

Policy: MBP 161.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Aliqopa (copanlisib)

I. Policy:

Aliqopa (copanlisib)

II. Purpose/Objective:

To provide a policy of coverage regarding Aliqopa (copanlisib)

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
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. 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:

Aliqopa (copanlisib) inhibits phosphatidylinositol 3-kinase (PI3K), primarily the P13K-alpha and P13K-delta isoforms which are expressed in malignant B-cells. Copanlisib induces tumor cell death through apoptosis and inhibition of proliferation of primary malignant B cell lines. In addition, copanlisib inhibits several signaling pathways, including B-cell receptor signaling, CXCR12 mediated chemotaxis of malignant B cells, and NFκB signaling in lymphoma cell lines.

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

Aliqopa (copanlisib) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed follicular B-cell non-Hodgkin lymphoma (FL) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to at least two prior systemic therapies

QUANTITY LIMIT: 180 mg (3 vials) per 28 days

AUTHORIZATION DURATION: Each treatment period will be defined as 12 months. Re-review will occur every 12 months. Aliqopa will no longer be considered medically necessary if there is medical record documentation of disease progression.

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.

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

Devised: 11/21/17

Revised: 8/22/22 (Medicaid PARP statement), 8/22/23 (LOB carve out, Medicaid business segment)

Reviewed: 9/28/18, 8/29/19, 8/26/20, 8/23/21