Sample letter of medical necessity for TECELRA® (afamitresgene autoleucel)

This letter provides an example of the types of information that may be provided when responding to a request from a patient's insurance company to provide a letter of medical necessity for TECELRA. Use of the information in this letter does not guarantee that the health plan will provide reimbursement for TECELRA and is not intended to be a substitute for or influence on the independent medical judgment of the physician.

Key reminders

- You may consider including a letter of medical necessity like this one with your prior authorization (PA) request to emphasize the medical necessity for TECELRA
- Letters of medical necessity should be **signed by the physician only**
- Include an appropriate *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) code based on your patient's diagnosis

Checklist summary

- ☐ Current/recent chart notes
  - — Date of initial diagnosis
  - — Response to all prior therapies (eg, name of therapy, dose, start date/stop date, length of treatment, and clinical response)
  - — Relevant comorbidities
- ☐ History prior to your care, if applicable
- ☐ Supportive literature
- ☐ TECELRA Prescribing Information
- ☐ Patient's narrative

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 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 patients 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 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.

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Please see full Prescribing Information, including Boxed Warning.

US WorldMeds

[Insert Physician Letterhead]
[Date]
To whom it may concern,

Member Name	[Patient name]
Date of Birth	[Patient date of birth]
Member ID Number	[Member ID number]
Member Group/Policy Number	[Member group/policy number]

I am writing on behalf of my patient, [patient name], to document the medical necessity for treatment with TECELRA® (afamitresgene autoleucel), [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.].

My clinical assessment indicates that TECELRA is medically necessary for [patient name].
[Please use the below table to clearly outline relevant details that document the patient's medical necessity. Note: Exercise medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Primary diagnosis	[unresectable or metastatic synovial sarcoma that received prior chemotherapy, is HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices. Indicated for the treatment of adults and pediatric patients 12 years of age and older. Please include confirmation that the patient is not heterozygous or homozygous for HLA-A*02:05P, given the contraindication.] [Insert biomarker testing results]
ICD-10-CM code	[CXX.XX]
No. of prior therapies	[No. of prior therapies]
Description of prior therapies and treatment response	[Description of prior therapy 1 and patient's treatment response] [Description of prior therapy 2 and patient's treatment response] [Description of prior therapy 3 and patient's treatment response] [Description of prior therapy 4 and patient's treatment response]
Relevant disease-related characteristics	[Insert relevant disease-related characteristics including, but not limited to, histology and prognostic factors]
Clinical fitness	[Insert relevant details on the patient's clinical fitness, including, but not limited to, ECOG performance status and/or organ function indicators]
Site of medical service	[Include site type (e.g., inpatient or hospital outpatient) and rationale (e.g., compliance or closely monitoring patients)]
Your professional opinion of the patient's likely prognosis or disease progression if they are not treated with TECELRA	[Describe the patient-specific clinical rationale and anticipated consequences of delayed or unavailable treatment, if medically appropriate and supported by the patient record.]

ECOG=Eastern Cooperative Oncology Group; FDA=US Food and Drug Administration; HLA=human leukocyte antigen; ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*; MAGE-A4=melanoma-associated antigen A4.

Rationale for treatment

[Summarize clinical rationale for treatment, including supporting evidence from:

- Prescribing Information
- Treatment guidelines and/or drug compendia
- Peer-reviewed literature

I believe TECELRA is medically necessary for [patient name]'s medical condition based on the evidence summarized above. If you have further questions regarding this patient's current medical status, please do not hesitate to contact my office at [phone number].

Sincerely,

[Provider Name and Signature]
[Provider Identification Number]
[Treatment Center Name and Address]

Attachments: [Include full TECELRA prescribing Information and additional support noted above]