



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1406-2
Program	Prior Authorization/Notification
Medication	Jaypirca [®] (pirtobrutinib)
P&T Approval Date	3/2023, 2/2024
Effective Date	5/1/2024

1. Background:

Jaypirca[®] (pirtobrutinib) is a kinase inhibitor indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton Tyrosine Kinase (BTK) inhibitor. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Jaypirca is also indicated for the treatment of 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 B-cell lymphoma 2 (BCL-2) inhibitor. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.¹

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria^a:

<p>A. <u>Patients less than 19 years of age</u></p> <p>1. Jaypirca will be approved based on the following criterion:</p> <p>a. Patient is less than 19 years of age</p> <p style="text-align: center;">Authorization will be issued for 12 months.</p> <p>B. <u>Mantle Cell Lymphoma (MCL)</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Jaypirca will be approved based on the following criteria:</p> <p>(1) <u>All</u> of the following:</p> <p>(a) Diagnosis of mantle cell lymphoma (MCL)</p> <p style="text-align: center;">-AND-</p>

(b) Disease is relapsed or refractory

-AND-

(c) Patient has received at least two prior systemic therapies [e.g., chemotherapy] for MCL, one of which is a Bruton Tyrosine Kinase (BTK) inhibitor therapy [e.g., Imbruvica (ibrutinib), Calquence (acalabrutinib), Brukinsa (zanubrutinib)]

Authorization will be issued for 12 months.

2. Reauthorization

a. **Jaypirca** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Jaypirca therapy

Authorization will be issued for 12 months.

C. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

1. Initial Authorization

a. **Jaypirca** will be approved based on **both** of the following criteria:

(1) Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

-AND-

(2) Patient has been previously treated with **both** of the following:

(a) Bruton Tyrosine Kinase (BTK) inhibitor therapy [e.g., Imbruvica (ibrutinib), Calquence (acalabrutinib), Brukinsa (zanubrutinib)]

(b) B-cell lymphoma 2 (BCL-2) inhibitor therapy [e.g., Venclexta (venetoclax)]

Authorization will be issued for 12 months.

2. Reauthorization

a. **Jaypirca** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Jaypirca** therapy

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Jaypirca [package insert]. Indianapolis, IN: Lilly USA, LLC. December 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed December 15, 2023.

Program	Prior Authorization/Notification – Jaypirca® (pirtobrutinib)
Change Control	
3/2023	New program.
2/2024	Added coverage for updated labeled indication for CLL/SLL in patients who have received at least two lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor. Updated references.