Clinical Policy Title:	tisotumab vedotin-tftv
Policy Number:	RxA.705
Drug(s) Applied:	Tivdak™
Original Policy Date:	12/07/2021
Last Review Date:	12/07/2021
Line of Business Policy Applies to:	All lines of business

Background

Tisotumab vedotin-tftv (Tivdak™) is a tissue factor-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
tisotumab vedotin-tftv (Tivdak™)	Recurrent or metastatic cervical cancer with disease progression on or after chemotherapy	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	2 mg/kg intravenous (Max: 200 mg)

Dosage Forms

- For Injection: 40 mg as a lyophilized cake or powder in a single-dose vial for reconstitution.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Cervical cancer (must meet all):

1. Diagnosis of cervical cancer;
2. Disease is recurrent or metastatic with disease progression on or after chemotherapy;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Patient should have received at least 1 prior platinum-based chemotherapy (eg. cisplatin or carboplatin);
6. Patient's ECOG performance status is 0-1;
7. Requested dose does not exceed 200 mg once every three weeks.

Approval Duration

Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Recurrent or metastatic cervical cancer (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 200 mg once every three weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Avastin®, Mvasi®, Zirabev™	15 mg/kg intravenous every 3 weeks with paclitaxel and cisplatin, or paclitaxel and topotecan	15 mg/kg intravenous every 3 weeks or 10 mg/kg intravenous every 2 weeks
Keytruda®	200 mg every 3 weeks or 400 mg every 6 weeks.	200 mg intravenous every 3 weeks OR 400 mg intravenous every 6 weeks.
topotecan (Hycamtin®)	0.75 mg/m^2 by intravenous infusion over 30 minutes on Days 1, 2, and 3, with cisplatin 50 mg/m^2 on Day 1, of a 21-day cycle	Intravenous: 4 mg intravenous Oral: 2.3 mg/m^2 per day orally

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

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - Ocular toxicity
    - Tivdak™ caused changes in the corneal epithelium and conjunctiva resulting in changes in vision, including severe vision loss, and corneal ulceration.
    - Conduct an ophthalmic exam at baseline, prior to each dose, and as clinically indicated.
    - Adhere to premedication and required eye care before, during, and after infusion.

- Withhold Tivdak™ until improvement and resume, reduce the dose, or permanently discontinue, based on severity.
- Caution should be used in patients with the following comorbidities, as these patients were excluded from enrollment in the innovaTV 204 clinical trial: patients with active ocular surface disease, grade ≥2 peripheral neuropathy, or known coagulation defects leading to an increased risk of bleeding.

APPENDIX D: General Information

- Tivdak™ may cause fertility problems in males, which may affect your ability to father children.

References

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Policy established.	12/07/2021	12/07/2021