Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Tebentafusp-tebn (Kimmtrak®)	MP-RX-FP-143-24	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of *Tebentafusp-tebn (Kimmtrak®),* a bispecific gp100 peptide-HLA-directed CD3 T cell engager that activates CD3+ T cells to inflammatory cytokines and cytolytic proteins, which results in direct lysis of uveal melanoma tumour cells.

Background Information

Tebentafusp-tebn is a bispecific gp100 peptide-HLA-directed CD3 T cell engager indicated for the treatment of HLA-A*02:01 – positive adult patients with unresectable or metastatic uveal melanoma. Tebentafusp is only effective in HLA-A*02:01-positive patients.

The NCCN guidelines also provides category 1 rating for this FDA indication in uveal melanoma.

Kimmtrak has a black box warning for cytokine release syndrome. Cytokine release syndrome (CRS), which may be serious or life- threatening, occurred in patients receiving Kimmtrak.

Definitions and Measures

- Melanoma: A type of cancer that begins in the melanocytes. Melanoma is also referred to as malignant melanoma and cutaneous melanoma.
- Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.
- Unresectable: Unable to be removed with surgery.

Approved Indications

A. Treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.

Other Uses

i. None.

Policy Name	Policy Number	Scope
Tebentafusp-tebn (Kimmtrak®)	MP-RX-FP-143-24	☒ MMM MA ☒ MMM Multihealth

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J9274	Injection, tebentafusp-tebn, 1 microgram [Kimmtrak]

ICD-10	Description
C69.30-C69.62	Malignant neoplasm of unspecified choroid

Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Tebentafusp-tebn (Kimmtrak®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual is 18 years of age or older: **AND**
ii. Individual has a diagnosis of unresectable or metastatic uveal melanoma; **AND**
iii. Individual is using Kimmtrak for the treatment of HLA-A*02:01 positive genotype uveal melanoma; **AND**
iv. Individual has an ECOG performance status of 0-1.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Tebentafusp-tebn (Kimmtrak®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. The following information should be submitted for reauthorization:

Policy Name	Policy Number	Scope
Tebentafusp-tebn (Kimmtrak®)	MP-RX-FP-143-24	☒ MMM MA ☒ MMM Multihealth

A. A current oncology note documenting the patient's response to treatment showing no progression of disease.
B. A current oncology note documenting the patient's response to treatment showing no evidence of unacceptable toxity.
C. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

i. Initial Approval Duration: Up to 6 months
ii. Reauthorization Approval Duration: Up to 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Requests for Kimmtrak may not be approved when the above criteria (section A: Criteria for Initial Approval) are not met and for all other indications.

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug dosage form and strength	Day	Recommended Dosage
Tebentafusp-tebn (Kimmtrak®) 100 mcg/0.5 mL SDV	1	20 mcg IV
	8	30 mcg IV
	15	68 mcg IV
	Once weekly thereafter	68mcg IV
Exceptions		
• Dosage interruption or permanent discontinuation may be required based on individual safety and tolerability. • Elevations in liver enzymes occurred in patients treated with KIMMTRAK. Monitor ALT, AST, and total bilirubin.		

Policy Name	Policy Number	Scope
Tebentafusp-tebn (Kimmtrak®)	MP-RX-FP-143-24	☒ MMM MA ☒ MMM Multihealth

Reference Information

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 11, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. Nathan P, Hassel JC, Rutkowski P, et al. Overall Survival Benefit with Tebentafusp in Metastatic Uveal Melanoma. N Engl J Med 2021;385:1196-1206.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 17, 2023
    a. Uveal Melanoma. V2.2022. Revised April 5, 2022.
7. NCT04960891. ClinicalTrials.gov. U.S National Library of Medicine, National Institutes of Health website. Available at: https://clinicaltrials.gov/ct2/show/NCT04960891?term=tebentafusp&draw=1&rank=1.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review 12/20/2024	Update service description. Added dosage form and strength, and monitoring recommendation per FDA label to quantity limits table. Updated references and federal statement. Minor wording and formatting changes. Coding Reviewed: No changes.	3/20/2025	4/2/2025
Policy Inception 01/26/2024	New Medical Policy creation	4/18/2024	6/28/2024