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HEALTHCARE YOU CAN FEEL GOOD ABOUT

CENTRAL HEALTH MEDICARE PLAN

Medical Policy

Tivdak® (tisotumab vedotin)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-102
CURRENT VERSION EFFECTIVE DATE	1/1/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov *for additional information.*

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Tivdak® (tisotumab vedotin) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Tivdak will be provided for 6 months and may be renewed.

- Max Units (per dose and over time): 200 mg every 21 days

Initial

A. Patient is 18 years of age or older; **AND**
B. Patient does not have active ocular surface disease or a history of cicatricial conjunctivitis; **AND**
C. Patient has not had prior Steven-Johnson syndrome; **AND**

D. Patient does not have Grade ≥2 peripheral neuropathy; **AND**
E. Patient does not have known coagulation defects leading to an increased risk of bleeding; **AND**
F. Patient has had an ophthalmic exam (i.e., visual acuity and slit lamp exam) at baseline, prior to each dose and as clinically indicated; **AND**
G. Tivdak will be used as single agent therapy; **AND**

Cervical Cancer

A. Patient has recurrent or metastatic disease; **AND**
B. Tivdak will be used as subsequent therapy; **AND**
C. Patient has not received more than two prior systemic regimens including at least one prior platinum-based chemotherapy regimen.

Renewal

A. Patient continues to meet initial criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc.; **AND**
B. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
C. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: peripheral neuropathy, hemorrhage, recurrent or persistent grade 2 or greater pneumonitis, keratitis, conjunctival ulceration, etc.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

A. TIVDAK™ (tisotumab vedotin-tftv) for injection, for intravenous use. Initial U.S. Approval: 2021
    a. TIVDAK (tisotumab vedotin-tftv) is supplied as a white to off-white lyophilized cake or powder in a 40 mg single-dose vial for reconstitution.

CODING

Applicable NDC Codes	
51144-0003-01	Tivdak 40 mg as a lyophilized cake or powder in a SDV for reconstitution:

Applicable Procedure Code	
J9999	Not otherwise classified, antineoplastic drug

Applicable ICD-10 Codes	
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix
C53.8	Malignant neoplasm of overlapping sites of cervix uteri

Applicable ICD-10 Codes	
C53.9	Malignant neoplasm of cervix uteri, unspecified

EVIDENCE BASED REFERENCES

1. Tivdak [package insert]. Bothell, WA; Seagen, Inc; January 2022. Accessed January 2022.

POLICY HISTORY

Original Effective Date	5/24/2022
Revised Date	March 1, 2023 - Adopted by MA UM Committee (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)
P&T Committee Endorsement	5/24/2022