Determine HLA-A*02:01 status today to inform treatment decisions in metastatic uveal melanoma (mUM)[1]

mUM patients' HLA-A*02:01 status may present a new opportunity[1]

- While HLA testing has traditionally been used to identify tissue matches for donor stem cell or organ transplants, it can now be used to determine whether patients with mUM are eligible for KIMMTRAK® (tebentafusp-tebn)[1-5]
- KIMMTRAK, the first and only FDA-approved immunotherapy for mUM, is indicated for adults who are HLA-A*02:01 positive[1]

≈50%
OF PATIENTS
with mUM are expected to be HLA-A*02:01 positive[6]

HLA status never changes, so determine it early with a simple blood test

Provide **a whole blood specimen** to a diagnostic lab and request a **high-resolution HLA test**[1,3,7]

- This test provides the necessary specificity, showing both ***02 and :01** portions
  - Low or intermediate resolution HLA test shows only the *02 portion

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

- Tumor chromosomal alterations may cause false negative HLA results[8]

Don't wait—test to determine your patients' HLA-A*02:01 status today.

HLA, human leukocyte antigen; HLA-A, human leukocyte antigen-A.

Please see Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** on subsequent pages and see full Prescribing Information.

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

A broader HLA panel is not necessary, as no other HLA gene/subtypes can be used to determine patient eligibility for KIMMTRAK[1]

Currently, an FDA-approved test for the detection of HLA-A*02:01 genotyping is not available.

- Any HLA test performed at a CLIA-certified laboratory can be used
- The SeCore® HLA Sequencing System was used in KIMMTRAK clinical trials[9]

What CPT codes could be relevant to determining your patients' 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.

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.

(continued)

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.

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 (≥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 (≥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. Kimmtrak. Package insert. Immunocore Ltd; 2022. **2.** Howard A, Fernandez-Vina MA, Appelbaum FR, et al. Recommendations for donor HLA assessment and matching for allogeneic stem cell transplantation: consensus opinion of the Blood and Marrow Transplant Clinical Trials Network (BMT CTN). *Biol Blood Marrow Transplant*. 2015;21(1):4-7. doi:10.1016/j.bbmt.2014.09.017 **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.** Zachary AA, Leffell MS. HLA mismatching strategies for solid organ transplantation: a balancing act. *Front Immunol*. 2016;7:575. doi:10.3389/fimmu.2016.00575 **5.** Alelign T, Ahmed MM, Bobosha K, et al. Kidney transplantation: the challenge of human leukocyte antigen and its therapeutic strategies. *J Immunol Res*. 2018;2018:5986740. doi:10.1155/2018/5986740 **6.** 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. **7.** 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 **8.** Park H, Hyun J, Park SS, Park MH, Song EY. False homozygosity results in HLA genotyping due to loss of chromosome 6 in a patient with acute lymphoblastic leukemia. *Korean J Lab Med*. 2011;31:302-306. doi: 10.3343/kjlm.2011.31.4.302 **9.** Data on file. Immunocore.

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