

Clinical Policy: Tisotumab Vedotin-tftv (Tivdak)

Reference Number: LA.PHAR.561

Effective Date:

Last Review Date: 05.01.23

Line of Business: Medicaid

Coding Implications
Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

Please note: This policy is for medical benefit

Description

Tisotumab vedotin-tftv (Tivdak[™]) is a tissue factor directed antibody and microtubule inhibitor conjugate.

FDA Approved Indication(s)

Tivdak is indicated for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections[®] that Tivdak is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

- **A.** Cervical Cancer (must meet all):
 - 1. Diagnosis of cervical cancer;
 - 2. Disease is recurrent or metastatic;
 - 3. Prescribed by or in consultation with an oncologist;
 - 4. Age \geq 18 years;
 - 5. Failure of single-agent or combination chemotherapy regimen (*see Appendix B for examples*);
 - 6. Prescribed as single-agent therapy;
 - 7. Documentation of member's current weight in kilograms;
 - 8. Request meets one of the following (a or b):*
 - a. Dose does not exceed 2 mg/kg (up to a maximum dose of 200 mg for members ≥ 100 kg) every 3 weeks;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

^{*}Prescribed regimen must be FDA-approved or recommended by NCCN



Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2):

- 1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
- 2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

II. Continued Therapy

A. Cervical Cancer (must meet all):

- 1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Tivdak for a covered indication and has received this medication for at least 30 days;
- 2. Member is responding positively to therapy;
- 3. Prescribed as single-agent therapy;
- 4. Member is receiving at least 0.9 mg/kg every 3 weeks;
- 5. Documentation of member's current weight in kilograms;
- 6. If request is for a dose increase, request meets one of the following (a or b):*
 - a. New dose does not exceed 2 mg/kg (up to a maximum dose of 200 mg for patients \geq 100 kg) every 3 weeks;
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

- 1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
- 2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives



This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization

and may require prior autho	rization.	
Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
paclitaxel/cisplatin ± bevacizumab (Avastin®, Mvasi®, Zirabev™)	 Paclitaxel: 135 mg/m2 or 175 mg/m2 IV on Day 1 Cisplatin: 50 mg/m² IV on Day 1 or 2 With or without bevacizumab: 15 mg/kg IV on day 	Varies
	Repeat every 3 weeks until disease progression or unacceptable toxicity	
paclitaxel/carboplatin ± bevacizumab (Avastin®, Mvasi®, Zirabev™)	 Paclitaxel 135 mg/m² IV over 3 hours Carboplatin target AUC 5 IV With or without bevacizumab: 15 mg/kg IV on day Repeat every 3 weeks until disease progression or unacceptable toxicity 	Varies
topotecan (Hycamtin®) /paclitaxel ± bevacizumab (Avastin®, Mvasi®, Zirabev™)	 Paclitaxel: 175 mg/m² on day 1 Topotecan: 0.75 mg/m² on days 1,2, and 3 With or without bevacizumab: 15 mg/kg IV on day Repeat every 3 weeks until disease progression or unacceptable toxicity 	Varies
paclitaxel/cisplatin	 Paclitaxel: 135 mg/m² over 24 hours Cisplatin: 50 mg/m² on day 1 Repeat every 3 weeks for a maximum of 6 cycles in non-responders or until disease progression or unacceptable toxicity 	Varies
paclitaxel/carboplatin	 Paclitaxel 135 mg/m² IV over 3 hours on day 1 until disease progression or unacceptable toxicity Carboplatin: Target AUC 5 IV every 3 weeks for 6 to 9 cycles 	Varies
cisplatin/topotecan (Hycamtin®)	 Cisplatin: 50 mg/m² IV on day 1 Topotecan: 0.75 mg/m²/day IV for days 1,2, and 3 	Varies



Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Repeat every 3 weeks for a maximum of 6 cycles in nonresponders or until disease progression or unacceptable toxicity	
paclitaxel/topotecan (Hycamtin®)	 Paclitaxel: 175 mg/m² on day 1 Topotecan: 0.75 mg/m² on days 1,2, and 3 	Varies
	Repeat every 3 weeks until disease progression or unacceptable toxicity	
Keytruda [®] (pembrolizumab) + paclitaxel/cisplatin ± bevacizumab (Avastin [®] , Mvasi [®] , Zirabev [™]) for PD-L1-positive tumors	Varies	Varies
cisplatin	40 mg/m ² over 4 hours to radiation therapy on days 1,8,15,22,29 and 36	Varies
carboplatin	400 mg/m ² on day 1 every 28 days	Varies
paclitaxel	Varies	Varies

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

• Contraindication(s): None reported

• Boxed warning(s): Ocular toxicity

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Cervical cancer	2 mg/kg IV over 30 minutes every 3 weeks until disease progression or	2mg/kg, 200 mg for members ≥ 100kg
	unacceptable toxicity	members ≥ 100kg

V. Product Availability

Intravenous powder for solution, single-dose vial: 40 mg

VI. References

- 1. Tivdak Prescribing Information. Bothell, WA: Seagen Inc.; January 2022. Available at: https://www.tivdakhcp.com. Accessed August 3, 2022.
- 2. A Trial of Tisotumab Vedotin in Cervical Cancer. ClinicalTrials.gov Identifier: NCT03438396. Available at: https://clinicaltrials.gov/ct2/show/NCT03438396. Accessed October 18, 2021.



- 3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 3, 2022.
- 4. National Comprehensive Cancer Network. Cervical Cancer Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf. Accessed August 2, 2022.
- 5. Kitagwa R, Katsumata N, Shibata T, et al. Paclitaxel Plus Carboplatin Versus Paclitaxel Plus Cisplatin in Metastatic or Recurrent Cervical Cancer: The Open-Label Randomized Phase III Trial. J Clin Oncol 2015; 33(19)2129-2135.
- 6. Tewari KS, Sill MW, Penson RT, et al. Bevacizumab for advanced cervical cancer: final overall survival and adverse event analysis of a randomised, controlled, open-label, phase 3 trial (Gynecologic Oncology Group 240). Lancet. 2017;390(10103):1654-1663.
- 7. Monk BJ, Sill MW, McMeekin DS, et al. Phase III trial of four cisplatin-containing doublet combinations in stage IVB, recurrent, or persistent cervical carcinoma: a Gynecologic Oncology Group study. J Clin Oncol. 2009;27(28):4649-4655. doi:10.1200/JCO.2009.21.8909.
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- 11. Weiss GR, Green S, Hannigan EV, et al. A phase II trial of carboplatin for recurrent or metastatic squamous carcinoma of the uterine cervix: a Southwest Oncology Group study. Gynecol Oncol. 1990;39(3):332-336.

Coding Implications

HCPCS	Description
Codes	
J9273	Injection, tisotumab vedotin-tftv, 1 mg

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Policy created	05.01.23	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program



approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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