



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 <input type="checkbox"/> Inpatient <input type="checkbox"/> |

| 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 # | <input type="checkbox"/> |

| Please check off if the patient has the following diagnosis and <u>HAS RELAPSED</u> ^a (second or later) or is <u>REFRACTORY</u> ^b : | |
|---|--------------------------|
| CD19-positive B-cell acute lymphoblastic leukemia with morphologic marrow tumor involvement (≥ 5% lymphoblasts) | <input type="checkbox"/> |

^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 | <input type="checkbox"/> |
| Patient has not received prior FDA approved, CD19-directed, chimeric antigen receptor T therapy, AND | <input type="checkbox"/> |
| Patient has adequate organ function with no significant deterioration in organ function expected within 4 weeks after apheresis | <input type="checkbox"/> |

CONTRAINDICATIONS

| Please check off that the patient DOES NOT HAVE ANY of the following contraindications: | |
|---|--------------------------|
| Burkitt lymphoma | <input type="checkbox"/> |
| Active hepatitis B, C, or any uncontrolled infection | <input type="checkbox"/> |
| Grade 2 to 4 graft-versus-host disease | <input type="checkbox"/> |
| Received allogeneic cellular therapy, such as donor lymphocyte infusion within 6 weeks prior to tisagenlecleucel infusion | <input type="checkbox"/> |
| Active central nervous system 3 acute lymphoblastic leukemia (ie, white blood cell count ≥ 5 cells/ μ L in cerebrospinal fluid with presence of lymphoblasts)* | <input type="checkbox"/> |

*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 | <input type="checkbox"/> |

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 | <input type="checkbox"/> |

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

| Code | Description | |
|-------------|--------------------|--------------------------|
| | | <input type="checkbox"/> |
| | | <input type="checkbox"/> |

Providers should enter other relevant code(s) below:

| Code | Description | |
|-------------|--------------------|--------------------------|
| | | <input type="checkbox"/> |
| | | <input type="checkbox"/> |