Enfortumab Vedotin (PADCEV)
Criteria for Use
November 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 enfortumab vedotin.

- ☐ Symptomatic CNS metastases
- ☐ Pre-existing sensory or motor neuropathy ≥ Grade 2
- ☐ Baseline active keratitis or corneal ulceration
- ☐ Moderate or severe hepatic impairment (total bilirubin > 1.5 times the ULN and any AST)
- ☐ 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
- ☐ Patients of child-bearing potential and patients with partners of child-bearing potential: counseling provided on contraception and risks vs. benefits of treatment. Use effective contraception during therapy and for 2 months after the last dose.

^Hyperglycemia and diabetic ketoacidosis occurred in patients with and without pre-existing diabetes mellitus. Patients with a baseline hemoglobin A1C ≥8% were excluded from the trial. Monitor blood glucose in all patients prior to each dose and manage hyperglycemia; hold dose of enfortumab vedotin until blood glucose is < 250mg/dL.

Additional Inclusion Criteria

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

- ☐ Locally advanced or metastatic urothelial carcinoma in patients who had previous PD-1 or PD-L1 inhibitor and platinum-containing chemotherapy
- ☐ Locally advanced or metastatic urothelial carcinoma in patients ineligible for platinum-containing chemotherapy and received at least 1 prior line of therapy

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