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.

Indications

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
- 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 BCL-2 inhibitor

These indications are approved under accelerated approval based on response rate. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial.

BCL-2=B-cell lymphoma 2; BTK=Bruton's tyrosine kinase.

Select Important Safety Information

Infections: Fatal and serious infections (bacterial, viral, fungal) and opportunistic infections (including *Pneumocystis jirovecii* pneumonia and fungal infection) have occurred in Jaypirca-treated patients. In a clinical trial of 593 patients with hematologic malignancies, Grade ≥3 infections occurred (24%), most commonly pneumonia (14%); fatal infections (4.4%), sepsis (6%), and febrile neutropenia (4%) occurred. In patients with CLL/SLL, Grade ≥3 infections occurred (32%), with fatal infections in 8%. Consider 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 6-9 and click for Prescribing Information and Patient Information for Jaypirca.

Lilly

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 and CLL[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

C91.1 Chronic lymphocytic leukemia of B-cell type	
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.11	Chronic lymphocytic leukemia of B-cell type in remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse

*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.

ICD-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 healthcare providers and their staff on the complex access and reimbursement landscape to help patients receive and start Jaypirca.

Jaypirca Dose Exchange Program

MyRightDose can help support eligible patients by‖:

- Continuing their Jaypirca therapy at the appropriate dose for them, without the hassle of delays or additional co-pays
- Shipping to the patient as early as 48 hours after receipt of the enrollment form
- Providing up to 3 separate dose exchanges of between 5 and 30 days of therapy per exchange at no cost to patients prescribed Jaypirca for an FDA-approved indication

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 healthcare provider; when medical questions arise, your patients will always be directed back to your office.

‖Additional terms and conditions apply. See the MyRightDose Enrollment Form for details.

†**TERMS AND CONDITIONS:** Subject to Lilly USA, LLC's (Lilly's) right to terminate, rescind, revoke or amend the Jaypirca Savings Card Program ("Card") eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason, the Card expires and savings end on 12/31/2024. **Card savings are not available to patients without commercial drug insurance or who are enrolled in any state, federal, or government funded healthcare program, including, without limitation, Medicaid, Medicare, Medicare Part D, Medicare Advantage, Medigap, DoD, VA, TRICARE®/CHAMPUS, or any state prescription drug assistance program.** MONTHLY AND ANNUAL MAXIMUM SAVINGS: For patients with commercial drug insurance coverage for Jaypirca: You must have commercial drug insurance that covers Jaypirca and a prescription consistent with FDA-approved product labeling to pay as little as $0 for a 1-month prescription fill of Jaypirca. Month is defined as 30-days. Card savings are subject to a maximum monthly savings of wholesale acquisition cost plus usual and customary pharmacy charges and separate maximum annual savings of up to $25,000 per calendar year. Subject to Lilly USA, LLC's ("Lilly") right to terminate, rescind, revoke, or amend Card eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason, Card expires and savings end on 12/31/2024. ADDITIONAL TERMS AND CONDITIONS:
You are responsible for any applicable taxes, fees and any amount that exceeds the monthly or annual maximum benefits. Savings card activation is required. This Card may be terminated, rescinded, revoked, or amended by Lilly at any time without notice and for any reason. Subject to additional terms and conditions. Eligibility criteria and terms and conditions for the Jaypirca Savings Card Program may change from time to time at Lilly's sole discretion and for any reason; the most current version can be found at https://www.Jaypirca.com. Card benefits void where prohibited by law.

‡**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-ofpocket ("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.

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

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Important Safety Information for Jaypirca (pirtobrutinib)

Infections: Fatal and serious infections (including bacterial, viral, fungal) and opportunistic infections occurred in Jaypirca-treated patients. In a clinical trial, Grade ≥3 infections occurred in 24% of patients with hematologic malignancies, most commonly pneumonia (14%); fatal infections occurred in 4.4%. Sepsis (6%) and febrile neutropenia (4%) occurred. In patients with CLL/SLL, Grade ≥3 infections occurred (32%), with fatal infections occurring in 8%. Opportunistic infections included *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 3% of patients, including gastrointestinal hemorrhage; fatal hemorrhage occurred (0.3%). Bleeding of any grade, excluding bruising and petechiae, occurred in 17%. Major hemorrhage occurred in patients taking Jaypirca with (0.7%) and without (2.3%) 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: Jaypirca can cause cytopenias, including neutropenia, thrombocytopenia, and anemia. In a clinical trial, Grade 3 or 4 cytopenias, including decreased neutrophils (26%), decreased platelets (12%), and decreased hemoglobin (12%), developed in Jaypirca-treated patients. Grade 4 decreased neutrophils (14%) and Grade 4 decreased platelets (6%) developed. Monitor complete blood counts regularly during treatment. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Cardiac Arrhythmias: Cardiac arrhythmias occurred in patients who received Jaypirca. In a clinical trial of patients with hematologic malignancies, atrial fibrillation or flutter were reported in 3.2% of Jaypirca-treated patients, with Grade 3 or 4 atrial fibrillation or flutter in 1.5%. Other serious cardiac arrhythmias such as supraventricular tachycardia and cardiac arrest occurred (0.5%). 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 9% of Jaypirca-treated patients. The most frequent malignancy was non-melanoma skin cancer (4.6%). 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: 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 fetal risk 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 7-9 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 Who Received Jaypirca

The most common (≥20%) ARs in the BRUIN pooled safety population of patients with hematologic malignancies (n=593) were decreased neutrophil count (46%), decreased hemoglobin (39%), fatigue (32%), decreased lymphocyte count (31%), musculoskeletal pain (30%), decreased platelet count (29%), diarrhea (24%), COVID-19 (22%), bruising (21%), cough (20%).

Mantle Cell Lymphoma

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 Jaypirca dose occurred in 7% of patients, most commonly due to infections (4.7%), including COVID-19 (3.1% of all patients).

Dose Modifications and Discontinuations: ARs led to dose 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 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).

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

Serious ARs ooccurred in 56% of patients. Serious ARs occurring in ≥5% of patients were pneumonia (18%), COVID-19 (9%), sepsis (7%), and febrile neutropenia (7%). **Fatal ARs** within 28 days of last Jaypirca dose occurred in 11% of patients, most commonly due to infections (10%), including sepsis (5%) and COVID-19 (2.7%).

Dose Modifications and Discontinuations: ARs led to dose reductions in 3.6%, treatment interruption in 42%, and permanent discontinuation of Jaypirca in 9% of patients. ARs resulting in dose reductions in >1% included neutropenia; treatment interruptions in >5% of patients included pneumonia, neutropenia, febrile neutropenia, and COVID-19; permanent discontinuation in >1% of patients included second primary malignancy, COVID-19, and sepsis.

Please see Important Safety Information continued on pages 8-9 and click for Prescribing Information and Patient Information for Jaypirca.

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Important Safety Information for Jaypirca (pirtobrutinib) (continued)

ARs in Patients Who Received Jaypirca (continued)

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (continued)

ARs (all Grades %; Grade 3-4 %) in ≥10% of Patients: fatigue (36; 2.7), bruising (36; -), cough (33; -), musculoskeletal pain (32; 0.9), COVID-19 (28; 7), pneumonia (27; 16), diarrhea (26; -), abdominal pain (25; 2.7), dyspnea (22; 2.7), hemorrhage (22; 2.7), edema (21; -), nausea (21; -), pyrexia (20; 2.7), headache (20; 0.9), arthritis/arthralgia (19; 1.8), rash (19; 0.9), peripheral neuropathy (16; 3.6), dizziness (15; -), fall (14; 0.9), constipation (14; -), insomnia (14; -), upper respiratory tract infections (13; 2.7), second primary malignancy (13; 2.7), renal insufficiency (12; 6), hypertension (12; 5), neurological changes (12; 2.7), mucositis (12; 0.9), decreased appetite (12; -), respiratory tract infection (11; 1.8), supraventricular tachycardia (10; 5).

Select Laboratory Abnormalities (all Grades %; Grade 3 or 4 %) that Worsened from Baseline in ≥20% of Patients: neutrophil count decreased (63; 45), hemoglobin decreased (48; 19), calcium decreased (40; 2.8), platelet count decreased (30; 15), sodium decreased (30; -), lymphocyte count decreased (23; 8), ALT increased (23; 2.8), AST increased (23; 1.9), creatinine increased (23; -), lipase increased (21; 7), alkaline phosphatase increased (21; -). Grade 4 laboratory abnormalities in >5% of patients included neutrophils decreased (23).

Drug Interactions

Strong CYP3A Inhibitors: Concomitant use with Jaypirca increased pirtobrutinib systemic exposure, which may increase risk of Jaypirca ARs. Avoid use of strong CYP3A inhibitors with Jaypirca. If concomitant use is unavoidable, reduce Jaypirca dosage according to 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 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 9 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: Due to 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 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, 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 increases pirtobrutinib exposure. Reduce Jaypirca dosage in patients with severe renal impairment according to approved labeling.

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Please click for Prescribing Information and Patient Information for Jaypirca.

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