| Reference number(s) |
| --- |
| 3101-A |

# Standard Medicare Part B Management Polivy

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Polivy | polatuzumab vedotin-piiq |

## 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.

### FDA-Approved Indications[1]

- 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.
- Polivy in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index score of 2 or greater.

### Compendial Uses[2,3]

#### B-cell Lymphomas

- High-grade B-cell lymphomas (HGBLs)
- Post-transplant lymphoproliferative disorders (B-cell type)


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- Human Immunodeficiency Virus (HIV) Related B-cell lymphomas (HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, HIV-related plasmablastic lymphoma, and human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma)
- Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
- Histological transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL2 without BCL6 rearrangements
- Diffuse large B-cell Lymphoma (DLBCL)

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

# Coverage Criteria

## Diffuse large B-cell lymphoma (DLBCL)[1-3]

Authorization of 6 months (up to 6 cycles) may be granted for treatment of DLBCL in any of the following settings:

- The requested drug is used as subsequent treatment as a single agent, or in combination with bendamustine and/or rituximab for relapsed or refractory disease when the member is not a candidate for transplant, or the requested medication will be used as a bridging option until CAR T-cell product is available.
- The requested drug is used as subsequent treatment in combination with mosunetuzumab-axgb in members with relapsed or refractory disease.
- The requested drug will be used as first line therapy in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) in members who have an International Prognostic Index score greater than 1.

## High-grade B-cell lymphomas (HGBLs)[2,3]

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

- The requested drug is used as subsequent treatment as a single agent, or in combination with bendamustine and/or rituximab and member is not a candidate for transplant or the requested medication will be used as a bridging option until CAR T-cell product is available.
- The requested drug is used as subsequent treatment in combination with mosunetuzumab-axgb in members with relapsed or refractory disease.
- The requested drug will be used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP).


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## Post-transplant lymphoproliferative disorders (B-cell type)[2,3]

Authorization of 6 months (for up to 6 cycles) may be granted for subsequent treatment of post-transplant lymphoproliferative disorders when any the following criteria are met:

- The requested drug is used as a single agent, or in combination with bendamustine and/or rituximab, and member is not a candidate for transplant or the requested medication will be used as a bridging option until CAR T-cell product is available.
- The requested drug is used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) and member has an International Prognostic Index score of 2 or greater in either of the following clinical settings:
    - As first line therapy monomorphic or systemic polymorphic disease.
    - As subsequent therapy for partial response, persistent, or progressive monomorphic or polymorphic disease.
- The requested drug is used as subsequent treatment in combination with mosunetuzumab-axgb in members with relapsed or refractory monomorphic disease.

## Human Immunodeficiency Virus (HIV) Related B-cell lymphomas (HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, HIV-related plasmablastic lymphoma, and human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma)[2,3]

Authorization of 6 months (for up to 6 cycles) may be granted for subsequent treatment of HIV-related B-cell lymphomas when all of the following criteria are met:

- The requested drug is used as a single agent, or in combination with bendamustine and/or rituximab, and member is not a candidate for transplant or the requested medication will be used as a bridging option until CAR T-cell product is available.
- The requested drug is used as subsequent treatment in combination with mosunetuzumab-axgb in members with relapsed or refractory disease.

## Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma (DLBCL)[2,3]

Authorization of 6 months (for up to 6 cycles) may be granted for treatment of histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma when any of the following criteria are met:

- The requested drug is used as a single agent subsequent therapy, or in combination with bendamustine and/or rituximab, and member is not a candidate for transplant.
- The requested drug will be used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) and member has an International Prognostic Index score of 2 or greater.


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### Histologic transformation of indolent lymphomas to transformation of indolent lymphomas to high-grade B-cell lymphoma[3]

Authorization of 6 months (for up to 6 cycles) may be granted for treatment of histologic transformation of indolent lymphomas to high grade B-cell lymphoma with MYC and BCL6 and without BCL2 rearrangements when the requested drug will be used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) and member has an International Prognostic Index score of 2 or greater.

# Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization up to 6 months (6 cycles total) may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested drug.
- The requested drug is being used to treat an indication in the coverage criteria section.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease progression while on the current regimen.
- The member has received less than 6 cycles of the requested drug.

# Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Polivy
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: B-cell lymphomas

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Polivy are covered in addition to the following:

- High-grade B-cell lymphomas (HGBLs)


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- Post-transplant lymphoproliferative disorders (B-cell type)
- Human Immunodeficiency Virus (HIV) Related B-cell lymphomas (HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, HIV-related plasmablastic lymphoma, and human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma)
- Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
- Histological transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL6 without BCL2 rearrangements
- Diffuse large B-cell Lymphoma (DLBCL)

# Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Polivy to treat the compendial indications listed in section IV can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

# References

1. Polivy [package insert]. South San Francisco, CA: Genentech, Inc.; April 2023.
2. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas. Version 2.2025. https://www.nccn.org. Accessed April 18, 2025.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 18, 2025.


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