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**

Duration 12 months

**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**

Section: Prescription Drugs  Effective Date: April 1, 2019
Subsection: Antineoplastic Agents  Original Policy Date: September 22, 2017
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Policy History

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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.