CLINICAL POLICY
Tebentafusp-tebn

Clinical Policy: Tebentafusp-tebn (Kimmtrak)

Reference Number: PA.CP.PHAR.575
Effective Date: 05/2022
Last Review Date: 04/2024

Description
Tebentafusp-tebn (Kimmtrak®) is a bispecific gp100 peptide-HLA-directed CD3 T cell engager.

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

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health and Wellness ® that Kimmtrak is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Uveal Melanoma (must meet all)**:**

1. Diagnosis of unresectable or metastatic uveal melanoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is HLA-A*02:01-positive;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 20 mcg (1 vial) on Day 1, 30 mcg (1 vial) on Day 8, 68 mcg (1 vial) on Day 15, and 68 mcg (1 vial) weekly thereafter;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Therapy

A. Uveal Melanoma (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 68 mcg (1 vial) weekly;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CRS: cytokine release syndrome
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): none reported
- Boxed warning(s): cytokine release syndrome (CRS)

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Uveal melanoma	20 mcg on Day 1, 30 mcg on Day 8, 68 mcg on Day 15, then 68 mcg once every week thereafter	68 mcg /week

V. Product Availability

Injection: 100 mcg/0.5 mL vial

VI. References

1. Kimmtrak Prescribing Information. Conshohocken, PA: Immunocore Commercial LLC; November 2022. Available at: https://www.kimmtrak.com/. Accessed February 12, 2024.
2. Clinical Pharmacology [database online]. Tampa, FL: Elsevier, Inc.; 2024. Available at: http://www.clinicalkeys.com/pharmacology. Accessed February 12, 2024.
3. National Comprehensive Cancer Network. Melanoma: Uveal Version 1.2023 Available at: https://www.nccn.org/professionals/physician_gls/pdf/uveal.pdf. Accessed February 12, 2024.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 12, 2024.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9274	Injection, tebentafusp-tebn, 1 mcg

Reviews, Revisions, and Approvals	Date
Policy created.	04/2022
Added HCPCS code [J9274].	01/2023
2Q 2023 annual review: no significant changes; removed inactive HCPCS codes C9095, J9999; references reviewed and updated.	04/2023
2Q 2024 annual review: no significant changes; references reviewed and updated.	04/2024