CLINICAL POLICY
Tebentafusp-tebn

Clinical Policy: Tebentafusp-tebn (Kimmtrak)

Reference Number: CP.PHAR.575
Effective Date: 05/2022
Last Review Date: 01/2023

Coding Implications
Revision Log

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
For treatment of HLA-A*2:01-positive unresectable or metastatic 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 Limited; January 2022. Available at: https://www.kimmtrak.com/. Accessed February 16, 2022.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2022. Available at: http://www.clinicalpharmacology-ip.com/. Accessed February 16, 2022.
3. National Comprehensive Cancer Network. Melanoma: Uveal Version 2.2021 Available at: https://www.nccn.org/professionals/physician_gls/pdf/uveal.pdf. Accessed February 10, 2022.

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
C9399 (NOC)*	Unclassified drugs or biologicals (hospital outpatient use)
J9274	Injection, tebentafusp-tebn, 1 mcg
J9999 (NOC)	Not otherwise classified, antineoplastic drugs

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04/2022	
Added HCPCS code [J9274].	01/2023	