

Medical Drug Clinical Criteria

Subject:	Kimmtrak (tebentafusp-tebn)		
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Overview

This document addresses the use of Kimmtrak (tebentafusp-tebn). Kimmtrak 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.

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.

Clinical Criteria

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.

Kimmtrak (tebentafusp-tebn)

Requests for Kimmtrak (tebentafusp-tebn) may be approved if the following criteria are met (Label, NCCN 1, NCT04960891):

- 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.

Requests for Kimmtrak (tebentafusp-tebn) may not be approved when the criteria above are not met and all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

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

ICD-10 Diagnosis

C69.30-C69.32	Malignant neoplasm of choroid
C69.40-C69.42	Malignant neoplasm of ciliary body
C69.60-C69.62	Malignant neoplasm of orbit

Document History

Reviewed: 02/21/2025

Document History:

- 02/21/2025 – Annual Review: No criteria changes. Coding Reviewed: Removed ICD-10-CM C69.50-C69.52 from range C69.30-C69.62 and updated descriptions.
- 02/23/2024 – Annual Review: No criteria changes. Added references. Coding Reviewed: No changes.
- 02/24/2023 – Annual Review: No Changes. Coding Reviewed: No changes.
- 02/25/2022 – Annual Review: New document for Kimmtrak clinical criteria. Coding Reviewed: Added HCPCS J3490, J3590, J9999, C9399. All diagnoses pend. Effective 7/1/2022 Added HCPCS C9095. Removed HCPCS C9399. Added ICD-10-CM C69.30-C69.32. Removed All Diagnoses pend. Effective 10/1/2022 Added HCPCS J9274. Removed HCPCS C9095, J3490, J3590, J9999.

References

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2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
4. 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.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 17, 2025.
 - a. Uveal Melanoma. V1.2024. Revised May 23, 2024.
6. 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 policies may take precedence over the application of this clinical criteria.

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