VENTURA COUNTY HEALTH CARE PLAN

Utilization Review Policy

POLICY: Oncology – Polivy™ (polatuzumab vedotin – piiq injection for intravenous use – Genentech)

APPROVAL DATE: 06/26/2019

OVERVIEW

Polivy is a CD79b-directed antibody-drug conjugate consisting of a humanized IgG monoclonal antibody directed against CD79b covalently linked to the anti-mitotic agent monomethyl auristatin E (MMAE).[1] The monoclonal antibody binds to the B-cell specific surface protein, CD79b and is internalized. Once inside the cell, lysosomal proteases cleave MMAE from the antibody enabling it to bind to microtubules, causing cell death by inhibiting cell division.

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] Accelerated approval was granted for this indication based on complete response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on B-Cell Lymphomas (Version 4.2019 – June 18, 2019) recommend Polivy for the second-line or subsequent treatment of DLBCL and high-grade B-cell lymphoma after ≥ 2 prior therapies in non-candidates for transplant.[2,3]

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 indication(s). 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.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Polivy is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Diffuse Large B-Cell Lymphoma.** Approve for 6 months if the patient meets the following criteria (A, B, C, and D):
   - **A)** The patient is ≥ 18 years of age; AND
   - **B)** The patient has been treated with at least two prior chemotherapy regimens; AND

C) Polivy will be used in combination with bendamustine and a rituximab product (e.g., Rituxan, Truxima); AND
D) Polivy is prescribed by or in consultation with an oncologist.

Dosing. Approve the following dosing regimen: Administer up to 1.8 mg/kg intravenously once every 21 days.[1]

The FDA-approved dose of Polivy is 1.8 mg/kg administered intravenously every 21 days for 6 cycles, in combination with bendamustine and a rituximab product.[1] Dose modifications are recommended in the prescribing information for peripheral neuropathy, infusion-related reactions, and myelosuppression. This may include holding the dose, dose reductions, or discontinuation of Polivy. See the prescribing information for more detail.

Other Uses with Supportive Evidence

2. **High-Grade B-Cell Lymphoma.** Approve for 6 months if the patient meets the following criteria (A, B, C, and D):
A) The patient is ≥ 18 years of age; AND
B) The patient has been treated with at least two prior chemotherapy regimens; AND
C) Polivy will be used in combination with bendamustine and a rituximab product (e.g., Rituxan, Truxima); AND
D) Polivy is prescribed by or in consultation with an oncologist.

Dosing. Approve the following dosing regimen: Administer up to 1.8 mg/kg intravenously once every 21 days.[1]

The FDA-approved dose of Polivy is 1.8 mg/kg administered intravenously every 21 days for 6 cycles, in combination with bendamustine and a rituximab product.[1] Dose modifications are recommended in the prescribing information for peripheral neuropathy, infusion-related reactions, and myelosuppression. This may include holding the dose, dose reductions, or discontinuation of Polivy. See the prescribing information for more detail.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Polivy has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

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™ injection for intravenous use [prescribing information]. South San Francisco, CA: Genentech; June 2019.
2. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (Version 4.2019 – June 18, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on June 24, 2019.
3. The NCCN Drugs & Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on June 24, 2019. Search term: polatuzumab.

HISTORY

Type of Revision	Summary of Changes*	Approval Date
New Policy	--	06/13/2019
Early annual revision	Added high-grade B-cell lymphoma to the Other Uses with Supportive Evidence section	06/26/2019