DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Xalkori Drug Quantity Management Policy – Per Rx
- Xalkori® (crizotinib capsules – Pfizer)

REVIEW DATE: 05/24/2023

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. 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

Xalkori, an oral kinase inhibitor, is indicated for the following uses:[1]

- **Anaplastic large cell lymphoma (ALCL)**, treatment of pediatric patients ≥ 1 year of age and young adults with relapsed or refractory, systemic ALCL that is anaplastic lymphoma kinase (*ALK)*-positive.
  Limitation of Use: The safety and efficacy of Xalkori have not been established in older adults with relapsed or refractory, systemic ALK-positive anaplastic large cell lymphoma.
- **Inflammatory myofibroblastic tumor (IMT),** treatment of patients ≥ 1 year of age with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor that is *ALK*-positive.
- **Non-small cell lung cancer (NSCLC)**, metastatic, whose tumors are *ALK*-positive or *ROS* proto-oncogene 1 (*ROS1)*-positive as detected by an FDA-approved test.

Dosing

Xalkori capsules should be swallowed whole.[1] If a dose is missed, take as soon as possible, unless the next dose is due within 6 hours. If vomiting occurs shortly after taking Xalkori, do not repeat the dose, take the dose at the next regular time.

For relapsed or refractory, systemic ALK-positive ALCL, the recommended dose is 280 mg/m^2 BID until disease progression or unacceptable toxicity.[1] Refer to Table 1 for dose based on body surface area. Per product labeling, combining different strengths of Xalkori capsules may be necessary to attain the desired dose. To manage AEs, hepatic impairment, or renal impairment, dose reductions may be needed based on BSA.

Table 1. Recommended Xalkori Dosage for Patients with ALCL and Pediatric Patients with IMT.[1]

Body Surface Area	Recommended Xalkori Dosage	First Dose Reduction*	Second Dose Reduction*
0.60 – 0.80 m^2	200 mg BID	250 mg QD	Permanently Discontinue
0.81 – 1.16 m^2	250 mg BID	200 mg BID	250 mg QD
1.17 – 1.51 m^2	400 mg BID	250 mg BID	200 mg BID
1.52 – 1.69 m^2	450 mg BID	250 mg BID	200 mg BID
1.70 m^2 or greater	500 mg BID	400 mg BID	250 mg BID

ALCL – Anaplastic large cell lymphoma; IMT – Inflammatory myofibroblastic tumor; * If needed to managed adverse events; BID – Twice daily; QD – Once daily.

For IMT, the recommended dose in adults is 250 mg BID until disease progression or unacceptable toxicity.[1] The dose in pediatric patients is 280 mg/m^2 BID.

For ALK-positive or ROS1-positive NSCLC, the recommended dose of Xalkori is 250 mg twice daily (BID) until disease progression or unacceptable toxicity.[1] To manage adverse events (AEs), hepatic impairment, or renal impairment, dose reductions to 200 mg BID or 250 mg once daily (QD) may be needed.

Availability
Xalkori is available as 200 mg and 250 mg capsules in bottles containing 60 capsules each.[1]

POLICY STATEMENT
This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Xalkori. 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 Limits

Product	Strength	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Xalkori® (crizotinib capsules)	200 mg capsules	60 capsules	180 capsules
	250 mg capsules	60 capsules	180 capsules

Oncology – Xalkori 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

Xalkori 200 mg capsules

1. If the patient has anaplastic large cell lymphoma and has a body surface area ≥ 1.17 m^2, approve the requested quantity, not to exceed 120 capsules per dispensing at retail or 360 capsules per dispensing at home delivery.

2. If the patient is < 18 years of age, has inflammatory myofibroblastic tumor, and has a body surface area ≥ 1.17 m^2, approve the requested quantity, not to exceed 120 capsules per dispensing at retail or 360 capsules per dispensing at home delivery.

Xalkori 250 mg capsules

1. If the patient has anaplastic large cell lymphoma and has a body surface area ≥ 1.70 m^2, approve the requested quantity, not to exceed 120 capsules per dispensing at retail or 360 capsules per dispensing at home delivery.

2. If the patient is < 18 years of age, has inflammatory myofibroblastic tumor, and has a body surface area ≥ 1.70 m^2, approve the requested quantity, not to exceed 120 capsules per dispensing at retail or 360 capsules per dispensing at home delivery.

REFERENCES

1. Xalkori® capsules [prescribing information]. New York, NY: Pfizer; July 2022.

History

Type of Revision	Summary of Changes	Review Date
New Policy	No change to existing quantity limits. Policy created to provide a new override for a patient has anaplastic large cell lymphoma and due to the body surface area requires 400 mg BID (200 mg capsules) or 500 mg BID (250 mg capsules).	05/25/2022
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. **Xalkori 200 mg capsules:** Override criteria were added to approve the requested quantity, not to exceed 120 capsules per dispensing at retail or 360 capsules per dispensing at home delivery, if the patient is < 18 years of age, has inflammatory myofibroblastic tumor, and has a body surface area ≥ 1.17 m^2. **Xalkori 250 mg capsules:** Override criteria were added to approve the requested quantity, not to exceed 120 capsules per dispensing at retail or 360 capsules per dispensing at home delivery, if the patient is < 18	05/24/2023

	years of age, has inflammatory myofibroblastic tumor, and has a body surface area ≥ 1.70 m^2.	