Clinical Policy Title:	tebentafusp-tebn
Policy Number:	RxA.754
Drug(s) Applied:	Kimmtrak®
Original Policy Date:	04/18/2022
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
tebentafusp-tebn (Kimmtrak®)	Unresectable or metastatic uveal melanoma	20 micrograms (mcg) Intravenous on day 1, 30 mcg Intravenous on day 8, 68 mcg Intravenous on day 15, and then 68 mcg Intravenous once weekly until disease progression	68 mcg Intravenous.

Dosage Forms

- Injection: 100 mcg/0.5 mL solution in a single-dose vial.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Unresectable or metastatic uveal melanoma (must meet all):

1. Diagnosis of unresectable or metastatic uveal melanoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Documentation of HLA-A*02:01 positive disease;
5. Member does not have any prior systemic therapy in the metastatic or advanced setting including chemotherapy, immunotherapy, or targeted therapy;
6. Member does not have prior regional, liver-directed therapy including chemotherapy, radiotherapy, or embolization;

7. Member has Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1;
8. If request is for a dose increase, request does not exceed 68 mcg Intravenous.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Unresectable or metastatic uveal melanoma (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request does not exceed 68 mcg Intravenous.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
ECOG: Eastern Cooperative Oncology Group
CRS: Cytokine release syndrome

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Keytruda®	Varies	Varies
Abraxane®	Varies	Varies
Mekinist®	Varies	Varies
Opdivo®	Varies	Varies

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None Reported.

- Boxed Warning(s):
  - Cytokine release syndrome (CRS), which may be serious or lifethreatening, occurred in patients receiving Kimmtrak. Monitor for at least 16 hours following first 3 infusions and then as clinically indicated.

*Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

APPENDIX D: General Information

- Tebentafusp-tebn is a bispecific gp100 peptide-HLA-A*02:01 directed T cell receptor CD3 T cell engager. The TCR arm binds to a gp100 peptide presented by human leukocyte antigen-A*02:01 (HLAA*02:01) on the cell surface of uveal melanoma tumor cells. In vitro, tebentafusp-tebn bound to HLA-A*02:01-positive uveal melanoma cells and activated polyclonal T cells to release inflammatory cytokines and cytolytic proteins, which results in direct lysis of uveal melanoma tumor cells.
- Caution should be used in patients with the following comorbidities, as these patients were excluded from enrollment in the IMCgp100-202 clinical trial:
  - Clinically significant cardiac disease
  - Symptomatic or untreated brain metastases

References

1. Kimmtrak® Prescribing Information. Conshohocken, PA: Immunocore Commercial LLC; January 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761228s000lbl.pdf. Accessed March 09, 2022
2. IPD Analytics Rx Insights_New Drug Review_ Kimmtrak 02.2022. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Kimmtrak. Accessed March 09, 2022.
3. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2021.Available at: http://www.clinicalkey.com Accessed March 09,2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/10/2022	04/18/2022