

Drug Quantity Management Policy - Per Rx

POLICY: Oncology – Jaypirca Drug Quantity Management Policy – Per Rx

Jaypirca[®] (pirtobrutinib tablets – Eli Lilly)

REVIEW DATE: 02/12/2025

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Jaypirca, a Bruton tyrosine kinase (BTK) inhibitor, is indicated for the treatment of:1

- 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

Dosing

The recommended dose of Jaypirca is 200 mg once daily (QD) continued until disease progression or unacceptable toxicity. Tablets should be swallowed whole and cannot be cut, crushed, or chewed. Dose reductions may be necessary to manage adverse events. Additionally, the dose of Jaypirca should be reduced to 100 mg QD (if the current dose of 200 mg QD), otherwise reduce the dose by 50 mg, if the patient has severe renal impairment (estimated glomerular filtration rate [eGFR] 15 to 29 mL/min). If the current dose is 50 mg QD, discontinue Jaypirca.

Drug Interactions

Use of Jaypirca should be avoided with strong cytochrome P450 (CYP)3A inhibitors, but if use cannot be avoided, reduce the Jaypirca dose by 50 mg.¹ If the current daily dose is 50 mg, then interrupt Jaypirca treatment while the patient is receiving the strong CYP3A inhibitor.

Similarly, use of Jaypirca with a moderate or strong CYP3A inducer should be avoided when possible.¹ However, if concomitant administration is necessary, increase the dose of Jaypirca to 300 mg QD (if the current dose is 200 mg QD) or increase the current daily dose by 50 mg (if the current dose is 50 or 100 mg QD).

Availability

Jaypirca is supplied as 50 mg (bottles of 30 tablets) and 100 mg tablets (bottles of 60 tablets).¹

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Jaypirca. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limit

Drug Quantity Emine			1
Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Jaypirca [™]	50 mg tablets	30 tablets	90 tablets
(pirtobrutinib tablets)	100 mg tablets	60 tablets	180 tablets

Oncology – Jaypirca Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Jaypirca 50 mg tablets

1. If the patient is taking a moderate or strong cytochrome P450 (CYP)3A inducer, approve 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.

<u>Note</u>: CYP3A inducers include, but are not limited to, rifampin, carbamazepine, rifabutin, and St. John's Wort.

2. If the patient is taking a strong CYP3A inhibitor, approve 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.

Note: CYP3A inhibitors include, but are not limited to, erythromycin, diltiazem, ketoconazole, and ritonavir.

³ Pages - Cigna National Formulary Coverage - Policy:Oncology - Jaypirca Drug Quantity Management Policy - Per Rx

Jaypirca 100 mg tablets

1. If the patient is taking a moderate or strong CYP3A inducer, approve 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.
Note: CYP3A inducers include, but are not limited to, rifampin, carbamazepine, rifabutin, and St. John's Wort.

REFERENCES

1. Jaypirca[™] tablets [prescribing information]. Indianapolis, IN: Eli Lilly; June 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy		02/08/2023
Annual Revision	No criteria changes.	02/09/2024
Annual Revision	Jaypirca 50mg tablets: Criteria was added to approve 90 tablets per dispensing at retail or 270 tablets at home delivery if the patient is taking a strong CYP3A inhibitor.	02/12/2025
Update	Jaypirca 50mg and 100mg tablets: Updated the note for CYP3A inducers to remove ritonavir.	02/13/2025

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