Reference number(s)
5150-A

STANDARD MEDICARE PART B MANAGEMENT

KIMMTRAK (tebentafusp-tebn)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Kimmtrak is indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
For initial requests: medical record documentation of HLA-A*02:01 phenotype.

III. CRITERIA FOR INITIAL APPROVAL

Uveal Melanoma
Authorization of 12 months may be granted for treatment of uveal melanoma when all of the following criteria are met:
A. The member is HLA-A*02:01-positive
B. The disease is unresectable or metastatic

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Kimmtrak
B. Kimmtrak is being used to treat an indication enumerated in Section III
C. The member is receiving benefit from therapy. Benefit is defined as:
    1. No evidence of unacceptable toxicity while on the current regimen and

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2. No evidence of disease progression while on the current regimen

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Kimmtrak.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Uveal melanoma

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Kimmtrak are covered.

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VII. REFERENCES

1. Kimmtrak [package insert]. Conshohocken, PA: Immunocore Commercial LLC; November 2022.