Clinical Policy Title:	ROS1 Inhibitors
Policy Number:	RxA.918
Drug(s) Applied:	Ibtrozi, Rozlytrek, Augtyro, and Vitrakvi
Original Policy Date:	12/11/2025
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all):

1. Diagnosis of recurrent or metastatic NSCLC
2. Disease is a ROS1 positive tumor, and request is for Ibtrozi, Rozlytrek, or Augtyro

Approval duration
All Lines of Business (except Medicare): 12 months

B. NTRK Fusion-Positive Cancer (Rozlytrek, Vitrakvi) (must meet all)**:**

1. Solid tumor which is metastatic or unresectable;
2. Tumor is positive for neurotrophic receptor tyrosine kinase (NRTK) gene fusion (e.g. ETV6-NTRK3, TPM3- NTRK1, LMNA-NTRK1, etc.);
3. Documentation of no known acquired tropomyosin receptor kinase resistance mutation (e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations);
4. One of the following (a or b):
   a. Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy);
   b. Disease has no satisfactory alternative treatments.

Approval duration
All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Non-Small Cell Lung Cancer (must meet all)**:**

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration
All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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2. Highlights of prescribing information.
   https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219713s000lbl.pdf

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	12/11/2025	12/11/2025

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