MASSACHUSETTS

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CAR T-Cell Therapy Services for B-cell Acute Lymphoblastic Leukemia (tisagenlecleucel) Prior Authorization Request Form #925

Medical Policy #066 Chimeric Antigen Receptor Therapy for Hematologic Malignancies

CLINICAL DOCUMENTATION

- Clinical documentation that supports the medical necessity criteria for CAR T-Cell Therapy Services for B-cell Acute Lymphoblastic Leukemia (tisagenlecleucel) must be submitted.
- If the patient does not meet all the criteria listed below, please submit a letter of medical necessity with a request for Clinical Exception (Individual Consideration) explaining why an exception is justified.

Requesting Prior Authorization Using Authorization Manager

Providers will need to use Authorization Manager to submit initial authorization requests for services. Authorization Manager, available 24/7, is the quickest way to review authorization requirements, request authorizations, submit clinical documentation, check existing case status, and view/print the decision letter. For commercial members, the requests must meet medical policy guidelines.

To ensure the request is processed accurately and quickly:

- Enter the facility's NPI or provider ID for where services are being performed.
- Enter the appropriate surgeon's NPI or provider ID as the servicing provider, *not* the billing group.

Authorization Manager Resources

- Refer to our Authorization Manager page for tips, guides, and video demonstrations.

Complete Prior Authorization Request Form for CAR T-Cell Therapy Services for B-cell Acute Lymphoblastic Leukemia (tisagenlecleucel) (925) using Authorization Manager.

For out of network providers: Requests should still be faxed to 888-973-0726.

Patient Information	
Patient Name:	Today's Date:
BCBSMA ID#:	Date of Treatment:
Date of Birth:	Place of Service: Outpatient ❒ Inpatient ❒

Physician Information	**Facility Information**
Name:	Name:
Address:	Address:
Phone #:	Phone #:
Fax#:	Fax#:
NPI#:	NPI#:

Please check off if the patient is enrolled in a Clinical Trial.

Clinical Trial #	❒

Please check off if the patient has the following diagnosis and HAS RELAPSED [a] (second or later) or is REFRACTORY [b] :	
CD19-positive B-cell acute lymphoblastic leukemia with morphologic marrow tumor involvement (≥ 5% lymphoblasts)	❒

[a] Relapsed disease describes the reappearance of leukemia cells in the bone marrow or peripheral blood after the attainment of a complete remission with chemotherapy and/or allogeneic cell transplant.

[b] Refractory (resistant) disease is defined as those patients who fail to obtain complete response with induction therapy, ie, failure to eradicate all detectable leukemia cells (<5% blasts) from the bone marrow and blood with subsequent restoration of normal hematopoiesis (>25% marrow cellularity and normal peripheral blood counts).

Please check off that the patient meets ALL the following criteria:	
1. Confirmed diagnosis of CD19-positive B-cell acute lymphoblastic leukemia with morphologic bone marrow tumor involvement (≥5% lymphoblasts); **AND**	❒
2. Meet any one of the following: a. Relapsed disease[a] defined as the reappearance of leukemia cells in the bone marrow or peripheral blood after the attainment of a complete remission with chemotherapy and/or allogeneic cell transplant; **OR** b. Refractory disease[b] defined as failure to obtain complete response with induction therapy (i.e., failure to eradicate all detectable leukemia cells [< 5% blasts] from the bone cellularity and normal peripheral blood counts); **AND**	❒ ❒
3. When Philadelphia chromosome-positive: failure of 2 tyrosine kinase inhibitors; **AND**	❒
4. Are up to 25 years of age at the time of infusion; **AND**	❒
5. Have not received prior CD19-directed chimeric antigen receptor T-cell treatment, any other cell therapy, or any gene therapy or are being considered for treatment with any other cell therapy or any gene therapy; **AND**	❒
6. Have adequate organ function with no significant deterioration in organ function expected within 4 weeks after apheresis; **AND**	❒
7. Do not have any of the following: a. Burkitt lymphoma. b. Active hepatitis B, C, or any uncontrolled infection. c. Grade 2 to 4 graft-versus-host disease. d. Concomitant genetic syndrome associated with bone marrow failure with the exception of Down syndrome. e. Received allogeneic cellular therapy, such as donor lymphocyte infusion, within 6 weeks prior to tisagenlecleucel infusion. f. Active central nervous system acute lymphoblastic leukemia (ie, white blood cell count ≥5 cells/μL in cerebrospinal fluid with presence of lymphoblasts).	❒

*Central nervous system (CNS) disease for B-cell acute lymphoblastic leukemia is defined by the following groups:

- CNS 1: Absence of blasts on cerebrospinal fluid cytospin preparation, regardless of the white blood cell (WBC) count
- CNS 2: WBC count of less than 5/mL and blasts on cytospin findings
- CNS 3: WBC count of 5/mL or more and blasts on cytospin findings and/or clinical signs of CNS leukemia (eg, facial nerve palsy, brain/eye involvement, hypothalamic syndrome).

Please check off if the facility is part of Risk Evaluation and Mitigation Strategy (REMS)	
The facility delivering the therapy is certified by Novartis that it has an adequate REMS protocol (Risk Evaluation and Mitigation Strategy) to address a cytokine release syndrome and neurotoxicity	❒

CPT CODES/ HCPCS CODES/ ICD CODES

HCPCS codes:	Code Description	
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	❒

Providers should enter the relevant diagnosis code(s) below:

Code	Description	
		❒
		❒

Providers should enter other relevant code(s) below:

Code	Description	
		❒
		❒