Billing and Coding Guide

KIMMTRAK® (tebentafusp-tebn)

New HCPCS J-Code Effective October 1, 2022:
J9274 - Injection, tebentafusp-tebn, 1 mcg

HCPCS, Healthcare Common Procedure Coding System.

Please see Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** on page 22 and see full Prescribing Information.

IMMUNOCORE

KIMMTRAK (tebentafusp-tebn)
Injection for Intravenous Use 100 mcg/0.5 mL

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Introduction

This guide contains coding and billing information to consider related to KIMMTRAK (tebentafusp-tebn). This guide is provided for informational purposes only and is not intended as coverage or coding advice. Individual coding decisions should be based upon the diagnosis and treatment of individual patients. Immunocore cannot provide specific reimbursement rates, and does not guarantee reimbursement. While we have attempted to be current as of the date of this document, the information may not be as current or comprehensive when you view it. You should always verify the appropriate reimbursement information for services or items you provide.

INDICATION

- KIMMTRAK 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.

DOSAGE AND ADMINISTRATION

- The recommended dose of KIMMTRAK is 20 mcg on Day 1, 30 mcg on Day 8 and 68 mcg on Day 15 and 68 mcg once every week thereafter.
- Dilute and administer the first 3 doses by intravenous infusion over 15-20 minutes.
- Patients should be monitored during infusion and for at least 16 hours following the first 3 infusions.
- If patients tolerated the first 3 infusions well, patients should be monitored for a minimum of 30 minutes after the next infusions.
- Injection: 100 mcg/0.5 mL clear, colorless to slightly yellowish solution in a single-dose vial.

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Coding Quick Reference Guide

Below is a list of codes that may be relevant when KIMMTRAK is administered in the hospital outpatient or physician office setting. This list is provided for informational purposes only and is not intended to serve as billing guidance. It is always the provider's responsibility to select codes based upon actual services rendered and medical judgments made for each patient.

Item	Code	Description	Notes
NDC	80446-401-01 (10 digit) 80446-0401-01 (11 digit)	KIMMTRAK (100 mcg/0.5 mL solution in a single-dose vial)	Required by Medicaid and many commercial plans
HCPCS	J9274	Injection, tebentafusp-tebn, 1 mcg	Effective for dates of service on or after October 1, 2022*
Modifier	JW	Drug amount discarded/not administered to any patient	Required by Medicare to report unused portion of single-use vial
CPT†	96413	Chemotherapy administration, intravenous (IV) infusion technique; up to 1 hour, single or initial substance/drug	For IV infusions > 15 minutes
	96409	Chemotherapy administration, IV, push technique; single or initial substance/drug	For IV infusions ≤ 15 minutes
ICD-10-CM Diagnosis	C69.3X C69.4X C69.6X C69.9X	Malignant neoplasm of choroid Malignant neoplasm of ciliary body Malignant neoplasm of orbit Malignant neoplasm of unspecified site of eye	Example codes shown; not an exhaustive list. Actual code(s) reported should reflect highest level of specificity
Revenue	0636 025X	Pharmacy – Drugs Requiring Detailed Coding Pharmacy	0636 required for Medicare hospital outpatient claims; revenue code for other payers may vary

The use of KIMMTRAK in accordance with its FDA-approved label may involve additional services, which will vary depending on the dose and site of care. Please see pages 12-14 for coding information for these additional services.

The HCPCS billing unit for J9274 is **1 mcg**.
The recommended dose of KIMMTRAK is 20 mcg on Day 1, 30 mcg on Day 8, 68 mcg on Day 15, and 68 mcg once every week thereafter.

* Note: For dates of service prior to October 1, 2022, HCPCS coding for KIMMTRAK will vary. Please see page 7 for additional information.

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KIMMTRAK Reimbursement Support Services

KIMMTRAK CONNECT®

Call a dedicated nurse case manager directly:

844-775-CARE (844-775-2273)

Available Monday-Friday, 9 AM-7 PM (EST)

Additionally, someone is available to help you 24/7.

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National Drug Code (NDC)

The NDC for KIMMTRAK is listed below:

10-Digit NDC	11-Digit NDC	Packaging
80446-401-01	80446-0401-01	100 mcg/0.5 mL solution in a single-dose vial

NDC reporting for provider-administered drugs is required by Medicaid and many commercial plans.

Under traditional Medicare, NDCs are not required for drugs with a product-specific HCPCS code, but must be included for drugs that are billed using a "miscellaneous" HCPCS code, such as C9399 or J9999, as part of the additional information that is reported on claims (see next page for more information). Medicare Advantage plans may have different NDC reporting policies from traditional Medicare.

Note: Providers should check with their local payers to determine NDC reporting requirements, including whether the payer requires the 10-digit vs 11-digit NDC.

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Healthcare Common Procedure Coding System (HCPCS) Code for KIMMTRAK

The Centers for Medicare and Medicaid Services (CMS) has established a new product-specific HCPCS J-code for KIMMTRAK effective October 1, 2022:

HCPCS	Description
J9274	Injection, tebentafusp-tebn, 1 mcg

The HCPCS billing unit for J9274 is 1 mcg.

For example:

20 mcg of KIMMTRAK = 20 units of J9274
30 mcg of KIMMTRAK = 30 units of J9274
68 mcg of KIMMTRAK = 68 units of J9274

The recommended dose of KIMMTRAK is 20 mcg on Day 1, 30 mcg on Day 8, 68 mcg on Day 15, and 68 mcg once every week thereafter.

HCPCS code J9274 should be used on hospital outpatient and physician office claims with dates of service on or after October 1, 2022.*

For dates of service prior to October 1, 2022, HCPCS coding for KIMMTRAK will vary.

- Medicare hospital outpatient claims:
  - C9095 – Injection, tebentafusp-tebn, 1 mcg (dates of service from 7/1/2022 - 9/30/2022)*
  - C9399 – Unclassified drugs or biologicals (dates of service through 6/30/2022)
- Physician office (all payers) and non-Medicare hospital outpatient claims:
  - J9999 – Not otherwise classified, antineoplastic drugs (dates of service through 9/30/2022)
- "Miscellaneous" drug HCPCS codes (eg, J9999 and C9399) should be billed with a service unit of 1, and claims with miscellaneous codes must include additional information, such as the name of the drug, NDC, and dosage administered. This additional information is reported in Item 19 of the CMS-1500 claim form or Locator 80 of the UB-04/CMS-1450 claim form. Providers should contact their local payers to determine specific requirements for reporting drugs using miscellaneous codes.

Modifier	Description
TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes

* **Note:** For Medicare hospital outpatient claims with dates of service on or after July 1, 2022, certain 340B hospitals must report the TB modifier with KIMMTRAK's product-specific HCPCS code (J9274 or C9095, depending on the date of service) to indicate that KIMMTRAK was acquired through the 340B Drug Pricing Program (when applicable). This requirement does not apply to physician offices or non-Medicare payers. For more information, please scan the QR code. Note: Medicare 340B modifier requirements are subject to change at the direction of CMS.

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Using the JW Modifier to Bill for Discarded Drug

Under Medicare's discarded drug policy, hospital outpatient departments and physician offices must use the JW modifier to report the amount of unused drug from a single-use vial that is discarded, and must document the amount of discarded drug in the patient's medical record. Medicare will pay for both the amount of drug that is administered and the amount of drug that is discarded, up to the amount that is indicated on the vial or package label.

Modifier	Description
JW	Drug amount discarded/not administered to any patient

When a portion of a single-use vial is discarded, the amount of discarded drug should be billed as a separate line item with the JW modifier. The examples provided below illustrate how the JW modifier might be used with HCPCS code J9274 (Injection, tebentafusp-tebn, 1 mcg) based on KIMMTRAK's recommended dosing.

Note: The recommended dose of KIMMTRAK is 20 mcg on Day 1, 30 mcg on Day 8, 68 mcg on Day 15, and 68 mcg once every week thereafter. KIMMTRAK is supplied in a 100 mcg single-dose vial.

EXAMPLE 1: 20 MCG DOSE OF KIMMTRAK

HCPCS Code	Modifier	HCPCS Units (per 1 mcg)	
J9274	---	20	Line item 1 (amount administered)
J9274	JW	80	Line item 2 (amount discarded)

EXAMPLE 2: 30 MCG DOSE OF KIMMTRAK

HCPCS Code	Modifier	HCPCS Units (per 1 mcg)	
J9274	---	30	Line item 1 (amount administered)
J9274	JW	70	Line item 2 (amount discarded)

EXAMPLE 3: 68 MCG DOSE OF KIMMTRAK

HCPCS Code	Modifier	HCPCS Units (per 1 mcg)	
J9274	---	68	Line item 1 (amount administered)
J9274	JW	32	Line item 2 (amount discarded)

The above examples are provided only for informational purposes. Providers should determine the appropriate number of HCPCS units based on the actual amounts administered and discarded for a specific patient.

Note: Wastage-reporting policies for payers other than Medicare may vary. Providers should check with their specific plans about policies related to billing for discarded drug and use of the JW modifier.

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Current Procedural Terminology (CPT®) Coding for Drug Administration Service

The following CPT codes may describe the intravenous (IV) infusion service for the administration of KIMMTRAK:

CPT	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96409	Chemotherapy administration, intravenous, push technique; single or initial substance/drug

According to CPT guidelines, a first-hour IV infusion code (eg, 96413) may be used to report IV infusions lasting at least 16 minutes. If the duration of the IV infusion is 15 minutes or less, then the administration service would need to be reported using an IV push CPT code (eg, 96409).

The appropriate CPT code for the administration of KIMMTRAK will depend on the actual service performed. Providers should consult a current CPT manual and always select the code that accurately describes the administration service, based on the specific patient encounter. In addition, providers should check with their local payers to confirm their policies regarding drug administration coding and required documentation.

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ICD-10-CM Diagnosis Codes

All hospital and physician office claims must include at least one International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis code to describe the patient's condition. The following diagnosis codes may be relevant when reporting metastatic uveal melanoma:

ICD-10-CM	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
C69.90	Malignant neoplasm of unspecified site of unspecified eye
C69.91	Malignant neoplasm of unspecified site of right eye
C69.92	Malignant neoplasm of unspecified site of left eye

The ICD-10-CM diagnosis codes listed above are provided only as examples of potentially relevant codes; this list is not exhaustive. Providers should consult a current ICD-10-CM manual and always select the most appropriate diagnosis code(s) with the highest level of specificity to describe a patient's actual condition. All diagnosis codes should be supported with adequate documentation in the patient's medical record.

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Revenue Codes (for hospital use)

All hospital claim forms must include a revenue code for each charge line item. The following revenue codes are most relevant for provider-administered drugs such as KIMMTRAK:

Code	Description
0636	Pharmacy – Drugs Requiring Detailed Coding
025X	Pharmacy

Revenue code 0636 is required when a drug HCPCS code is billed on Medicare hospital outpatient claims. For payers other than Medicare, the revenue code may vary. Although some private payers and Medicaid plans accept revenue code 0636, others may require a different revenue code, such as 025X.

The revenue code for the drug administration service and other associated services may vary depending on the type of procedure and the cost center in which the procedure is performed.

Note: Revenue codes are not used in the physician office setting.

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Coding for Additional Services

Coding for Observation and Evaluation and Management (E/M) Services

Patients receiving KIMMTRAK should be monitored for at least 16 hours following the first 3 infusions and then as clinically indicated. Medicare requires hospitals and physicians to use different codes when billing for observation and E/M services. Examples of potentially relevant codes are listed below. These codes are provided only for informational purposes and are not intended to serve as billing guidance.

HCPCS Observation Codes for Hospital Use

Hospitals use HCPCS G-codes to report observation services on Medicare claims:

HCPCS	Description
G0378	Hospital observation service, per hour
G0379	Direct admission of patient for hospital observation care
G0463	Hospital outpatient clinic visit for assessment and management of a patient

Hospitals should scan the QR code to review the billing instructions for observation services in sections 290.5.2, 290.5.3, and 290.6 of chapter 4 of the Medicare Claims Processing Manual.

CPT E/M Codes for Physician Use

CPT codes for physician E/M services provided to hospital patients in observation care include those listed below:

CPT	Description (abbreviated)*
99217	Observation care discharge day management
99218-99220	Initial observation care, per day, for the evaluation and management of a patient
99224-99226	Subsequent observation care, per day, for the evaluation and management of a patient
99234-99236	Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date

* Please see a current CPT manual for complete descriptors for these codes.

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Coding for Additional Services (continued)

In the office setting, if a physician provides medically necessary E/M services that are separate and distinct from the drug administration procedure, and if the requirements for billing an E/M service are met, then it may be appropriate to report an E/M "office visit" code. CPT codes for office-based E/M services for established patients include the following:

CPT	Description
99212	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 10-19 minutes of total time is spent on the date of the encounter.
99213	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 20-29 minutes of total time is spent on the date of the encounter.
99214	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30-39 minutes of total time is spent on the date of the encounter.
99215	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 40-54 minutes of total time is spent on the date of the encounter.

Physicians should consult a current CPT manual to review all available E/M codes and applicable CPT guidelines, and to determine which E/M code (if any) is most appropriate for a specific patient encounter. In addition, physicians should scan the QR code to review the billing instructions for E/M services in section 30.6 of chapter 12 of the Medicare Claims Processing Manual.

Note: Observation and E/M coding requirements for payers other than Medicare may vary. Hospitals and physicians should check with their local payers for guidance on billing for observation and E/M services.

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Coding for Additional Services (continued)

HCPCS Codes for Human Albumin

The FDA-approved prescribing information for KIMMTRAK includes instructions for adding albumin (human) to the infusion bag. The available HCPCS codes for human albumin are listed below:

CPT	Description
P9041	Infusion of albumin (human), 5%, 50 ml
P9045	Infusion of albumin (human), 5%, 250 ml
P9046	Infusion of albumin (human), 25%, 20 ml
P9047	Infusion of albumin (human), 25%, 50 ml

The HCPCS codes listed above are provided only for informational purposes and are not intended to serve as billing guidance. Providers should check with their local payers to determine whether human albumin is separately billable when used with KIMMTRAK in accordance with the FDA-approved product label.

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Considerations for Billing and Payment in the Hospital Inpatient Setting

Hospital inpatient reimbursement differs significantly from reimbursement in outpatient settings. Below, we provide a high-level overview of some key considerations related to billing and payment under Medicare's hospital inpatient prospective payment system (IPPS).

Coding

HCPCS and CPT codes are generally not used on hospital inpatient claims; instead, hospitals typically report inpatient charges using only revenue codes. Revenue code 0250 (Pharmacy) is often used to bill for charges associated with drugs administered in the inpatient setting.

In addition, hospitals use ICD-10-CM and International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) codes to report diagnoses and procedures, respectively, on inpatient claims.

Payment

Under IPPS, each hospital inpatient case is assigned to a single Medicare Severity Diagnosis-Related Group (MS-DRG) based on the patient's diagnosis(es) and the procedure(s) performed. The MS-DRG provides a fixed, hospital-specific payment that is intended to cover nearly all costs incurred during the hospital inpatient stay. There are more than 700 MS-DRGs; therefore, payment rates for inpatient stays can vary greatly depending on the specifics of a particular case.

Nearly all drugs are considered bundled into the MS-DRG payment amount and are not eligible for separate payment in the inpatient setting.

3-Day Payment Window

In some cases, hospital outpatient services provided prior to an inpatient admission may be subject to a Medicare policy called the "3-day payment window." This policy bundles most outpatient services into a hospital's inpatient MS-DRG payment if the services are provided by the same hospital (or by an entity that is wholly owned or wholly operated by the admitting hospital) on the day of admission or during the 3 calendar days prior to admission (or 1 day prior to admission, for certain hospitals not paid under IPPS). In situations where the 3-day payment window applies, the hospital would need to bill for most services that it provides during the specified pre-admission timeframe (including drugs administered in the outpatient department) as part of the inpatient stay.

Hospitals should scan the QR code for more information on the 3-day payment window, including exceptions to the policy, in section 40.3 of chapter 3 of the Medicare Claims Processing Manual.

Note: The above information is specific to Medicare. Although policies for other payers may vary, bundled reimbursement is a common characteristic across most inpatient payment systems; under these systems, separate payment is usually not available for drugs administered in the inpatient setting. Hospitals should contact their local payers for plan-specific information on inpatient billing and reimbursement.

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Sample UB-04 (CMS-1450) Hospital Outpatient Claim Form

Note: This Sample Form is presented for illustrative purposes only; it does not constitute advice or recommendation as to the correct coding choices to be used for each specific patient. Each provider is responsible for completing forms and choosing codes based upon services rendered and medical judgments made for each patient.

Locator 42. Revenue Codes

Enter the appropriate revenue code for KIMMTRAK. For Medicare, use revenue code 0636 (Drugs Requiring Detailed Coding). For other payers, the revenue code may vary; although some private payers and Medicaid plans accept revenue code 0636, others may require a different revenue code, such as 0250 (Pharmacy).

Enter the appropriate revenue code for the administration service based on the cost center in which the procedure is performed.

	42 REV. CD	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
1	**0636**		**J9274**		**XX**
2	**0636**		**J9274JW**		**YY**

Locator 43. Description

Enter description for each revenue code.

Note: If NDC reporting is required (for example, for Medicaid and some commercial payers), enter the NDC information for KIMMTRAK in Locator 43. Check with the payer to determine the proper format for NDC reporting.

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
1	**0636**		**J9274**		**XX**
2	**0636**		**J9274JW**		**YY**

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Sample UB-04 (CMS-1450) Hospital Outpatient Claim Form (continued)

Locator 44. Product and Procedure Codes

Enter the appropriate HCPCS code for KIMMTRAK:

J9274 - Injection, tebentafusp-tebn, 1 mcg

(Effective for dates of service on or after October 1, 2022*)

For Medicare, unused drug should be reported as a separate line item with the HCPCS code and JW modifier. Wastage-reporting requirements for other payers may vary.

* **Note:** For dates of service prior to October 1, 2022, HCPCS coding for KIMMTRAK will vary. Please see page 7 for additional information.

Enter the appropriate CPT code(s) for the administration service based on the actual service performed. For example, a chemotherapy IV infusion lasting at least 16 minutes would be reported using CPT code 96413 - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug. Infusions lasting 15 minutes or less would need to be billed as an IV push.

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
1	**0636**		**J9274**		**XX**
2	**0636**		**J9274JW**		**YY**

Locator 46. Service Units

Report units of service for each HCPCS or CPT code in accordance with the code descriptor. For HCPCS code J9274, 1 service unit = 1 mcg of KIMMTRAK. The service units for the line item with the JW modifier (when applicable) should reflect the unused portion of the 100 mcg single-dose vial. See page 18 for 3 examples based on KIMMTRAK's recommended dosing.

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Sample UB-04 (CMS-1450) Hospital Outpatient Claim Form (continued)

Locator 46. Service Units (continued)

The below examples are intended to reflect KIMMTRAK's recommended dosing. The examples are provided only for informational purposes. Providers should determine the appropriate number of HCPCS units based on the actual amounts administered and discarded for a specific patient.

The recommended dose of KIMMTRAK is 20 mcg on Day 1, 30 mcg on Day 8, 68 mcg on Day 15, and 68 mcg once every week thereafter. KIMMTRAK is supplied in a 100 mcg single-dose vial.

EXAMPLE 1: 20 MCG DOSE OF KIMMTRAK

20 mcg administered, 80 mcg discarded

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
1	**0636**		**J9274**		**20**
2	**0636**		**J9274JW**		**80**

EXAMPLE 2: 30 MCG DOSE OF KIMMTRAK

30 mcg administered, 70 mcg discarded

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
1	**0636**		**J9274**		**30**
2	**0636**		**J9274JW**		**70**

EXAMPLE 3: 68 MCG DOSE OF KIMMTRAK

68 mcg administered, 32 mcg discarded

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
1	**0636**		**J9274**		**68**
2	**0636**		**J9274JW**		**32**

Locator 67. Diagnosis Code(s)

Enter the appropriate ICD-10-CM diagnosis code(s) to describe the patient's condition.
Example ICD-10-CM code shown; actual code(s) reported should reflect the highest level of specificity.

66 DX									
	C69.XX	A	B	C	D	E	F	G	H
	I	J	K	L	M	N	O	P	Q

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Sample CMS-1500 Physician Office Claim Form

Note: This Sample Form is presented for illustrative purposes only; it does not constitute advice or recommendation as to the correct coding choices to be used for each specific patient. Each provider is responsible for completing forms and choosing codes based upon services rendered and medical judgments made for each patient.

Item 21. Diagnosis Code(s)

Enter the appropriate ICD-10-CM diagnosis code(s) to describe the patient's condition. Example ICD-10-CM code shown; actual code(s) reported should reflect the highest level of specificity.

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)			ICD ind.
A. **C69.XX**	B.	C.	D.
E.	F.	G.	H.
I.	J.	K.	L.

Item 24A. Date(s) of Service

Enter the date of service.

Note: If NDC reporting is required (for example, for Medicaid and some commercial payers), enter the NDC information for KIMMTRAK in the shaded portion of Item 24A above the date of service. Check with the payer to determine the proper format for NDC reporting.

	24. A. DATE(S) OF SERVICE					
	From			To		
	MM	DD	YY	MM	DD	YY
1						
	12	**06**	**22**			
2						

Item 24D. Product and Procedure Codes

Enter the appropriate HCPCS code for KIMMTRAK.

J9274 - Injection, tebentafusp-tebn, 1 mcg

(Effective for dates of service on or after October 1, 2022*)

For Medicare, unused drug should be reported as a separate line item with the HCPCS code and JW modifier. Wastage-reporting requirements for other payers may vary.

* **Note:** For dates of service prior to October 1, 2022, HCPCS coding for KIMMTRAK will vary. Please see page 7 for additional information.

Billing and coding instruction is current as of September 2022.

Please see Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** on page 22 and see full Prescribing Information.

KIMMTRAK (tebentafusp-tebn)
Injection for Intravenous Use 100 mcg/0.5 mL

Sample CMS-1500 Physician Office Claim Form (continued)

Item 24D. Product and Procedure Codes (continued)

Enter the appropriate CPT code(s) for the administration service based on the actual service performed. For example, a chemotherapy IV infusion lasting at least 16 minutes would be reported using CPT code 96413 - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug. Infusions lasting 15 minutes or less would need to be billed as an IV push.

24. * D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS
J9274		A		XX
J9274	JW	A		YY

Item 24G. Service Units

Report units of service for each HCPCS or CPT code in accordance with the code descriptor. For HCPCS code J9274, 1 service unit = 1 mcg of KIMMTRAK. The service units for the line item with the JW modifier (when applicable) should reflect the unused portion of the 100 mcg single-dose vial. See below and next page for 3 examples based on KIMMTRAK's recommended dosing.

The following examples are intended to reflect KIMMTRAK's recommended dosing. The examples are provided only for informational purposes. Providers should determine the appropriate number of HCPCS units based on the actual amounts administered and discarded for a specific patient.

The recommended dose of KIMMTRAK is 20 mcg on Day 1, 30 mcg on Day 8, 68 mcg on Day 15, and 68 mcg once every week thereafter. KIMMTRAK is supplied in a 100 mcg single-dose vial.

EXAMPLE 1: 20 MCG DOSE OF KIMMTRAK

20 mcg administered, 80 mcg discarded

24. * D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS
J9274		A		20
J9274	JW	A		80

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KIMMTRAK (tebentafusp-tebn)
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Sample CMS-1500 Physician Office Claim Form (continued)

EXAMPLE 2: 30 MCG DOSE OF KIMMTRAK

30 mcg administered, 70 mcg discarded

D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS
J9274		A		30
J9274	JW	A		70

EXAMPLE 3: 68 MCG DOSE OF KIMMTRAK

68 mcg administered, 32 mcg discarded

D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS
J9274		A		68
J9274	JW	A		32

Item 24E. Diagnosis Pointer

Specify the diagnosis from Item 21 that corresponds to each CPT or HCPCS code.

	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS
1	J9274		A		XX
2	J9274	JW	A		YY

Billing and coding instruction is current as of September 2022.

Please see Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** on page 22 and see full Prescribing Information.

KIMMTRAK (tebentafusp-tebn)
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Indication and Important Safety Information Including Boxed Warning

Indication

KIMMTRAK 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.

Important Safety Information Including Boxed Warning

WARNING: CYTOKINE RELEASE SYNDROME

Cytokine 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. Manifestations of CRS may include fever, hypotension, hypoxia, chills, nausea, vomiting, rash, elevated transaminases, fatigue, and headache. CRS occurred in 89% of patients who received KIMMTRAK with 0.8% being grade 3 or 4. Ensure immediate access to medications and resuscitative equipment to manage CRS. Ensure patients are euvolemic prior to initiating the infusions. Closely monitor patients for signs or symptoms of CRS following infusions of KIMMTRAK. Monitor fluid status, vital signs, and oxygenation level and provide appropriate therapy. Withhold or discontinue KIMMTRAK depending on persistence and severity of CRS.

Skin Reactions

Skin reactions, including rash, pruritus, and cutaneous edema occurred in 91% of patients treated with KIMMTRAK. Monitor patients for skin reactions. If skin reactions occur, treat with antihistamine and topical or systemic steroids based on persistence and severity of symptoms. Withhold or permanently discontinue KIMMTRAK depending on the severity of skin reactions.

Elevated Liver Enzymes

Elevations in liver enzymes occurred in 65% of patients treated with KIMMTRAK. Monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total blood bilirubin prior to the start of and during treatment with KIMMTRAK. Withhold KIMMTRAK according to severity.

Embryo-Fetal Toxicity

KIMMTRAK may cause fetal harm. Advise pregnant patients of potential risk to the fetus and patients of reproductive potential to use effective contraception during treatment with KIMMTRAK and 1 week after the last dose.

The most common adverse reactions (≥30%) in patients who received KIMMTRAK were cytokine release syndrome, rash, pyrexia, pruritus, fatigue, nausea, chills, abdominal pain, edema, hypotension, dry skin, headache, and vomiting. The most common (≥50%) laboratory abnormalities were decreased lymphocyte count, increased AST, increased ALT, decreased hemoglobin, and decreased phosphate.

Please see full Prescribing Information, including BOXED WARNING for CRS.

Billing and coding instruction is current as of September 2022.

KIMMTRAK
(tebentafusp-tebn)
Injection for Intravenous Use 100 mcg/0.5 mL

Sources

1. Kimmtrak. Package insert. Immunocore Ltd; 2022. **2.** NDC: The Drug Listing Act of 1972 requires registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. (See Section 510 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 360]). Drug products are identified and reported using a unique, three-segment number, called the NDC, which serves as a universal product identifier for drugs. FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory which is updated daily. The information submitted as part of the listing process, the NDC number, and the NDC Directory are used in the implementation and enforcement of the Act. **3.** HCPCS Level II Coding Process & Criteria: The Centers for Medicare and Medicaid (CMS) published on August 17, 2000 (45 CFR 162.10002) to implement the HIPAA requirement for standardized coding systems established the HCPCS level II codes as the standardized coding system for describing and identifying healthcare equipment and supplies in healthcare transactions that are not identified by the HCPCS level I, CPT codes. The HCPCS level II coding system was selected as the standardized coding system because of its wide acceptance among both public and private insurers. Public and private insurers were required to be in compliance with the August 2000 regulation by October 1, 2002. The HCPCS level II Coding Process/ Criteria document describes HCPCS level II coding procedures and coding criteria. **4.** The International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) is a system used by physicians and other healthcare providers to classify and code all diagnoses, symptoms, and procedures recorded in conjunction with hospital care in the United States. The Centers for Disease Control developed and maintains the ICD-10-CM code set. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ICD9-10CM-ICD10PCS-CPT-HCPCS-Code-Sets-Educational-Tool-ICN900943.pdf **5.** CPT: The AMA developed and maintains the official CPT code set. According to the AMA website (https://www.ama-assn.org/amaone/cpt-current-procedural-terminology) the CPT is the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs. CPT is maintained by the CPT Editorial Panel, which meets 3 times a year to discuss issues associated with new and emerging technologies as well as difficulties encountered with procedures and services and their relation to CPT codes. **6.** CMS-1500 Form: The Form CMS-1500 is the standard paper claim form to bill Medicare Fee-For-Service (FFS) Contractors when a paper claim is allowed. In addition to billing Medicare, Form CMS-1500 may be suitable for billing various government and some private insurers. https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/837p-cms-1500.pdf **7.** UB-04 (CMS-1450) Form: The Form CMS-1450, also known as the UB-04, is the standard claim form to bill Medicare Administrative Contractors (MACs) when a paper claim is allowed. In addition to billing Medicare, the 837I and Form CMS-1450 may be suitable for billing various government and some private insurers. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/837I-FormCMS-1450-ICN006926.pdf

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BOXED WARNING for Cytokine Release Syndrome (CRS)
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Thank you

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KIMMTRAK
(tebentafusp-tebn)
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