Drug Coverage Policy

Effective Date……07/01/2026
Coverage Policy Number…… DQM026
Policy Title……Xalkori Drug Quantity Management Policy – Per Days

Oncology (Oral – Anaplastic Lymphoma Kinase [ALK]-Positive Agent) – Xalkori Drug Quantity Management Policy – Per Days

- Xalkori® (crizotinib capsules and pellets – Pfizer)

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 where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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.

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

- **Anaplastic large cell lymphoma (ALCL)**, treatment of relapsed or refractory, systemic ALCL that is anaplastic lymphoma kinase (*ALK)*-positive in pediatric patients ≥ 1 year of age and young adults.
  Limitation of Use: The safety and efficacy of Xalkori have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL.
- **Inflammatory myofibroblastic tumor (IMT),** treatment of unresectable, recurrent, or refractory IMT that is *ALK*-positive in patients ≥ 1 year of age.
- **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 in adults.

Dosing
ALCL
For pediatric patients ≥ 1 year of age and young adults with relapsed or refractory, systemic ALK-positive ALCL, the recommended dose is 280 mg/m^2 twice daily (BID) until disease progression or unacceptable toxicity.[1] Refer to Table 1 for dose based on body surface area (BSA). To manage adverse events (AEs), hepatic impairment, or renal impairment, dose reductions may be needed based on BSA (Table 2).

IMT
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 (Table 1).

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

BSA	Recommended Xalkori Dosage to achieve 280 mg/m^2	Xalkori Pellets per Dose	Xalkori Capsules per Dose
0.38 to 0.46m^2	120 mg BID	1 x 20 mg + 2 x 50 mg	--
0.47 to 0.51 m^2	140 mg BID	2 x 20 mg + 2 x 50 mg	--
0.52 to 0.61 m^2	150 mg BID	1 x 150 mg	--
0.62 to 0.80 m^2	200 mg BID	1 x 50 mg + 1 x 150 mg	--
0.81 to 0.97 m^2	250 mg BID	2 x 50 mg + 1 x 150 mg	--
0.98 to 1.16 m^2	300 mg BID	2 x 150 mg	--
1.17 to 1.33 m^2	350 mg BID	1 x 50 mg + 2 x 150 mg	--
1.34 to 1.51 m^2	400 mg BID	2 x 50 mg + 2 x 150 mg	2 x 200 mg
1.52 – 1.69 m^2	450 mg BID	3 x 150 mg	1 x 200 mg + 1 x 250 mg

1.7 m^2 or greater	500 mg BID	1 x 50 mg + 3 x 150 mg	2 x 250 mg

ALCL – Anaplastic large cell lymphoma; IMT – Inflammatory myofibroblastic tumor; BSA – Body surface area; BID – Twice daily; * No more than 4 oral pellet shells are to be used for a single dose.

Table 2. Recommended Xalkori Dosage Reductions* for Patients with ALCL or Pediatric Patients with IMT.[1]

BSA	First Dose Reduction		Second Dose Reduction	
	Dosage	Dose Form/Strength to Achieve Recommended Dose	Dosage	Dose Form/Strength to Achieve Recommended Dose
0.38 to 0.46m^2	90 mg BID	Pellets 2 x 20 mg + 1 x 50 mg	70 mg BID	Pellets 1 x 20 mg + 1 x 50 mg
0.47 to 0.51 m^2	100 mg BID	Pellets 2 x 50 mg	80 mg BID	Pellets 4 x 20 mg
0.52 to 0.61 m^2	120 mg BID	Pellets 1 x 20 mg + 2 x 50 mg	90 mg BID	Pellets 2 x 20 mg + 1 x 50 mg
0.62 to 0.80 m^2	150 mg BID	Pellets 1 x 150 mg	120 mg BID	Pellets 1 x 20 mg + 2 x 50 mg
0.81 to 0.97 m^2	200 mg BID	Pellets 1 x 50 mg + 1 x 150 mg	150 mg BID	Pellets 1 x 150 mg
0.98 to 1.16 m^2	220 mg BID	Pellets 1 x 20 mg + 1 x 50 mg + 1 x 150 mg	170 mg BID	Pellets 1 x 20 mg + 1 x 150 mg
1.17 to 1.33 m^2	250 mg BID	Pellets 2 x 50 mg + 1 x 150 mg	200 mg BID	Pellets 1 x 50 mg + 1 x 150 mg
1.34 to 1.69 m^2	250 mg BID	Pellets 2 x 50 mg + 1 x 150 mg -OR- Capsules 1 x 250 mg	200 mg BID	Pellets 1 x 50 mg + 1 x 150 mg -OR- Capsules 1 x 200 mg
1.7 m^2 or greater	400 mg BID	Pellets 2 x 50 mg + 2 x 150 mg -OR- Capsules 2 x 200 mg	250 mg BID	Pellets 2 x 50 mg + 1 x 150 mg -OR- Capsules 1 x 250 mg

* Dose reductions to manage adverse events, hepatic impairment, renal impairment, or drug interactions; ALCL – Anaplastic large cell lymphoma; IMT – Inflammatory myofibroblastic tumor; BSA – Body surface area; BID – Twice daily; * No more than 4 oral pellet shells are to be used for a single dose.

NSCLC
For adults with ALK-positive or ROS1-positive metastatic NSCLC, the recommended dose of Xalkori is 250 mg BID until disease progression or unacceptable toxicity.[1] For adults who cannot swallow capsules, the recommended dose is 250 mg BID using 2 x 50 mg pellets and 1 x 150 mg pellet per dose. To manage AEs, hepatic impairment, renal impairment, or drug interactions, dose reductions to 200 mg BID or 250 mg once daily (QD) may be needed.

Availability/Administration
Xalkori is available as 200 mg and 250 mg capsules in bottles containing 60 capsules each.[1] Xalkori capsules should be swallowed whole.

Xalkori is also available as 20 mg, 50 mg, and 150 mg oral pellets, supplied in bottles of 60 pellets each.[1] Xalkori pellets should not be chewed or crushed. The pellets are supplied encapsulated in shells but should not be swallowed in the shell. The shell may be opened and the contents emptied directly into the patient's mouth. Alternatively, the shell may be opened and emptied into an oral dosing aid (e.g., spoon, medicine cup) and then administered into the patient's mouth via the aid. A sufficient amount of water should be given to ensure that all medication is swallowed immediately following administration of the Xalkori pellets.

Coverage Policy

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. Meeting Drug Quantity Management Program Criteria does not satisfy any other prior authorization or medical necessity criteria requirements.

Drug Quantity Limits

Product	Strength	Retail Maximum Quantity per 30 days	Home Delivery Maximum Quantity per 90 days
Xalkori® (crizotinib capsules)	200 mg capsules	120 capsules	360 capsules
	250 mg capsules	120 capsules	360 capsules
	20 mg pellets	120 pellets	360 pellets
	50 mg pellets	120 pellets	360 pellets
	150 mg pellets	180 pellets	540 pellets

Exceptions to the quantity limits listed above are covered as medically necessary when ONE of the following criteria is met. Any other exception is considered not medically necessary.

CRITERIA

Xalkori 20 mg pellets
1. If the patient has anaplastic large cell lymphoma and requires a dose reduction to 80 mg twice daily, approve the requested quantity, not to exceed 240 pellets per dispensing at retail or 720 pellets per dispensing at home delivery.

2. If the patient is < 18 years of age, has inflammatory myofibroblastic tumor, and requires a dose reduction to 80 mg twice daily, approve the requested quantity, not to exceed 240 pellets per dispensing at retail or 720 pellets per dispensing at home delivery.

Xalkori 50 mg pellets, Xalkori 150 mg pellets, Xalkori 200 mg capsules and Xalkori 250 mg capsules
No overrides recommended.

References

1. Xalkori® capsules [prescribing information]. New York, NY: Pfizer; September 2023.

Revision Details

Summary of Changes	Review Date	Effective Date
New policy.	05/14/2026	07/01/2026

The policy effective date is in force until updated or retired.