

## SPECIALTY GUIDELINE MANAGEMENT

### POLIVY (polatuzumab vedotin-piiq)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

###### A. 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.

###### B. Compendial Uses

1. High-grade B-cell lymphomas (HGBLs) with translocations of MYC and BCL2 and/or BCL6 after 2 or more prior therapies
2. Partially responsive, nonresponsive, or progressive DLBCL

All other indications are considered experimental/investigational and not medically necessary.

##### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review for coverage of high-grade B cell lymphomas (HGBLs): Documentation of MYC and BCL2 and/or BCL6 translocations as detected by fluorescence in situ hybridization (FISH) or standard cytogenetics.

##### III. CRITERIA FOR INITIAL APPROVAL

###### A. **Diffuse large B-cell lymphoma**

Authorization of 6 months may be granted for treatment of diffuse large B-cell lymphoma (DLBCL) when all of the following criteria are met:

1. Polivy is used in combination with bendamustine and a rituximab product
2. Disease is partially responsive, not responsive, relapsed, refractory, or progressive after prior therapies
3. Member has received at least two prior therapies
4. Member will not receive more than 6 cycles of therapy
5. Member is not a candidate for transplant

###### B. **High-grade B-cell lymphomas (HGBLs)**

Authorization of 6 months may be granted for treatment of high-grade B-cell lymphomas (HGBLs) (also referred to as “double-hit” or “triple-hit” lymphomas) when all of the following criteria are met:

1. Member has translocations of MYC and BCL2 and/or BCL6 as detected by FISH or standard cytogenetics
2. Polivy is used in combination with bendamustine and a rituximab product

Reference number(s)
3095-A

3. Disease is partially responsive, not responsive, relapsed, refractory, or progressive after prior therapies
4. Member has received at least two prior therapies
5. Member will not receive more than 6 cycles of therapy
6. Member is not a candidate for transplant

#### IV. CONTINUATION OF THERAPY

Authorization up to 6 months (6 cycles total) may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III who have not experienced disease progression or an unacceptable toxicity and who have not received 6 or more cycles of Polivy.

#### V. REFERENCES

1. Polivy [package insert]. South San Francisco, CA: Genentech, Inc.; June 2019.
2. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas. Version 4.2019. <https://www.nccn.org>. Accessed June 19, 2019.
3. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed June 19, 2019.