Tisotumab vedotin-tftv (TIVDAK)
Criteria for Use
November 2025

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 tisotumab.

- ☐ Absolute Neutrophil Count greater than or equal to 1500/mcL unless associated with Duffy-null Associated Neutrophil Count (DANC)
- ☐ Platelet count greater than or equal to 100,000/mcL
- ☐ Clinically significant cardiovascular disease [1]
- ☐ Active or uncontrolled infection
- ☐ Clinically significant bleeding risk (coagulation defects, diffuse alveolar hemorrhage from vasculitis, known bleeding diathesis, ongoing major bleeding, trauma with increased risk of life-threatening bleeding, severe head trauma or intracranial surgery within past 8 weeks)
- ☐ History of intracerebral arteriovenous malformation, cerebral aneurysm or stroke
- ☐ Active ocular surface disease or high-risk for cicatrizing conjunctivitis (e.g. Wagner syndrome, atopic keratoconjunctivitis, autoimmune disease affecting eyes), ocular Stevens-Johnson syndrome, mucus pemphigoid or penetrating ocular transplant. [2]
- ☐ Peripheral neuropathy greater than or equal to grade 2
- ☐ Moderate or severe hepatic impairment (AST greater than 3 times upper limit of normal or total bilirubin greater than 1.5 times the upper limit of normal)
- ☐ Severe renal impairment (CrCl 15 to less than 30 ml/min) or end-stage renal disease
- ☐ Unmanageable drug-drug interaction identified
- ☐ Prior treatment with monomethyl auristatin E (MMAE)-containing drugs
- ☐ Pregnancy
- ☐ Lactating

[1] Including unstable angina or acute MI 6 months prior; CHF (NYHA grade III/IV); reduced EF < 45%; prolonged QTc interval

[2] Patients should be advised NOT to wear contact lenses throughout the course of therapy

Inclusion Criteria

All of the following criteria must be met.

- ☐ Diagnosis of cervical cancer (squamous cell, adenocarcinoma or adenosquamous histology)
- ☐ Disease progression on or after at least one prior chemotherapy regimen for recurrent or metastatic disease and bevacizumab, if eligible, and pembrolizumab, if eligible

Additional Inclusion Criteria

- ☐ Care provided by a VA/VA Community Care hematology/oncology provider
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented
- ☐ Eastern Cooperative Oncology Group Performance Status 0-1

Additional Inclusion Criteria

- ☐ 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 (4 months for male patients with female partners)
- ☐ Advise patients not to breastfeed during treatment and for at least 1 week after the last dose

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