Tecelra®
afamitresgene autoleucel
suspension for IV infusion

A Biomarker Testing Guide

for Treatment With TECELRA

NCCN GUIDELINES®
CATEGORY 2A

National Comprehensive Cancer Network® (NCCN®) Recommends as an NCCN Category 2A Treatment Option[1]

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) include afamitresgene autoleucel as a treatment option for patients with advanced/metastatic synovial sarcoma who have received prior therapy, are positive for HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P, and whose tumor expresses the MAGE-A4 antigen.[1]

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.

Please see additional Important Safety Information, including Boxed Warning, throughout this brochure. Please see full Prescribing Information.

Discover if TECELRA Is an Option for Your Adult Patients With Synovial Sarcoma

- **HLA-A*02** subtype and **MAGE-A4** status are both required to identify adult patients with advanced synovial sarcoma who are eligible for treatment with TECELRA[2]
- Testing all patients with synovial sarcoma at diagnosis, or as early as possible, may enable development of long-term treatment plans, including TECELRA, if appropriate[2]

HLA-A*02 Typing

HLA-A*02 Status Helps Determine if TECELRA Might Be Right for Your Adult Patients With Synovial Sarcoma†

- HLA typing is a well-established process used in tissue matching for stem cell and solid organ transplant and is also important for identifying patients eligible for treatment with TECELRA[2,3]
- Patients meet the HLA-A*02 criteria for TECELRA if they are[2]:
  - Positive for at least 1 inclusion allele (HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P), AND
  - Negative for HLA-A*02:05P
- In a study of patients with cancer in North America and Europe, 44.8% were positive for HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P and negative for HLA-A*02:05P[4,‡]

HLA, human leukocyte antigens; MAGE-A4, melanoma-associated antigen 4.
†Patients must meet both HLA-A*02 and MAGE-A4 eligibility criteria.[2] ‡Based on data from 6,606 patients aged 18 to 75 years with advanced solid or hematologic malignancy from 43 sites in the US (30), Canada (1), Spain (7), the United Kingdom (2), and France (3) who had their HLA-A type determined.[4]

IMPORTANT SAFETY INFORMATION (cont)

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.

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How to Test for HLA-A*02 Alleles

1. The Test and Sample

- A high-resolution blood test is used to determine if a patient has at least one inclusion allele (HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P) and does not have the exclusion allele (HLA-A*02:05P)[2,4]
- Information on the FDA-approved test for HLA-A*02 is available at fda.gov/companiondiagnostics
- Testing takes approximately 5 days from the time sample is received[5,†]
- To learn more about testing options, please call AdaptimmuneAssist at 1-855-24MYADAP (1-855-246-9232) Monday through Friday from 8:00 AM to 8:00 PM ET, or visit the website, TECELRA-HCP.com

FDA, US Food and Drug Administration.
†Based on independent laboratory experience.[5]

IMPORTANT SAFETY INFORMATION (cont)

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.

2. Interpreting Test Results[2]

Look for the presence of at least 1 HLA-A*02 allele that is compatible with TECELRA and check that the test is negative for the HLA-A*02:05 allele that is contraindicated. This indicates that your patient has an HLA-A*02 subtype eligible for TECELRA.

Sample HLA Testing Results

SAMPLE 1:			SAMPLE 2:			SAMPLE 3:		
A1	A*02:06	☑	A1	A*01:01	☐	A1	A*02:01	☑
A2	A*02:24	☐	A2	A*03:01	☐	A2	A*02:05	☒
B1	B*07:02	☐	B1	B*35:43	☐	B1	B*40:02	☐
B2	B*40:06	☐	B2	B*51:01	☐	B2	B*44:03	☐
C1	C*03:04	☐	C1	C*06:02	☐	C1	C*07:02	☐
C2	C*15:05	☐	C2	C*07:01	☐	C2	C*04:01	☐
HLA Eligibility:	ELIGIBLE		HLA Eligibility:	INELIGIBLE		HLA Eligibility:	INELIGIBLE	

IMPORTANT SAFETY INFORMATION (cont)

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.

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.

MAGE-A4 Expression

Detection of MAGE-A4 Will Inform Treatment Options for Certain Adult Patients With Synovial Sarcoma

- MAGE-A4 is an intracellular cancer-testis antigen that is expressed in multiple solid tumors and is particularly prevalent in synovial sarcoma[2,4]
  - While MAGE-A4 can be found within tumor cells, expression is restricted in normal healthy tissue

- ≈70% of patients with synovial sarcoma have tumors that express high levels of MAGE-A4, as measured by clinical trial assay[4,†]

How to Test for MAGE-A4 Expression

The Test and Sample

- MAGE-A4 testing requires tumor tissue[4]
  - MAGE-A4 can be tested on fresh or archival patient tumor tissue. Tissue samples must be formalin fixed and paraffin embedded[4,6]
- Information on the FDA-approved test for the detection of MAGE-A4 expression in synovial sarcoma is available at fda.gov/companiondiagnostics
- Testing takes approximately 5 days from the time sample is received[5,‡]
- To learn more about testing options, please call AdaptimmuneAssist at 1-855-24MYADAP (1-855-246-9232) Monday through Friday from 8:00 AM to 8:00 PM ET, or visit the website, TECELRA-HCP.com

IHC, immunohistochemistry.
†Patients must meet both HLA-A*02 and MAGE-A4 eligibility criteria.[2]
‡Based on independent laboratory experience.[5]

IMPORTANT SAFETY INFORMATION (cont)

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.

If you have any questions on testing or would like to talk to a Cell Therapy Navigator, please call AdaptimmuneAssist at 1-855-24MYADAP (1-855-246-9232) Monday through Friday from 8:00 AM to 8:00 PM ET or visit the website, TECELRA-HCP.com.

IMPORTANT SAFETY INFORMATION (cont)

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.

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References

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Soft Tissue Sarcoma V.4.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed February 11, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

2. Tecelra. [Prescribing information]. Adaptimmune; 2024.

3. De'Ath A, Rees MT, Pritchard D. The history and evolution of HLA typing external proficiency testing schemes in UK NEQAS for H&I. *Front Genet*. 2023;14:1272618. doi:10.3389/fgene.2023.1272618

4. Wang T, Navenot JM, Rafail S, et al. Identifying MAGE-A4–positive tumors for TCR T-cell therapies in HLA-A*02–eligible patients. *Mol Ther Methods Clin Dev.* 2024;32(2):101265. doi.org/10.1016/j.omtm.2024.101265

5. Data on file. Adaptimmune.

6. MAGE-A4 IHC 1F9 PharmDx. Agilent Technologies; 2024.

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