Reference number(s)
3095-A

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
B-Cell Lymphomas
i. High-grade B-cell lymphomas (HGBLs)
ii. Monomorphic post-transplant lymphoproliferative disorders (B-cell type)
iii. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, AIDS-related plasmablastic lymphoma, and human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma)
iv. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma
v. Histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma without translocations of MYC and BCL2 and/or BCL6
vi. Follicular lymphoma

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

II. CRITERIA FOR INITIAL APPROVAL

B-Cell Lymphomas
Authorization of 6 months may be granted for subsequent treatment of B-cell lymphomas with any of the following subtypes:

1. Diffuse large B-cell lymphoma when all of the following criteria are met:
   i. The requested drug is used as a single agent, or in combination with bendamustine with or without rituximab, and
   ii. Member will not receive more than 6 cycles of therapy, and
   iii. Member is not a candidate for transplant.
2. High-grade B-cell lymphomas (HGBLs) (also referred to as “double-hit” or “triple-hit” lymphomas) when all of the following criteria are met:
   i. The requested drug is used as a single agent, or in combination with bendamustine with or without rituximab, and
   ii. Member will not receive more than 6 cycles of therapy, and
   iii. Member is not a candidate for transplant.
4. Monomorphic post-transplant lymphoproliferative disorders (B-cell type) when all the following criteria are met:

i. The requested drug is used as a single agent, or in combination with bendamustine with or without rituximab, and
ii. Member has received at least two prior chemoimmunotherapies, and
iii. Member will not receive more than 6 cycles of therapy.

5. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, AIDS-related plasmablastic lymphoma, and human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma) when all of the following criteria are met:
   i. The requested drug is used as a single agent, or in combination with bendamustine with or without rituximab, and
   ii. Member will not receive more than 6 cycles of therapy.
6. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma (DLBCL) when all of the following criteria are met:
   i. The requested drug is used as a single agent, or in combination with bendamustine with or without rituximab, and
   ii. Member has received at least two prior chemoimmunotherapies, and
   iii. Member will not receive more than 6 cycles of therapy.
7. Histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma (DLBCL) without translocations of MYC and BCL2 and/or BCL6 when all of the following criteria are met:
   i. The requested drug is used as a single agent, or in combination with bendamustine with or without rituximab, and
   ii. Member will not receive more than 6 cycles of therapy.
8. Follicular lymphoma when all the following criteria are met:
   i. The requested drug is used as a single agent, or in combination with bendamustine with or without rituximab, and
   ii. Member will not receive more than 6 cycles of therapy.

III. 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 II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and who have not received 6 or more cycles of the requested drug.

IV. REFERENCES

1. Polivy [package insert]. South San Francisco, CA: Genentech, Inc.; September 2020.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 5, 2021.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas. Version 1.2020. https://www.nccn.org. Accessed April 9, 2020.