SmartHealth

Ascension

Tebentafusp-tebn

(Kimmtrack®) C9095 HOPD and Misc J9999 (1 mcg)

Albumin used for infusion preparation: 5% 50 mL P9041; 5% 250 mL P9045; 25% 20 mL P9046; 25% 50 mL P9047

Covered with prior authorization

Treatment of unresectable or metastatic uveal melanoma with positive HLA-A*02:01 genotyping test

Initial Therapy

- Patient is 18 years of age or older and being prescribed treatment under the care of an Oncology Specialist

  AND

- Diagnosis of unresectable uveal melanoma or metastatic uveal melanoma

  AND

- **Positive** HLA-A*02:01 genotyping test from whole blood specimen using a high-resolution HLA CLIA compliant test

  AND

- Patient has ECOG performance status of 0-1

  AND

- Patient has not received prior systemic therapy for metastatic or advanced uveal melanoma or localized liver directed therapy

AND

Kimmtrack® (tebentafusp-tebn) dosing is:

- 20 mcg IV over 15-20 minutes day 1
- 30 mcg IV over 15-20 minutes day 8
- 68 mcg IV over 15-20 minutes day 15 and once every week thereafter

AND

- Authorization will be for 6 months after initial 3 infusions and may be renewed

Reauthorization/Continuation of Care Criteria

- For patients currently on Kimmtrack® (tebentafusp-tebn), continued use will be approved based on the following criteria:
    - Patient continues to meet pre identified criteria above; **AND**
    - Patient does not have identifiable toxicity from the drug such as cytokine release syndrome, severe dermatological reactions, elevated liver enzymes, etc; **AND**
    - Identified disease response with treatment as defined by stabilization of disease or decrease in tumor size or tumor spread; **AND**
    - Kimmtrack® (tebentafusp-tebn) dosing is in accordance with the United States Food and Drug Administration approved labeling: dosing of 68 mcg IV weekly; **AND**
    - Authorization is for no more than 6 months.

Exclusion criteria

- Any diagnosis other than HLA-A*02:01-positive unresectable or metastatic uveal melanoma
- Patients with severe or life threatening cytokine release syndrome, skin reactions, or other adverse reactions should permanently discontinue the medication
- Patients with extreme elevations in liver enzymes should permanently discontinue the medication
- Patients who are pregnant, plan to become pregnant, or are breastfeeding

Step/Alternative Therapies:

No identified alternatives for specific qualifying uveal melanoma

Initial authorization is up to 6 months.

Reauthorizations will require medical chart documentation that the patient has been seen within the past 6 months and continues to meet criteria for use as well as disease response with treatment has stabilized or tumor has decreased in size or spread

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:

This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.
Kimmtrack® (tebentafusp-tebn) is a bispecific gp100 peptide-HLA-directed CD3 T cell engager indicated for:

- Treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma

References:

Kimmtrack® (tebentafusp-tebn) label. (2022, January). Accessdata.fda.gov. Retrieved August 10, 2022 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761228s000lbl.pdf

Khoja L, Atenafu EG, Suciu S, et al. Meta-analysis in metastatic uveal melanoma to determine progression free and overall survival benchmarks: an International Rare Cancers Initiative (IRCI) ocular melanoma study. *Ann Oncol.* 2019;30(8):1370-1380.

Rantala ES, Hernberg M, Kivelä TT. Overall survival after treatment for metastatic uveal melanoma: a systematic review and meta-analysis. *Melanoma Res.* 2019;29(6):561-568.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Melanoma: Uveal V.2.2022. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed August 10, 2022.

Middleton MR, McAlpine C, Woodcock VK, et al. Tebentafusp, a TCR/anti-CD3 bispecific fusion protein targeting gp100, potently activated antitumor immune responses in patients with metastatic melanoma. *Clin Cancer Res.* 2020;26(22):5869-5878.

Damato BE, Dukes J, Goodall H, Carvajal RD. Tebentafusp: T cell redirection for the treatment of metastatic uveal melanoma. *Cancers (Basel).* 2019;11(7):971.

Nathan P, Hassel JC, Rutkowski P, et al; IMCgp100-202 Investigators. Overall survival benefit with tebentafusp in metastatic uveal melanoma. *N Engl J Med.* 2021;385(13):1196-1206. doi:10.1056/NEJMoa21034

Criteria History/ Revision Information:

Date	Summary of Changes
August 2022	Developed by Hematology Oncology Expert Review Panel
December 2022	Approved by Ascension Ambulatory Care Steering Committee
January 2023	Approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.