DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Vitrakvi Drug Quantity Management Policy – Per Rx
- Vitrakvi® (larotrectinib capsules and oral solution – Bayer)

REVIEW DATE: 05/11/2022

OVERVIEW

Vitrakvi, a kinase inhibitor, is indicated in adult and pediatric patients for the treatment of **solid tumors** that: have a **neurotrophic receptor tyrosine kinase (NTRK) gene fusion** without a known acquired resistance mutation; are metastatic or where surgical resection is likely to result in severe morbidity; and have no satisfactory alternative treatments or that have progressed following treatment.[1]

Dosing

The recommended dose of Vitrakvi in patients with a body surface area (BSA) ≥ 1 m^2 is 100 mg twice daily (BID) until disease progression or unacceptable toxicity.[1] For a patient with a BSA < 1 m^2, the recommended dose of Vitrakvi is 100 mg/m^2 BID. Dose adjustments to 75 mg BID, 50 mg BID, or 100 mg once daily (if BSA ≥ 1 m^2) or 75 mg/m^2 BID, 50 mg/m^2 BID, or 25 mg/m^2 BID (if BSA < 1 m^2) may be needed to manage adverse events. Use of Vitrakvi with strong cytochrome P450 (CYP)3A4 inhibitors or inducers should be avoided. However, if coadministration with a strong CYP3A4 inhibitor cannot be avoided, the dose of Vitrakvi should be reduced by 50%. Conversely, if coadministered with a strong CYP3A4 inducer, the dose of Vitrakvi should be doubled. Additionally, the starting dose of Vitrakvi should be reduced by 50% in patients with moderate to severe hepatic impairment.

Availability

Vitrakvi is available as 25 mg and 100 mg capsules supplied in bottles of 60 capsules.[1] It is also available as a 20 mg/mL oral solution in 100 mL bottles.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Vitrakvi. 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 Dosage Form	Maximum Quantity per Rx
Vitrakvi® (larotrectinib capsules and oral solution)	25 mg capsules	180 capsules[α]
	100 mg capsules	60 capsules[*]
	20 mg/mL (100 mL bottle)	300 mL (3 bottles)[*]

[α] This is a sufficient quantity for a 30-day supply of Vitrakvi dosed at 75 mg BID. [*] This is a sufficient quantity for a 30-day supply of Vitrakvi dosed at 100 mg BID.

CRITERIA

Vitrakvi 25 mg capsules

1. If the patient is taking a strong cytochrome P450 (CYP)3A inducer, approve 360 capsules per dispensing.
Note: Strong CYP3A inducers include, but are not limited to, apalutamide, carbamazepine, enzalutamide, mitotane, phenytoin, rifampin, St. John's wort.

Vitrakvi 100 mg capsules

1. If the patient is taking a strong cytochrome P450 (CYP)3A inducer, approve 120 capsules per dispensing.
Note: Strong CYP3A inducers include, but are not limited to, apalutamide, carbamazepine, enzalutamide, mitotane, phenytoin, rifampin, St. John's wort.

Vitrakvi 20 mg/mL oral solution

1. If the patient is taking a strong cytochrome P450 (CYP)3A inducer, approve 600 mL (6 bottles) per dispensing.
Note: Strong CYP3A inducers include, but are not limited to, apalutamide, carbamazepine, enzalutamide, mitotane, phenytoin, rifampin, St. John's wort.

REFERENCES

1. Vitrakvi® capsules and oral solution [prescribing information]. Whippany, NJ: Bayer; March 2021.