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 indication: Polivy in combination with bendamustine and a rituximab product is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, after at least two prior therapies (1).

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** in patients 18 years of age and older with relapsed or refractory diffuse large B-cell lymphoma (DLBCL and if the conditions indicated below are met.

Polivy may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

**Age** 18 years of age or older

**Diagnosis**

Patient must have the following:

Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

**AND ALL** of the following:

a. Used in combination with bendamustine and a rituximab product
b. Patient has received at least two prior therapies
c. Patient will be premedicated with an antihistamine and antipyretic
d. 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
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
Section: Prescription Drugs  Effective Date: October 1, 2019
Subsection: Antineoplastic Agents  Original Policy Date: June 28, 2019
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.