Kimmtrak (tebentafusp-tebn)
PAM – 050

Iowa Medicaid Program	Prior Authorization	**Effective Date**	10/01/2022
Revision Number	4	**Last Reviewed**	01/16/2026
Reviewed By	Medicaid Medical Director	**Next Review**	01/15/2027
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	01/20/2023

Overview

Medication: [1]	tebentafusp-tebn
Brand Name:	Kimmtrak®
Pharmacologic Category:	Antineoplastics; bispecific gp100 peptide-HLA-directed CD3 T cell engager
FDA-Approved Indication(s):	Treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma (mUM). <u>Patient Selection</u> Select patients for treatment of unresectable or metastatic uveal melanoma based on a positive HLA-A*02:01 genotyping test. • *An FDA-approved test for the detection of HLA-A*02:01 genotyping is not currently available.* • CPT 81381 can be used for the lab to detect HLA-A*02:01 genotyping. ○ 81381: HLA class I typing, high resolution; one allele or allele group, each. A broader HLA panel is not necessary, as no other HLA gene/subtypes can be used to determine patient eligibility for Kimmtrak®.
How Supplied:	Single-dose vial; 100 mcg in 0.5 mL
Dosage:	Day 1: 20 mcg; Day 8: 30 mcg; Day 15: 68 mcg; then 68 mcg once weekly thereafter until unacceptable toxicity or disease progression. <u>Administration</u>: • 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. • 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.
Benefit Category:	Medical

WARNING: Cytokine release syndrome (CRS)

Cytokine release syndrome (CRS), which may be serious or life-threatening, occurred in patients receiving Kimmtrak®. Monitor for at least 16 hours following first three infusions and then as clinically indicated.

Descriptive Narrative

Uveal melanoma (UM) is a rare malignancy that arises from melanocytes within the uveal tract of the eye (includes the iris, ciliary body, and choroid). UM comprises approximately 85 percent of all ocular melanomas, with the remainder arising in the conjunctiva or (rarely) the orbit.

Local treatment for primary uveal melanoma is effective in preventing recurrence in over 90 percent of cases, yet up to 50 percent of patients are at risk for metastatic disease. It is rare for patients diagnosed with UM to have detectable metastatic disease at the time of primary tumor diagnosis (occurs in less than 4 percent of patients diagnosed with UM). Most of the patients who do develop metastatic UM do so within 5 to 7 years of treatment to the primary eye tumor, with a median time of approximately 3 years. Metastases can also appear after a decade or longer.[2,3]

Guidelines

The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology document evidence-based, consensus-driven management to ensure that all patients receive preventive, diagnostic, treatment, and supportive services that are most likely to lead to optimal outcomes. The guidelines are developed and updated by 63 individual panels, comprising over 1,900 clinicians and oncology researchers from the 33 NCCN Member Institutions. The categories for recommendations are based on both the level of clinical evidence available and the degree of consensus within the NCCN Guidelines Panel.

The library of NCCN Guidelines® currently apply to more than 97 percent of people living with cancer or anyone at risk for a diagnosis of cancer in the United States. The guidelines incorporate real-time updates in keeping with the rapid advancements in the field of cancer research and management and are intended to assist all individuals who impact decision-making in cancer care, including physicians, nurses, pharmacists, payers, patients and their families, and others.

The NCCN Guidelines provide recommendations based on the best evidence available at the time they are derived. Because new data are published continuously, it is essential that the NCCN Guidelines also be continuously updated and revised* to reflect new data and clinical information that may add to or alter current clinical practice standards.[4,5]

The information referenced at the time of this policy writing/revision is from the NCCN Guidelines® for (note version number and effective date):[6]

- Melanoma: Uveal (v.2.2025 – November 6, 2025)

* To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

NCCN Guidelines® Recommendation(s) in Uveal Melanoma
(1) Systemic Therapy for Metastatic or Unresectable Disease, HLA-A*02:01-Positive [a] a. Tebentafusp-tebn (Kimmtrak®): Category 1, Preferred Regimen [b]

[a] Referral to centers with expertise in the management of uveal melanoma is recommended.

[b] A phase III randomized trial was conducted in previously untreated HLA-A*02:01-positive, metastatic uveal melanoma. Patients were randomized to receive tebentafusp-tebn (a bispecific protein) or investigator's choice of either pembrolizumab, ipilimumab, or dacarbazine. Treatment with tebentafusp-tebn resulted in longer overall survival compared to control therapy. Agents that are effective for metastatic cutaneous melanoma may be used as first-line therapy for HLA-A* 02:01-negative disease and after disease progression with first-line use of tebentafusp-tebn for HLA-A* 02:01-positive disease. If disease is confined to the liver, regional therapies such as chemoembolization, radioembolization, or immunoembolization should be considered. Since tebentafusp-tebn response rates are low, symptomatic patients may be better palliated by liver-directed treatment first or their disease may respond better to ipilimumab/nivolumab.

NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Eastern Cooperative Oncology Group (ECOG) Performance Status Scale [7]

Developed by the Eastern Cooperative Oncology Group (ECOG), now part of the ECOG-ACRIN Cancer Research Group, and published in 1982, the ECOG Performance Status Scale describes a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). It is used by doctors and researchers to assess how a patient's disease is progressing, how the disease affects the daily living abilities of the patient, and to determine appropriate treatment and prognosis.

Grade	ECOG Performance Status [Synonyms: WHO/Zubrod score]
0	Fully active, able to carry on all pre-disease performance without restriction.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours.
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours.
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair.
5	Dead.

Criteria

Prior authorization is required.

Kimmtrak® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of unresectable or metastatic uveal melanoma; **AND**
2. Member is HLA-A*02:01-positive; **AND**
3. Member is 18 years of age or older; **AND**
4. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **AND**
5. Prescribed by, or in consultation with, an oncologist; **AND**
6. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 20 mcg on day 1, 30 mcg on day 8, 68 mcg on day 15, and then 68 mcg once weekly thereafter until unacceptable toxicity or disease progression; or,
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Kimmtrak® is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile; **AND**
3. Prescribed by, or in consultation with, an oncologist; **AND**
4. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 68 mcg once weekly until unacceptable toxicity or disease progression; or,
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	12 months
Quantity Limits	• Day 1: 20 mcg • Day 8: 30 mcg • Day 15: 68 mcg • Then 68 mcg once weekly thereafter	68 mcg once weekly until unacceptable toxicity or disease progression

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J9274	Injection, tebentafusp-tebn, 1 mcg
81381	HLA Class I typing, high resolution (i.e., alleles or allele groups); one allele or allele group (e.g., B*57:01P), each

ICD-10	Description
C69.30 – C69.62	Malignant neoplasm of unspecified choroid

NDC (Strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units/ Pkg
80446-0401-01 (single-dose vial, 100 mcg/0.5 mL)	Immunocore Commercial LLC (80446)	1 mcg	1	EA	100

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Kimmtrak® prescribing information (06/2024). Immunocore Commercial LLC: Conshohocken, PA. Available online: www.kimmtrakhcp.com. Accessed October 27, 2025.

[2] Harbour JW, Shih HA. Initial management of uveal and conjunctival melanomas. Yushak M, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed November 12, 2025.

[3] Carvajal RD, Harbour JW. Metastatic uveal melanoma. Shah S, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed November 12, 2025.

[4] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[5] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[6] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced (note version number and effective date):

- Melanoma: Uveal (v.1.2024 – May 23, 2024)

[7] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. PMID 7165009.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

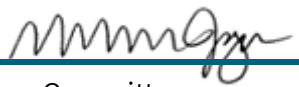
Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
01/16/2026	CAC	Annual review. No changes.	4
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
01/17/2025	CAC	Annual review. Updated boxed warning. Updated description of NCCN Guidelines in Guidelines section.	3
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
01/19/2024	CAC	Annual review. Updated NCCN Guidelines to include amended trial information included in the most recent version of the guidelines. Added dosing information into criteria.	2
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
01/20/2023	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee