Kimmtrak® (tebentafusp-tebn)
(Intravenous)

Document Number: SHP-0658

Last Review Date: 07/01/2022
Date of Origin: 03/01/2022
Dates Reviewed: 03/2022, 07/2022

I. Length of Authorization

Coverage will be provided for 6 months (after the initial first three infusions) and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Kimmtrak 100 mcg/0.5 mL solution in a SDV: 1 vial per 7 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 68 billable units (68 mcg) weekly

III. Initial Approval Criteria [1]

> Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e. genetic and mutational testing) supporting initiation when applicable. Medical records may be submitted via direct upload through the PA web portal or by fax.

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient has received the first three infusions (i.e., Day 1, 8, 15) in an appropriate healthcare setting and did not experience any Grade 2 or worse hypotension (i.e., hypotension requiring medical intervention); **AND**

Universal Criteria

- Patient does not have a clinically significant cardiac disease or impaired cardiac function (i.e., congestive heart failure [NYHA grade ≥ 2], uncontrolled hypertension or clinically significant arrhythmia requiring medical treatment, QT interval > 470 msec or congenital

long QT syndrome, acute myocardial infarction or unstable angina pectoris < 6 months prior to start of therapy); **AND**

- Patient does not have symptomatic or untreated brain metastases; **AND**

Uveal Melanoma † Φ [1-4]

- Patient has unresectable or metastatic disease; **AND**
- Patient has HLA-A*02:01 genotype positive disease as determined by an FDA-approved or CLIA compliant test❖; **AND**
- Patient has not received prior systemic therapy for metastatic or advanced uveal melanoma or localized liver-directed therapy *(Note: Prior neoadjuvant or adjuvant therapy is allowed provided administered in the curative setting in patients with localized disease)*

❖ *If confirmed using an immunotherapy assay-*[*http://www.fda.gov/companiondiagnostics*](http://www.fda.gov/companiondiagnostics)

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s); Φ Orphan Drug

III. Renewal Criteria [1]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: persistent/severe cytokine release syndrome, severe dermatological reactions, severe elevated liver enzymes, etc.; **AND**
- Patient has received the first three infusions (i.e., Day 1, 8, 15) in an appropriate healthcare setting and did not experience any Grade 2 or worse hypotension (i.e., hypotension requiring medical intervention); **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

IV. Dosage/Administration [1]

Indication	Dose
Uveal Melanoma	Administer Kimmtrak, intravenously, according to the following schedule: • 20 mcg on Day 1 • 30 mcg on Day 8 • 68 mcg on Day 15, then • 68 mcg once every week thereafter Treat patients until unacceptable toxicity or disease progression occur.

– *Administer the first three infusions of Kimmtrak in an appropriate healthcare setting by intravenous infusion over 15-20 minutes. Monitor patients during the infusion and for at least 16 hours after the infusion is complete.*

– *Patients mut be euvolemic prior to initiating the infusions*

– *If the patient does not experience Grade 2 or worse hypotension (requiring medical intervention) during or after the third infusion, administer subsequent doses in an appropriate ambulatory care setting, and monitor patients for a minimum of 30 minutes following each of these infusions.*

V. Billing Code/Availability Information

HCPCS Code:

- J9999 – Not otherwise classified, antineoplastic drug *(Discontinue use on 10/01/2022)*
- C9095 – Injection, tebentafusp-tebn, 1 mcg; 1 billable unit = 1 mcg *(Discontinue use on 10/01/2022)*
- J9274 – Injection, tebentafusp-tebn, 1 mcg; 1 billable unit = 1 mcg *(Effective 10/01/2022)*

NDC:

- Kimmtrak 100 mcg/0.5 mL solution in a SDV: 80446-0401-xx

VI. References

1. Kimmtrak [package insert]. Conshohocken, PA; Immunocare, Ltd., January 2022. Accessed February 2022.
2. 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 Sep 23;385(13):1196-1206. doi: 10.1056/NEJMoa2103485.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) tebentafusp. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed February 2022.
4. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Melanoma: Uveal Version 2.2021. National Comprehensive Cancer Network, 2021. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed February 2022.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C69.30	Malignant neoplasm of unspecified choroid

C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
C69.60	Malignant neoplasm of unspecified orbit
C69.61	Malignant neoplasm of right orbit
C69.62	Malignant neoplasm of left orbit

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Article and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC