

Tivdak (tisotumab vedotin-tftv)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Tivdak (tisotumab vedotin-tftv)

APPROVAL CRITERIA

Requests for Tivdak (tisotumab vedotin-tftv) may be approved if the following criteria are met:

- I. Individual has a diagnosis of recurrent or metastatic cervical cancer; **AND**
- II. Individual is using as single agent; **AND**
- III. Individual is using as second-line or subsequent therapy after confirmed disease progression on chemotherapy (Label, NCCN 2A); **AND**
- IV. Individual has a current ECOG performance status of 0 to 1.

Tivdak (tisotumab vedotin-tftv) may not be approved for the following:

- I. Individual has moderate or severe hepatic impairment (defined as total bilirubin greater than 1.5 x ULN); **OR**
- II. When the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology powered by ClinicalKey. Tampa (FL): Elsevier. 2022. Available from: <http://www.clinicalkey.com>. Updated periodically.
2. Coleman RL, Lorusso D, Gennigens C, et al. Efficacy and safety of tisotumab vedotin in previously treated recurrent or metastatic cervical cancer (innovaTV 204/GOG-3023/ENGOT-cx6): a multicentre, open-label, single-arm, phase 2 study. *Lancet Oncol*. 2021;22(5):609-619. doi:10.1016/S1470-2045(21)00056-5.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 30, 2022.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 30, 2022.
 - a. Cervical Cancer. V1.2022. Revised October 26, 2021.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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