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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Antineoplastic Agents	**Original Policy Date:**	September 22, 2017
Subject:	Aliqopa	**Page:**	1 of 4

Last Review Date: March 12, 2021

Aliqopa

Description

Aliqopa (copanlisib)

Background
Aliqopa (copanlisib) is an inhibitor of phosphatidylinositol-3-kinase (PI3K) for the treatment of adults with relapsed follicular lymphoma who have received at least two prior treatments known as systemic therapies. Follicular lymphoma is a slow-growing type of non-Hodgkin lymphoma, a cancer of the lymph system. The lymph system is part of the body's immune system and is made up of lymph tissue, lymph nodes, the spleen, thymus, tonsils and bone marrow. Aliqopa has been shown to induce tumor cell death by apoptosis and inhibition of proliferation of primary malignant B cell lines (1-2).

Regulatory Status
FDA approved indication: Aliqopa is a kinase inhibitor indicated for the treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies (1).

There are many warnings and precautions with use of this agent including monitoring for signs and symptoms of systemic toxicities and adverse reactions. Some adverse reactions and toxicities include: infections, hyperglycemia, hypertension, non-infectious pneumonitis (NIP), neutropenia, severe cutaneous reactions, and embryo-fetal toxicity (1).

Safety and effectiveness in pediatric patients have not been established (1).

Related policies

Copiktra, Imbruvica, Zydelig

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Aliqopa may be considered **medically necessary** for patients 18 years of age or older with the diagnosis of relapsed follicular lymphoma when the conditions indicated below are met.

Aliqopa may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsed follicular lymphoma (FL)

AND ALL of the following:

1. Patient has received at least two prior systemic therapies
2. Prescriber agrees to monitor patient for signs of severe adverse reactions and toxicity

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsed follicular lymphoma (FL)

AND the following:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor patient for signs of severe adverse reactions and toxicity

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Aliqopa is a tyrosine kinase inhibitor in an intravenous infusion indicated for the treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies. Follicular lymphoma is a specific type of Non-Hodgkin lymphoma that effects B-lymphocytes. Some adverse reactions and toxicities from the use of this agent include: infections, hyperglycemia, hypertension, non-infectious pneumonitis (NIP), neutropenia, severe cutaneous reactions, and embryo-fetal toxicity (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Aliqopa while maintaining optimal therapeutic outcomes.

References

1. Aliqopa [package insert]. Whippany, NJ: Bayer Healthcare Pharmaceuticals, Inc.; November 2020.
2. NCCN Clinical Practice Guidelines in Oncology® B-cell Lymphomas (Version 4.2020). National Comprehensive Cancer Network, Inc. August 2020.

Policy History

Date	Action
September 2017	Addition to PA
December 2017	Annual review
March 2018	Annual editorial review Addition of requirement to renewal section: prescriber agrees to monitor patient for signs of severe adverse reactions and toxicity per SME
June 2018	Annual review
March 2019	Annual review and reference update
June 2020	Annual review and reference update
March 2021	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.