Kimmtrak (tebentafusp-tebn)

Humana

Pharmacy Coverage Policy

Effective Date: March 23, 2022
Revision Date: March 23, 2022
Review Date: March 15, 2023
Line of Business: Medicare, Commercial, Medicaid - South Carolina, Medicaid - Ohio
Policy Type: Prior Authorization

Products Affected

Kimmtrak intravenous solution

Listed Indications

Metastatic Uveal Melanoma

Metastatic Uveal Melanoma

Does the member meet all of the following criteria?	
Criteria #1	The member has a diagnosis of unresectable or metastatic uveal melanoma
Criteria #2	The member has documentation of HLA-A*02:01-positive disease by assay results
Criteria #3	Kimmtrak (tebentafusp-tebn) will be used as monotherapy
Does the member have any of the following exclusions? If yes, approval may not be appropriate. NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.	
Exclusion #1	Members that have experienced disease progression while on Kimmtrak (tebentafusp-tebn)
Approval Duration	
Initial	Kimmtrak (tebentafusp-tebn) will be approved in plan year durations or as determined through clinical review.

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Background

This is a prior authorization policy about Kimmtrak (tebentafusp-tebn).

- Uveal Melanoma (UM) is a rare cancer (~2600 cases in US) with generally poor prognosis, which arises from the melanocytes of the uveal tract of the eye.

- Black Box warnings: 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.

- Warnings and Precautions:
  - Skin reactions: Rash, pruritus, and cutaneous edema occurred in patients treated with KIMMTRAK. If skin reactions occur, treat based on persistence and severity of symptoms
  - Elevated liver enzymes: Elevations in liver enzymes occurred in patients treated with KIMMTRAK. Monitor ALT, AST, and total bilirubin
  - Embryo-Fetal toxicity: May cause fetal harm. Advise patients of reproductive potential of the potential risk to the fetus and to use effective contraception

Kimmtrak (tebentafusp-tebn) comprises an affinity enhanced soluble T-cell receptor (TCR) domain fused to an anti-CD3 single chain variable fragment (scFv). The TCR component targets a specific peptide of gp100 that is overexpressed by melanoma cells and presented on the surface by the major histocompatibility complex (MHC), specifically the human leucocyte antigen (HLA)system. Expression of gp100 is restricted to cells that synthesize melanin, including normal melanocytes and most melanomas.

Tebentafusp targets a specific peptide fragment of gp100 (the YLEPGPVTA peptide) presented at the cell surface complexed with HLA-A*02:01. The mechanism constitutes part of the natural cell processing of all proteins and presentation at the cell surface for recognition by the adaptive immune system. For tebentafusp to bind and exert its therapeutic effect, gp100 must be correctly processed to the 9-residue peptide (YLEPGPVTA) and presented at the surface as the HLA-A*02:01-peptide complex. Therefore, the antitumor activity of tebentafusp is restricted to patients with the HLA-A*02:01 allele, which is one of the most prevalent HLA types in the United States.

Kimmtrak (tebentafusp-tebn) is indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.

Tebentafusp-tebn is available as KIMMTRAK in 100 mcg in 0.5 mL solution contained in a vial.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Kimmtrak; Tebentafusp-tebn; HLA; Uveal Melanoma; UM

References

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Kimmtrak [prescribing information]. Immunocore. Conshohochen, PA. January 2022.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically.

NCCN Drug and Biologics Compendium. Fort Washington, PA: National Comprehensive Cancer Network (NCCN); Updated periodically.

Disclaimer	State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically.