Clinical Policy: Tisotumab Vedotin-tftv (Tivdak)

Reference Number: PA.CP.PHAR.561
Effective Date: 10/2022
Last Review Date: 11/2024

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

It is the policy of PA Health & Wellness® that Tivdak is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Cervical Cancer, Vaginal Cancer (off-label) (must meet all)**:**

1. Diagnosis of cervical cancer or vaginal cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is recurrent or metastatic;
5. Disease has progressed on or after prior chemotherapy (*see Appendix B for examples*);
6. Prescribed one of the following:
   a. As a single-agent;
   b. With Keytruda for PD-L1 positive tumors (combined positive score [CPS] ≥ 1) if no prior immuno-oncology therapy received;
7. Documentation of member's current weight in kilograms (kg);
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*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. Prescribed one of the following:
    a. As a single-agent;
    b. With Keytruda for PD-L1 positive tumors (combined positive score [CPS] ≥ 1) if no prior immuno-oncology therapy received;
4. Documentation of member's current weight in kg;
5. Dose is at least 0.9 mg/kg every 3 weeks;
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 ≥ 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*).

Approval duration: 12 months

B. Other diagnoses/indications

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. 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 and may require prior authorization.

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/m^2 IV on Day 1 or 2	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	• With or without bevacizumab: 15 mg/kg IV on day Repeat every 3 weeks until disease progression or unacceptable toxicity	
paclitaxel/carboplatin ± bevacizumab (Avastin®, Mvasi®, Zirabev™)	• Paclitaxel 135 mg/m^2 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/m^2 on day 1 • Topotecan: 0.75 mg/m^2 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/m^2 over 24 hours • Cisplatin: 50 mg/m^2 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/m^2 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/m^2 IV on day 1 • Topotecan: 0.75 mg/m^2/day IV for days 1,2, and 3 Repeat every 3 weeks for a maximum of 6 cycles in nonresponders or until disease progression or unacceptable toxicity	Varies
paclitaxel/topotecan (Hycamtin®)	• Paclitaxel: 175 mg/m^2 on day 1 • Topotecan: 0.75 mg/m^2 on days 1,2, and 3 Repeat every 3 weeks until disease progression or unacceptable toxicity	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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

V. Dosage and Administration

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

VI. Product Availability

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

VII. References

1. Tivdak Prescribing Information. Bothell, WA: Seagen Inc.; January 2022. Available at: https://www.tivdakhcp.com. Accessed July 17, 2024.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 8, 2024.
3. National Comprehensive Cancer Network. Cervical Cancer Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf. Accessed August 8, 2024.
4. National Comprehensive Cancer Network. Vaginal Cancer Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/vaginal.pdf. Accessed August 8, 2024.

Coding Implications

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

Reviews, Revisions, and Approvals	Date
Policy created	10/2022
4Q 2023 annual review: no significant changes; references reviewed and updated.	10/2023
4Q 2023 annual review: added vaginal cancer per NCCN; references reviewed and updated.	10/2024