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

Please use this form to assist in identifying members who meet Blue Cross Blue Shield of Massachusetts' (BCBSMA's) medical necessity criteria for CAR T-Cell Therapy Services for B-cell Acute Lymphoblastic Leukemia (tisagenlecleucel). For members who do not meet the criteria, submit a letter of medical necessity with a request for Clinical Exception (Individual Consideration). Once completed, fax to**:**

Once completed, please fax to: 888-973-0726

CLINICAL DOCUMENTATION
Copies of clinical documentation that supports the medical necessity criteria for CAR T-Cell Therapy Services for B-cell Acute Lymphoblastic Leukemia (tisagenlecleucel) must be submitted with this form. **If the patient does not meet all the criteria listed below, please submit a letter of medical necessity explaining why an exception is justified.**

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:	
Patient is 25 years old or younger at the time of infusion	❒
Patient has not received prior treatment with tisagenlecleucel or any other gene therapy or is being considered for treatment with any other gene therapy	❒
Patient has adequate organ function with no significant deterioration in organ function expected within 4 weeks after apheresis	❒

CONTRAINDICATIONS

Please check off that the patient DOES NOT HAVE ANY of the following contraindications:	
Burkitt lymphoma	❒
Active hepatitis B, C, or any uncontrolled infection	❒
Grade 2 to 4 graft-versus-host disease	❒
Received allogeneic cellular therapy, such as donor lymphocyte infusion within 6 weeks prior to tisagenlecleucel infusion	❒
Active central nervous system 3 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**	
		❒
		❒