

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).

Ibtrozi SGM 7050-A P2025.docx

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

# **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.