DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Gavreto Drug Quantity Management Policy – Per Rx
- Gavreto® (pralsetinib capsules – Genentech

REVIEW DATE: 05/11/2022

OVERVIEW
Gavreto, a kinase inhibitor, is indicated for the treatment of the following conditions:[1]
- **Medullary thyroid cancer**, in adults and pediatric patients ≥ 12 years of age with advanced or metastatic rearranged during transfection (*RET*)-mutant disease who require systemic therapy.
- **Non-small cell lung cancer**, in adults with metastatic *RET* fusion-positive disease as detected by an FDA approved test.
- **Thyroid cancer**, in adults and pediatric patients ≥ 12 years of age with advanced or metastatic *RET* fusion-positive disease who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

Dosing
The recommended dose of Gavreto is 400 mg once daily (QD) given on an empty stomach.[1] Treatment should be continued until disease progression or unacceptable toxicity. If vomiting occurs after Gavreto, the patient should not take an additional dose, but continue with the next dose as scheduled. Dose reductions to either 300 mg, 200 mg, or 100 mg QD may be needed to manage adverse events or drug interactions with combined P-glycoprotein and strong cytochrome P450 (CYP)3A inhibitors. Patients taking Gavreto should avoid coadministration with strong CYP3A inducers. However, if coadministration with a strong CYP3A inducer cannot be avoided, increase the starting dose of Gavreto to double the current dose starting on Day 7 of coadministration. After the inducer has been discontinued for at least 14 days, the prior dose of Gavreto may be resumed.

Availability
Gavreto is available as 100 mg capsules supplied in bottles of 60 or 90 capsules.[1]

POLICY STATEMENT
This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Gavreto. 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
Gavreto® (pralsetinib capsules)	100 mg capsules	120 capsules*

* This is a sufficient quantity for a 30-day supply of Gavreto dosed at 400 mg once daily.

CRITERIA
1. If the patient is taking a strong cytochrome P450 (CYP)3A inducer, approve 240 tablets per dispensing.

Note: Strong CYP3A4 inducers include, but are not limited to, apalutamide, carbamazepine, enzalutamide, mitotane, phenytoin, rifampin, and St. John's wort.

REFERENCES

1. Gavreto® capsules [prescribing information]. South San Francisco, CA: Genentech; February 2022.