Applicable Drugs: Ibtrozi (taletrectinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 11/17/2025

Date Last Reviewed / Revised: 10/15/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to IV are met.)

I. Documentation of one of the following FDA-approved diagnosis AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Non-Small Cell Lung Cancer (NSCLC)

i. Documentation of locally advanced or metastatic NSCLC

ii. Documentation of ROS1-positive NSCLC

iii. Ibtrozi will be used as a single agent.

iv. Documented treatment failure or contraindication to another ROS1 inhibitor (ex: Rozlytrek [entrectinib] or Xalkori [crizotinib], etc.)

v. Minimum age requirement : 18 years old or order

Other Uses With Supportive Evidence

A. Central nervous system cancers – brain metastases

II. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

Quantity / Days Supply Restrictions

- Available as 200 mg capsules
- Maximum recommended dose: 600 mg orally once daily
- Maximum quantity: 90 capsules / 30 days

Approval Length

- **Authorization:** 6 months
- **Re-Authorization:** 6 months - An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of symptomatic progressive disease with multiple lesions.

Appendix

N/A

References

1. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer. Version 9.2026. Updated September 22, 2026. Accessed October 8, 2026. www.nccn.org/professionals/physician_gls/pdf/nscl/pdf
2. Ibtrozi. Prescribing Information. Nuvation Bio Inc. 2026. Accessed October 8, 2026. https://Ibtrozi-pi.com/IBTROZI_taletrectinib-prescribing-information.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Central Nervous System Cancers. Version 3.2026. Updated August 17, 2026. Accessed October 8, 2026. www.nccn.org/professionals/physician_gls/pdf/cns/pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.