Entrectinib (ROZLYTREK)
Criteria for Use
March 2021

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

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.

See the VA National PBM-MAP-VPE Monograph on this drug at *www.pbm.va.gov* or *PBM INTRAnet* for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive entrectinib.

- ☐ Prior history of prolonged QTc interval (repeated QTc interval >450 msec) or risk factors for torsade de pointes
- ☐ Gastrointestinal condition that may interfere with entrectinib absorption
- ☐ Interstitial lung disease, interstitial fibrosis , or tyrosine kinase inhibitor-induced pneumonitis
- ☐ Prior ROS1 or NTRK tyrosine kinase inhibitor therapy
- ☐ Unmanageable drug interaction identified
- ☐ Creatinine clearance <30 mL/min
- ☐ Total bilirubin >1.5 times the ULN (unless with Gilbert's syndrome)
- ☐ Pregnancy (i.e. known pregnancy or positive pregnancy test)
- ☐ Breastfeeding

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order 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
- ☐ Female patients of child-bearing potential or male patients with female partner of child-bearing potential: counseling provided on contraception and risks vs. benefits of treatment. Use effective contraception during therapy and for at least for 5 weeks (female patients) or 3 months (males and female partners) after the final dose.

Additional Inclusion Criteria

The answer to ONE of the following must be fulfilled in order to meet criteria:

- ☐ Patient with metastatic non-small cell lung cancer whose tumor is ROS1-positive
- ☐ Patient with solid tumor that is metastatic or unresectable and:
  - has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation AND
  - has progressed following treatment or has no satisfactory alternative therapy

Prepared: March 2021. Contact: Mark C. Geraci, Pharm.D., BCOP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 12PBM