PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Jaypirca Prior Authorization Policy
- Jaypirca® (pirtobrutinib tablets – Eli Lilly)

REVIEW DATE: 06/19/2024; selected revision 06/26/2024

OVERVIEW

Jaypirca, a Bruton tyrosine kinase (BTK) inhibitor, is indicated for the treatment of:

- Chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL), in adults who have received at least two prior lines of therapy, including a BTK inhibitor and B-cell lymphoma-2 (BCL-2) inhibitor.
- Mantle cell lymphoma, relapsed or refractory in adults after at least two lines of systemic therapy, including a BTK inhibitor.[1]
  Both indications are 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.

Guidelines

Jaypirca is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **B-Cell Lymphoma**: NCCN guidelines (version 2.2024 – April 30, 2024) discuss mantle cell lymphoma and marginal zone lymphoma.[2,4]
  - **Mantle cell lymphoma**: Brukinsa® (zanubrutinib capsules) and Calquence® (acalabrutinib tablets) [both covalent BTK inhibitors] are cited as "preferred regimens" for second-line and subsequent therapy (both category 2A). Imbruvica® (ibrutinib capsules, tablets and oral suspension) [also a covalent BTK inhibitor], given with or without rituximab, is cited as an "Other Recommended Regimen" for second-line and subsequent therapy (category 2A). Jaypirca, a non-covalent BTK inhibitor, is recommended as a second-line and subsequent therapy for progressive disease after prior covalent BTK inhibitor as "useful in certain circumstances" (category 2A). It is noted that head-to-head clinical trials in other B-cell malignancies have demonstrated a more favorable toxicity profile for Brukinsa and Calquence compared with Imbruvica without compromising efficacy. Imbruvica + Venclexta® (venetoclax tablets) is cited as "useful in certain circumstances" for second-line and subsequent therapy (category 2A).
  - **Marginal zone lymphoma**: Jaypirca is recommended as a "preferred" non-covalent BTK inhibitor after prior covalent BTK inhibitor as second-line and subsequent therapy for relapsed, refractory, or progressive disease in patients with indications for treatment, including for older or infirm patients with tolerability of combination chemoimmunotherapy is a concern (category 2A).
- **Chronic Lymphocytic Leukemia (CLL)**: NCCN guidelines (version 3.2024 – March 26, 2024) recommend Jaypirca for CLL or SLL with or without del(17p)/TP53 mutation as second-line or third-line therapy as "Useful in Certain Circumstances" for resistance or intolerance to prior covalent BTK inhibitor (category 2A). Jaypirca is also listed as "Other Recommended Regimens" for relapsed or refractory disease after prior BTK inhibitor and Venclexta-based regimens (if not previously used) [category 2A]. Jaypirca is also recommended as additional therapy for histologic (Richter) transformation to diffuse large B-cell lymphoma (clonally related or unknown clonal status) as a single agent in patients with del(17p)/TP53 mutation or who are chemotherapy refractory or unable to receive chemoimmunotherapy (category 2A).[3,4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Jaypirca. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Jaypirca is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Chronic Lymphocytic Leukemia.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has resistance or intolerance to Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules); OR
     - **ii.** Patient meets BOTH of the following (a and b):
       - **a)** Patient has relapsed or refractory disease; AND
       - **b)** Patient meets BOTH of the following [(1) and (2)]:
         - **(1)** Patient has tried a Bruton tyrosine kinase (BTK) inhibitor; AND
           Note: Examples of Bruton tyrosine kinase inhibitor include: Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules).
         - **(2)** Patient has tried Venclexta (venetoclax tablet).

2. **Mantle Cell Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has tried at least one systemic chemotherapy regimen; OR
       Note: Examples of a systemic regimen contain one or more of the following products: rituximab, cytarabine, carboplatin, cisplastin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, methotrexate, bendamustine, Velcade (bortezomib intravenous or subcutaneous injection), and lenalidomide.
     - **ii.** According to the prescriber, patient is not a candidate for a systemic regimen (i.e., an elderly patient who is frail); AND
   - **C)** Patient has tried one Bruton tyrosine kinase inhibitor (BTK) for mantle cell lymphoma.
     Note: Examples of BTK inhibitors indicated for mantle cell lymphoma include Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib tablets), and Imbruvica (ibrutinib capsules, tablets, and oral suspension).

3. **Small Lymphocytic Lymphoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has resistance or intolerance to Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules); OR

ii. Patient meets BOTH of the following (a and b):
- **a)** Patient has relapsed or refractory disease; AND
- **b)** Patient meets BOTH of the following [(1) and (2)]:
  - **(1)** Patient has tried a Bruton tyrosine kinase (BTK) inhibitor; AND
    Note: Examples of Bruton tyrosine kinase inhibitor include: Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules).
  - **(2)** Patient has tried Venclexta (venetoclax tablet).

Other Uses with Supportive Evidence

4. Marginal Zone Lymphoma. Approve for 1 year if the patient meets BOTH of the following (A and B):
Note: Marginal zone lymphoma includes gastric mucosa-associated lymphoid tissue (MALT) lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma.
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has tried at least one Bruton tyrosine kinase inhibitor.
  Note: Examples of a Bruton tyrosine inhibitor include: Calquence (acalabrutinib tablets), Brukinsa (zanubrutinib capsules), and Imbruvica (ibrutinib tablets, capsules, and oral solution).

5. Richter's Transformation to Diffuse Large B-Cell Lymphoma. Approve for 1 year if the patient meets BOTH of the following (A and B):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (i or ii):
  - **i.** Patient has tried at least one chemotherapy regimen; OR
    Note: Examples of a chemotherapy regimen include: EPOCH-R (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin, rituximab); HyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone) alternating with high-dose methotrexate and cytarabine + rituximab, oxaliplatin; OFAR (oxaliplatin, fludarabine, cytarabine, rituximab); RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone); and venetoclax + RCHOP
  - **ii.** Patient is not a candidate for a chemotherapy regimen.
    Note: Examples of a chemotherapy regimen include: EPOCH-R (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin, rituximab); HyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone) alternating with high-dose methotrexate and cytarabine + rituximab, oxaliplatin; OFAR (oxaliplatin, fludarabine, cytarabine, rituximab); RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone); and venetoclax + RCHOP

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Jaypirca is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Jaypirca® tablets [prescribing information]. Indianapolis, IN: Eli Lilly; December 2023.

2. The NCCN B-Cell Lymphomas Guidelines in Oncology (version 2.2024 – April 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 14, 2024.
3. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 3.2024 – March 26, 2024). © 2024 National Comprehensive Cancer Network. Available at http://www.nccn.org. Accessed on June 14, 2024.
4. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 14, 2024. Search term: pirtobrutinib.