# Clinical Criteria

Subject: Kimmtrak (tebentafusp-tebn)

**Document #:** ING-CC-0211 **Publish Date:** 03/16/2022

Status: New Last Review Date: 02/25/2022

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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.

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, 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**

J3490	Unclassified drugs (when specified as [Kimmtrak] (tebentafusp-tebn))
J3590	Unclassified biologics (when specified as [Kimmtrak] (tebentafusp-tebn))
J9999	Not otherwise classified, antineoplastic drugs (when specified as [Kimmtrak] (tebentafusp-tebn))
C9399	Unclassified drugs or biologicals (when specified as [Kimmtrak] (tebentafusp-tebn))

#### ICD-10 Diagnosis

All Diagnoses pend

## **Document History**

New: 02/25/2022 Document History:

> 02/25/2022 – Annual Review: New document for Kimmtrak clinical criteria. Coding Reviewed: Added HCPCS J3490, J3590, J9999, C9399. All diagnoses pend.

### References

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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.

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