at least 6 months, and 2 (20%) had a DoR of at least 12 months

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/polivy/