UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1406-3
Program	Prior Authorization/Notification
Medication	Jaypirca® (pirtobrutinib)
P&T Approval Date	3/2023, 2/2024, 2/2025
Effective Date	5/1/2025

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. The National Comprehensive Cancer Network (NCCN) recommends the use of Jaypirca for the treatment of B-cell lymphomas, including splenic and nodal marginal zone lymphoma, extranodal marginal zone lymphoma (EMZL) of the stomach, extranodal marginal zone lymphoma of nongastric sites (noncutaneous), and Waldenström macroglobulinemia/lymphoplasmacytic lymphoma.

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]:

A. <u>Patients less than 19 years of age</u>

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>B-Cell Lymphomas</u>

1. **<u>Initial Authorization</u>**

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

(1) **All** of the following:

(a) Diagnosis of **one** of the following:
i. extranodal marginal zone lymphoma of nongastric sites (noncutaneous)
ii. extranodal marginal zone lymphoma of the stomach
iii. mantle cell lymphoma (MCL)
iv. nodal marginal zone lymphoma
v. splenic marginal zone lymphoma

-AND-

(b) Disease is relapsed, refractory, or progressive

-AND-

(c) Patient has received at least two prior systemic therapies [e.g., chemotherapy], 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. <u>Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma</u>

1. Initial Authorization

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

(1) Diagnosis of Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma which has been previously treated

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.

E. <u>NCCN Recommended Regimens</u>

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. June 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed January 7, 2025.

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.
2/2025	Annual review. Added criteria for B-cell lymphomas and Waldenström Macroglobulinemia according to NCCN guidelines. Updated references.