

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 \geq 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:

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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: <ol style="list-style-type: none"> 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