Medical Policy:

Tivdak (tisotumab vedotin) injection; powder for solution

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.344	January 2, 2024	December 9, 2021

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Tivdak, a tissue factor-directed antibody and microtubule inhibitor conjugate, is indicated for the treatment of adults with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

Length of Authorization

Approvals with be granted for 12 months

Dosing Limits [Medical Benefit]

2 mg/kg (MAX 200 mg for patients 100 kg or greater) IV infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity
200 billable units (200 mg) every 21 days

Guideline

I. Initial Approval Criteria

1. **Cervical cancer:** Approve if the patient meets all the following criteria:
   A. Patient is > 18 years of age **AND**
   B. Patient has a diagnosis of recurrent or metastatic Cervical cancer; **WITH**
   C. Disease progression on or after chemotherapy **AND**
   D. Medication is prescribed by or in consultation with an oncologist

Limitations/Exclusions

1. Disease progression while taking Tivdak (tisotumab vedotin-tftv).
2. Concurrent use with other anticancer therapy.
3. Dosing exceeds single dose limit of Tivdak (tisotumab vedotin-tftv) 2 mg/kg (up to maximum 200 mg for weight ≥ 100 kg).

Applicable Procedure Codes

Code	Description
J9273	Injection, tisotumab vedotin-tffv, 1mg

Applicable NDCs

Code	Description
51144-0003-01	Tivdak 40mg Solution, reconstituted

ICD-10 Diagnoses

Code	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

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: Initial Criteria: Cervical Cancer: Removed: "Prior Keytruda (pembrolizumab) therapy if PD-L1 (combined positive score [CPS ≥1]) confirmed by any test AND"
EmblemHealth & ConnectiCare	4/17/2023	Annual Review: Removed codes D06.1, D06.7 and D06.9
EmblemHealth & ConnectiCare	1/17/2023	Transfer to New Template, remove unclassified codes (C9399 and J9999), added J9273
EmblemHealth & ConnectiCare	12/9/2021	New Policy

References

1. Tivdak™ intravenous infusion [prescribing information]. Bothell, WA: Seagen, and Plainsboro, NJ: Genmab; November 2021.