DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Rozlytrek Drug Quantity Management Policy – Per Rx
- Rozlytrek™ (entrectinib capsules – Genentech)

REVIEW DATE: 06/15/2022

OVERVIEW

Rozlytrek, a kinase inhibitor, is indicated for the following uses:[1]
- **Non-small cell lung cancer (NSCLC)**, in adults with metastatic *ROS1*-positive NSCLC.
- **Solid tumors**, in patients ≥ 12 years of age with solid tumors that a) have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion without a known acquired resistance mutation, b) are metastatic or where surgical resection is likely to result in severe morbidity, and c) have either progressed following treatment or have no satisfactory alternative therapy.

Dosing

ROS1-Positive NSCLC
- Adults: 600 mg once daily (QD) with or without food until disease progression or unacceptable toxicity.

NTRK Gene Fusion-Positive Solid Tumors
- Adults: 600 mg QD with or without food until disease progression or unacceptable toxicity.
- Adolescents ≥ 12 years of age: dose based on body surface area (BSA) [refer to Table 1 below].

Table 1. Rozlytrek Dosing in Pediatric Patients ≥ 12 Years of Age.[1]

BSA	Recommended Dose
> 1.50 m^2	600 mg QD
1.11 to 1.50 m^2	500 mg QD
0.91 to 1.10 m^2	400 mg QD

BSA – Body surface area; QD – Once daily.

To manage adverse events (AEs), dose modifications may be required (Table 2).

Table 2. Rozlytrek Dose Adjustments to Manage AEs.[1]

Action	Adults and Pediatric Patients ≥ 12 years of age with BSA > 1.50 m^2	Pediatric Patients ≥ 12 years of age with BSA 1.11 to 1.50 m^2	Pediatric Patients ≥ 12 years of age with BSA 0.91 to 1.10 m^2
First dose reduction	400 mg QD	400 mg QD	300 mg QD
Second dose reduction	200 mg QD	200 mg QD	200 mg QD

AEs – Adverse events; BSA – Body surface area; QD – Once daily.

Rozyltrek should not be administered with moderate or strong cytochrome P450 (CYP)3A inhibitors.[1] However, if coadministration cannot be avoided in adults or pediatric patients ≥ 12 years of age with a BSA > 1.50 m^2, reduce the dose to 200 mg QD (if used with moderate CYP3A inhibitors) or 100 mg QD (if used with strong CYP3A inhibitors). The patient may resume the previous dose 3 to 5 elimination half-lives following discontinuation of a strong or moderate CYP3A inhibitor.

Availability

Rozlytrek is available as 100 mg capsules (bottles of 30 capsules) and 200 mg capsules (bottles of 90 capsules).[1]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Rozlytrek. 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 and Form	Maximum Quantity per Rx
Rozlytrek™ (entrectinib capsules)	100 mg capsules	30 capsules
	200 mg capsules	90 capsules

CRITERIA

Rozlytrek 100 mg capsules

1. If the patient requires a dose of 300 mg daily, approve 90 capsules per dispensing.
Note: For doses of 400 mg or 600 mg daily, the patient should use the 200 mg capsules.

2. If the patient requires a dose of 500 mg daily, approve 150 capsules per dispensing.
Note: For doses of 400 mg or 600 mg daily, the patient should use the 200 mg capsules.

Rozlytrek 200 mg capsules

No overrides recommended.

REFERENCES

1. Rozlytrek™ capsules [prescribing information]. South San Francisco, CA: Genentech; August 2019.