Tarlatamab-dlle (IMDELLTRA)
Criteria for Use
November 2024

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 the *PBM INTRAnet* site for further information.

Exclusion Criteria

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

- ☐ Facility is not equipped to monitor and manage Cytokine Release Syndrome (CRS) and immune effector cell-associated neurotoxicity (ICANS), if necessary
- ☐ Patient is unable to be monitored during and for 22-24 hours after step-up doses on Cycle 1 Day 1 and Day 8 at an appropriate healthcare setting
- ☐ Patient is unable to stay within 1 hour of an appropriate healthcare facility for 48 hours after Cycle 1 Day 1 and Day 8 infusions
- ☐ Untreated or symptomatic brain metastases and leptomeningeal disease
- ☐ Prior recurrent grade 2 or higher pneumonitis or severe immunotherapy-related adverse events leading to discontinuation
- ☐ Evidence of interstitial lung disease or active, non-infectious pneumonitis
- ☐ Pregnancy
- ☐ Lactation

Inclusion Criteria

All of the following criteria must be met.

- ☐ Extensive stage small cell lung cancer with disease progression after first-line platinum-based chemotherapy
- ☐ Care is provided by a VA/VA Community Care oncology or hematology 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

- ☐ For patients who can become pregnant and patients with partners who can become pregnancy: 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 patients with treated brain metastases: definitive therapy must have been completed at least 2 weeks prior to treatment with no evidence of radiographic central nervous system progression afterwards.

Other Justification

- ☐ _____

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