Tivdak (tisotumab vedotin-tftv)

Humana

Pharmacy Coverage Policy

Effective Date: December 24, 2021
Revision Date: November 30, 2022
Review Date: November 16, 2022
Line of Business: Medicare, Commercial, Medicaid - South Carolina, Medicaid - Ohio
Policy Type: Prior Authorization

Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. 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. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically.

Description

Tivdak (tisotumab vedotin-tftv), a tissue factor-directed antibody and microtubule inhibitor conjugate, binds to the human IgG1.
Tivdak (tisotumab vedotin-tftv) is indicated for treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.
Tisotumab vedotin-tftv is available Tivdak 40 mg lyophilized cake or powder in a single-dose vial for reconstitution.

Coverage Determination

Please note the following regarding medically accepted indications:

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per

CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Tivdak (tisotumab vedotin-tftv) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Recurrent/ Metastatic Cervical Cancer

- The member has recurrent or metastatic cervical cancer **AND**
- The member experienced disease progression after chemotherapy **AND**
- If the disease expresses CPS score of greater than equal to 1 **AND**
    - The member has a medical reason why Keytruda (pembrolizumab) can not be initiated as subsequent therapy* **AND**
- Tivdak (tisotumab vedotin-tftv) is administered as monotherapy as subsequent therapy

*For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.

Tivdak (tisotumab vedotin-tftv) will be approved in six month durations or as determined through clinical review.

Coverage Tivdak (tisotumab vedotin-tftv) therapy is not considered medically necessary for

Limitations

members with the following concomitant conditions:

- Member experiences disease progression on Tivdak (tisotumab vedotin-tftv)
- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Tivdak (tisotumab vedotin-tftv).

Warnings and Precautions:

- Peripheral Neuropathy
- Hemorrhage
- Pneumonitis
- Embryo-fetal toxicity

Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Tivdak; tisotumab vedotin-tftv; metastatic; recurrent; cervical cancer; antibody drug conjugate

References

Tivdak (tisotumab vedotin-tftv) [prescribing information]. Seagen Inc. Bothell, WA; January 2022.