Medical Drug Clinical Criteria

Subject:	Tivdak (tisotumab vedotin-tftv)		
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Overview

This document addresses the use of Tivdak (tisotumab vedotin-tftv), an antibody-drug conjugate directed at tissue factor that is primarily used to treat cervical cancer.

The FDA approved indication for Tivdak is for the treatment of adults with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. The National Comprehensive Cancer Network compendia also provides a 2A recommendation for this use in the Cervical Cancer and Vaginal Cancer Clinical Practice Guidelines, stating use as second-line or subsequent therapy in recurrent or metastatic disease as a single agent.

Tivdak is the first antibody-drug conjugate to treat adults with recurrent or metastatic cervical cancer and works by targeting tissue factor on cervical cancer cells, resulting in slowing of cell growth or cellular death. In clinical trials, Tivdak was administered to subjects with no more than two prior systemic regimens in the recurrent or metastatic setting, including at least one prior platinum-based (cisplatin, injection or carboplatin, injection) chemotherapy regimen. Approximately 70% of the women had received prior bevacizumab. Treatment for cervical cancer typically includes surgery, radiation, chemotherapy, vascular endothelial growth factor (VEGF) inhibitor bevacizumab, and PD-1 inhibitor pembrolizumab. The chemotherapy most often used to treat recurrent or metastatic cervical cancer includes cisplatin, carboplatin, paclitaxel and topotecan injections.

Definitions and Measures

Chemotherapy: Medical treatment of a disease, particularly cancer, with drugs or other chemicals.

Disease Progression: Cancer that continues to grow or spread.

Line of Therapy:

- First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Tivdak (tisotumab vedotin-tftv)

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 or vaginal cancer (NCCN 2A); **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.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9273	Injection, tisotumab vedotin-tftv, 1 mg [Tivdak]

ICD-10 Diagnosis

C52	Malignant neoplasm of vagina
C53.0-C53.9	Malignant neoplasm of cervix uteri

Document History

Revised: 11/15/2024
Document History:

- 11/15/2024 – Annual Review: Add NCCN 2A recommendation for use in vaginal cancer. Coding Reviewed: Added ICD-10-CM C52.
- 11/19/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 11/18/2022 – Annual Review: Add language for use as second-line in addition to subsequent therapy for use in recurrent or metastatic cervical cancer. Coding Reviewed: No changes.
- 11/19/2021 – Annual Review: Add new clinical criteria document for Tivdak. Coding Review: Add HCPCS J3490, J3590, J9999. All diagnoses pend. Effective 4/1/2022 Added HCPCS J9273. Added ICD-10-CM C53.0-C53.9. Removed HCPCS J3490, J3590, J9999. Removed all diagnoses pend.

References

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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: October 10, 2024.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 10, 2024.
    a. Cervical Cancer. V4.2024. Revised September 24, 2024.
    b. Vaginal Cancer. V2.2025. Revised August 8, 2024.