DRUG QUANTITY MANAGEMENT POLICY – PER RX

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

REVIEW DATE: 05/25/2022

OVERVIEW

Xalkori, an oral kinase inhibitor, is indicated for the treatment of patients with:[1]

- **Non-small cell lung cancer**, metastatic, whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.
- **Non-small cell lung cancer**, metastatic, whose tumors are ROS1-positive as detected by an FDA-approved test.
- **Anaplastic large cell lymphoma**, treatment of pediatric patients ≥ 1 year of age and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma that is 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.

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 ALK-positive or ROS1-positive non-small cell lung cancer, 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.

For relapsed or refractory, systemic ALK-positive anaplastic large cell lymphoma, 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 Anaplastic Large Cell Lymphoma.[1]

Body Surface Area	Recommended Xalkori Dosage
0.60 – 0.80 m^2	200 mg BID
0.81 – 1.16 m^2	250 mg BID
1.17 – 1.51 m^2	400 mg BID
1.52 – 1.69 m^2	450 mg BID
1.70 m^2 or greater	500 mg BID

BID – Twice daily.

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.

Automation: None.

Drug Quantity Limits

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

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 up to 120 capsules per dispensing.

Xalkori 250 mg capsules

1. If the patient has anaplastic large cell lymphoma and has a body surface area ≥ 1.70 m^2, approve up to 120 capsules per dispensing.

REFERENCES

1. Xalkori® capsules [prescribing information]. New York, NY: Pfizer; September 2021.