

Medical Drug Clinical Criteria

Subject: Polivy (polatuzumab vedotin-piiq)

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Overview

This document addresses the use of Polivy (polatuzumab vedotin-piiq). Polivy is a monoclonal antibody-drug conjugate (ADC) that consists of a humanized IgG1 antibody specific for CD79b and a small molecule, monomethyl auristatin E (MMAE), a microtubule-disrupting agent. The anticancer activity is due to the binding of the ADC to CD79b-expressing cells, cleavage of MMAE component, and killing dividing cells by inhibiting cell division and inducing apoptosis. The target CD79b is a surface protein found exclusively on B-cells and Polivy is indicated to treat diffuse large B-cell lymphoma (DLBCL).

The FDA approved indications for Polivy include in combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, after at least two prior therapies. Accelerated approval was based on positive results from a phase 2 trial comparing Polivy plus bendamustine and rituximab (BR) to BR alone. Patients included in this study were not eligible for autologous hematopoietic stem cell transplantation (HSCT). The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the use of Polivy, noting it is an appropriate treatment option for patients with relapsed or refractory high-grade B-cell lymphoma with translocations of *MYC* and *BCL2* and/or *BCL6* (after ≥2 prior lines of therapy) ineligible for HSCT.

Other Uses

NCCN also recommends Polivy in other types of B-cell lymphoma including follicular lymphoma, AIDS-related lymphomas, and B-Cell Post-Transplant lymphoproliferative disorders. In addition, all NCCN recommendations have been updated to include the option of using Polivy as a single agent or in combination with bendamustine and/or rituximab. Polivy was studied as monotherapy very early in its development (NCT01290549), but more recent ongoing phase 2 and 3 studies are evaluating Polivy in various combination regimens. Further studies in larger populations are needed to determine the optimal combination regimen and place in therapy for Polivy in lymphomas other than DLBCL.

Definitions and Measures

Hematopoietic stem cells: Primitive cells capable of replication and formation into mature blood cells in order to repopulate the bone marrow.

Line of Therapy:

- **First-line therapy:** The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- **Second-line therapy:** Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- **Third-line therapy:** Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

Monoclonal antibody: A protein developed in the laboratory that can locate and bind to specific substances in the body and on the surface of cancer cells.

Non-Hodgkin Lymphoma (NHL): A group of malignant solid tumors or lymphoid tissues.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Polivy (polatuzumab vedotin-piiq)

Requests for Polivy (polatuzumab vedotin-piiq) may be approved if the following criteria are met:

- I. Individual has a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (including high-grade B-cell lymphomas); **AND**
- II. Individual is using in combination with bendamustine and a rituximab (including rituximab biosimilars); **AND**
- III. Individual has received at least two prior lines of therapy (NCCN 2A); **AND**
- IV. Individual is ineligible for autologous hematopoietic stem cell transplantation (HSCT);

OR

- V. Individual has a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (including high-grade B-cell lymphomas); **AND**
- VI. Individual is using as a bridging option (typically 1 or more cycles as necessary) until CAR T-cell product is available (NCCN 2A);

OR

- VII. Individual has a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (including high-grade B-cell lymphomas); **AND**
- VIII. Individual is using in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone; **AND**
- IX. Individual has international prognostic index for diffuse large B-cell Lymphoma (IPI) 2 or higher; **AND**
 - A. Individual meets one of the following:
 1. Individual has stage 2 disease with extensive mesenteric disease (NCCN 2A); **OR**
 2. Individual has previously untreated diffuse large B-Cell Lymphoma (Label).

Requests for Polivy (polatuzumab vedotin-piiq) may not be approved when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9309 Injection, polatuzumab vedotin-piiq, 1 mg [Polivy]

ICD-10 Diagnosis

C82.00-C82.99 Follicular Lymphoma

C83.30-C83.39 Diffuse large B-cell lymphoma

C85.10-C85.29 Unspecified B-cell lymphoma/ Mediastinal (thymic) large B-cell lymphoma

Document History

Reviewed: 05/19/2023

Document History:

- 05/19/2023 – Annual Review: add DLBCL stage 2 mesenteric and fda approval for untreated DLBCL. Coding Reviewed: No changes.
- 05/20/2022 – Annual Review: Clarify prior therapy requirement and add use as bridging therapy to CAR-T per NCCN. Coding Reviewed: No changes.
- 05/21/2021 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/15/2020 – Annual Review: Clarify use in combination with rituximab to include biosimilar. Coding reviewed: No changes.

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- 08/16/2019 – Annual Review: Add clinical criteria for new agent Polivy. Coding Reviewed: Added HCPCS codes J9999, C9399. All Diagnosis codes allowed. Coding change update: Delete J9999 and C9399 for Polivy. Add J9309 for Polivy effective 1/1/2020. Deleted All Diagnoses and added C82.00-C82.99, C83.30-C83.39, C85.10-C85.29.

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