Telisotuzumab vedotin (EMRELIS)
Criteria for Use
November 2025

VA Pharmacy Benefits Management 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.

See the VA National Formulary Committee Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

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

- ☐ Absolute neutrophil count (ANC) <1,000/mm^3 (unless Duffy null phenotype), platelets <100,000/mm^3
- ☐ CrCl <30 mL/minute
- ☐ Moderate or severe hepatic impairment: total bilirubin >1.5 times ULN and any AST or with liver metastases: total bilirubin >1.5 times ULN, or AST or ALT >5 times ULN
- ☐ Symptomatic or unstable brain metastases
- ☐ History of interstitial lung disease (ILD) or pneumonitis requiring steroids, or prior ILD or pneumonitis within 3 months
- ☐ Evidence of pulmonary fibrosis
- ☐ Grade ≥2 or history of Grade ≥3 peripheral neuropathy
- ☐ Known Pregnancy
- ☐ Lactating

ULN=Upper Limit of Normal; CrCl=creatinine clearance

Inclusion Criteria

ALL of the following criteria must be met:

- ☐ Locally-advanced or metastatic non-squamous *EGFR*-wildtype non-small cell lung cancer (NSCLC)
- ☐ High c-Met protein overexpression (≥50% of tumor cells with strong 3+ staining)
- ☐ Progression on prior systemic cytotoxic chemotherapy and immunotherapy

Additional Inclusion Criteria

All of the following criteria must be met:

- ☐ Care is provided by a VA/VA Community Care oncology provider
- ☐ Eastern Cooperative Oncology Group (ECOG) performance status 0-1
- ☐ 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 provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 2 months after stopping treatment for women and 4 months after for men.

Other Justification

- ☐ _____

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