

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 3200-1
Program	Step Therapy
Medication	Ibtrozi® (taletrectinib)
P&T Approval Date	11/2025
Effective Date	2/1/2026

1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a patient trial of or contraindication to Augtyro® (repotrectinib) or Rozlytrek™ (entrectinib) before providing coverage for Ibtrozi (taletrectinib).

Ibtrozi (taletrectinib) is a kinase inhibitor indicated for the treatment of adult patients with advanced or metastatic disease ROS1-positive non-small cell lung cancer (NSCLC).

Augtyro (repotrectinib) is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic ROS1-positive NSCLC.

Rozlytrek (entrectinib) is a kinase inhibitor indicated for the treatment of adult patients with ROS1-positive metastatic NSCLC.

Members currently on Ibtrozi therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

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,b}:**A. Patients less than 19 years of age**

1. **Ibtrozi** 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. ROS1-positive Non-Small Cell Lung Cancer

1. **Ibtrrozi** will be approved based on all of the following:

a. Diagnosis of ROS1-positive non-small cell lung cancer

-AND-

b. **One** of the following:

(1) Patient has a contraindication or history of intolerance to one of the following:

(a) Augtyro (repotrectinib)

(b) Rozlytrek (entrectinib)

-OR-

(2) **Both** of the following:

(a) As continuation of therapy

-AND-

(b) Patient has not received a manufacturer supplied sample at no cost from a prescriber's office, or any form of assistance from the manufacturer sponsored patient support program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) or a 30-day free trial from a pharmacy as a means to establish as a current user of Ibtrrozi

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer program shall be required to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

C. Other Indications

1. **Ibtrrozi** will be approved

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.

^b Coverage of oncology medications may be approved based on state mandates.

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 and/or Notification may be in place.
- Coverage of oncology medications may be approved based on state mandates.

4. References:

1. Ibtrizi [package insert]. Burlington, MA: Nuvation Bio, Inc; June 2025.
2. Augtyro [package insert]. Bristol-Myers Squibb Company: Princeton, NJ; June 2024.
3. Rozlytrek [package insert]. Genentech USA, Inc.: South San Francisco, CA; January 2024.
4. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/ Accessed October 10, 2025.

Program	Step Therapy – Ibtrizi (taletrectinib)
Change Control	
11/2025	New program.