

If your patient has metastatic uveal melanoma (mUM), it's time to:



A

Acquire
a whole blood
specimen



C

Confirm
your patient's
HLA status



T

Treat
with KIMMTRAK
if eligible

NOW. Request the test.

Indication

KIMMTRAK® (tebentafusp-tebn) is a bispecific gp100 peptide-HLA-directed CD3 T cell engager indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.

HLA-A, human leukocyte antigen-A.

Please see Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** on pages 6-7 and see [full Prescribing Information](#).

 **KIMMTRAK**
(tebentafusp-tebn)
Injection for Intravenous Use 100 mcg/0.5 mL

Knowing your patient's HLA-A*02:01 status could provide a new opportunity

A simple blood test can help determine if your patient is eligible for KIMMTRAK²

- KIMMTRAK is the first and only FDA-approved immunotherapy for HLA-A*02:01-positive adults who have mUM²
- A high-resolution HLA test is all it takes to help determine if your patient is eligible for treatment²⁻⁴
- ≈50% of patients with mUM are expected to be HLA-A*02:01 positive⁵

Consider this hypothetical patient case study

Patient was diagnosed with mUM after routine MRI surveillance. Since HLA tests based on liver tumor biopsy may lead to a discrepancy in results due to tumor heterogeneity,⁶ a blood sample for HLA genotype was requested.

mUM patient

Tumor biopsy results	Blood test results
HLA-A*02:09	HLA-A*02:01
HLA-B*09:22	HLA-A*02:09 HLA-B*09:22

The blood test results showed the patient was positive for HLA-A*02:01, indicating that the patient is a candidate for 1L treatment with KIMMTRAK.

Please see Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** on pages 6-7 and see [full Prescribing Information](#).

How to order an HLA test to determine HLA-A*02:01 positivity



Provide a **whole blood specimen** to your lab and request a **high-resolution HLA test** (ie, to the fourth digit)²⁻⁴

- This test provides the necessary specificity, showing both ***02 and :01** portions
 - Low or intermediate resolution HLA test shows only the *02 portion
- Information on FDA-approved tests is available at www.fda.gov/companiondiagnostics²



Do **not** use a biopsy tumor sample test for HLA

- Tumor chromosomal alterations may cause false negative HLA results⁶

What CPT codes could be relevant to determining your patient's HLA-A*02:01 status?

- CPT 81379: HLA class I typing, high resolution
- CPT 81380: HLA class I typing, high resolution; one locus
- CPT 81381: HLA class I typing, high resolution; one allele or allele group

Information provided is not intended as coverage or coding advice. Individual coding decisions should be based upon the diagnosis and treatment of individual patients. Immunocore does not guarantee reimbursement. The information may not be as current or comprehensive when you view it. You should always verify the appropriate reimbursement information for services or items you provide. It is recommended you consult with your facility's coding and reimbursement experts.

CPT, Current Procedural Terminology.

* As part of a complete diagnostic workup.

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=National Comprehensive Cancer Network® (NCCN®).

Sample reports of patients who are *positive* for HLA-A*02:01

Sample #1

HLA A A*02:01-Specific

Status: **Final result**

Visible to patient: **Yes (MyChart)**

Next appt: **Today at 03:30 PM in Oncology**

0 Result Notes

Component 3 wk ago

HLA-A Comment **A*02:01:01:01**

HLA-A Comment **A*03:01:01:01**

HLA-A*02:01 is POSITIVE.

Sample #2

TESTS	RESULT	FLAG
HLA-A*02:01		
HLA-A	A*02:01:01:01	
HLA-A	A*03:01:01:01	
HLA-A*02:01 is POSITIVE.		

Note: These are abbreviated versions of HLA-A*02:01-positive sample reports.

Only HLA-A*02:01-positive patients can receive KIMMTRAK²

Please see Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** on pages 6-7 and see [full Prescribing Information](#).

Sample reports of patients who are *negative* for HLA-A*02:01

Sample #1

HLA CLASS I MOLECULAR TYPING DISEASE ASSOCIATION

Status: **Final result**

Visible to patient: **Yes (seen)**

ABC DisAssoc Comment	Ref Range & Units	1 mo ago
		DNR
A - 1 Equivalent	N/A	A3
A - 2 Equivalent	N/A	A3
A - 1 Molecular	N/A	A*03
A - 2 Molecular	N/A	A*03
B - 1 Equivalent	N/A	B62
B - 2 Equivalent	N/A	B51

Sample #2

TESTS	RESULT	FLAG
HLA (HR)		
HLA-A	A*23:AFCTD	
HLA-A	A*74:01	
Code Translation: AFCTD 01/17/69 HLA allele interpretation for all loci based on IMGT/HLA database version 3.21		

Note: These are abbreviated versions of HLA-A*02:01-negative sample reports.

 **KIMMTRAK**
(tebentafusp-tebn)
Injection for Intravenous Use 100 mcg/0.5 mL

Indication and Important Safety Information Including Boxed Warning

Indication

KIMMTRAK is a bispecific gp100 peptide-HLA-directed CD3 T cell engager indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.

Important Safety Information Including Boxed Warning

WARNING: CYTOKINE RELEASE SYNDROME

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. Manifestations of CRS may include fever, hypotension, hypoxia, chills, nausea, vomiting, rash, elevated transaminases, fatigue, and headache. CRS occurred in 89% of patients who received KIMMTRAK with 0.8% being grade 3 or 4. Ensure immediate access to medications and resuscitative equipment to manage CRS. Ensure patients are euvolemic prior to initiating the infusions. Closely monitor patients for signs or symptoms of CRS following infusions of KIMMTRAK. Monitor fluid status, vital signs, and oxygenation level and provide appropriate therapy. Withhold or discontinue KIMMTRAK depending on persistence and severity of CRS.

Manifestations of CRS may include fever, hypotension, hypoxia, chills, nausea, vomiting, rash, elevated transaminases, fatigue, and headache. CRS occurred in 89% of patients who received KIMMTRAK with 0.8% being grade 3 or 4. Ensure immediate access to medications and resuscitative equipment to manage CRS. Ensure patients are euvolemic prior to initiating the infusions. Closely monitor patients for signs or symptoms of CRS following infusions of KIMMTRAK. Monitor fluid status, vital signs, and oxygenation level and provide appropriate therapy. Withhold or discontinue KIMMTRAK depending on persistence and severity of CRS.

Skin Reactions

Skin reactions, including rash, pruritus, and cutaneous edema occurred in 91% of patients treated with KIMMTRAK. Monitor patients for skin reactions. If skin reactions occur, treat with antihistamine and topical or systemic steroids based on persistence and severity of symptoms. Withhold or permanently discontinue KIMMTRAK depending on the severity of skin reactions.

Elevated Liver Enzymes

Elevations in liver enzymes occurred in 65% of patients treated with KIMMTRAK. Monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total blood bilirubin prior to the start of and during treatment with KIMMTRAK. Withhold KIMMTRAK according to severity.

(continued)

Indication and Important Safety Information Including Boxed Warning (continued)

Embryo-Fetal Toxicity

KIMMTRAK may cause fetal harm. Advise pregnant patients of potential risk to the fetus and patients of reproductive potential to use effective contraception during treatment with KIMMTRAK and 1 week after the last dose.

The most common adverse reactions ($\geq 30\%$) in patients who received KIMMTRAK were cytokine release syndrome, rash, pyrexia, pruritus, fatigue, nausea, chills, abdominal pain, edema, hypotension, dry skin, headache, and vomiting. The most common ($\geq 50\%$) laboratory abnormalities were decreased lymphocyte count, increased creatinine, increased glucose, increased AST, increased ALT, decreased hemoglobin, and decreased phosphate.

Please see [full Prescribing Information](#), including **BOXED WARNING for CRS.**

References: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Melanoma: Uveal V.1.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed May 24, 2023. To view the most recent and complete version of the guideline, 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. 2. Kimmtrak. Package insert. Immunocore Ltd; 2022. 3. Tiercy JM. How to select the best available related or unrelated donor of hematopoietic stem cells? *Haematologica*. 2016;101(6):680-687. doi:10.3324/haematol.2015.141119 4. Nunes E, Heslop H, Fernandez-Vina M, et al. Definitions of histocompatibility typing terms. *Blood*. 2011;118(23):e180-e183. doi:10.1182/blood-2011-05-353490 5. Marincola FM, Venzon D, White D, et al. HLA association with response and toxicity in melanoma patients treated with interleukin 2-based immunotherapy. *Cancer Res*. 1992;52(23):6561-6566. 6. Fonseca C, Pinto-Proença R, Bergeron S, et al. Intratumoral heterogeneity in uveal melanoma. *Ocul Oncol Pathol*. 2021;7(1):17-25. doi:10.1159/000508517

 **KIMMTRAK**
(tebentafusp-tebn)
Injection for Intravenous Use 100 mcg/0.5 mL

A	C	T
Acquire a whole blood specimen	Confirm your patient's HLA status	Treat with KIMMTRAK if eligible

NOW. Request the test.

Visit KIMMTRAK.com/#status
to see why your patient
with mUM may be asking you
about HLA testing

Please see Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** on pages 6-7 and see [full Prescribing Information](#).

IMMUNOCORE

KIMMTRAK and Immunocore are registered trademarks of Immunocore Ltd. All other trademarks, company and product names, and logos are the property of their respective owners.

©2023 Immunocore Ltd. All rights reserved.

CM-US-TEBE-2300001 September 2023

 **KIMMTRAK**
(tebentafusp-tebn)
Injection for Intravenous Use 100 mcg/0.5 mL