

Enfortumab Vedotin (PADCEV) for Combination Therapy in Bladder Cancer

Criteria for Use

March 2024

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 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 \geq Grade 2
- Baseline active keratitis or corneal ulceration
- Moderate or severe hepatic impairment (total bilirubin $>$ 1.5 times the ULN and any AST)
- Immunosuppression including corticosteroid equivalent to $>$ 10 mg per day of prednisone
- Active Autoimmune Disease requiring systemic treatment
- Pregnancy (i.e. known pregnancy or positive pregnancy test)
- Breastfeeding

Inclusion Criteria¹

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

¹Hyperglycemia and diabetic ketoacidosis occurred in patients with and without pre-existing diabetes mellitus. Patients with a baseline hemoglobin A1C \geq 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 the following must be fulfilled in order to meet criteria:

- Locally advanced or metastatic urothelial carcinoma in combination with Pembrolizumab

Additional Inclusion Criteria- Select if applicable

- For patients who can become pregnant and patients 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

Other Justification



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