UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 1430-2
Program	Prior Authorization/Notification
Medication	Augtyro™ (repotrectinib)
P&T Approval Date	1/2024, 8/2024
Effective Date	11/1/2024

1. Background:

Augtyro (repotrectinib) is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive non-small cell lung cancer (NSCLC). Augtyro is also indicated for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that: have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy. 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 the confirmatory trials.

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]:

A. <u>Patients less than 19 years of age</u>

1. **Augtyro** 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. <u>Non-small cell lung cancer (NSCLC)</u>

1. **<u>Initial Authorization</u>**

   a. **Augtyro** will be approved based on **<u>all</u>** of the following criteria:

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

-AND-

(2) Disease is **one** of the following:

(a) Advanced
(b) Metastatic

-AND-

(3) Disease is *ROS1*-positive

Authorization will be issued for 12 months.

2. **Reauthorization**

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

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

Authorization will be issued for 12 months.

C. Solid Tumors

1. **Initial Authorization**

a. **Augtyro** will be approved based on **all** of the following criteria:

(1) Presence of solid tumor(s)

-AND-

(2) Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., *ETV6-NTRK3*, *TPM3-NTRK1*, *LMNA-NTRK1*, etc.)

-AND-

(3) Disease is **one** of the following:

(a) Locally advanced
(b) Metastatic
(c) Unresectable

Authorization will be issued for 12 months.

2. **Reauthorization**

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

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

Authorization will be issued for 12 months.

D. 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.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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:

1. Augtyro [package insert]. Bristol-Myers Squibb Company: Princeton, NJ; June 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed July 5, 2024.

Program	Prior Authorization/Notification - Augtyro (repotrectinib)
Change Control	
1/2024	New program.
8/2024	Updated background and coverage criteria to include new indication for solid tumors with NTRK gene fusion per package insert. Updated references.