

# Billing and Coding Guide

An overview of the key information needed for billing and coding for TECELRA and related services

Please see Important Safety Information on pages 18-20 of this guide and accompanying full [Prescribing Information](#) for TECELRA, including Boxed Warning.

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# 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.<sup>1</sup>

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.<sup>1</sup>

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.

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# 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<sup>1</sup>:

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<sup>2,3</sup>:

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.<sup>3</sup>

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



## Lymphodepleting Chemotherapy<sup>1</sup>:

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<sup>1</sup>:

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](http://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 and related services.



## Hospital “Inpatient”

When provided in the inpatient hospital setting, TECELRA and its administration are not typically paid separately but, rather, are included in a bundled payment amount that covers all services provided during 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.**

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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# 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 considerations in mind.

### PA Checklist:

- Physician and facility information including name, NPI, and tax ID number
- Patient's name, date of birth, insurance ID number, and insurance group number
  - Include a complete record of the patient's personal and member/beneficiary information
- Patient's diagnosis and corresponding ICD-10-CM code(s)
- Relevant codes, specifically CPT® and HCPCS, for services/products to be performed or provided
- Expected setting of care and dates of service
- Letter of Medical Necessity summarizing the patient's current clinical status, previous lines of therapy, and disease response assessments
- Applicable clinical guidelines, clinical data, and clinical documentation to support medical necessity for PA request
- TECELRA Prescribing Information

In the event the PA is denied, a [Letter of Appeal](#) template is available.

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

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

The patient must be a resident of the United States or US territories and meet eligibility requirements (see below). Applying for a program is not a guarantee that assistance will be available. Adaptimmune reserves the right to rescind, revoke, or amend these programs without notice.



### Travel Assistance Program

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

- Patient eligibility information
  - Must live more than 2 hours or 200 miles from their TECELRA Treatment Center
  - Must meet Travel Assistance Program income criteria\*



### Copay Assistance Program

For commercially insured patients, AdaptimmuneAssist may cover out-of-pocket obligations specific to TECELRA.

- Patient eligibility information
  - Not available to patients enrolled in Medicare, Medicaid, TRICARE, Veterans Affairs (VA), or any other federal or state healthcare program



### Adaptimmune Treatment Access Program

AdaptimmuneAssist can provide financial assistance for product costs to eligible patients who are uninsured, underinsured, or experiencing a delay in insurance approval for treatment (ie, prior authorization, appeal denial).

- Patient eligibility information
  - Must meet Adaptimmune Treatment Access Program income criteria\*

\*Patient must provide access to household income information and meet income eligibility criteria to qualify for support. Providing income information does not guarantee eligibility for Travel Assistance Program and/or Adaptimmune Treatment Access Program.

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## Summary of Billing Codes for TECELRA

Code Type	Code	Description
ICD-10-CM <sup>4</sup>	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
10-digit NDC (5-4-1 format) <sup>1</sup>	83205-0001-2	TECELRA (afamitresgene autoleucl) suspension for autologous intravenous infusion
11-digit NDC (5-4-2 format) <sup>1</sup>	83205-0001-02	
HCPCS	Q2057	Afamitresgene autoleucl, including leukapheresis and dose preparation procedures, per therapeutic dose
ICD-10-PCS <sup>5</sup>	XW03368	Introduction of afamitresgene autoleucl immunotherapy into peripheral vein, percutaneous approach, new technology group 8
	XW04368	Introduction of afamitresgene autoleucl immunotherapy into central vein, percutaneous approach, new technology group 8
CPT <sup>®</sup> Codes <sup>6</sup>	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
Revenue codes <sup>7</sup>	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)

CPT, Current Procedural Terminology; FDA, US Food and Drug Administration; 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.

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# Billing codes and modifiers for TECELRA

## Diagnostic Testing

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

**Table 1 | Diagnostic Testing Billing Codes<sup>6</sup>**

Diagnostic Testing	CPT <sup>®</sup> 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

## ICD-10-CM Diagnosis Codes

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 2 | ICD-10-CM Diagnosis Codes<sup>4</sup>**

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

CPT, Current Procedural Terminology; FDA, US Food and Drug Administration; HLA, human leukocyte antigen; ICD-10-CM, *International Classification of Diseases, 10th Revision, Clinical Modification*; MAGE-A4, melanoma-associated antigen A4.

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## Billing codes and modifiers for TECELRA (cont'd)

### NDC

The NDC is used to identify TECELRA as the administered therapy and many payers will require the NDC to be included on the claim form.

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).<sup>8</sup>

**Table 3 | TECELRA NDC<sup>1</sup>**

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

### HCPCS Level II Codes

HCPCS Level II codes are used primarily to identify products, supplies, and services not included in the CPT<sup>®</sup> codes when used outside a physician's office.

**Table 4 | HCPCS Level II Coding For TECELRA<sup>9</sup>**

HCPCS Code	Description
Q2057	Afamitresgene autoleucl, including leukapheresis and dose preparation procedures, per therapeutic dose

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code.

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# Billing codes and modifiers for TECELRA (cont'd)

## ICD-10-PCS Procedure Codes

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.<sup>10</sup>

**Table 5 | TECELRA ICD-10-PCS<sup>5</sup>**

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

## CPT® Codes

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

**Table 6 | CPT® Codes for T Cell Administration Services<sup>6</sup>**

CPT® Code	Description
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; ICD-10-PCS, *International Classification of Diseases, 10th Revision, Procedure Coding System*.

\*List separately in addition to code for primary procedure.

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# Billing codes and modifiers for TECELRA (cont'd)

## Other Potential Codes of Interest

### Revenue Codes

When TECELRA is administered in a hospital setting, the therapy, cell collection and processing services, and associated supplies should be reported with a revenue code that maps to the specific cost center that aligns to where the cost of those services are assigned in the hospital's cost report. The following revenue codes should be reported with the applicable CPT® codes for TECELRA and associated services.

**Table 7 | Revenue Codes for TECELRA and Associated Services<sup>7</sup>**

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

CPT, Current Procedural Terminology; FDA, US Food and Drug Administration.

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# Billing codes and modifiers for TECELRA (cont'd)

## Reporting Wastage

TECELRA is supplied in one or more infusion bags containing a frozen suspension of genetically modified autologous T cells in 5% DMSO.<sup>1</sup> CMS guidance recommends using JZ modifier (zero drug amount discarded/not administered to any patient) on all claims where there is no discarded amount.<sup>11</sup>

**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 8 | Reporting Wastage<sup>11</sup>**

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

## Reporting 340B Acquired Drugs

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. The TB modifier is for informational purposes only and does not affect payment.

**Table 9 | 340B Modifiers<sup>12</sup>**

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

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

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# Sample CMS-1450 claim forms for TECELRA



Services and supplies provided in institutional facilities such as hospitals or outpatient facilities are billed using the CMS-1450 claim form. A sample CMS-1450 claim form is on pages 15–16.

## Claims Submission



**When preparing claims, keep the following in mind:**

- Claims should be submitted in accordance with the ASA\* requirements, as well as any additional guidelines from the health plan.
- Depending on the health plan, claims may need to be submitted using paper forms.
- 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.

## Claim Preparation Tips



**Use the correct billing codes in the correct sequence**

- Accurate coding is essential to facilitate prompt processing and appropriate reimbursement.
- Unique coding or billing considerations may be provided by the health plan during the benefit investigation or through the plans' published policy.

**Gather necessary documentation to support claims processing**

- Prescribing information for TECELRA
- Medical chart notes
- Prior authorization number
- Additional information as required by or agreed to with the payer (ie, invoice, itemized claims, etc.)

**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.**

\*To learn more about ASA, visit [www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA](http://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA).

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

The CMS-1450 form is a 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.

- 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 related 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, Q2057 for TECELRA and 38999 for administration)
- E** Field 46: Enter appropriate number of units of service (eg, 1)
- F** Fields 67A-67Q: Enter the appropriate diagnosis code
- Note:** Other diagnosis codes often apply
- G** Field 74: Enter principal ICD-10-PCS code (for example, XW03368)
- H** Field 80: Enter drug-identifying information, as required by payer (eg, drug name, NDC 11-digit format, dosage, method of administration)

The image shows a sample CMS-1450 (UB-04) claim form for inpatient hospital facilities. The form is a complex grid with various fields for patient information, revenue codes, descriptions, HCPCS codes, units of service, diagnosis codes, and drug information. Key fields are highlighted with callouts A through H.

- 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 related 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, Q2057 for TECELRA and 38999 for administration)
- E** Field 46: Enter appropriate number of units of service (eg, 1)
- F** Fields 67A-67Q: Enter the appropriate diagnosis code
- G** Field 74: Enter principal ICD-10-PCS code (for example, XW03368)
- H** 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 determined by the payer

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

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

The CMS-1450 form is also 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.

- A** Field 4: Enter code for bill type (eg, 0131 for outpatient hospital)
- B** Field 42: Enter the appropriate revenue codes (eg, 0891)
- 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, Q2057 for TECELRA and 38999 for administration)
- E** Field 46: Enter appropriate number of units of service (eg, 1)
- F** 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

The image shows a sample CMS-1450 (UB-04) claim form with several fields annotated with callouts A through F. Callout A points to Field 4 (Bill Type), Callout B to Field 42 (Revenue Code), Callout C to Field 43 (Description), Callout D to Field 44 (HCPCS/CPT Code), Callout E to Field 46 (Units of Service), and Callout F to Field 67A (Diagnosis Code). The form includes sections for Patient Information, Insurance Information, Treatment Authorization, and Billing Information. The main table contains two rows of service data: 0891 Specialized Processed Drug - FDA approved Cell Therapy with HCPCS code Q2057 and 0874 Cell/Gene Therapy - Infusion of Modified Cells with HCPCS code 38999. Both rows show 1 unit of service.

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

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# References

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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  $\geq$ 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  $\geq 3$  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.

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)

### 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  $\geq 20\%$ ) 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  $\geq 20\%$ ) 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 ( $\geq 5\%$ ) were cytokine release syndrome and pleural effusion.

Please see full **Prescribing Information**, including **Boxed Warning**.