

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – ROS1 Inhibitor) – Ibrozi Prior Authorization Policy

- Ibrozi™ (taletrectinib capsules – Nuvation Bio)

REVIEW DATE: 06/18/2025

OVERVIEW

Ibrozi is indicated for the treatment of locally advanced or metastatic **ROS1-positive** non-small cell lung cancer (NSCLC) in adults.¹

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on NSCLC (version 5.2025 – June 20, 2025) recommends Ibrozi, Augtyro™ (repotrectinib capsules), Rozlytrek® (entrectinib capsules and oral pellets), and Xalkori® (crizotinib capsules and oral pellets) as “Preferred” first-line options (all category 2A). NCCN notes that Ibrozi, Rozlytrek, or Augtyro may be better for patients with brain metastases. For subsequent therapy, Ibrozi (if not previously given), Augtyro (if not previously given) or Lorbrena® (lorlatinib tablets) are recommended (all category 2A). For symptomatic progression to the brain, Ibrozi, Augtyro, or Lorbrena (all “Preferred”), or Rozlytrek (useful in certain circumstances, if previously treated with Xalkori), or clinical trial is recommended. Augtyro or Ibrozi is noted as an option for resistant mutations, such as *ROS1* G2032R.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ibrozi. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ibrozi is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has locally advanced or metastatic disease; AND
 - C) Patient has *ROS1*-positive non-small cell lung cancer; AND
 - D) The mutation was detected by an approved test.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ibrozi is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Ibrozi™ capsules [prescribing information]. Burlington, MA: Nuvation Bio Inc.; June 2025.
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2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 5.2025 – June 20, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on June 22, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/18/2025
