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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	February 17, 2023
Subject:	Jaypirca	**Page:**	1 of 4

Last Review Date: March 8, 2024

Jaypirca

Description

Jaypirca (pirtobrutinib)

Background
Jaypirca (pirtobrutinib) is a small molecule, noncovalent inhibitor of Bruton's tyrosine kinase (BTK) and cytokine receptor pathways. In B-cells, BTK signaling results in activation of pathways necessary for B-cell proliferation, trafficking, chemotaxis, and adhesion. Jaypirca binds to wild type BTK and BTK harboring C481 mutations, leading to inhibition of BTK kinase activity. Jaypirca inhibits BTK-mediated B-cell CD69 expression and inhibits malignant B-cell proliferation (1).

Regulatory Status
FDA-approved indications: Jaypirca is a kinase inhibitor indicated for the treatment of (1):

1. Adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor.
2. Adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor.

Jaypirca contains warnings regarding the following: infections, hemorrhage, cytopenias, atrial fibrillation and atrial flutter, and second primary malignancies (1).

Jaypirca can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment with Jaypirca and for one week after the last dose (1).

The safety and effectiveness of Jaypirca in pediatric patients less than 18 years of age have not been established (1).

Related policies
Brukinsa, Calquence, Imbruvica

Policy

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

Jaypirca may be considered **medically necessary** if the conditions indicated below are met.

Jaypirca may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Relapsed or refractory mantle cell lymphoma (MCL)
   a. Patient has received at least two lines of systemic therapy, including a BTK inhibitor

2. Chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL)
   a. Patient has received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor

AND ALL of the following:

a. Prescriber agrees to monitor for infections and malignancies
b. Prescriber agrees to monitor complete blood count (CBC) for cytopenias
c. Prescriber agrees to monitor for atrial fibrillation and atrial flutter

d. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Jaypirca and for 1 week after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Relapsed or refractory mantle cell lymphoma (MCL)
2. Chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL)

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor for infections and malignancies
c. Prescriber agrees to monitor CBC for cytopenias
d. Prescriber agrees to monitor for atrial fibrillation and atrial flutter
e. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Jaypirca and for 1 week after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Daily Dosing Limits
50 mg	300 mg per day
100 mg	

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Jaypirca (pirtobrutinib) is a BTK inhibitor indicated for the treatment of relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor and for the treatment of patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor. Jaypirca contains warnings regarding infections, hemorrhages, and cytopenias, among others. The safety and effectiveness of Jaypirca in pediatric patients less than 18 years of age have not been established (1).

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

References

1. Jaypirca [package insert]. Indianapolis, IN: Eli Lilly and Company; December 2023.
2. NCCN Drugs & Biologics Compendium® Pirtobrutinib 2024. National Comprehensive Cancer Network, Inc. Accessed on January 17, 2024.

Policy History

Date	Action
February 2023	Addition to PA
June 2023	Annual review and reference update
December 2023	Per PI update, addition of indication CLL/SLL
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.