Adaptimmune

Billing and Coding Guide

An overview of the key coding descriptors that capture diagnoses, medical procedures, and product information needed for billing and coding for TECELRA

Please see Important Safety Information on pages 23-25 of this guide and accompanying full Prescribing Information for TECELRA, including Boxed Warning.

Tecelra®
afamitresgene autoleucel
suspension for IV infusion

Table of contents

Introduction and disclaimers 3

The TECELRA patient-care process 4

Hospital considerations regarding TECELRA patient status 5

Coding summary for TECELRA 6

Relevant codes and modifiers for TECELRA 8

- Diagnostic Testing 8
- T cell Retrieval, Preparation, and Administration Services 8
- National Drug Code 9
- ICD-10-PCS Procedure Codes 9
- ICD-10-CM Diagnosis Codes 10
- HCPCS Level II Codes 11
- 340B Modifiers 12
- Reporting Wastage 12
- Other Codes of Interest (Revenue Codes) 13

Sample CMS-1450 claim form for TECELRA 14

Sample annotated CMS-1450 (UB-04) inpatient claim form 16

Sample annotated CMS-1450 (UB-04) outpatient claim form 18

Preparing to submit a prior authorization 20

References 22

Important Safety Information 23

Please see Important Safety Information on pages 23-25 of this guide and accompanying full Prescribing Information for TECELRA, including Boxed Warning.

Introduction and disclaimers

TECELRA is a MAGE-A4-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive, and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices.[1]

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.[1]

Adaptimmune has developed this guide to provide general information regarding the key coding descriptors that capture diagnoses, medical procedures, and product information needed for billing and coding for TECELRA. This information is intended for healthcare providers and administrative staff involved in prescribing and/or claim submission for TECELRA.

- The content is provided for informational purposes only and is not intended to replace a healthcare provider's professional judgment or serve as legal advice. It is the sole responsibility of the treating healthcare provider (HCP) to confirm accurate coverage, coding, and claim submission status with the patient's health insurance plan.
- Adaptimmune does not guarantee payer coverage or reimbursement for TECELRA.
- Please note that the information specific to coding, coverage policies, and payment methodologies is subject to change and the HCP/administrative staff should be verified for each patient prior to treatment. The information in the guide is current as of August 2024.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION: DO NOT use TECELRA in adults who are heterozygous or homozygous for HLA-A*02:05P.

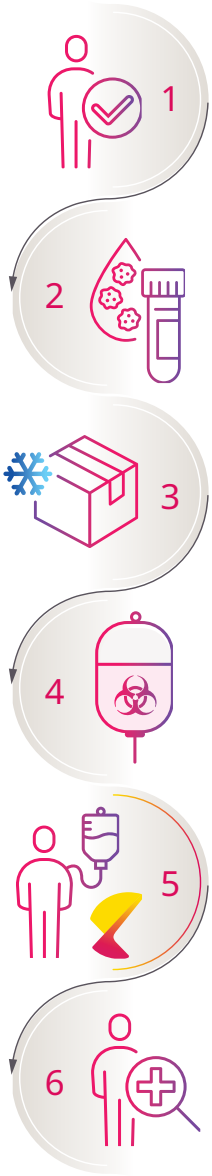
BOXED WARNING: Cytokine release syndrome (CRS), which may be severe or life-threatening, occurred in patients receiving TECELRA. At the first sign of CRS, immediately evaluate patient for hospitalization and institute treatment with supportive care. Ensure that healthcare providers administering TECELRA have immediate access to medications and resuscitative equipment to manage CRS.

FDA, US Food and Drug Administration; HLA, human leukocyte antigen; MAGE-A4, melanoma-associated antigen A4.

Please see additional Important Safety Information on pages 23-25 of this guide and accompanying full Prescribing Information for TECELRA.

The TECELRA patient-care process

TECELRA is administered as a one-time infusion at an Authorized Treatment Center (ATC). Patients will likely be in a hospital before and after getting TECELRA to be monitored for side effects that can be severe or life-threatening. The entire treatment process consists of 6 distinct steps.



Patient Identification[1]:

Adult patient with unresectable or metastatic synovial sarcoma who has received prior chemotherapy, and is:

- Positive for HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P*
- AND whose tumor expresses the MAGE-A4 antigen*

TECELRA is contraindicated in adults who are heterozygous or homozygous for HLA-A*02:05P.

Leukapheresis[2,3]:

Patients undergo leukapheresis to isolate T cells from the peripheral blood.

Cell Manufacturing:

Harvested T cells from patients are shipped fresh to Adaptimmune to be engineered into T cell receptor (TCR) T cells and then expanded in number.[3]

- Once the final product is ready, it is shipped frozen back to the ATC.

Lymphodepleting Chemotherapy[1]:

Patient undergoes 4 days of a lymphodepleting chemotherapy prior to TECELRA infusion.

Infusion:

TECELRA is administered to the patient at an ATC.

Monitoring for Adverse Reactions[1]:

Patients are monitored at a healthcare facility for at least 7 days following TECELRA infusion. Patients should plan to stay close to a healthcare facility for at least 4 weeks.

FDA, US Food and Drug Administration; HLA, human leukocyte antigen; MAGE-A4, melanoma-associated antigen A4.

*As determined by FDA-approved or cleared companion diagnostic devices. Information on FDA-approved tests is available at www.fda.gov/companiondiagnostics.

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Hospital considerations regarding TECELRA patient status

Confirming the status of the patient at each step in the TECELRA episode of care is key to understanding coverage, coding, and billing of TCR T cell therapy services.

- The inpatient or outpatient status of a hospital patient is critically important, since it determines the code sets used to report TCR T cell therapy services, hospital claim requirements, and, ultimately, reimbursement.

Hospital "Inpatient"

When provided in the inpatient hospital setting, TECELRA and its administration are not paid separately but, rather, are included in a bundled payment amount that covers the inpatient stay. The types of code sets commonly required for billing TECELRA provided in the inpatient hospital setting include:

- ICD-10-CM diagnosis codes
- ICD-10-PCS procedure codes
- Revenue codes
- HCPCS Level II Codes

Hospital "Outpatient"

When provided in the outpatient hospital setting, TECELRA and its administration may be paid separately. Several payers, including managed Medicare plans (Medicare Advantage) will typically pay for the product and service separately; however, coding requirements and payment methodologies may vary. Code types commonly required for billing TECELRA provided in the outpatient hospital setting include:

- ICD-10-CM diagnosis codes
- HCPCS Level II codes
- CPT® codes: Category I
- National Drug Codes (NDC)
- Revenue codes

Contact your patient's payer to determine if there are any specific coding requirements for the hospital outpatient setting

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, *International Classification of Diseases, 10th Revision, Clinical Modification;* ICD-10-PCS, *International Classification of Diseases, 10th Revision, Procedure Coding System;* TCR, T cell receptor.

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Potential billing codes for TECELRA

Code Type	Code	Description	Inpatient Hospital	Outpatient Hospital
CPT® Codes[4]	38999	Unlisted procedure, hemic or lymphatic system	N/A	✓
	96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug		
	96415	Chemotherapy administration, intravenous infusion technique; each additional hour		
10-digit NDC (5-4-1 format)[1]	83205-0001-2	TECELRA (afamitresgene autoleucel) suspension for autologous intravenous infusion	If required by payer	
11-digit NDC (5-4-2 format)[1]	83205-0001-02			
ICD-10-PCS[5]	XW03368	Introduction of afamitresgene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 8	✓	
	XW04368	Introduction of afamitresgene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 8		

CPT, Current Procedural Terminology; ICD-10-PCS, *International Classification of Diseases, 10th Revision, Procedure Coding System;* NDC, National Drug Code.

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Potential billing codes for TECELRA (cont'd)

Code Type	Code	Description	Inpatient Hospital	Outpatient Hospital
ICD-10-CM[6]	C38.0-C38.8	Malignant neoplasm of heart, mediastinum and pleura	✓	✓
	C48.1-C48.8	Malignant neoplasm of retroperitoneum and peritoneum		
	C49.0-C49.9	Malignant neoplasm of connective and soft tissue		
Revenue codes[7]	0871	Cell collection	✓	✓
	0872	Specialized biologic processing and storage, prior to transport		
	0873	Storage and processing after receipt of cells from manufacturer		
	0874	Infusion of modified cells		
	0891	Special processed drugs–FDA-approved cell therapy (report actual invoice/acquisition cost with this revenue code)		

ICD-10-CM, *International Classification of Diseases, 10th Revision, Clinical Modification;* FDA, US Food and Drug Administration.

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Potential codes and modifiers for TECELRA

Diagnostic Testing

Testing for HLA and MAGE-A4 are required to identify TECELRA-eligible patients.[1] Information on FDA-approved tests for these biomarkers is available at www.fda.gov/companiondiagnostics.

Table 1 | Diagnostic Testing Billing Codes[4]

Diagnostic Testing	CPT® Code	Description
HLA	81378	HLA class I and II typing, high resolution
	81379	HLA class I typing, high resolution
	81380	HLA class I typing, high resolution; one locus
	81381	HLA class I typing, high resolution; one allele or allele group
MAGE-A4	88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure
	88344	Immunohistochemistry or immunocytochemistry, per specimen; each multiplex antibody stain procedure

CPT® Codes

Providers use CPT® codes to report medical services and procedures provided by HCPs in most settings of care. T cell administration, retrieval, and preparation services are required for TECELRA therapy and may be reported using an appropriate CPT® code.

Table 2 | CPT® Codes for T Cell Administration Services[4]

CPT® Code	T Cell Services
38999	Unlisted procedure, hemic or lymphatic system
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour*

CPT, Current Procedural Terminology; FDA, US Food and Drug Administration; HLA, human leukocyte antigen; MAGE-A4, melanoma-associated antigen A4.

*List separately in addition to code for primary procedure.

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Potential codes and modifiers for TECELRA (cont'd)

NDC

The use of an NDC is critical to identifying TECELRA as the administered therapy. State Medicaid programs may require the NDC for all outpatient medical drug claims.

The 11-digit TECELRA NDC format should be used on medical claims to comply with requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[8]

Table 3 | TECELRA NDC[1]

Product	NDC
TECELRA (afamitresgene autoleucel) suspension for autologous intravenous infusion	10-digit NDC (5-4-1 format): 83205-0001-2 11-digit NDC (5-4-2 format): 83205-0001-02

Potential ICD-10-PCS Procedure Codes for TECELRA Therapy

The following ICD-10-PCS codes may be appropriate for inpatient facility services associated with TECELRA administration. The ICD-10-PCS is a procedure classification system used to report procedures performed in inpatient hospital healthcare settings. New technology (section X) codes fully represent the specific procedure described in the code title and do not require additional codes from other sections of ICD-10-PCS.[9]

Table 4 | TECELRA ICD-10-PCS[5]

ICD-10-PCS Code	Description
XW03368	Introduction of afamitresgene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 8
XW04368	Introduction of afamitresgene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 8

ICD-10-PCS, *International Classification of Diseases, 10th Revision, Procedure Coding System*; NDC, National Drug Code.

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Potential codes and modifiers for TECELRA (cont'd)

Potential ICD-10-CM Diagnosis Codes for TECELRA Therapy

ICD-10-CM codes are used to report patient conditions, illnesses, or symptoms that support the medical necessity for healthcare services. The following ICD-10-CM diagnosis codes may be appropriate to describe an encounter with a patient receiving treatment with TECELRA therapy.

Table 5 | ICD-10-CM Diagnosis Codes[6]

ICD-10-CM Codes	Description
C38.0-C38.8	Malignant neoplasm of heart, mediastinum and pleura
C48.1-C48.8	Malignant neoplasm of retroperitoneum and peritoneum
C49.0-49.9	Malignant neoplasm of connective and soft tissue

ICD-10-CM, *International Classification of Diseases, 10th Revision, Clinical Modification*.

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Potential codes and modifiers for TECELRA (cont'd)

HCPCS Level II Codes

J-codes are permanent codes that are used by hospitals, physicians, and other health professionals who bill Medicare and commercial payers for non–orally-administered medication and chemotherapy drugs.

TECELRA must be billed using a miscellaneous HCPCS code (see potential codes in the table below) until a product-specific code is assigned.

Note: Effective July 1, 2023, CMS and most payers require prescribers to record drug waste. A JW modifier may be required for reporting that there was discarded drug (ie, J3590-JW). A JZ modifier may be required for reporting there was no discarded drug (ie, J3590-JZ).

Table 6 | HCPCS Level II Coding For TECELRA[10]

HCPCS Code	Description
J3490	Unclassified drugs
J3590	Unclassified biologic
J9999	Not otherwise classified, antineoplastic
C9399 (Facility Use Only Code)	Unclassified drug or biologic

CMS, Centers for Medicare and Medicaid Services; HCPCS, Healthcare Common Procedure Coding System.

Potential codes and modifiers for TECELRA (cont'd)

Potential 340B Modifiers for TECELRA Product Codes

Medicare requires that appropriate HCPCS modifier codes be reported on claims billed by outpatient hospital facilities. Specifically, if TECELRA is acquired with the 340B Drug Pricing Program Discount. Both the JG and TB modifiers are for informational purposes only and do not affect payment. Appropriate modifier selection is based on the type of entity reporting and the status indicator of the drug.

Table 7 | 340B Modifiers[11]

HCPCS Code	Description
JG	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes
TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities

Reporting Wastage

TECELRA is supplied in one or more infusion bags containing a frozen suspension of genetically modified autologous T cells in 5% DMSO.[1] CMS guidance recommends using JZ modifier (zero drug amount discarded/not administered to any patient) on all claims where there is no discarded amount.[12]

Table 8 | Reporting Wastage[12]

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

CMS, Centers for Medicare and Medicaid Services; DMSO, dimethyl sulfoxide; HCPCS, Healthcare Common Procedure Coding System.

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Potential codes and modifiers for TECELRA (cont'd)

Other Potential Codes of Interest

Revenue Codes

When TECELRA is administered in a hospital setting, payers require the medication, cell collection and processing services, and associated supplies to be reported on claims, along with a revenue code that maps to a specific cost center. The following revenue codes may be appropriate to report on claims for TECELRA when it is administered.

Table 9 | Revenue Codes for Services Associated With TCR T Cell Process[7]

Code	Description
0871	Cell collection
0872	Specialized biologic processing and storage, prior to transport
0873	Storage and processing after receipt of cells from manufacturer
0874	Infusion of modified cells
0891	Special Processed Drugs—FDA-approved cell therapy

FDA, US Food and Drug Administration; TCR, T cell receptor.

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Sample CMS-1450 claim form for TECELRA

Completing the Claim Forms

Following treatment with TECELRA, the ATC should file a claim for reimbursement with the patient's health insurance plan. Services and supplies provided in institutional facilities such as hospitals or outpatient facilities are billed using the CMS-1450 claim form.

The CMS-1450 claim form requires patient demographic information, insurance policy number, coded descriptions of services, National Provider Identifier (NPI), and revenue codes as needed.

Most providers today are filing the CMS-1450 claim form electronically via the 837I format, following Administrative Simplification Act (ASA) requirements rather than using the paper version. A sample CMS-1450 claim form is on pages 16–19. Additionally, professional claims for TCR T cell services and related services may also be billed using the CMS-1500 form.

Claim Form Considerations

When preparing claim submissions, keep the following in mind:

- Claims should be submitted in accordance with the ASA* requirements, taking into account the health insurance plan's submission guidelines.
- Claims may need to be submitted using paper forms if additional documentation that cannot be submitted electronically is required.
- To receive timely and appropriate reimbursement, claim forms should be completed fully and accurately, and submissions should address any additional medical necessity or prior authorization (PA) criteria.

ATC, authorized treatment center; TCR, T cell receptor.

*To learn more about ASA, visit www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA.

Please see Important Safety Information on pages 23-25 of this guide and accompanying full Prescribing Information for TECELRA, including Boxed Warning.

Sample CMS-1450 claim form for TECELRA (cont'd)

Claims Tips

Use the correct billing codes in the correct sequence

- Accurate coding is essential to facilitate prompt processing and reimbursement.
- Duplicative claims and claims that lack proper information are some of the top reasons why coverage is denied.
- Preferred codes may be provided by the health insurance plan during the benefits investigation process.

Ensure all necessary PAs have been obtained

Gather all of the documentation needed to support the claims process

- Health insurance plans may require that claims be submitted with additional documentation such as:
  - Letter of medical necessity
  - Invoice for purchase of TECELRA
  - Prescribing information for TECELRA
  - Medical chart notes
  - Prior authorization number

It is the sole responsibility of the HCP to select the proper codes, and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

HCP, healthcare provider; PA, prior authorization.

Please see Important Safety Information on pages 23-25 of this guide and accompanying full Prescribing Information for TECELRA, including Boxed Warning.

Sample annotated CMS-1450 (UB-04) claim form for **inpatient** hospital facilities

The CMS-1450 form is a Medicare claim form used by institutions when TECELRA is administered in the inpatient setting.

Key components of this form are described below and illustrated on the sample form on page 17.

A Field 4: Enter code for bill type (0111 for inpatient hospital)

B Field 42: Enter the appropriate revenue codes corresponding to the HCPCS code in Field 44 (eg, 0891 for TECELRA and applicable codes for TCR T cell services)

C Field 43: Enter the descriptions corresponding to the revenue codes in Field 42

D Field 44: Enter the appropriate HCPCS/CPT® codes and modifiers if applicable (eg, J3590 for TECELRA and 38999 for administration)

E Field 45: Enter dates of service

F Field 46: Enter appropriate number of units of service (eg, XXXXX is a per therapeutic dose, so a "1" would be entered in this field)

G Field 47: Enter total charges

H Fields 67A-67Q: Enter the appropriate diagnosis code (eg, ICD-10-CM: C49.0 for malignant neoplasm of connective and soft tissue of head, face and neck)

Note: Other diagnosis codes often apply

I Field 74: Enter principal ICD-10-PCS code (for example, XW03368, introduction of afamitresgene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 8)

J Field 80: Enter drug-identifying information, as required by payer (eg, drug name, NDC 11-digit format, dosage, method of administration)

Note: Additional information may also be electronically sent via attachment or other format, as allowed by the payer

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, *International Classification of Diseases, 10th Revision, Clinical Modification*; ICD-10-PCS, *International Classification of Diseases, 10th Revision, Procedure Coding System;* NDC, National Drug Code; TCR, T cell receptor.

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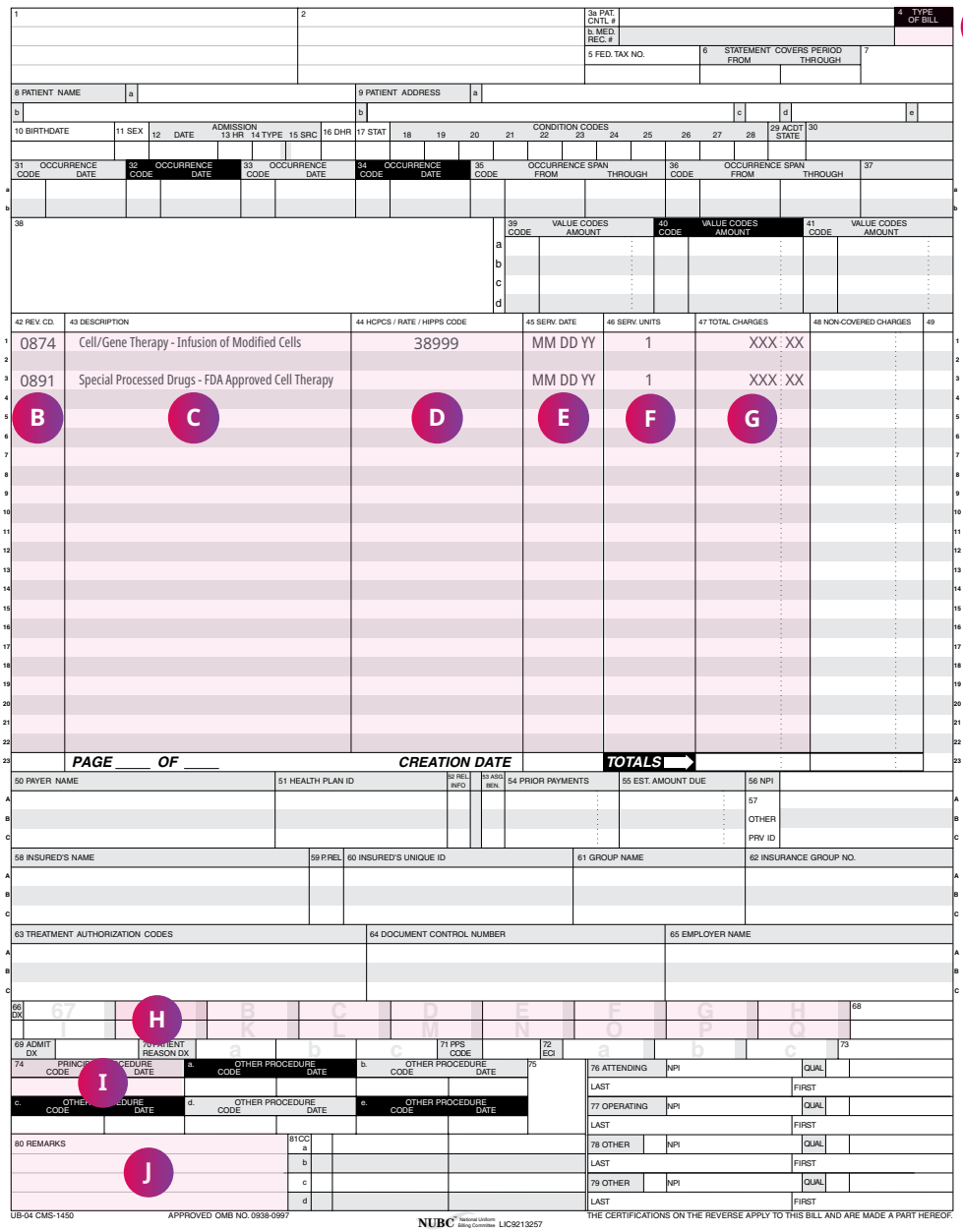
Sample annotated CMS-1450 (UB-04) claim form for **inpatient** hospital facilities (cont'd)



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Sample annotated CMS-1450 (UB-04) claim form for **outpatient** hospital facilities

The CMS-1450 form may also be utilized by institutions when TECELRA is administered in the outpatient setting.

Key components of this form are described below and illustrated on the sample form on page 19.

- **A** Field 4: Enter code for bill type (0131 for outpatient hospital)
- **B** Field 42: Enter the appropriate revenue codes corresponding to the HCPCS code in Field 44 (eg, 0891 for TECELRA and applicable codes for TCR T cell services)
- **C** Field 43: Enter the descriptions corresponding to the revenue codes in Field 42
- **D** Field 44: Enter the appropriate HCPCS/CPT® codes and modifiers if applicable (eg, J3590 for TECELRA and 38999 for administration)
- **E** Field 45: Enter dates of service
- **F** Field 46: Enter appropriate number of units of service (eg, XXXXX is a per therapeutic dose, so a "1" would be entered in this field)
- **G** Field 47: Enter total charges
- **H** Fields 67A-67Q: Enter the appropriate diagnosis code (eg, ICD-10-CM: C49.0 for malignant neoplasm of connective and soft tissue of head, face and neck)

  Note: Other diagnosis codes often apply

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, *International Classification of Diseases, Tenth Revision, Clinical Modification*; TCR, T cell receptor.

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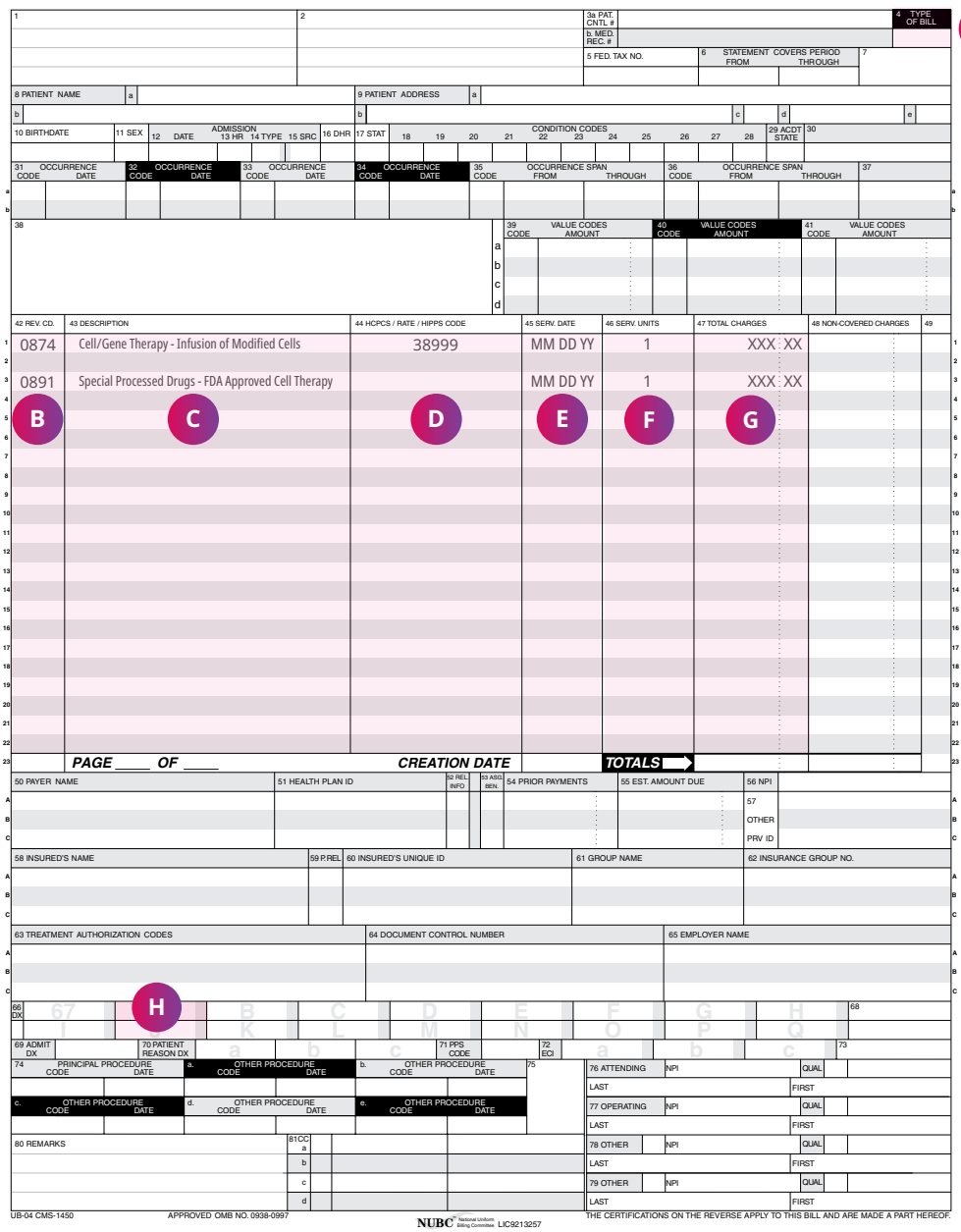
Sample annotated CMS-1450 (UB-04) claim form for **outpatient** hospital facilities (cont'd)



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Tecelra®
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suspension for IV infusion

Preparing to submit a prior authorization

Prior Authorizations (PAs)

PAs are intended to demonstrate to the payer that the health plan's specific requirements have been completed or to explain why TECELRA is the best treatment option for a patient. When submitting a PA on behalf of your patient, keep the following PA requirements in mind; including this information may prevent a PA denial.

PA Checklist:

- ☐ Patient's name, date of birth, insurance ID number, insurance group number, and dates of service
  - Include a complete record of the patient's personal and member/beneficiary information
- ☐ Patient's diagnosis and corresponding ICD-10-CM code(s)
- ☐ Current and previous therapies
- ☐ Current disease stage

It may also be necessary to include the following information at the request of the payer:

- Physician information, including name and tax ID number
- Facility information, including name and tax ID number
- Setting of care
- Date of service
- Patient clinical notes detailing relevant diagnosis
- Supporting documentation for treatment decisions, including laboratory and imaging results
- Relevant codes, specifically CPT® and HCPCS, for services/products to be performed or provided
- TECELRA Prescribing Information
- Clinical guidelines

Submitting **complete and accurate PA** forms along with supporting documentation can help to **avoid delays** in processing or avoid a PA denial.

In the event the PA is denied, additional payer denial and appeals resources can be found at AdaptimmuneAssist.com. Contact your Adaptimmune Field Reimbursement Manager or the patient's insurer if you have questions.

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, *International Classification of Diseases, 10th Revision, Clinical Modification*.

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AdaptimmuneAssist™

AdaptimmuneAssist provides eligible patients with personalized support throughout their treatment journey with TECELRA.

Travel Assistance Program

AdaptimmuneAssist can offer **transportation and lodging support** for eligible patients and their caregiver(s) during the treatment journey.*

Adaptimmune Treatment Access Program (ATAP)

AdaptimmuneAssist can **provide financial assistance** for product costs to patients with insurance coverage delays or without commercial insurance.†

To learn more, contact AdaptimmuneAssist at **1-855-24MYADAP** (1-855-246-9232) or visit **AdaptimmuneAssist.com**

*Eligibility requirements apply.
†Eligibility requirements apply. Financial assistance only applies to prescription costs.

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References

1. TECELRA® (afamitresgene autoleucel) [prescribing information]. Philadelphia, PA: Adaptimmune, LLC.; August 2024.
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Indication and Important Safety Information

INDICATION

TECELRA® (afamitresgene autoleucel) is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices.

This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION: DO NOT use TECELRA in adults who are heterozygous or homozygous for HLA-A*02:05P.

BOXED WARNING: Cytokine release syndrome (CRS), which may be severe or life-threatening, occurred in patients receiving TECELRA. At the first sign of CRS, immediately evaluate patient for hospitalization and institute treatment with supportive care. Ensure that healthcare providers administering TECELRA have immediate access to medications and resuscitative equipment to manage CRS.

CRS

- CRS occurred in 75% of patients (2% Grade ≥3) with a median onset of 2 days (range: 1 to 5 days) and median resolution of 3 days (range: 1 to 14 days). CRS (including Grade 1) was managed with tocilizumab in 55% of patients who experienced CRS.
- In patients who experienced CRS, the most common symptoms included fever, tachycardia, hypotension, nausea/vomiting, and headache.

Please see additional Important Safety Information on the following pages of this guide and accompanying full Prescribing Information for TECELRA, including Boxed Warning.

IMPORTANT SAFETY INFORMATION (cont'd)

Immune Effector Cell–associated Neurotoxicity Syndrome (ICANS)

- ICANS has been observed following administration of TECELRA. One patient (2%) had Grade 1 ICANS with a median onset of 2 days and resolution of 1 day.
- ICANS symptoms can include mental status changes, disorientation to time and place, drowsiness, inattention, altered level of consciousness, seizures, cerebral edema, impairment of cognitive skills, progressive aphasia, and motor weakness.
- Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy machinery or potentially dangerous machinery for 4 weeks following infusion due to the potential for neurologic events, including dizziness and presyncope.

Monitoring for CRS and ICANS During and Following TECELRA Infusion

- Ensure that healthcare providers administering TECELRA have immediate access to medications and resuscitative equipment to manage CRS and ICANS. Ensure patients are euvolemic prior to initiating TECELRA.
- During and following TECELRA administration, closely monitor patients for signs and symptoms of CRS and ICANS. Following treatment with TECELRA, monitor patients for at least 7 days at the healthcare facility. Continue to monitor patients for at least 4 weeks following treatment with TECELRA. Counsel patients to seek medical attention should signs or symptoms of CRS or ICANS occur.
- At the first sign of CRS or ICANS, immediately evaluate patients for hospitalization and administer supportive care based on severity and consider further management per clinical practice guidelines.

Prolonged Severe Cytopenia

- Anemia, neutropenia, and/or thrombocytopenia can occur for several weeks following lymphodepleting chemotherapy and TECELRA infusion. Patients with Grade ≥3 cytopenia not resolved by week 4 included anemia (9%), neutropenia (11%), and thrombocytopenia (5%). The median time to resolution was 7.3 weeks (range: 6.1 to 8.4 weeks) for anemia, 9.3 weeks (range: 6.4 to 12.3 weeks) for neutropenia, and 6.3 weeks (range: 6.1 to 6.4 weeks) for thrombocytopenia.
- Monitor blood counts after TECELRA infusion. Manage cytopenia with growth factor and blood product transfusion according to clinical practice guidelines.

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IMPORTANT SAFETY INFORMATION (cont'd)

Infections

- Infections may occur following lymphodepleting chemotherapy and TECELRA infusion and occurred in 32% of patients (14% Grade 3).
- Do not administer TECELRA to patients with active infections and/or inflammatory disorders.
- Monitor patients for signs and symptoms of infection before and after TECELRA infusion and treat patients appropriately.
- Febrile neutropenia was observed in patients after TECELRA infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care, as medically indicated.
- Viral reactivation has occurred in patients following TECELRA. Perform screening for Epstein-Barr virus, cytomegalovirus, hepatitis B virus, hepatitis C virus, and human immunodeficiency virus (HIV) or any other infectious agents if clinically indicated. Consider antiviral therapy to prevent viral reactivation per local guidelines.

Secondary Malignancies

- Patients treated with TECELRA may develop secondary malignancies or recurrence of their cancer. Monitor for secondary malignancies.

Hypersensitivity Reactions

- Serious hypersensitivity reactions, including anaphylaxis, may occur due to dimethyl sulfoxide (DMSO) in TECELRA. Observe patients for hypersensitivity reactions during infusion.

Potential for HIV Nucleic Acid Test False-Positive Results

- The lentiviral vector used to make TECELRA has limited, short spans of genetic material that are identical to HIV. Therefore, some commercial HIV nucleic acid tests may yield false-positive results in patients who have received TECELRA.

Adverse Reactions

- Most common adverse reactions (incidence ≥20%) were CRS, nausea, vomiting, fatigue, infections, pyrexia, constipation, dyspnea, abdominal pain, non-cardiac chest pain, decreased appetite, tachycardia, back pain, hypotension, diarrhea, and edema.
- Most common Grade 3 or 4 laboratory abnormalities (incidence ≥20%) were lymphocyte count decreased, neutrophil count decreased, white cell blood count decreased, red blood cell decreased, and platelet count decreased.
- Most common serious adverse reactions (≥5%) were cytokine release syndrome and pleural effusion.

Please see full Prescribing Information, including Boxed Warning.