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Section:	Prescription Drugs	**Effective Date:**	July 1, 2023
Subsection:	Antineoplastic Agents	**Original Policy Date:**	February 25, 2022
Subject:	Kimmtrak	**Page:**	1 of 5

Last Review Date: June 15, 2023

Kimmtrak

Description

Kimmtrak (tebentafusp-tebn) injection

Background
Kimmtrak (tebentafusp-tebn) is an immune-mobilizing monoclonal T-cell receptor against cancer (ImmTAC) that is engineered to have a high affinity for a specific peptide on a target cells surface. The ImmTAC will bind and help activate polyclonal T cells to release cytokines and cytolytic mediators against the target cell. Kimmtrak is specific to gp100 peptide-HLA-A*02:01, which is expressed on the cell surface of uveal melanoma tumor cells. Uveal melanoma is the most common intraocular cancer in adults and is distinct from cutaneous melanoma (1).

Regulatory Status
FDA-approved 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 (1).

Kimmtrak has a boxed warning for Cytokine Release Syndrome (CRS). This condition may be life threatening and patients should be monitored for at least 16 hours following the first three infusions and then as clinically indicated (1).

Kimmtrak also has warnings regarding skin reactions, elevated liver enzymes and embryo-fetal toxicity. Rash, pruritus, and cutaneous edema occurred in patients treated with Kimmtrak. Skin reactions should be treated as clinically indicated. Patients' ALT, AST, and total bilirubin should also be monitored (1).

Kimmtrak may also cause fetal harm. Pregnancy status should be verified in females of reproductive potential prior to initiating Kimmtrak treatment. Females of reproductive potential should be advised to use effective contraception during treatment with Kimmtrak and for 1 week after the last dose (1).

The safety and effectiveness of Kimmtrak in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Kimmtrak may be considered **medically necessary** if the conditions indicated below are met.

Kimmtrak may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Unresectable or metastatic uveal melanoma
    a. HLA-A*02:01 genotype positive

AND ALL of the following:

1. Prescriber agrees to monitor patient for Cytokine Release Syndrome (CRS) for at least 16 hours following the first three infusions and then as clinically indicated
2. Prescriber agrees to monitor patient's ALT, AST, and total bilirubin
3. Females of reproductive potential **only**: patient will have pregnancy testing completed before starting treatment with Kimmtrak and patient will be advised to

use effective contraception during treatment with Kimmtrak and for 1 week after the last dose

Prior–Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Unresectable or metastatic uveal melanoma
    a. HLA-A*2:01 genotype positive

AND ALL of the following:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor for Cytokine Release Syndrome (CRS) as clinically indicated
3. Prescriber agrees to monitor patient's ALT, AST, and total bilirubin
4. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Kimmtrak and for 1 week after the last dose

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Duration 12 months

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary
Kimmtrak (tebentafusp-tebn) is a bispecific gp100 peptide-HLA-directed CD3 T cell engager indicated for the treatment of HLA-A*02:01-positive unresectable or metastatic uveal melanoma. Kimmtrak works by activating polyclonal T cells to release inflammatory cytokines and cytolytic proteins to directly lyse uveal melanoma tumor cells. Kimmtrak has a boxed warning for Cytokine Release Syndrome (CRS), and patients should be monitored for reaction for the first three infusions for 16 hours and then as clinically indicated. Kimmtrak may also cause fetal harm based on its mechanism of action. Female patients of reproductive potential should have a pregnancy test to confirm their pregnancy status before starting Kimmtrak and be advised to use effective contraception during treatment and for 1 week after the last dose of Kimmtrak. The safety and effectiveness of Kimmtrak in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Kimmtrak while maintaining optimal therapeutic outcomes.

References

1. Kimmtrak [package insert]. Conshohocken, PA: Immunocore Commercial LLC; November 2022.
2. NCCN Drugs & Biologics Compendium® Tebentafusp-tebn 2023. National Comprehensive Cancer Network, Inc. Accessed on April 19, 2023.

Policy History

Date	Action
February 2022	Addition to PA
June 2022	Annual review and reference update
June 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 15, 2023 and is effective on July 1, 2023.