Jaypirca™
pirtobrutinib 50, 100 mg tablets

Jaypirca

Access, Distribution, and Reimbursement Guide

The following information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. Individual coding decisions should be based upon diagnosis and treatment of individual patients. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact third-party payers for specific information on their coverage, coding, and payment policies. Please consult with your legal counsel or reimbursement specialist for any reimbursement or billing questions. For more information, please call the Lilly Oncology Support Center at 1-866-472-8663.

Indication

Jaypirca is a kinase inhibitor indicated for the treatment of adult patients with relapsed or refractory (R/R) mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a 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.

BTK=Bruton's tyrosine kinase.

Select Important Safety Information

Infections: Fatal and serious infections (bacterial, viral, or fungal) and opportunistic infections have occurred in patients treated with Jaypirca. In the clinical trial, Grade ≥3 infections occurred in 17% of 583 patients with hematologic malignancies, most commonly pneumonia (9%); fatal infections occurred in 4.1% of patients. Sepsis (4.5%) and febrile neutropenia (2.9%) occurred. Opportunistic infections included *Pneumocystis jirovecii* pneumonia and fungal infection. Consider prophylaxis, including vaccinations and antimicrobial prophylaxis, in patients at increased risk. Monitor patients for signs and symptoms of infection; based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Please see Important Safety Information on pages 6-8 and click for Prescribing Information and Patient Information for Jaypirca.

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Introduction

This guide includes:

1. Key information on Jaypirca
2. Prescription, ordering, and patient support services offered through the Lilly Oncology Support Center
3. Specialty pharmacy network and specialty distributor network

Jaypirca Supply and NDCs[1]

All coding and documentation requirements for drugs should be confirmed with each payer.

Dosage	Code
100-mg tablets — 60-count bottle	NDC: 0002-7026-60
50-mg tablets — 30-count bottle	NDC: 0002-6902-30

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NDC=National Drug Code.

Diagnosis Codes for MCL[2]

C83.1 Mantle cell lymphoma	
C83.10	Unspecified site
C83.11	Lymph nodes of head, face, and neck
C83.12	Intrathoracic lymph nodes
C83.13	Intra-abdominal lymph nodes
C83.14	Lymph nodes of axilla and upper limb
C83.15	Lymph nodes of inguinal region and lower limb
C83.16	Intrapelvic lymph nodes
C83.17	Spleen
C83.18	Lymph nodes of multiple sites
C83.19	Extranodal and solid organ sites

*Please check to ensure that codes are used to the highest level of specificity. Providers should use current ICD-10-CM codes to report a patient's diagnosis on claim submissions. This list of ICD-10-CM diagnosis codes may be reasonably related to a diagnosis within the product's approved label. Other codes may be appropriate.

CD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

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There Are Several Ways to Get Jaypirca, Depending on the Patient's Insurance

Jaypirca is available through

Contracted specialty pharmacies*

Hospital and health system practices

In-office dispensing practices (IODs)

Jaypirca is available through contracted specialty pharmacies. For a full list of specialty pharmacies, please visit www.jaypirca.com/hcp/savings-support#access-resources.

Jaypirca can be purchased through authorized specialty distributors, which can be found at www.trade.lilly.com.

*Eligible pharmacies can purchase Jaypirca through our distribution partners. A list of authorized distributors can be found at www.trade.lilly.com.

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Jaypirca Savings & Support

Support tailored to an eligible patient's Jaypirca treatment journey*

Savings & Affordability

Jaypirca Savings Card Program

- Eligible, commercially insured patients pay as little as $0 a month†
- Digital cards can be downloaded online. You and your patients can get a savings card by visiting https://www.jaypirca.com/hcp/savings-support#savings

Patient Initiation & Support

Jaypirca Interim Access Program

The Jaypirca Interim Access Program may provide a temporary supply of Jaypirca at no cost to insured, eligible patients who have been prescribed Jaypirca for the first time and are experiencing a delay in their insurance coverage decision.‡

Insurance & Coverage Assistance*

May help eligible Jaypirca patients minimize co-pay or out-of-pocket costs by providing:

- A benefits investigation
- Guidance through the specialty pharmacy process
- Identification of savings opportunities

Jaypirca Ongoing Support*

The Lilly Oncology Support Center can help eligible Jaypirca patients by:

- Connecting them to relevant resources, based on questions or needs
- Reiterating treatment information when taking Jaypirca§

Field Reimbursement Managers (FRMs)

FRMs help patients access prescribed Lilly FDA-approved medicines and educate HCPs and their staff on the complex access and reimbursement landscape to help patients receive and start Jaypirca.

To enroll your eligible patients in all or any of these support programs,* please visit www.Jaypirca.com/hcp/savings-support#savings.

*Jaypirca support programs and offerings are not a guarantee of coverage. Terms and conditions apply for all programs. See Jaypirca enrollment form for details.

§The Lilly Oncology Support Center does not replace a trained HCP; when medical questions arise, your patients will always be directed back to your office.

†**TERMS AND CONDITIONS:** Offer good for up to 12 months. Patients must have coverage for Jaypirca through their commercial drug insurance coverage to pay as little as $0 for a 30-day supply of Jaypirca. Offer subject to a monthly cap and a separate annual cap of $25,000. Offer void where prohibited by law. Patient is responsible for any applicable taxes, fees, or amounts exceeding monthly or annual caps. **This offer is invalid for patients without commercial drug insurance or whose prescription claims for Jaypirca are eligible to be reimbursed, in whole or in part, by any governmental program, including, without limitation, Medicaid, Medicare, Medicare Part D, Medigap, DoD, VA, TRICARE®/CHAMPUS, or any state patient or pharmaceutical assistance program.** Offer void where prohibited by law and subject to change or discontinue without notice. Card activation is required. Subject to additional terms and conditions, which can be found at www.jaypirca.com/savings-support#savings.

‡**TERMS AND CONDITIONS:** The Jaypirca Interim Access Program (or "Program") provides a 15-day supply of Jaypirca at no charge for eligible, insured patients who are: 1) prescribed Jaypirca for the first time, 2) experiencing a minimum 5-business-day delay in insurance coverage determination, 3) prescribed Jaypirca for an FDA-approved indication or an indication medically supported by CMS-recognized compendia, 4) enrolled in the Lilly Oncology Support Center, and 5) residents of the United States or Puerto Rico. May not be combined with any other offer. Not available to patients whose insurers have made a final determination to deny the patient coverage for Jaypirca. If a denial is received after the initial 5 business days have passed and appeal rights are being pursued, or if there is a persistent coverage delay, the patient, under appropriate circumstances, may be eligible for up to 3 additional 15-day supplies of Jaypirca. Product provided through the Program is only available through the Program non-commercial specialty pharmacy. Product is provided free of charge and may not be sold, bartered, or returned for credit. Reimbursement cannot be sought from any third party for product provided under the Program. Patients enrolled in Medicare Part D are prohibited from counting any portion of the cost of the product provided under the Program towards true out-of-pocket ("TrOOP") costs for prescription drug calculations. No purchase contingency or other obligation accompanies program participation. This Program is not health insurance and does not guarantee coverage. Lilly reserves the right to change or end the program at any time. Benefits under the program are not transferable.

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CMS=Centers for Medicare & Medicaid Services; DoD=US Department of Defense; FDA=US Food and Drug Administration; HCP=healthcare provider; VA=US Department of Veterans Affairs.

Important Safety Information for Jaypirca (pirtobrutinib)

Infections: Fatal and serious infections (including bacterial, viral, or fungal) and opportunistic infections have occurred in patients treated with Jaypirca. In the clinical trial, Grade ≥3 infections occurred in 17% of 583 patients with hematologic malignancies, most commonly pneumonia (9%); fatal infections occurred in 4.1% of patients. Sepsis (4.5%) and febrile neutropenia (2.9%) occurred. Opportunistic infections after Jaypirca treatment included, but are not limited to, *Pneumocystis jirovecii* pneumonia and fungal infection. Consider prophylaxis, including vaccinations and antimicrobial prophylaxis, in patients at increased risk for infection, including opportunistic infections. Monitor patients for signs and symptoms, evaluate promptly, and treat appropriately. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Hemorrhage: Fatal and serious hemorrhage has occurred with Jaypirca. Major hemorrhage (Grade ≥3 bleeding or any central nervous system bleeding) occurred in 2.4% of 583 patients with hematologic malignancies treated with Jaypirca, including gastrointestinal hemorrhage; fatal hemorrhage occurred in 0.2% of patients. Bleeding of any grade, excluding bruising and petechiae, occurred in 14% of patients. Major hemorrhage occurred in patients taking Jaypirca with (0.7%) and without (1.7%) antithrombotic agents. Consider risks/benefits of co-administering antithrombotic agents with Jaypirca. Monitor patients for signs of bleeding. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca. Consider benefit/risk of withholding Jaypirca 3-7 days pre- and post-surgery depending on type of surgery and bleeding risk.

Cytopenias: Grade 3 or 4 cytopenias, including neutropenia (24%), anemia (11%), and thrombocytopenia (11%) have developed in patients with hematologic malignancies treated with Jaypirca. In a clinical trial, Grade 4 neutropenia (13%) and Grade 4 thrombocytopenia (5%) developed. Monitor complete blood counts regularly during treatment. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Atrial Fibrillation and Atrial Flutter: Atrial fibrillation or atrial flutter were reported in 2.7% of patients, with Grade 3 or 4 atrial fibrillation or flutter reported in 1% of 583 patients with hematologic malignancies treated with Jaypirca. Patients with cardiac risk factors such as hypertension or previous arrhythmias may be at increased risk. Monitor for signs and symptoms of arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea) and manage appropriately. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Second Primary Malignancies: Second primary malignancies, including non-skin carcinomas, developed in 6% of 583 patients with hematologic malignancies treated with Jaypirca monotherapy. The most frequent malignancy was non-melanoma skin cancer (3.8%). Other second primary malignancies included solid tumors (including genitourinary and breast cancers) and melanoma. Advise patients to use sun protection and monitor for development of second primary malignancies.

Embryo-Fetal Toxicity: Based on animal findings, Jaypirca can cause fetal harm in pregnant women. Administration of pirtobrutinib to pregnant rats during organogenesis caused embryo-fetal toxicity, including embryo-fetal mortality and malformations at maternal exposures (AUC) approximately 3-times the recommended 200 mg/day dose. Advise pregnant women of potential risk to a fetus and females of reproductive potential to use effective contraception during treatment and for one week after last dose.

Please see Important Safety Information continued on pages 7 and 8 and click for Prescribing Information and Patient Information for Jaypirca.

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Important Safety Information for Jaypirca (pirtobrutinib) (continued)

Adverse Reactions (ARs) in Patients with Mantle Cell Lymphoma Who Received Jaypirca

Serious ARs occurred in 38% of patients. Serious ARs occurring in ≥2% of patients were pneumonia (14%), COVID-19 (4.7%), musculoskeletal pain (3.9%), hemorrhage (2.3%), pleural effusion (2.3%), and sepsis (2.3%). **Fatal ARs** within 28 days of last dose of Jaypirca occurred in 7% of patients, most commonly due to infections (4.7%), including COVID-19 (3.1%).

Dose Modifications and Discontinuations: ARs led to dosage reductions in 4.7%, treatment interruption in 32%, and permanent discontinuation of Jaypirca in 9% of patients. ARs resulting in dosage modification in >5% of patients included pneumonia and neutropenia. ARs resulting in permanent discontinuation of Jaypirca in >1% of patients included pneumonia.

ARs (all Grades %; Grade 3-4 %) in ≥10% of Patients: fatigue (29; 1.6), musculoskeletal pain (27; 3.9), diarrhea (19; -), edema (18; 0.8), dyspnea (17; 2.3), pneumonia (16; 14), bruising (16; -), peripheral neuropathy (14; 0.8), cough (14; -), rash (14; -), fever (13; -), constipation (13; -), arthritis/arthralgia (12; 0.8), hemorrhage (11; 3.1), abdominal pain (11; 0.8), nausea (11; -), upper respiratory tract infections (10; 0.8), dizziness (10; -).

Select Laboratory Abnormalities (all Grades %; Grade 3 or 4 %) that Worsened from Baseline in ≥10% of Patients: hemoglobin decreased (42; 9), platelet count decreased (39; 14), neutrophil count decreased (36; 16), lymphocyte count decreased (32; 15), creatinine increased (30; 1.6), calcium decreased (19; 1.6), AST increased (17; 1.6), potassium decreased (13; 1.6), sodium decreased (13; -), lipase increased (12; 4.4), alkaline phosphatase increased (11; -), ALT increased (11; 1.6), potassium increased (11; 0.8). Grade 4 laboratory abnormalities in >5% of patients included neutrophils decreased (10), platelets decreased (7), lymphocytes decreased (6).

All grade ARs with higher frequencies in the total BRUIN population of patients with hematologic malignancies (n=583) were decreased neutrophil count (41%), bruising (20%), diarrhea (20%).

Drug Interactions

Strong CYP3A Inhibitors: Concomitant use with Jaypirca increased pirtobrutinib systemic exposure, which may increase risk of Jaypirca adverse reactions. Avoid use of strong CYP3A inhibitors during Jaypirca treatment. If concomitant use is unavoidable, reduce Jaypirca dosage according to the approved labeling.

Strong or Moderate CYP3A Inducers: Concomitant use with Jaypirca decreased pirtobrutinib systemic exposure, which may reduce Jaypirca efficacy. Avoid concomitant use of Jaypirca with strong or moderate CYP3A inducers. If concomitant use with moderate CYP3A inducers is unavoidable, increase Jaypirca dosage according to the approved labeling.

Sensitive CYP2C8, CYP2C19, CYP3A, P-gp, or BCRP Substrates: Concomitant use with Jaypirca increased their plasma concentrations, which may increase risk of adverse reactions related to these substrates for drugs that are sensitive to minimal concentration changes. Follow recommendations for these sensitive substrates in their approved labeling.

Please see Important Safety Information continued on page 8 and click for Prescribing Information and Patient Information for Jaypirca.

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Important Safety Information for Jaypirca (pirtobrutinib) (continued)

Use in Special Populations

Pregnancy and Lactation: Inform pregnant women of potential for Jaypirca to cause fetal harm. Verify pregnancy status in females of reproductive potential prior to starting Jaypirca and advise use of effective contraception during treatment and for one week after last dose. Presence of pirtobrutinib in human milk and effects on the breastfed child or on milk production is unknown. Advise women not to breastfeed while taking Jaypirca and for one week after last dose.

Geriatric Use: In the pooled safety population of patients with hematologic malignancies, 392 (67%) were ≥65 years of age. Patients aged ≥65 years experienced higher rates of Grade ≥3 ARs and serious ARs compared to patients <65 years of age.

Renal Impairment: Severe renal impairment (eGFR 15-29 mL/min) increases pirtobrutinib exposure. Reduce Jaypirca dosage in patients with severe renal impairment according to the approved labeling. No dosage adjustment is recommended in patients with mild or moderate renal impairment.

Please click for Prescribing Information and Patient Information for Jaypirca.

PT HCP ISI MCL APP

References: 1. Jaypirca (pirtobrutinib). Prescribing Information. Lilly USA, LLC.
2. American Medical Association. AAPC CPT® 2022. Accessed March 24, 2022. https://www.aapc.com/codes/cpt-codes

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