Tivdak® (tisotumab vedotin-tftv)
(Intravenous)

-E-

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 200 billable units (200 mg) every 21 days

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1,2]

- Patient has had an ophthalmic exam (i.e., visual acuity and slit lamp exam of the anterior segment of the eye, and an assessment of normal eye movement) at baseline, prior to every cycle for the first nine cycles, and as clinically indicated

Cervical Cancer † ‡ [1-5]

- Used as subsequent therapy; **AND**
- Patient has recurrent or metastatic disease; **AND**
- Patient has adenocarcinoma, adenosquamous, or squamous cell carcinoma histology; **AND**
  - Used as single agent therapy **†**; **AND**
    - Patient has received at least one prior platinum-based chemotherapy regimen**; OR**
  - Used in combination with pembrolizumab **‡**; **AND**

- Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test; **AND**
- Patient is immuno-oncology therapy naïve

Vaginal Cancer ‡ [2-4,2e]

- Used as subsequent therapy; **AND**
- Patient has recurrent or metastatic disease; **AND**
- Patient has adenocarcinoma or squamous cell carcinoma histology; **AND**
- Used as single agent therapy; **AND**
- Patient has received at least one prior platinum-based chemotherapy regimen; **AND**

• Use of tisotumab vedotin will be restricted to patients with a contraindication or intolerance to cemiplimab

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

v *If confirmed using an FDA-approved assay – http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1]

Prior authorization validity may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: peripheral neuropathy, hemorrhage, persistent or recurrent grade 2 or greater pneumonitis, ocular adverse reactions (e.g., conjunctival adverse reactions, dry eye, corneal adverse reactions, blepharitis, ulcerative keratitis, etc.), severe cutaneous adverse reactions including Stevens-Johnson Syndrome (SJS), etc.

V. Dosage/Administration [1,3,5]

Indication	Dose
All indications	Administer 2 mg/kg (up to a maximum of 200 mg) by intravenous infusion every 3 weeks until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code:

- J9273 – Injection, tisotumab vedotin-tftv, 1 mg; 1 billable unit = 1 mg

NDC:

- Tivdak 40 mg as a lyophilized cake or powder in a single-dose vial for reconstitution: 51144-0003-xx

VII. References (STANDARD)

1. Tivdak [package insert]. Bothell, WA; Seagen, Inc; July 2023. Accessed October 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) tisotumab vedotin. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2025.
3. Coleman RL, Lorusso D, Gennigens C, et al; innovaTV 204/GOG-3023/ENGOT-cx6 Collaborators. 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 May;22(5):609-619. doi: 10.1016/S1470-2045(21)00056-5. Epub 2021 Apr 9.
4. Vergote I, Gonzalez-Martin A, Fujiwara K, et al. Tisotumab Vedotin as Second- or Third-Line Therapy for Recurrent Cervical Cancer. N Engl J Med 2024; 391:44-45. doi: 10.1056/NEJMoa2313811. PMID: 38959480.
5. Vergote I, Van Nieuwenhuysen E, O'Cearbhaill RE, et al. Tisotumab Vedotin in Combination With Carboplatin, Pembrolizumab, or Bevacizumab in Recurrent or Metastatic Cervical Cancer: Results From the innovaTV 205/GOG-3024/ENGOT-cx8 Study. J Clin Oncol 2023;41:5536-5549. doi: 10.1200/JCO.23.00720.

VIII. References (ENHANCED)

1e. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Cervical Cancer. Version 4.2025. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2025.

2e. Tewari KS, Monk BJ, Vergote I, et al. Survival with Cemiplimab in Recurrent Cervical Cancer. N Engl J Med 2022;386:544-555.

3e. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Vaginal Cancer. Version 5.2025. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2025.

4e. Prime Therapeutics Management. Tivdak Clinical Literature Review Analysis. Last updated October 2025. Accessed October 2025.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C52	Malignant neoplasm of vagina
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix

C53.8	Malignant neoplasm of overlapping sites of cervix uteri
C53.9	Malignant neoplasm of cervix uteri, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC