Aliqopa (copanlisib)

Line(s) of Business:
HMO; PPO; QUEST Integration
Medicare Advantage

Original Effective Date:
12/01/2018

POLICY

A. 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 Indication

- Aliqopa is indicated for the treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies.

Compendial Use

- Second-line or subsequent therapy for refractory or progressive disease that is refractory to at least 2 prior therapies

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

- Initial therapy
  - Documentation of prior therapies
  - Documentation of FL , with relapse, refractory or progression of disease
- Continuation of therapy
  - Documentation of clinical benefit for Aliqopa therapy

C. EXCLUSIONS

- Age < 18 years

D. CRITERIA FOR APPROVAL

1. Relapsed follicular lymphoma (FL)

Authorizations of 12 months may be granted to member second-line or subsequent therapy for refractory or progressive disease that is refractory to at least 2 prior therapies.

E. CONTINUATION OF THERAPY

Relapsed follicular lymphoma (FL)

1. No previous authorization/precertification:
   All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section D.

2. Reauthorization:
   Members who were previously approved for Aliqopa by HMSA/CVS may request reauthorizations after their initial approval. Approval for an additional 3 months may be granted when the following documentation shows no progression of disease:
   - A current oncology note documenting the patient's response to treatment showing no progression of disease
   - Current imaging studies and other objective measures showing no progression of disease when compared with previous results

F. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

G. ADMINISTRATIVE GUIDELINES

Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

H. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA/CVS has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA/ determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

I. REFERENCES

1. Aliqopa [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; September 2017.
2. The NCCN Drugs & Biologics Compendium™ © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 21, 2018.

Document History

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