1. **Background:**
Gavreto (pralsetinib) is a kinase inhibitor indicated for the treatment of adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC).

Gavreto is also indicated for adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy, and for the treatment of advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

**Coverage Information:**
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. **Coverage Criteria:**

A. **Patients less than 19 years of age**

1. **Gavreto** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   **Authorization will be issued for 12 months.**

B. **Non-Small Cell Lung Cancer (NSCLC)**

1. **Initial Authorization**
a. **Gavreto** will be approved based on all of the following criteria:

(1) Diagnosis of non-small cell lung cancer (NSCLC)

-AND-

(2) Disease is one of the following:
   (a) Recurrent
   (b) Advanced
   (c) Metastatic

-AND-

(3) Presence of RET gene fusion-positive or RET rearrangement positive tumors

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Gavreto** will be approved based on the following criterion:

   (1) Patient does not show evidence of progressive disease while on Gavreto therapy

Authorization will be issued for 12 months.

B. **Thyroid Carcinoma**

1. **Initial Authorization**

a. **Gavreto** will be approved based on one of the following criteria:

   (1) All of the following:

      (a) Diagnosis of one of the following:

         i. Follicular carcinoma
         ii. Hürthle cell carcinoma
         iii. Papillary carcinoma

         -AND-

      (b) One of the following:
i. Unresectable locoregional recurrent disease
ii. Persistent disease
iii. Metastatic disease

-AND-

(c) Disease is RET-fusion positive

-AND-

(d) Disease is not amenable to radioactive iodine therapy

-OR-

(2) All of the following:

(a) Diagnosis of medullary carcinoma

-AND-

(b) One of the following:
   i. Disease is recurrent, persistent, or progressive
   ii. Disease is symptomatic with distant metastases

-AND-

(c) Disease is RET-mutation positive

-OR-

(3) All of the following:

(a) Diagnosis of anaplastic carcinoma

-AND-

(b) One of the following:
   i. Disease is stage IVA or IVB (locoregional)
   ii. Disease is metastatic

-AND-

(c) Disease is RET-fusion positive
Authorization will be issued for 12 months.

2. Reauthorization

a. Gavreto will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Gavreto therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

3. Additional Clinical Rules:
   - Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
   - Supply limits may be in place.

4. References:

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization/Notification – Gavreto™ (pralsetinib)</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/2020</td>
<td>New program.</td>
</tr>
<tr>
<td>11/2021</td>
<td>Annual review. Added criteria for thyroid carcinoma according to label and NCCN compendium. Updated background and references.</td>
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