Billing and Coding Guide

KIMMTRAK® (tebentafusp-tebn)

Please see Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** on pages 23-24 and see full Prescribing Information.

IMMUNOCORE

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

Acronym Glossary

Acronym	Definition
AMA	American Medical Association
CMS	Center for Medicare and Medicaid Services
CPT	Common Procedural Terminology
CRS	Cytokine Release Syndrome
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DRG	Diagnosis Related Group
E/M	Evaluation and Management
ICD	International Classification of Diseases
ICD-10-CM	International Classification of Diseases, 10th Revision, Clinical Modification
ICD-10-PCS	International Classification of Diseases, 10th Revision, Procedure Coding System
ICU	Intensive Care Unit
HCPCS	Healthcare Common Procedure Coding System
HOPD	Hospital Outpatient Department
NDC	National Drug Classification
NSAID	Non-Steroidal Anti-Inflammatory Drugs

Table of Contents

Billing and coding instruction is current as of July 2022.

Please see Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** on pages 23-24 and see full Prescribing Information.

KIMMTRAK (tebentafusp-tebn)
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Introduction

This guide contains coding and billing information to consider related to KIMMTRAK (tebentafusp-tebn). This guide is provided for information 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 three infusions.
- If patients tolerated the first three 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.

For complete dosage and administration, see full Prescribing Information.

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KIMMTRAK

Coding Quick Reference Guide

KIMMTRAK Billing Considerations:
Coding and reimbursement vary by site of care, with unique considerations in the inpatient setting.

Item	Code	Description	Relevant Site Care
HCPCS Code	J9999	Not otherwise classified, antineoplastic drugs	All Sites
10 Digit NDC	80446-401-01	KIMMTRAK (100 mcg/0.5 mL)	All Sites
11 Digit NDC	80446-0401-01	KIMMTRAK (100 mcg/0.5 mL)	All Sites
ICD-10-CM Codes (Not Exhaustive)**	Z51.11 Z85.840	Encounter for antineoplastic chemotherapy Personal history of malignant neoplasm of eye	All Sites
	C69.30	Malignant neoplasm of choroid	All Sites
CPT Code	96413	Chemotherapy administration, intravenous infusion technique	All Sites
	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (initial, up to 1 hour/Level 3 Drug Administration)	All Sites
Hospital Outpatient HCPCS Code	C9095	Inj, tebentafusp-tebn, 1 mcg	HOPD
Observational G-Code	G0378 G0463	Observation services, per hour Hospital outpatient clinic visit for assessment and management of a patient	HOPD
Discarded Drug Billing	JW Modifier	Billing for drug or biological amount discarded or not administered to patient	HOPD
Revenue Codes	250 260	General pharmacy IV therapy	HOPD + Inpatient
DRG*	124, 125	Other disorders of the eye	Inpatient
ICD-10-PCS Codes (Not Exhaustive)	3E03302 3E0330M 3E03305	Percutaneous approach, high dose Interleukin 2 Percutaneous approach, monoclonal antibody Percutaneous approach, other antineoplastic	Inpatient

The first 3 doses of KIMMTRAK should be administered in a hospital clinic setting. Patients require regular monitoring during infusion and for at least 16 hours afterward. If the first 3 doses of KIMMTRAK are well tolerated, subsequent doses can be administered in an appropriate ambulatory care setting. Patients should then be observed for a minimum of 30 minutes following each infusion.

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.

1 mcg KIMMTRAK = 1 billing unit

* DRG is not a drug specific code, but a diagnosis related group code for inpatient billing. KIMMTRAK is not reimbursed separately for inpatient billing, but in a bundled payment amount that covers the inpatient episode of care.

** Not exhaustive list, as many ICD-10-CM codes correspond to possible diagnoses triggering KIMMTRAK use. Displayed above is sample of diagnoses associated with surgical procedures that may incur KIMMTRAK use.

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Summary Drug Administration Scenarios and Coding Implications

Scenario	Description	Summary Billing Guidance
Physician office administration	KIMMTRAK is administered in a physician office setting	Refer to form on Page 17
HOPD administration	KIMMTRAK is administered in a hospital outpatient facility setting	Refer to form on Page 19
Inpatient hospital admission and drug administration	KIMMTRAK is administered to a patient admitted to the hospital for an inpatient episode of care	Refer to form on Page 21
HOPD administration followed by inpatient hospital admission for longer than 48 hours	KIMMTRAK is administered in a hospital outpatient facility setting, followed by ICU admission to manage toxicity syndromes	Refer to form on Page 21 For further details, refer to Key Considerations for Hospital Inpatient Billing on page 25.

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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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Healthcare Common Procedure Coding System (HCPCS) Codes for KIMMTRAK

Potential Level II HCPCS Codes for Billing KIMMTRAK

HCPCS Code	Description	Use
J9999	Not otherwise classified, antineoplastic drugs	Not otherwise classified "Chemotherapy drug" therapy used in medical care
C9095	Inj, tebentafusp-tebn, 1 mcg	Outpatient Claims billed under Medicare using the Hospital Outpatient Prospective Claims System

Dosing

Dosing schedules are likely to approximately follow this regimen: 20 mcg at day 1, 30 mcg at day 8, and 68 mcg at day 15, with weekly infusions thereafter.

The NDC for KIMMTRAK is:

10-Digit NDC Number	Description
80446-401-01	National Drug Code

11-Digit NDC Number	Description
80446-0401-01	National Drug Code

Note: Contact payer for specific requirements for using 11 digit vs 10 digit NDC code.

KIMMTRAK Updated Billing Overview

C-Code Guidance for Billing KIMMTRAK		
Title	**Item**	**Code**
Medicare Hospital Outpatient for dates of service before June 30	Miscellaneous C-code	C9399
Medicare Hospital Outpatient for dates of service on or after July 1	New product-specific C-code	C9095
Non-Medicare Hospital Outpatient	Miscellaneous J-code	J9999
Physician Office	Miscellaneous J-code	J9999

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Healthcare Common Procedure Coding System (HCPCS) Codes for Albumin Infusion

Potential Level II HCPCS Codes for Billing Human Albumin Infusion

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

Note: Contact your local payer for specific guidance on billing for human albumin infusion.

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Relevant HCPCS G-Codes for Procedures/Professional Services (Temporary Codes)

G-codes are temporary codes assigned to services and procedures that are under review before being included in the CPT coding system. The below codes may be relevant to KIMMTRAK in some payer specific situations, and often added to provide additional context for other services being billed, such as observation services. Providers should consult with their local payers to identify the most appropriate coding procedures, as payment for these services is under the jurisdiction of the local carriers.

G-Code	Description
G0378	Observation service provided *(Note: reimbursement is considered for observation period that meets or exceeds 8 hours)*
G0379	Observation services provided following direct referral/admission for observation care without an associated ER, critical care, or hospital outpatient clinic visit on the day of initiation *(Note: code must be submitted on the same date of service as G0379)*
G0463	Hospital outpatient clinic visit for assessment and management of a patient that has not occurred on the same day as drug administration

Note: Commercial payer coding guidance may vary.
Please refer to your local payer guidance on appropriate observational service coding.

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Relevant HCPCS Code Modifier for Vial Wastage of Discarded Drug Amount

Billing Guidance for Discarded or Unused Drug in a Single Use Vial

Providers should consult with their local payers to identify the most appropriate administration coding procedures and required documentation.

Modifier	Code Description
JW	Drug or biological amount discarded or not administered to patient – JW modifier is a HCPCS Level II modifier used on a Medicare Part B drug claim to report the amount of drug that is discarded and eligible for payment under the CMS discarded drug policy – The vial wastage should be billed on a separate claim line with the JW modifier and should reflect the amount of drug discarded

Note: Commercial payer coding guidance may vary.

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Relevant Level II Current Procedural Terminology (CPT) Administration Codes for Billing KIMMTRAK

Providers should consult with their local payers to identify the most appropriate administration coding procedures and required documentation. The following codes may be used for intravenous infusion of KIMMTRAK.

CPT Codes	Description
96413	Chemotherapy administration, intravenous infusion technique (single or initial, up to 1 hour/Level 4 Drug Administration)
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (initial, up to 1 hour/Level 3 Drug Administration)

Established patients (physician office and outpatient setting only)

CPT Codes	Description
99212	Visit for straightforward medical evaluation ~20mins
99213	Examination, low level of medical decision making ~30mins
99214	Detailed examination and medical decision making of moderate complexity ~40mins
99215	Comprehensive examination; medical decision making of high complexity ~55mins

Key inpatient administration codes

CPT Codes	Description
99231	Patient is stable, recovering, or improving
99232	Patient is responding inadequately to therapy or has developed a minor complication
99233	Patient is unstable or has a significant new problem or complication

Note: Commercial payer coding guidance may vary.

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Relevant Level II Current Procedural Terminology (CPT) Observational Codes for Billing KIMMTRAK

Observation Care Admission and Discharge Services on Same Date

Reporting should be completed for evaluation and management (E/M) services provided to new or established patients designated as “observation status” in a hospital.

CPT Codes	Description
99224	Typically, 15 minutes at the bedside and on the patient’s hospital floor or unit
99225	Typically, 25 minutes at the bedside and on the patient’s hospital floor or unit
99226	Typically, 35 minutes at the bedside and on the patient’s hospital floor or unit

Physician Billed Observation

Guidance is for reporting E/M services provided to patients admitted and discharged on the same date of service, including admission and discharge.

Requires 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity.

CPT Codes	Description
99234	Typically, 40 minutes are spent at the bedside and on the patient's hospital floor or unit
99235	Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit
99236	Typically, 55 minutes are spent at the bedside and on the patient's hospital floor or unit

Note: Commercial payer coding guidance may vary.

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Relevant Level II Current Procedural Terminology (CPT) for Human Leukocyte Antigen (HLA) Typing

Human Leukocyte Antigen (HLA) typing is performed to identify HLA alleles and allele groups (antigen equivalents) associated with specific diseases and individualized responses to drug therapy as well as other clinical uses. One or more HLA genes may be tested in specific clinical situations. Each HLA gene typically has multiple variant alleles or allele groups that can be identified by typing. HLA antigens are divided into types: Class I (A, B, C) and Class II (DR, DP, DQ).

Coding for HLA typing will likely be submitted separate from administration of KIMMTRAK, as HLA typing is typically completed prior to determination of KIMMTRAK usage to ensure patient eligibility.

CPT Codes	Description
81379	HLA Class I typing, high resolution (ie, alleles or allele groups); complete (ie, HLA-A, HLA-B, and HLA-C)
81380	HLA Class I typing, high resolution (ie, alleles or allele groups); one locus (eg, HLA-A, HLA-B, and HLA-C)
81381	HLA Class I typing, high resolution (ie, alleles or allele groups); one allele or allele group (eg, B*57:01P)

Note: Commercial payer coding guidance may vary.
Please refer to your local payer guidance on appropriate observational service coding.

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Relevant ICD-10-CM Codes for Use When Billing a KIMMTRAK Claim; Use Most Specific Sub-Coding Possible

10th Revision, Clinical Modification (ICD-10-CM) Codes for use when billing a KIMMTRAK claim.

ICD-10-CM Code	Code Description
Z51.11	Encounter for antineoplastic chemotherapy
Z51.89	Encounter for other specified aftercare
Z85.840	Personal history of malignant neoplasm of eye
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

Not exhaustive list as many ICD-10-CM codes correspond to possible diagnoses triggering KIMMTRAK use.
Displayed above is sample of diagnoses associated with surgical procedures which may require the use of KIMMTRAK.

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Relevant ICD-10-PCS Codes for Hospital Inpatient Procedures

Providers should consult with their local payers to identify the most appropriate administration coding procedures and required documentation. The following codes may be used for intravenous infusion of KIMMTRAK in the hospital inpatient setting.

ICD-10-PCS Code	Code Description
3E03302	Introduction of high dose Interleukin 2 into peripheral vein, percutaneous approach
3E0330M	Introduction of monoclonal antibody into peripheral vein, percutaneous approach
3E0430M	Introduction of monoclonal antibody into central vein, percutaneous approach
3E03305	Introduction of other antineoplastic into peripheral vein, percutaneous approach
3E04305	Introduction of other antineoplastic into central vein, percutaneous approach

Note: Commercial payer coding guidance may vary.

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Physician Office Sample Claim Form

CMS-1500

ITEM 19	When billing a not-otherwise-classified HCPCS code like J9999, some payers may ask providers to specify KIMMTRAK with dosage administered and NDC number *NOTE: Some payers require alternate product codes (i.e., Medicaid claims). Please consult with your local payers.*
ITEM 21	Indicate diagnosis/diagnoses using appropriate ICD-10-CM codes
ITEM 24D	Indicate appropriate CPT and HCPCS codes and modifiers if required *NOTE: Individual payers will require documentation to adjudicate any claim billed with an unlisted CPT code. Please consult with your local payer. Additional information on the procedure may be placed in Item 19.*
ITEM 24E	Refer to the diagnosis for this service (see box 21). Enter only one diagnosis pointer per line.
ITEM 24G	Enter number of MGs of active ingredient utilized in one row, followed by number of MGs wasted in subsequent row

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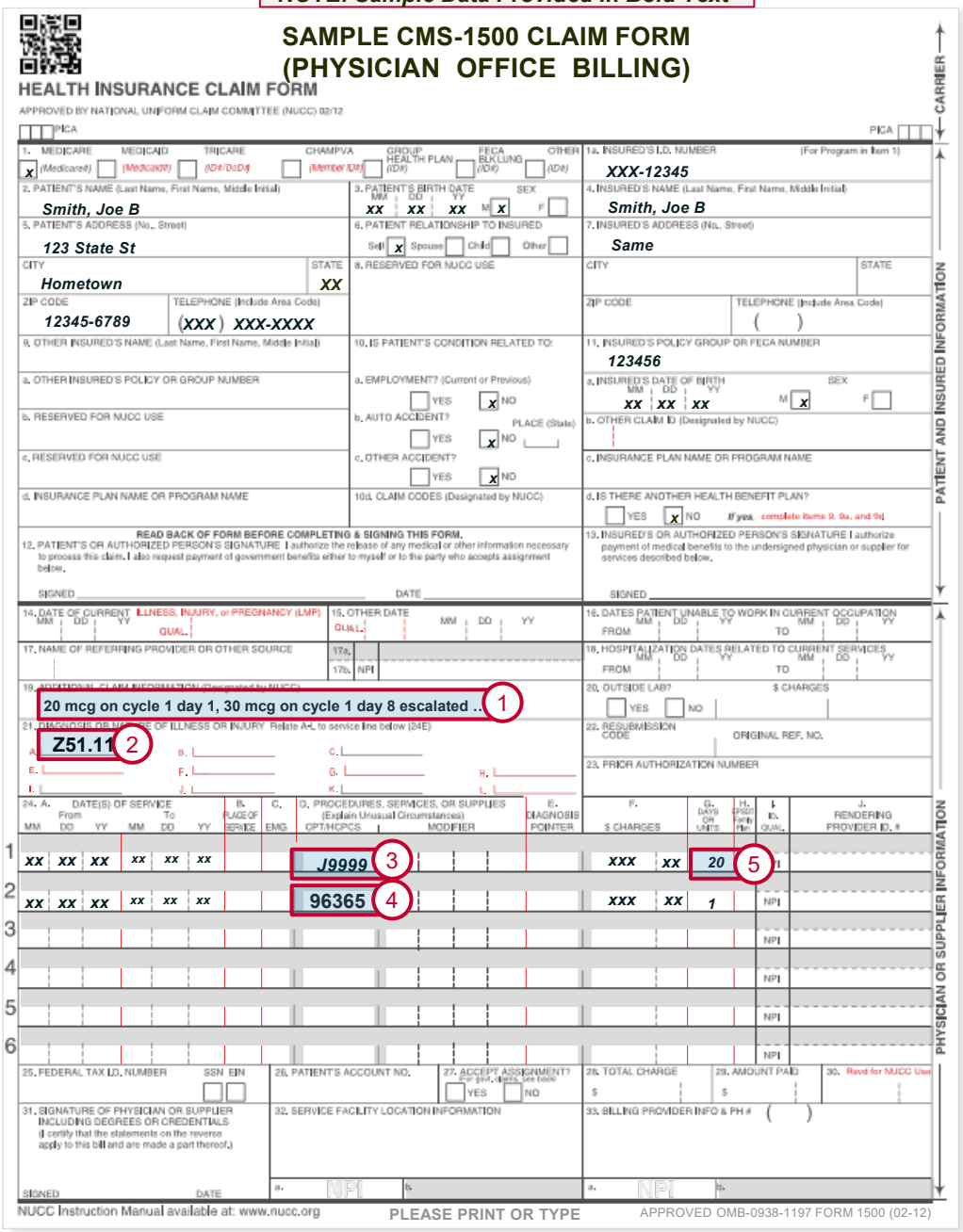
KIMMTRAK

Sample CMS-1500 claim form (physician office billing)

NOTE: Sample Data Provided in Bold Text



SAMPLE CMS-1500 CLAIM FORM (PHYSICIAN OFFICE BILLING)

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE (Medicare#) X	1a. INSURED'S I.D. NUMBER: XXX-12345
2. PATIENT'S NAME: Smith, Joe B	3. PATIENT'S BIRTH DATE: xx xx xx; SEX: M X
4. INSURED'S NAME: Smith, Joe B	
5. PATIENT'S ADDRESS: 123 State St	6. PATIENT RELATIONSHIP TO INSURED: Self X
7. INSURED'S ADDRESS: Same	
CITY: Hometown	STATE: XX
ZIP CODE: 12345-6789	TELEPHONE: (XXX) XXX-XXXX
11. INSURED'S POLICY GROUP OR FECA NUMBER: 123456	
11a. INSURED'S DATE OF BIRTH: xx xx xx; SEX: M X	
19. ADDITIONAL CLAIM INFORMATION: 20 mcg on cycle 1 day 1, 30 mcg on cycle 1 day 8 escalated .. (1)	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY: A. Z51.11 (2)	

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 xx xx xx	xx xx xx			J9999 (3)			xxx xx	20 (5)		NPI	
2 xx xx xx	xx xx xx			96365 (4)			xxx xx	1		NPI	
3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN | 26. PATIENT'S ACCOUNT NO. | 27. ACCEPT ASSIGNMENT? YES NO | 28. TOTAL CHARGE $ | 29. AMOUNT PAID $ | 30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION a. NPI b.

33. BILLING PROVIDER INFO & PH # ( ) a. NPI b.

NUCC Instruction Manual available at: www.nucc.org | PLEASE PRINT OR TYPE | APPROVED OMB-0938-1197 FORM 1500 (02-12)

1. Additional Claim Information
Field19
Enter drug name, dosage, and NDC

2. Diagnosis Code
Field 21
*Sample data provided in the form; refer to page 13 for list of potential applicable codes

3. Product Code
Field 24D
*Sample data provided in the form; refer to page 8 for list of potential applicable codes

4. Procedure Code
Field 24D
*Sample data provided in the form; refer to pages 9 and 10 for list of potential applicable codes

5. Service Units
Field 24G
For rows with procedure-specific CPT codes, enter '1'. For rows with product HCPCS code, enter number of units billed (where units are smallest billable units -1mg).

Note: Contact payer for specific coding requirements for billing wastage. For Medicare claims and some Commercial claims (not including those for J3490, J3590, or J9999), it may be necessary to enter one product row for utilized product amount and separate product row for wasted amount. Row corresponding to wasted amount would have 'JW' entered into modifier field. This is not necessary if amount of wasted active ingredient < smallest billable unit (1 mg).

All coding and documentation requirements should be confirmed with each payer.

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Injection for Intravenous Use 100 mcg/0.5 mL

2020 HOPD Sample Claim Form

UB-04/CMS-1450

LOCATOR

BOX 42	List revenue codes in ascending order • Code 250 for general pharmacy • Code 260 for IV therapy
BOX 43	NDC code
BOX 44	Indicate appropriate CPT and HCPCS codes and modifiers if required *NOTE: Individual payers will require documentation to adjudicate any claim billed with an unlisted CPT code. Please consult with your local payer.*
BOX 46	Enter number of MGs of active ingredient utilized in one row, followed by number of MGs wasted in subsequent row
BOX 47	Indicate total charges
BOX 67	Indicate diagnosis/diagnoses using appropriate ICD-10-CM codes
BOX 80	When billing a not-otherwise-classified HCPCS code like C9399, some payers may ask providers to specify KIMMTRAK with dosage administered, vial size and NDC code in addition to the HCPCS J-code. When required by the payer, report the NDC. Verify the payer-specific claim submission requirements. *NOTE: KIMMTRAK is packaged in single-use vials.*

All coding and documentation requirements should be confirmed with each payer.

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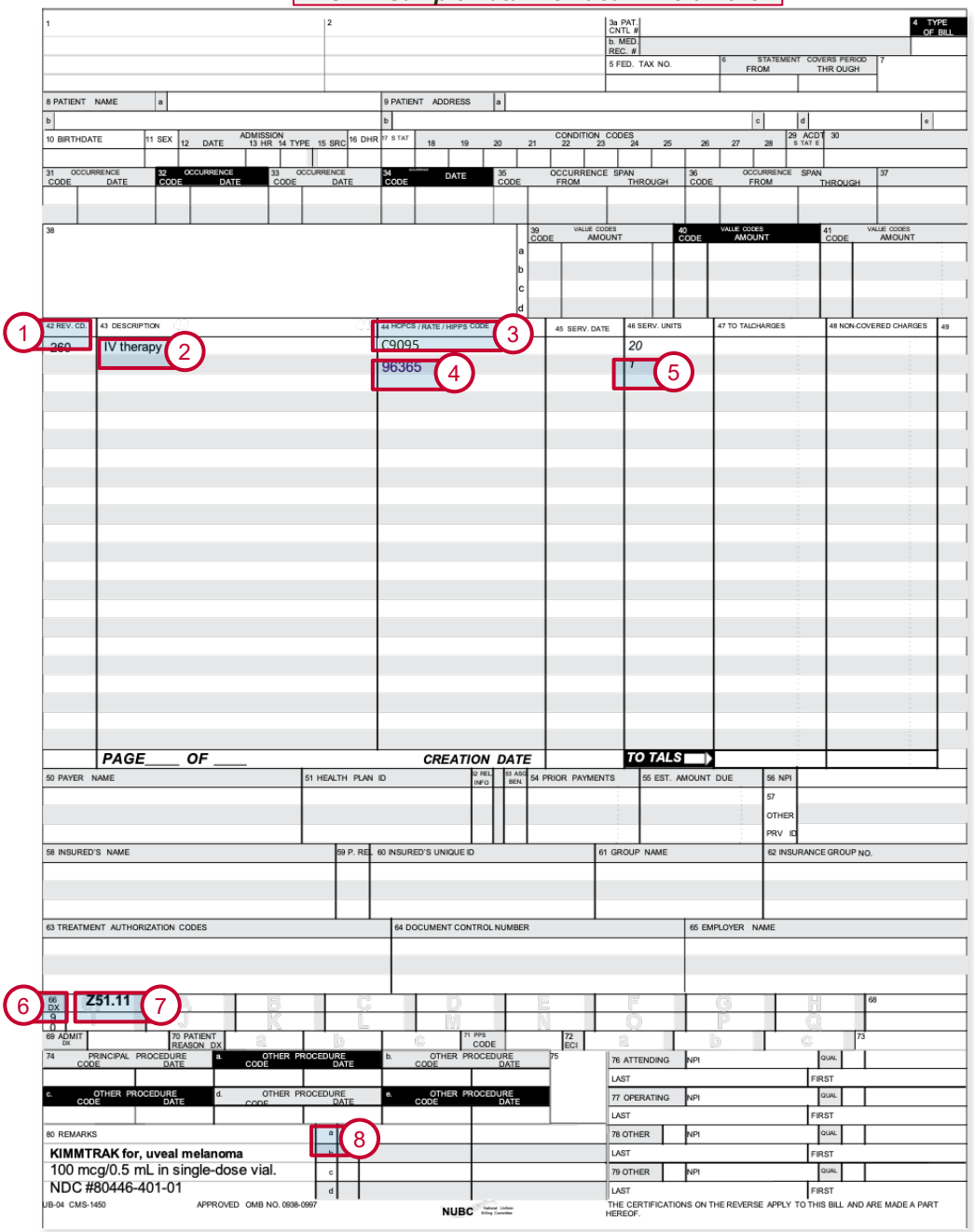
KIMMTRAK

Sample UB-04 (CMS-1450) claim form (institutional billing)

NOTE: Sample Data Provided in Bold Text



1. **Revenue Code**
   Field 42
   *Sample data provided in the form; refer to page 5 for list of potential applicable codes

2. **Description**
   Field 43
   Contact payer for specific requirements for using 11-digit vs 10-digit NDC code.

3. **HCPCS Code**
   Field 44
   *Sample data provided in the form; refer to page 8 for list of potential applicable codes

4. **Procedure Code**
   Field 42D
   *Sample data provided in the form; refer to pages 9 through 11 for list of potential applicable codes

5. **Service Units**
   Field 46
   For row with procedure-specific CPT code, enter '1'. For row with product HCPCS code, enter number of units billed (where units are smallest billable units - 1mg).

6. **Diagnosis and Procedure Code Qualifier**
   Field 66

7. **Diagnosis Code**
   Field 67
   *Sample data provided in the form; refer to page 13 for list of potential applicable codes

8. **Remarks**
   Field 80
   Note that if C9399 is used in Field 44, some payers may request that Field 80 should include name of drug, dosage, vial size, route of administration and NDC.

Note: Contact payer for specific coding requirements for billing wastage. For Medicare claims and some Commercial claims (not including those for J3490, J3590, or J9999), may be necessary to enter one product row for utilized product amount and separate product row for wasted amount. Row corresponding to wasted amount would have 'JW' entered into Field 44 next to product or procedure code. Not necessary if amount of wasted active ingredient < smallest billable unit (1 mg).

* Quantity qualifier options include F2 (international unit), GR (gram), ML (milliliter), UN (units)

All coding and documentation requirements should be confirmed with each payer.

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Injection for Intravenous Use 100 mcg/0.5 mL

Inpatient Administration Sample Claim Form

UB-04/CMS-1450

LOCATOR

BOX 42	List revenue codes in ascending order • Code 250 for general pharmacy • Code 260 for IV therapy
BOX 43	NDC code
BOX 44	Indicate appropriate CPT and HCPCS codes and modifiers if required *NOTE: Individual payers will require documentation to adjudicate any claim billed with an unlisted CPT code. Please consult with your local payer.*
BOX 46	Enter number of MGs of active ingredient utilized in one row, followed by number of MGs wasted in subsequent row
BOX 47	Indicate total charges
BOX 67	Indicate diagnosis/diagnoses using appropriate ICD-10-CM codes
BOX 74	Indicate principal ICD-10-PCS codes
BOX 80	When billing a not-otherwise-classified HCPCS code like C9399, some payers may ask providers to specify KIMMTRAK with dosage administered and NDC code

All coding and documentation requirements should be confirmed with each payer.

Billing and coding instruction is current as of July 2022.

Please see Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** on pages 23-24 and see full Prescribing Information.

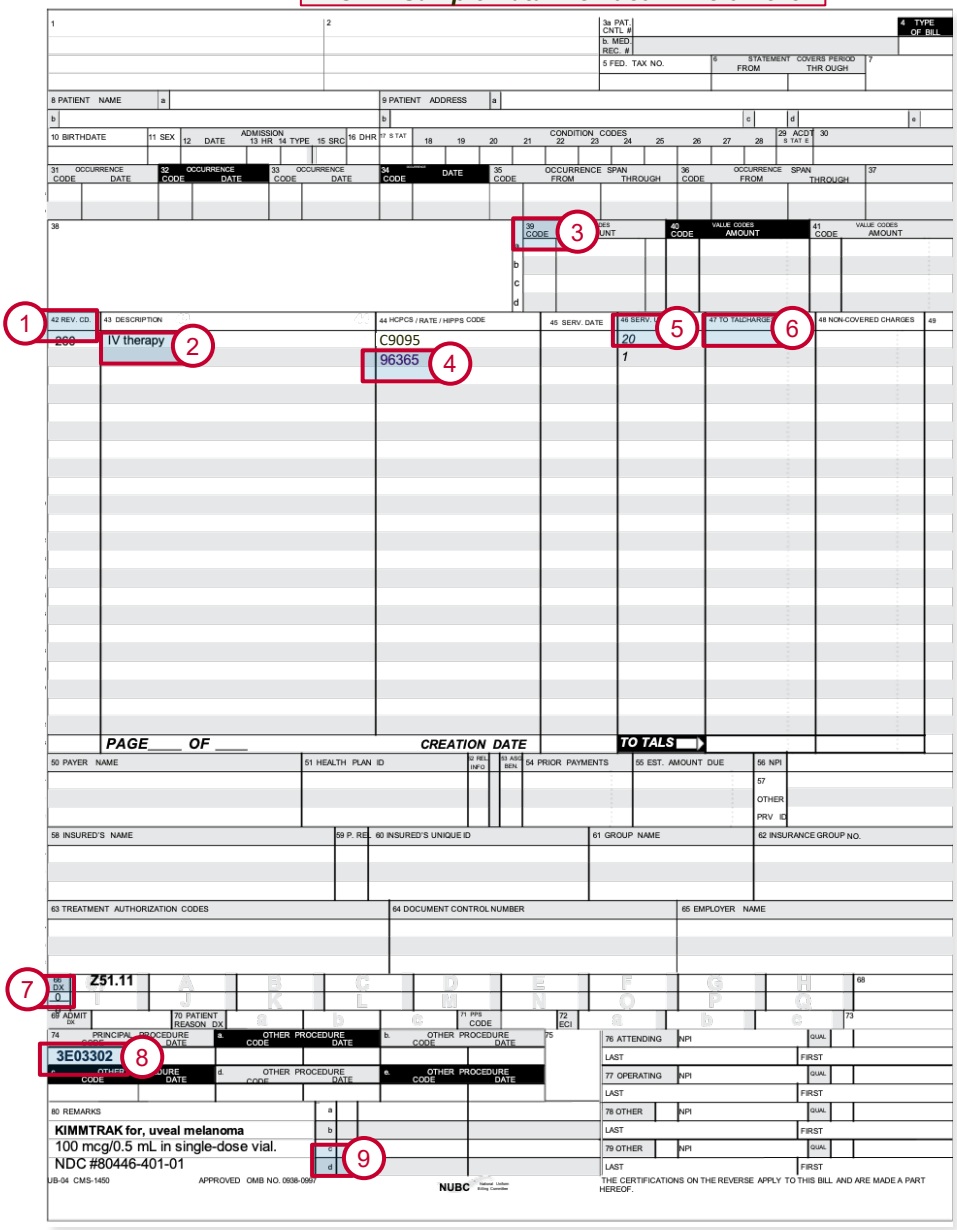
KIMMTRAK (tebentafusp-tebn)
Injection for Intravenous Use 100 mcg/0.5 mL

Disclaimer: 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 judgements made for each patient.

KIMMTRAK

Sample UB-04 (CMS-1450) claim form (institutional billing)

NOTE: Sample Data Provided in Bold Text



1. **Revenue Codes**
   Field 42 and
   Descriptions
   Field 43
   Medicare: Enter the appropriate revenue codes, such as 250 for General pharmacy and 260 for IV therapy
   *Sample data provided in the form; refer to page 5 for list of potential applicable codes

2. **Description**
   Field 43
   Refer to payer for specific requirements for using 11-digit vs 10-digit NDC code

3. **Value Code**
   Field 39
   Enter the appropriate value codes and amounts, and ensure monetary values are right-justified and nonmonetary values are left-justified. If there is only 1 value code applicable to the claim, then the first field is populated – 39. There are 3 spots because more than 1 value code may be applicable or required to correctly bill the claim.

4. **Product and Procedure Codes**
   Field 44
   HCPCS and CPT codes are not required by Medicare in the inpatient setting, but they may be used for itemization purposes with all payers

5. **Service Units**
   Field 46
   Report units of service for both units administered and amount of discarded drug. Dose reported as 1 unit per mcg.

6. **Total Charges**
   Field 47
   Report appropriate charges for product used and related procedures

7. **Diagnosis Codes**
   Field 67 and 67A-Q
   Enter the appropriate diagnosis code
   Final codes depend on medical record documentation and payer requirements
   *Sample data provided in the form; refer to page 13 for list of potential applicable codes

8. **Principal Procedure**
   Field 74
   Enter principal ICD-10-PCS procedure code
   •Procedure code – description
   *Sample data provided in the form; refer to page 14 for list of potential applicable codes

9. **Remarks**
   Field 80
   When reporting KIMMTRAK, some payers may require listing the NDC in addition to the HCPCS code

* Quantity qualifier options include F2 (international unit), GR (gram), ML (milliliter), UN (units)

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Important Safety Information (ISI) *(1 of 2)*

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.

Billing and coding instruction is current as of July 2022.

Please see Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** on pages 23-24 and see full Prescribing Information.

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Important Safety Information (ISI) *(2 of 2)*

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 creatinine, increased glucose, 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 July 2022.

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KIMMTRAK

Key Considerations for Hospital Inpatient Billing

Key Considerations	Description
Key Codes for Inpatient Hospital Billing	In the hospital inpatient setting, KIMMTRAK is not paid for separately but included in a bundled payment amount that covers the inpatient episode of care. The following codes must be used in the UB-04 form for the hospital inpatient setting when billing for KIMMTRAK and its administration: • International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes • International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) Procedure Codes • Revenue Codes
Medicare Three-Day Rule	**Medicare 3-Day (1-Day) Payment Window Policy - Outpatient Services Treated As Inpatient:** Section 102 of the law pertains to Medicare's policy for payment of outpatient services provided on either the date of a beneficiary's admission or during the three calendar days immediately preceding the date of a beneficiary's inpatient admission to a "subsection (d) hospital" subject to the inpatient prospective payment system, "IPPS" **KIMMTRAK Billing Implications:** KIMMTRAK administration in the HOPD setting will be billed as part of an inpatient episode of care if the patient is transitioned to inpatient care within three days due to an adverse event
Additional Inpatient Billing Considerations	• Medicare reimbursement in the inpatient setting is bundled into the Medicare Diagnosis Related Groups called MS-DRGs • Medicare uses the DRG-based grouping methodology, which assigns patients with similar conditions into specific groups and provides payment for the full episode of care, including for treatment administration • Most Medicaid plans and many commercial plans use the DRG-based grouping methodology, but the coding and reimbursement methodologies used may vary across states and payers • Please refer to specific payer and state guidelines for direction on appropriate code selection

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Sources

1. **NDC National Drug Code:** 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 (Act) (21 U.S.C. § 360)). Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (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.

2. **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 health care equipment and supplies in health care 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.

3. **ICD-10-CM:** 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

4. **CPT, Current Procedural Terminology:** The American Medical Association developed and maintains the official Current Procedural Terminology (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 three 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.

5. **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

6. **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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Thank you

Reference: 1. Kimmtrak. Package insert. Immunocore Ltd; 2022.

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