Medical Policy

Kimmtrak® (tebentafusp-tebn)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-105
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Kimmtrak® (tebentafusp-tebn) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Kimmtrak will be provided for 6 months (after the initial first three infusions) and may be renewed.

- Max Units (per dose and over time): 68 mcg weekly

Initial

A. Patient is 18 years of age or older; **AND**

B. Patient has received the first three infusions (i.e., Day 1, 8, 15) in an appropriate healthcare setting and did not experience any Grade 2 or worse hypotension (i.e., hypotension requiring medical intervention); **AND**
C. Patient does not have a clinically significant cardiac disease or impaired cardiac function (i.e., congestive heart failure [NYHA grade ≥ 2], uncontrolled hypertension or clinically significant arrhythmia requiring medical treatment, QT interval > 470 msec or congenital long QT syndrome, acute myocardial infarction, or unstable angina pectoris < 6 months prior to start of therapy); **AND**
D. • Patient does not have symptomatic or untreated brain metastases; **AND**

Uveal Melanoma

A. Patient has unresectable or metastatic disease; **AND**
B. Patient has HLA-A*02:01 genotype positive disease as determined by an FDA-approved or CLIA compliant test (If confirmed using an immunotherapy assay- http://www.fda.gov/companiondiagnostics); **AND**
C. Patient has not received prior systemic therapy for metastatic or advanced uveal melanoma or localized liver-directed therapy (Note: Prior neoadjuvant or adjuvant therapy is allowed provided administered in the curative setting in patients with localized disease).

Renewal

A. Patient continues to meet initial criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc.; **AND**
B. Patient has received the first three infusions (i.e., Day 1, 8, 15) in an appropriate healthcare setting and did not experience any Grade 2 or worse hypotension (i.e., hypotension requiring medical intervention); **AND**
C. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
D. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: persistent/severe cytokine release syndrome, severe dermatological reactions, severe elevated liver enzymes, etc.

LIMITATIONS/EXCLUSIONS

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

DEFINITIONS

A. KIMMTRAK (tebentafusp-tebn) injection, for intravenous use. Initial U.S. Approval: 2022
    a. Each KIMMTRAK (tebentafusp-tebn) injection carton (NDC 80446-401-01) contains:
    b. One single-dose vial containing 100 mcg of tebentafusp-tebn in 0.5 mL of sterile, preservative-free, clear, colorless or slightly yellowish solution.

CODING

Applicable NDC Codes	
80446-0401-xx	Kimmtrak 100 mcg/0.5 mL solution in a SDV

Applicable Procedure Code	
J9274	Injection, tebentafusp-tebn, 1 microgram

Applicable ICD-10 Codes	
C69.30	Malignant neoplasm of unspecified choroid
C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
C69.60	Malignant neoplasm of unspecified orbit
C69.61	Malignant neoplasm of right orbit
C69.62	Malignant neoplasm of left orbit

EVIDENCE BASED REFERENCES

1. Kimmtrak [package insert]. Conshohocken, PA; Immunocare, Ltd., January 2022. Accessed February 2022.

POLICY HISTORY

Original Effective Date	5/24/2022
Revised Date	**V2:** 2/16/2023 - Updated HCPCS for Kimmtrack (J9274) **V3:** 01/01/2024 - Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan
P&T Committee Endorsement	5/24/2022 V2: 2/28/2023