Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 200.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Polivy (polatuzumab vedotin-piiq)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Polivy (polatuzumab vedotin-piiq)

II. Purpose/Objective:
To provide a policy of coverage regarding Polivy (polatuzumab vedotin-piiq)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Polivy (polatuzumab vedotin-piiq) is an antibody drug conjugate (ADC) directed at CD79b which consists of 3 components: 1) a CD79b-specific humanized IgG1 antibody; 2) a microtubule-disrupting agent, monomethylauristatin E (MMAE); and 3) a protease cleavable linker (which covalently conjugates MMAE to the polatuzumab antibody). The conjugate binds to CD79b (B-cell specific cell surface protein commonly expressed in mature B cell lymphomas, and forms a complex which is internalized within the cell and releases MMAE. MMAE binds to the tubules and disrupts the cellular microtubule network, inducing cell cycle arrest (G2/M phase) and apoptosis.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Polivy (polatuzumab vedotin-piiq) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

Diffuse Large B-Cell Lymphoma, Relapsed or Refractory
- Prescription written by an oncologist/hematologist **AND**
- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation of relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified **AND**
- Medical record documentation that Polivy will be used in combination with bendamustine and rituximab **AND**
- Medical record documentation Polivy will be used as subsequent therapy after a trial of ≥ 2 prior therapies

Previously Untreated B-Cell Lymphoma
- Medical record documentation that the prescription is written by an oncologist/hematologist **AND**
- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation of previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified, or high-grade B-cell lymphoma (HGBL) **AND**
- Medical record documentation of an International Prognostic Index score of 2 or greater **AND**
- Medical record documentation Polivy will be used in combination with rituximab, cyclophosphamide, doxorubicin and prednisone (R-CHP).

AUTHORIZATION DURATION: Approval will be for 6 months.

Authorization for Polivy should not exceed the FDA-approved treatment duration of 6, 21 day cycles. For requests exceeding the above limit, medical record documentation of the following is required:
- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Polivy [prescribing information]. South San Francisco, CA: Genentech Inc; April 2023.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 7/16/19

Revised: 5/8/23 (LOB carve out, Medicaid business segment), 6/23/23 (untreated lymphoma), 12/29/23 (references added), 5/21/25 (LOB table, taglines)

Reviewed: 7/1/20, 5/27/21, 5/11/22 (Medicaid PARP statement), 5/29/24

MA UM Committee approval: 12/31/23, 12/31/24, 7/14/25

DHS PARP approval: 6/9/25