# Drug Quantity Management – Per Rx
# Oncology – Gavreto® (pralsetinib capsules)

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## Product Identifier(s)

105994

***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. 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.*

## National Formulary Medical Necessity

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.

**Drug Quantity Limits**

| Product | Strength and Dosage Form | Maximum Quantity per Rx |
|---|---|---|
| Gavreto®<br>(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.

**Cigna covers quantities as medically necessary when the following criteria are met:**

**1.** If the individual 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.

## Conditions Not Covered

Any other exception is considered not medically necessary.

## Background

**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.

## References

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

## Revision History

| Type of Revision | Summary of Changes | Approval Date |
|---|---|---|
| New Policy | No change to existing quantity limit. Policy created to provide a new override for a patient who is taking Gavreto with a strong cytochrome P450 3A inducer. | 05/11/2022 |