

Taletrectinib (IBTROZI)

Criteria for Use

August 2026

VHA Pharmacy Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for taletrectinib.

- ☐ Unstable brain metastases
- ☐ History of prolonged QTc interval (> 450 msec for males or > 470 msec for females)
- ☐ Prior ROS1, ALK, or NTRK tyrosine kinase inhibitor therapy (except for crizotinib)
- ☐ Interstitial lung disease, interstitial fibrosis, or lung disease from prior tyrosine kinase inhibitors
- ☐ Unmanageable drug interactions
- ☐ Creatinine clearance or eGFR <30 mL/min
- ☐ Moderate to severe liver dysfunction (Child-Pugh score B/C or NCI Organ Dysfunction Working Group classification unless with Gilbert syndrome)
- ☐ History of stem cell or organ transplant
- ☐ Pregnancy
- ☐ Lactating

Inclusion Criteria

All of the following must be selected to meet criteria.

- ☐ Patient with locally advanced or metastatic non-small cell lung cancer whose tumor is ROS1 positive

Additional Inclusion Criteria

All of the following criteria must be selected to meet criteria.

- ☐ Care is provided by a VA/VA Community Care oncology provider
- ☐ Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented

Additional Inclusion Criteria – Select If Applicable

- ☐ For females who can become pregnant and males with partners who can become pregnant: Counseling on treatment risks vs benefits and use of effective contraception during and for 3 weeks after last treatment for women and 3 weeks for men

Other Justification

☐ _____

Contact: Mark C. Geraci, Pharm.D., BCOP, National Program Manager, VHA Pharmacy Services – Formulary Management