MASSACHUSETTS

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CAR T-Cell Therapy Services for the Treatment of Diffuse Large B-cell Lymphoma (axicabtagene cilleucel or tisagenlecleucel) Prior Authorization Request Form #924

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 the Treatment of Diffuse Large B-cell Lymphoma (axicabtagene cilleucel or 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, 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 the Treatment of Diffuse Large B-cell Lymphoma (axicabtagene cilleucel or 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 ONE of the following histologically confirmed diagnoses and HAS RELAPSED or is REFRACTORY[a]:	
Diffuse large B-cell lymphoma, not otherwise specified	❒
Primary mediastinal large B-cell lymphoma	❒

High-grade B-cell lymphoma[b]	❒
Diffuse large B-cell lymphoma arising from follicular lymphoma	❒

[a] Relapsed or refractory disease, defined as progression after 2 or more lines of systemic therapy (which may or may not include therapy supported by autologous cell transplant).
[b] Tisagenlecleucel intravenous infusion is considered investigational for the treatment of relapsed or refractory primary mediastinal large B-cell lymphoma.

Please check off that the patient meets ALL the following criteria:	
Adult (age ≥18) at the time of infusion	❒
Received adequate prior therapy including all of the following: • Anti-CD20 monoclonal antibody for CD20-positive tumor • Anthracycline-containing chemotherapy regimen • For subjects with transformed follicular lymphoma, prior chemotherapy for follicular lymphoma and subsequently have chemorefractory disease after transformation to diffuse large B-cell lymphoma	❒
If patient has a history of allogeneic stem cell transplant, has no signs of active graft versus host disease	❒
No active autoimmune disease requiring systemic immunosuppression	❒
Has adequate organ and bone marrow function as determined by the treating oncologist/hematologist with no significant deterioration in organ function expected within 4 weeks after apheresis	❒
Has not received prior CD19-directed CAR T-cell therapy treatment or any other gene therapy or are being considered for treatment with any other gene therapy, AND	❒
Does not have primary central nervous system lymphoma.	❒

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

Note: Other adoptive immunotherapy, using adoptive cellular therapy for the administration of cytotoxic T-lymphocytes, cytokine-induced killer cells, tumor-infiltrating lymphocytes, antigen-loaded autologous dendritic cells, or genetically-engineered T-cells is considered **INVESTIGATIONAL**.

CPT CODES/ HCPCS CODES/ ICD CODES

HCPCS codes:	Code Description	
C9399	Unclassified drugs or biologicals	❒
J3490	Unclassified drugs	❒
J3590	Unclassified biologics	❒
J9999	Not otherwise classified, antineoplastic drugs	❒
Q2041	Axicabtagene Ciloleucel, up to 200 Million Autologous Anti-CD19 CAR T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Infusion	❒
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	❒
S2107	Adoptive immunotherapy, i.e., development of specific anti-tumor reactivity (e.g., tumor infiltrating lymphocyte therapy) per course of treatment	❒

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

Code	Description	
		❒

		❒

Providers should enter <u>other relevant code(s)</u> below:

Code	Description	
		❒
		❒