

Specialty Guideline Management

Jaypirca

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Jaypirca	pirtobrutinib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indication

Relapsed or Refractory Mantle Cell Lymphoma (MCL)

Jaypirca is 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.

Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)

Jaypirca is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) who have received at least two prior lines of therapy including a BTK inhibitor and a BCL-2 inhibitor.

Compendial Use

- Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)
 - relapsed or refractory disease

- histologic (Richter's) transformation to diffuse large B-cell lymphoma
- Marginal Zone Lymphoma (MZL)
 - Extranodal (gastric and nongastric MALT) marginal zone lymphoma
 - Nodal marginal zone lymphoma
 - Splenic marginal zone lymphoma
- Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Mantle Cell Lymphoma (MCL)

Authorization of 12 months may be granted for treatment of relapsed or refractory MCL when the member has tried at least two lines of prior systemic therapy, including a BTK inhibitor.

Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)

- Authorization of 12 months may be granted as a single agent for treatment of relapsed or refractory CLL/SLL when the member has previously tried BTK inhibitor and venetoclax based regimens, or when member has had resistance or intolerance to prior covalent BTK inhibitor therapy (e.g., acalabrutinib, zanubrutinib).
- Authorization of 12 months may be granted as a single agent for histologic (Richter's) transformation to diffuse large B-cell lymphoma.

Marginal Zone Lymphoma (MZL)

Authorization of 12 months may be granted for subsequent treatment of relapsed, refractory, or progressive MZL, including extranodal (gastric or non-gastric MALT lymphoma) marginal zone lymphoma, nodal marginal zone lymphoma, or splenic marginal zone lymphoma.

Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma

Authorization of 12 months may be granted for treatment of Waldenström macroglobulinemia/lymphoplasmacytic lymphoma when the requested medication is used as a single agent for previously treated disease.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Jaypirca [package insert]. Indianapolis, IN: Eli Lilly and Company; June 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed October 3, 2024.