09-J3000-43

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Reviewed: 01/08/25

Revised: 02/15/25

Subject: Polatuzumab vedotin-piiq (Polivy®) Infusion

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Polatuzumab vedotin-piiq (Polivy) is a CD79b-directed antibody-drug conjugate that was first approved by the U.S. Food and Drug Administration (FDA) in June 2019 in combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), after at least two prior therapies. In April 2023, the FDA-approved indication was expanded to include first-line use, specifically the new indication is worded as “Polivy in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) is indicated 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”. Polatuzumab vedotin was previously granted orphan designation by the FDA for the treatment of DLBCL in December 2016. The antibody-drug conjugate consists of three components: the humanized immunoglobulin G1 (IgG1) monoclonal antibody specific for human CD79, the small molecule anti-mitotic agent MMAE; and a protease-cleavable linker, mc-vc-PAB, that covalently attaches MMAE to the polatuzumab antibody. Upon binding CD79b, polatuzumab vedotin is internalized, and the linker is cleaved by lysosomal proteases to enable intracellular delivery of MMAE. MMAE binds to microtubules and kills dividing cells by inhibiting cell division and inducing apoptosis.

Diffuse large B-cell lymphomas are the most common lymphoid neoplasms in adults, and account for approximately 32% of non-Hodgkin’s lymphomas (NHLs) cases diagnosed annually. The DLBCLs exhibits large heterogeneity in morphologic, genetic, and clinical aspects. Multiple clinicopathologic entities are defined by the 2017 World Health Organization (WHO) classification, which are sufficiently distinct to be considered separate diagnostic categories. Based on a number of prognostic factors, 20% to 50% of DLBCL cases are refractory or relapse after first-line chemotherapy and the response rates to subsequent salvage chemotherapy and consolidation with autologous hematopoietic stem cell

transplantation (HSCT) is suboptimal. The National Comprehensive Cancer Network (NCCN) B-cell Lymphoma Guidelines list polatuzumab vedotin [as a single agent, in combination with mosunetuzumab (Lunsumio), or in combination with bendamustine and/or rituximab] as a category 2A recommendation for the treatment of HIV-related B-cell lymphomas, DLBCL (including transformation from indolent lymphomas), high-grade B-cell lymphomas, and monomorphic post-transplant lymphoproliferative disorder (PTLD) (B-cell type) as second-line and subsequent therapy. In addition, based on the results of the POLARIX trial, the NCCN lists the Pola-R-CHP (polatuzumab vedotin, rituximab, cyclophosphamide, doxorubicin, and prednisone) regimen as a preferred, category 1 recommended, first-line therapy for the treatment of stage I-II (excluding stage II with extensive mesenteric disease) in patients with a baseline stage modified International Prognostic Index (smIPI) greater than 1 and stage II with extensive mesenteric disease or stage III-IV DLBCL in patients with a baseline International Prognostic Index (IPI) score of 2 or greater. This recommendation also includes histologic transformation of indolent lymphomas to DLBCL. This is the first NCCN recommendation for the use of polatuzumab vedotin in previously untreated patients. The NCCN also includes the Pola-R-CHP regimen as a first-line treatment option for monomorphic (B-cell type) or polymorphic (B-cell type) PTLD and extracutaneous primary cutaneous diffuse large B-cell lymphoma, leg type. Second-line use of Pola-R-CHP is also recommended for PTLD.

The safety and efficacy of polatuzumab vedotin leading to initial FDA approval was assessed in Study GO29365 (NCT02257567), an open-label, multicenter clinical trial that included a cohort of 80 patients with relapsed or refractory DLBCL after least one prior regimen. Patients were randomized 1:1 to receive either polatuzumab vedotin in combination with bendamustine and a rituximab product (BR) or BR alone for six 21-day cycles. Randomization was stratified by duration of response (DOR) to last therapy. Eligible patients were NOT candidates for autologous HSCT at study entry. The study excluded patients with Grade 2 or higher peripheral neuropathy, prior allogeneic HSCT, active central nervous system lymphoma, or transformed lymphoma. Following premedication with an antihistamine and antipyretic, polatuzumab vedotin was given by intravenous infusion at 1.8 mg/kg on Day 2 of Cycle 1 and on Day 1 of Cycles 2 to 6. Bendamustine was administered at 90 mg/m^2 intravenously daily on Days 2 and 3 of Cycle 1 and on Days 1 and 2 of Cycles 2 to 6. A rituximab product was administered at a dose of 375 mg/m^2 intravenously on Day 1 of Cycles 1 to 6. Of the included patients, the median age was 69 years (range: 30 to 86 years), 66% were male, and 71% were white. Most patients (98%) had DLBCL not otherwise specified. The primary reasons patients were not candidates for HSCT included age (40%), insufficient response to salvage therapy (26%), and prior transplant failure (20%). The median number of prior therapies was 2 (range: 1 to 7), with 29% receiving one prior therapy, 25% receiving 2 prior therapies, and 46% receiving 3 or more prior therapies. Eighty percent of patients had refractory disease to last therapy. In the of polatuzumab vedotin plus BR arm, patients received a median of 5 cycles, with 49% receiving 6 cycles. In the BR arm, patients received a median of 3 cycles, with 23% receiving 6 cycles. Efficacy was based on complete response (CR) rate at the end of treatment and DOR, as determined by an independent review committee (IRC). Other efficacy measures included IRC-assessed best overall response. The response rates are summarized in the table below.

Table: Response Rates in Study GO29365

Response per IRC	polatuzumab vedotin + BR (n=40)	BR (n=40)
Objective Response at End of Treatment (95% CI)	18 (45%) (29, 62)	7 (18%) (7, 33)

CR (95% CI)	16 (40%) (25, 57)	7 (18%) (7, 33)
Difference in CR rates (95% CI)	22% (3, 41)	
Best Overall Response of CR or PR (95% CI)	25 (63%) (46, 77)	10 (25%) (13, 41)
Best Response of CR (95% CI)	20 (50%) (34, 66)	9 (23%) (11, 38)

In the polatuzumab vedotin plus BR arm, of the 25 patients who achieved a partial or complete response, 16 (64%) had a DOR of at least 6 months, and 12 (48%) had a DOR of at least 12 months. In the BR arm, of the 10 patients who achieved a partial or complete response, 3 (30%) had a DOR lasting at least 6 months, and 2 (20%) had a DOR lasting at least 12 months. Fatal adverse reactions occurred in 7% of recipients of polatuzumab vedotin plus BR within 90 days of last treatment. Serious adverse reactions occurred in 64%, most often from infection. Serious adverse reactions in ≥5% of recipients of polatuzumab vedotin plus BR included pneumonia (16%), febrile neutropenia (11%), pyrexia (9%), and sepsis (7%). In recipients of polatuzumab vedotin plus BR, adverse reactions led to dose reduction in 18%, dose interruption in 51%, and permanent discontinuation of all treatment in 31%. The most common adverse reactions leading to treatment discontinuation were thrombocytopenia and/or neutropenia. In recipients of polatuzumab vedotin plus BR, adverse reactions in ≥20% of patients included neutropenia, thrombocytopenia, anemia, peripheral neuropathy, fatigue, diarrhea, pyrexia, decreased appetite, and pneumonia.

POSITION STATEMENT:

Administration of polatuzumab vedotin-piiq (Polivy) **meets the definition of medical necessity** when **ANY** of the following are met (“1”, “2”, or “3”):

1. **ALL** of the following (“a” to “e”):
    a. Member has a confirmed diagnosis of **ANY** of the following (“i” to “v”):
        i. HIV-related B-cell lymphoma that includes any of the following subtypes:
            - Diffuse large B-cell lymphoma (DLBCL)
            - Plasmablastic lymphoma
            - Primary effusion lymphoma
            - HHV8-positive DLBCL, not otherwise specified (NOS)
        ii. Diffuse large B-cell lymphoma (DLBCL) [including DLBCL transformed from indolent lymphoma]
        iii. High-grade B-cell lymphoma [includes high-grade B-cell lymphoma, NOS and high-grade B-cell lymphomas with translocation of *MYC* and *BCL2* and/or *BCL6* (double-/triple-hit lymphoma) and high-grade B-cell lymphoma transformed from indolent lymphoma]
        iv. Monomorphic post-transplant lymphoproliferative disorder (PTLD) (B-cell type)

b. Polatuzumab vedotin will be used as either second-line or subsequent therapy **OR** as a bridging option until CAR T-cell product is available for members with intention to proceed to CAR T-cell therapy

c. **ANY** of the following regimens will be used*:

i. Polatuzumab vedotin as single-agent therapy

ii. Polatuzumab + mosunetuzumab Lunsumio)**

iii. Polatuzumab vedotin + a rituximab product

iv. Polatuzumab vedotin + bendamustine

v. Polatuzumab vedotin + bendamustine + a rituximab product

For HIV-related plasmablastic lymphoma only, the regimen should **NOT contain rituximab*

***Polatuzumab + mosunetuzumab (Lunsumio) is **NOT** permitted for use as bridging therapy prior to CAR T-cell treatment*

d. Dosage of polatuzumab vedotin does not exceed 1.8 mg/kg IV every 21 days for 6 cycles

2. **ALL** of the following ("a" to "f"):

a. Polatuzumab vedotin will be used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (i.e., the Pola-R-CHP regimen)

b. Member has a diagnosis of **ANY** of the following ("I" to "vi"):

i. Diffuse large B-cell lymphoma (DLBCL) stage I-II (excluding stage II with extensive mesenteric disease), **AND** a stage modified International Prognostic Index (smIPI) score of greater than 1

ii. DLBCL stage II (with extensive mesenteric disease) or stage III-IV, **AND** an International Prognostic Index (IPI) score of 2 or greater

iii. Extracutaneous primary cutaneous diffuse large B-cell lymphoma, leg type, **AND** an IPI score of 2 or greater

iv. High-grade B-cell lymphoma [includes high-grade B-cell lymphoma, NOS and high-grade B-cell lymphomas with translocation of MYC and BCL2 and/or BCL6 (double-/triple-hit lymphoma)], **AND** an IPI score of 2 or greater

v. Monomorphic or polymorphic post-transplant lymphoproliferative disorder (PTLD) (B-cell type), **AND** an IPI score of 2 or greater

vi. DLBCL or high-grade B-cell lymphoma transformed from indolent lymphoma, **AND** an IPI score of 2 or greater

c. The Pola-R-CHP regimen will be used as first-line therapy for members with previously untreated disease#

*#Exception applies to PTLD for which treatment can be given as second-line therapy, and for DLBCL or high-grade B-cell lymphoma transformed from indolent lymphoma in which only the treatments given **AFTER** the transformation are used to determine if the member has "previously untreated disease".*

d. Dosage of polatuzumab vedotin does not exceed 1.8 mg/kg IV every 21 days for 6 cycles

3. Member has another FDA-approved or NCCN-supported diagnosis, and **ALL** of the following criteria are met ("a", "b", and "c"):

a. **EITHER** of the following ("i" or "ii"):

   i. Member is diagnosed with a condition that is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert), **AND** member meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information (or package insert)

   ii. Indication **AND** usage are recognized in NCCN Drugs and Biologics Compendium as a Category 1 or 2A recommendation

b. Polatuzumab vedotin is used in a treatment regimen in accordance with the FDA-approved prescribing information or applicable NCCN guideline recommendation for the diagnosis

c. Dosage of polatuzumab vedotin does not exceed the maximum recommended in the FDA-approved prescribing information or the maximum recommended by the applicable NCCN guidelines for the diagnosis

Approval duration: 6 months

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- Previously untreated DLBCL, NOS or HGBL - Polivy in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) is indicated 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.
- Relapsed or refractory DLBCL, NOS - 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 (NOS), after at least two prior therapies.
- The recommended dose of Polivy is 1.8 mg/kg administered as IV infusion every 21 days for 6 cycles. If not already premedicated, administer an antihistamine and antipyretic at least 30 minutes prior to Polivy. Administer prophylaxis for Pneumocystis jiroveci pneumonia and herpesvirus throughout treatment. Administer tumor lysis syndrome prophylaxis for patients at increased risk of tumor lysis syndrome. Administer prophylactic granulocyte colony-stimulating factor (G-CSF) for neutropenia in patients receiving Polivy plus R-CHP. Consider prophylactic G-CSF administration for neutropenia in patients receiving Polivy plus bendamustine and a rituximab product.

Dose Adjustments

- Adverse events – dose adjustment to 1.4 or 1 mg/kg, treatment interruption, or complete discontinuation of therapy may be required for thrombocytopenia, neutropenia, infusion-related reactions, and peripheral neuropathy. Refer to the prescribing information for specific recommendations.
- Renal impairment - no dosage adjustment is needed for mild to moderate renal impairment (CrCl ≥30 mL/min). There is no data in patients with severe renal impairment or end stage renal disease.

- Hepatic Impairment - In mild hepatic impairment (AST>ULN or total bilirubin 1 to 1.5 × ULN), there was an 11% and 40% increase in monomethyl auristatin E (MMAE) exposure in patients with previously untreated DLBCL and with relapsed or refractory DLBCL respectively, which was not deemed clinically significant, and no dosage adjustment is needed. Avoid administration in patients with moderate or severe hepatic impairment (total bilirubin greater than 1.5 × ULN); use has not been studied. Patients with moderate or severe hepatic impairment are likely to have increased exposure to MMAE, which may increase the risk of adverse reactions.

Drug Availability

- 30 mg and 140 mg single-dose vials as a preservative-free, white to grayish-white lyophilized powder
- Store refrigerated at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not use beyond the expiration date shown on the carton. Do not freeze. Do not shake.

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- None

Precautions/Warnings

- **Peripheral Neuropathy**: Monitor patients for peripheral neuropathy and modify or discontinue dose accordingly.
- **Infusion-Related Reactions:** Premedicate with an antihistamine and antipyretic. Monitor patients closely during infusions. Interrupt or discontinue infusion for reactions.
- **Myelosuppression**: Monitor complete blood counts. Manage using dose delays or reductions and growth factor support. Monitor for signs of infection.
- **Serious and Opportunistic Infections**: Closely monitor patients for signs of bacterial, fungal, or viral infections.
- **Progressive Multifocal Leukoencephalopathy (PML)**: Monitor patients for new or worsening neurological, cognitive, or behavioral changes suggestive of PML.
- **Tumor Lysis Syndrom**e: Closely monitor patients with high tumor burden or rapidly proliferative tumors.
- **Hepatotoxicity**: Monitor liver enzymes and bilirubin.
- **Lactation**: Advise not to breastfeed.
- **Embryo-Fetal Toxicity**: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 3 months after the last dose.
- **Drug Interactions**: Concomitant use with a strong CYP3A4 inhibitor may increase unconjugated MMAE AUC which may increase toxicities. Monitor patients for signs of toxicity. Concomitant use with a strong CYP3A4 inducer may decrease unconjugated MMAE AUC.

BILLING/CODING INFORMATION:

HCPCS Coding

J9309	Injection, polatuzumab vedotin-piiq, 1 mg

ICD-10 Diagnosis Codes That Support Medical Necessity

B20	Human immunodeficiency virus [HIV] disease [for AIDS-related B-cell lymphomas only and only used in combination with C83.30-C83.39, C83.80-C83.89, or C85.80-C85.89]
C83.30 – C83.38	Diffuse large B-cell lymphoma
C83.398	Diffuse large B-cell lymphoma of other extranodal and solid organ
C83.80 – C83.89	Other non-follicular lymphoma
C83.90 – C83.99	Non-follicular (diffuse) lymphoma, unspecified
C85.10 – C85.19	Unspecified B-cell lymphoma
C85.20 – C85.29	Mediastinal (thymic) large B-cell lymphoma
C85.80 – C85.89	Other specified types of non-Hodgkin lymphoma
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)

REIMBURSEMENT INFORMATION:

Refer to section entitled.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of guideline creation.

DEFINITIONS:

Diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS): The 2008 WHO classification of mature B-cell lymphomas included DLBCL, NOS as a new category to include germinal center B-cell (GCB) subtype, activated B-cell (ABC) subtype as well as other DLBCL cases that do not belong to any of the four specific subtypes (T-cell/histiocyte rich large B-cell lymphoma, primary CNS DLBCL, primary cutaneus DLBCL ("leg type"), or EBV+ DLBCL of the elderly). The updated 2016 WHO classification system created additional categories that fall outside of the definition of DLBCL, NOS.

RELATED GUIDELINES:

Chimeric Antigen Receptor (CAR) T-Cell Therapies, 09-J3000-94
Loncastuximab Tesirine-lpyl (Zynlonta) IV Infusion, 09-J4000-05

OTHER:

International Prognostic Index (all patients)

One point each for: • Age >60 years • Serum LDH > normal • Performance status 2 to 4 • Stage III or IV • Extranodal involvement	• Low = 0 to 1 • Low-intermediate = 2 to 3 • High-intermediate = 3 • High = 4 or 5

Stage-Modified International Prognostic Index (Stage I or II patients)

One point each for: • Age >60 years • Serum LDH > normal • Performance status 2 to 4 • Stage II or IIE	• Low = 0 to 1 • High = 2 to 4

International Working Group (IWG) Response Criteria for Malignant Lymphoma

Response	Definition	Nodal Masses	Spleen, Liver	Bone Marrow
Complete remission (CR)	Disappearance of all evidence of disease	(a) FDG-avid or PET positive prior to therapy; mass of any size permitted if PET negative (b) Variably FDG-avid or PET negative; regression to normal size on CT	Not palpable, nodules disappeared	Infiltrate cleared on repeat biopsy; if indeterminate by morphology, immuno-histochemistry should be negative
Partial remission (PR)	Regression of measurable disease and no new sites	≥50% decrease in SPD of up to 6 largest dominant masses; no increase in size of other nodes (a) FDG-avid or PET positive prior to therapy; one or more PET positive at previously involved site (b) Variably FDG-avid or PET negative; regression on CT	≥50% decrease in SPD of nodules (for single nodule in greatest transverse diameter); no increase in size of liver or spleen	
Stable disease (SD)	Failure to attain CR/PR or PD	(a) FDG-avid or PET positive prior to therapy; PET positive at prior sites of disease and no new sites on CT or PET (b) Variably FDG-avid or PET negative; no change in size of previous lesions on CT		
Relapsed disease or progressive disease (PD)	Any new lesion or increase by ≥50% of previously involved sites from nadir	Appearance of a new lesion(s) >1.5 cm in any axis, ≥50% increase in SPD of more than one node, or ≥50% increase in longest diameter of a previously identified node >1 cm in short axis Lesions PET positive if FDG-avid lymphoma or PET positive prior to therapy	>50% increase from nadir in the SPD of any previous lesions	New or recurrent involvement

FDG - [^{18}F] fluorodeoxyglucose; PET - positron emission tomography; CT - computed tomography; SPD - sum of the product of the diameters

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 01/08/25.

GUIDELINE UPDATE INFORMATION:

09/15/19	New Medical Coverage Guideline.
01/01/20	Revision: HCPCS code updates. Added J9309 and deleted J9999.

03/15/20	Revision to the guideline including updates to the description section, position statement, billing/coding, and references based on new NCCN recommendations for various B-cell lymphomas.
02/15/21	Review and revision to the guideline including updates to the description section, position statement, billing/coding, and references.
02/15/22	Review and revision to the guideline including updates to the description section, position statement, billing/coding, related guidelines, and references.
02/15/23	Review and revision to the guideline including updates to the description section, position statement, billing/coding, related guidelines, and references.
05/15/23	Revision to guidelines including updates to the description, position statement, and references based on the NCCN recommendation regarding first-line use of Polivy in certain patients.
06/15/23	Revision to guidelines including updates to the description, dosage/administration section, and references based on the FDA approval of Polivy for the treatment of adult patients who have previously untreated DLBCL, NOS or HGBL and who have an International Prognostic Index score of 2 or greater.
02/15/24	Review and revision to the guideline including updates to the description section, position statement, and references.
10/01/24	Revision: ICD-10 code updates.
02/15/25	Review and revision to the guideline including updates to the description section, position statement, billing/coding, other section, and references. Per NCCN updates, follicular lymphoma removed as a covered indication. Removed the requirement that the member does not intend to proceed to a stem cell transplant. For the Pola-R-CHP regimen, broadened coverage to include several new indications. Polatuzumab + Lunsumio combination added for second-line or subsequent therapy for several indications.