Tivdak™ (tisotumab vedotin-tftv)
(Intravenous)

Document Number: IC-0624

Last Review Date: 04/01/2022
Date of Origin: 10/01/2021
Dates Reviewed: 10/2021, 04/2022

I. Length of Authorization

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

II. Dosing Limits

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

- Tivdak 40 mg SDV: 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 at least 18 years of age; **AND**

Universal Criteria [1]

- Patient does not have active ocular surface disease or a history of cicatricial conjunctivitis; **AND**
- Patient has not had prior Steven-Johnson syndrome; **AND**
- Patient does not have Grade ≥2 peripheral neuropathy; **AND**
- Patient does not have known coagulation defects leading to an increased risk of bleeding; **AND**
- 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 † [1,2,3]

- Patient has recurrent or metastatic disease; **AND**
- Used as subsequent therapy; **AND**
- Patient has not received more than two prior systemic regimens including at least one prior platinum-based chemotherapy regimen

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

IV. Renewal Criteria [1,10,13]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet 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 the following: peripheral neuropathy, hemorrhage, recurrent or persistent grade 2 or greater pneumonitis, keratitis, conjunctival ulceration, etc.

V. Dosage/Administration [1,11-13]

Indication	Dose
Cervical Cancer	Administer 2 mg/kg (up to a maximum of 200 mg) given as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code:

- J9999 – Not otherwise classified, antineoplastic drug *(Discontinue use on 04/01/2022)*
- C9399 – Unclassified drug, not otherwise specified (Hospital outpatient use only) *(Discontinue use on 04/01/2022)*
- J9273 – Injection, tisotumab vedotin-tftv, 1 mg; 1 billable unit = 1 mg *(Effective on 04/01/2022)*

NDC:

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

VII. References

1. Tivdak [package insert]. Bothell, WA; Seagen, Inc; September 2021. Accessed September 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) tisotumab vedotin. National Comprehensive Cancer Network, 2021. 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 September 2021.
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)

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered 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