Clinical Policy: Tebentafusp-tebn (Kimmtrak)

Reference Number: ERX.SPA.469
Effective Date: 06.01.22
Last Review Date: 05.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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, and 68 mcg (1 vial) on Day 15, and 68 mcg (1 vial) weekly thereafter;
   b. Dose is supported by practice guideline or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Kimmtrak for a covered indication and has received this medication for at least 30 days;
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 guideline or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents

IV. 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)

V. 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

VI. Product Availability

Injection: 100 mcg/0.5 mL vial

VII. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	02.10.22	05.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of

physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.