

Reference number(s)

7050-A

# Specialty Guideline Management Ibtrozi

## **Products Referenced by this Document**

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ibtrozi	taletrectinib

### **Indications**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indications<sup>1</sup>

Treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC)

### Compendial Uses<sup>2</sup>

NSCLC, recurrent, advanced or metastatic ROS1 rearrangement-positive tumors

All other indications are considered experimental/investigational and not medically necessary.

### **Documentation**

Submission of the following information is necessary to initiate the prior authorization review: ROS1 status (where applicable).

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# **Coverage Criteria**

### Non-Small Cell Lung Cancer<sup>1,2</sup>

Authorization of 12 months may be granted for treatment of recurrent, advanced, or metastatic ROS1-positive non-small cell lung cancer as a single agent.

# **Continuation of Therapy**

## ROS1-positive Non-Small Cell Lung Cancer (NSCLC)1,2

Authorization of 12 months may be granted for continued treatment of ROS1-positive non-small cell lung cancer (NSCLC) in members requesting reauthorization when there is no evidence of unacceptable toxicity while on the current regimen.

### References

- 1. Ibtrozi [package insert]. Burlington, MA: Nuvation Bio Inc.; June 2025.
- 2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed June 23, 2025.