Clinical Policy Title:	tebentafusp-tebn
Policy Number:	RxA.754
Drug(s) Applied:	Kimmtrak®
Original Policy Date:	04/18/2022
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

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. Request meets one of the following (a or b):*
   a. Dose does not exceed 68 mcg Intravenous;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

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, member meets one of the following (a or b):*
   a. Dose does not exceed 68 mcg Intravenous;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network Guidelines. Melanoma: Uveal. Version 2.2022. Available at:

https://www.nccn.org/professionals/physician_gls/pdf/uveal.pdf. Accessed March 30, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/10/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria I.A.6: Updated to remove Member does not have prior regional, liver-directed therapy including chemotherapy, radiotherapy, or embolization. 2. Initial Approval Criteria I.A.7: Updated to remove Member has Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1. 3. Continued Therapy Approval: Approval duration updated from 6 months to 12 months. 4. References were reviewed and updated.	03/30/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023