

Generic Name: pirtobrutinib

Preferred: N/A

Therapeutic Class or Brand Name: Jaypirca

Non-preferred: N/A

Applicable Drugs: Jaypirca (pirtobrutinib)

Date of Origin: 11/13/2023

Date Last Reviewed / Revised: 11/4/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met)

- I. Documentation of one of the following diagnoses A through B AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Mantle cell lymphoma (MCL)

- i. Documentation of relapsed or refractory disease.
- ii. Documented treatment failure after at least two lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor (e.g., Brukinsa [zanubrutinib], Calquence [acalbrutinib], and Imbruvica [ibrutinib]).

B. Chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL)

- i. Documented treatment failure after at least two lines of systemic therapy including a Bruton tyrosine kinase (BTK) inhibitor (e.g., Brukinsa [zanubrutinib], Calquence [acalbrutinib], and Imbruvica [ibrutinib]) **AND** a B-cell lymphoma 2 (BCL-2) inhibitor (e.g., Venclexta [venetoclax]).

Other uses with supportive evidence:

C. Marginal Zone Lymphoma

D. Richter's Transformation

E. Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma (WM/LPL)

- II. Minimum age requirement: 18 years old.
- III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 60 tablets per 30 days.

APPROVAL LENGTH

- **Authorization:** 1 year
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

- N/A

REFERENCES

1. Jaypirca. Prescribing information. Lilly USA LLC; 2024. Accessed October 24, 2025. <https://uspl.lilly.com/jaypirca/jaypirca.html#pi>
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. B-cell Lymphomas. Version 3.2025. Updated August 18, 2025. Accessed November 4, 2025. https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. Version 1.2026. Updated October 10, 2025. Accessed November 4, 2025. https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma. Version 1.2026. Updated June 24, 2025. Accessed November 4, 2025. https://www.nccn.org/professionals/physician_gls/pdf/waldenstroms.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.