Tivdak® (tisotumab vedotin-tftv)
(Intravenous)

Document Number: EOCCO-0624

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Tivdak 40 mg single-dose vial: 5 vials every 21 days

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

- 200 billable units (200 mg) every 21 days

III. Initial Approval Criteria [1]

Coverage 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) at baseline, prior to each dose, and as clinically indicated; **AND**
- Used as single agent therapy; **AND**

Cervical Cancer † ‡ [1-3]

- Used as subsequent therapy; **AND**
- Patient has recurrent or metastatic disease; **AND**
- Patient has adenocarcinoma, adenosquamous, or squamous cell carcinoma histology

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

IV. Renewal Criteria [1]

Coverage 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]

Indication	Dose
Cervical Cancer	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

1. Tivdak [package insert]. Bothell, WA; Seagen, Inc; July 2023. Accessed January 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) tisotumab vedotin. National Comprehensive Cancer Network, 2024. 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 January 2024.
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.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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