Medical Policy:

Kimmtrak (tebentafusp-tebn) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.353	February 14, 2024	May 12, 2022

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This 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. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions:

Kimmtrak, a bispecific gp 100 peptide-human leukocyte antigen (HLA)-directed T cell receptor CD3 T cell engager, is indicated for the treatment of adults with HLA-A*02:01-positive, unresectable or metastatic uveal melanoma.

Safety: Kimmtrak has a Boxed Warning for cytokine release syndrome which may be serious or life-threatening

Length of Authorization

Coverage will be provided for 12 months

Dosing Limits [Medical Benefit]

- Approve up to 68 mcg administered by intravenous infusion given no more frequently than once weekly. (68 billable units (68 mcg) weekly)

Guideline

INITIAL APPROVAL CRITERIA

1. **<u>Uveal Melanoma</u>:**
   A. Patient is ≥ 18 years of age; **AND**
   B. Patient has unresectable or metastatic disease; **AND**
   C. The tumor is HLA-A*02:01 positive; **AND**
   D. Prescribed by or in consultation with an Oncologist.

RENEWAL CRITERIA:
1. Member is responding positively to therapy, as determined by the prescriber; **AND**
2. Member has not experienced unacceptable toxicity from the drug

Dosing/Administration:

20 mcg intravenously (IV) on Day 1, 30 mcg IV on Day 8, 68 mcg IV on Day 15, and 68 mcg IV once every week thereafter. Patients receive treatment until unacceptable toxicity or disease progression occurs.

Administer the first 3 infusions of Kimmtrak in an appropriate healthcare setting by intravenous infusion over 15-20 minutes. Monitor patients during the infusion and for at least 16 hours after the infusion is complete.

Applicable Procedure Codes

Code	Description
J9274	Injection, tebentafusp-tebn, 1 mcg; 1 billable unit = 1 mcg

Applicable NDCs

Code	Description
80446-0401-01	Kimmtrak 100 mcg/0.5 mL, single dose vial

ICD-10 Diagnoses

Code	Description
C69.30	Malignant neoplasm of unspecified choroid
C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
C69.60	Malignant neoplasm of unspecified orbit
C69.61	Malignant neoplasm of right orbit
C69.62	Malignant neoplasm of left orbit

Revision History

Company(ies)	DATE	REVISION

EmblemHealth & ConnectiCare	2/14/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	6/14/2023	Annual Review: Removed codes: C9399 and J9999. Added code: J9274. Removed ICD-10 codes: C69.90, C69.91 and C69.92
EmblemHealth & ConnectiCare	5/12/2022	New Policy

References

1. Kimmtrak intravenous infusion [prescribing information]. Conshohocken, PA: Immunocore; January 2022.
2. Kimmtrak IBM Micromedex® [database online]. Immunocore Commercial LLC (per FDA), Conshohocken, PA, 2022. Available at: https://www.micromedexsolutions