Tecelra®
afamitresgene autoleucel
suspension for IV infusion

How to Order TECELRA

As part of the TECELRA Authorized Treatment Center (ATC) team, you have the ability to create an order in the MyCellAssist Order Portal. Once your account is created, you can order TECELRA for your patients.

If you do not practice at an ATC and think TECELRA might be an appropriate treatment for your patient, you can locate an ATC at TECELRA-HCP.com/ATC. You can also connect with a Cell Therapy Navigator (CTN) to help with an ATC referral by calling 1-855-246-9232.



LOG IN

Visit https://order.mycellassist.com/ and log into the MyCellAssist portal to get started. You can also access the portal from the MyCellAssist website at any time.



COMPLETE

Fill out the required information about your patient, which includes the patient's name, date of birth, diagnosis, and Medical Record Number (MRN). You will also need your patient's insurance information at this time.



CONNECT

A CTN will be in touch to assist you with your order and next steps, including selecting an apheresis pickup date.

MyCellAssist can offer travel, and access assistance for eligible patients.

If you think your patient may need help in one or more of these areas, fill out and submit the TECELRA Request Form for Patient Services through the MyCellAssist Order Portal.

ATC=Authorized Treatment Center; CTN=Cell Therapy Navigator.

Learn more about TECELRA at TECELRA-HCP.com

INDICATION

TECELRA is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of adults and pediatric patients 12 years of age and older 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.

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 on reverse.

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IMPORTANT SAFETY INFORMATION (CONT'D)

CRS

- CRS occurred in 72% of patients (2% Grade ≥3) with a median onset of 2 days (range: 1 to 7 days) and median resolution of 3 days (range: 1 to 14 days). CRS (including Grade 1) was managed with tocilizumab (40%) and siltuximab (1 patient) in patients who experienced CRS.
- In patients who experienced CRS, the most common symptoms included fever, tachycardia, hypotension, nausea/vomiting, and headache.

Immune Effector Cell–associated Neurotoxicity Syndrome (ICANS)

- ICANS has been observed following administration of TECELRA. Six patients (4%) had Grade 1 or Grade 2 ICANS with a time to onset of 2 to 8 days and resolution of 1 to 7 days.
- 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 2 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 2 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 neutropenia (11%), anemia (6%), and thrombocytopenia (5%). The median time to resolution was 7.0 weeks (range: 6.1 to 12.4 weeks) for neutropenia, 6.4 weeks (range: 5.3 to 12.1 weeks) for anemia, and 9 weeks (range: 5.3 to 12.1 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 35% of patients (12% Grade 3 or higher).
- 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 10% of 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, fatigue, musculoskeletal pain, infections, pyrexia, constipation, vomiting, headache, diarrhea, cough, tachycardia, edema, dyspnea, and rash.
- Most common Grade 3 or 4 laboratory abnormalities (incidence ≥20%) were lymphocyte count decreased, white blood cell count decreased, neutrophil count decreased, and red blood cell count decreased.
- Most common serious adverse reactions (≥5%) were cytokine release syndrome and infections.

Please see full Prescribing Information, including Boxed Warning.

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