UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Kimmtrak Utilization Management Medical Policy
- Kimmtrak® (tebentafusp-tebn intravenous infusion – Immunocore)

REVIEW DATE: 02/19/2025

OVERVIEW

Kimmtrak, a bispecific gp100 peptide-human leukocyte antigen (HLA)-directed CD3 T cell engager, is indicated for the treatment of HLA-A*02:01-positive, unresectable or metastatic **uveal melanoma** in adults.[1]

Dosing Information

The recommended dose of Kimmtrak administered by intravenous infusion is:[1]
- 20 mcg on Day 1
- 30 mcg on Day 8
- 68 mcg on Day 15 and once weekly thereafter.

It is recommended that treatment continue until disease progression or unacceptable toxicity.

Guidelines

The National Comprehensive Cancer Network melanoma: uveal (version 1.2024 – May 23, 2024) clinical practice guidelines recommend Kimmtrak as a "Preferred" regimen for patients with metastatic or unresectable disease who are HLA-A*02:01 positive (category 1).[2,3]

Safety

Kimmtrak has a Boxed Warning for cytokine release syndrome which may be serious or life-threatening.[1]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Kimmtrak. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Kimmtrak as well as the monitoring required for adverse events and long-term efficacy, approval requires Kimmtrak to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Kimmtrak is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. **Uveal Melanoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has unresectable or metastatic disease; AND
   - **C)** The tumor is HLA-A*02:01 positive; AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 68 mcg administered by intravenous infusion given no more frequently than once weekly.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Kimmtrak is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Kimmtrak intravenous infusion [prescribing information]. Conshohocken, PA: Immunocore; June 2024.
2. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 10, 2025. Search term: tebentafusp.
3. The NCCN Melanoma: Uveal Clinical Practice Guidelines in Oncology (version 1.2024 – May 23, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 10, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	02/08/2023
Annual Revision	No criteria changes.	02/07/2024
Annual Revision	No criteria changes.	02/19/2025