

# CAR T-Cell Therapy Services for B-cell Acute Lymphoblastic Leukemia (Brexucabtagene Autoleucel) Prior Authorization Request Form #945

## <u>Medical Policy #066 Chimeric Antigen Receptor Therapy for Hematologic</u> <u>Malignancies</u>

#### **CLINICAL DOCUMENTATION**

- Clinical documentation that supports the medical necessity criteria for CAR T-Cell Therapy Services for B-cell Acute Lymphoblastic Leukemia (Brexucabtagene Autoleucel) 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 <u>Authorization Manager</u> 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**

Patient Name:

Refer to our <u>Authorization Manager</u> page for tips, guides, and video demonstrations.

Complete Prior Authorization Request Form CAR T-Cell Therapy Services for B-cell Acute Lymphoblastic Leukemia (Brexucabtagene Autoleucel) Prior Authorization Request Form (945) using Authorization Manager.

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

Tallon Hamo.	Today o Baio.
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#:

Today's Data:

Officer That if	
Please check off if the patient has the following diagnosis and HAS RELAPSED a or is REFRACTORY :	
Confirmed diagnosis of CD19-positive B-cell acute lymphoblastic leukemia with morphologic bone marrow	
tumor involvement (≥5% lymphoblasts)	

marrow tumor involvement (≥5% lymphoblasts); AND  2. Meet any one of the following:  a. Relapsed diseasea 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 diseaseb defined as failure 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]).  3. When Philadelphia chromosome-positive: failure of tyrosine kinase inhibitors; AND  4. At least 18 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	Ple	ease check off that the patient meets <u>ALL</u> the following criteria:	
a. Relapsed diseasea 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 diseaseb defined as failure 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]).  3. When Philadelphia chromosome-positive: failure of tyrosine kinase inhibitors; AND  4. At least 18 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 brexucabtagene autoleucel infusion.  f. Active central nervous system acute lymphoblastic leukemia (ie, white blood cell count ≥5 cells/µL	1.		
blood after the attainment of a complete remission with chemotherapy and/or allogeneic cell transplant; OR  b. Refractory diseaseb defined as failure 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]).  3. When Philadelphia chromosome-positive: failure of tyrosine kinase inhibitors; AND  4. At least 18 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 brexucabtagene autoleucel infusion. f. Active central nervous system acute lymphoblastic leukemia (ie, white blood cell count ≥5 cells/µL	2.	Meet any one of the following:	
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]).  3. When Philadelphia chromosome-positive: failure of tyrosine kinase inhibitors; AND  4. At least 18 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 brexucabtagene autoleucel infusion. f. Active central nervous system acute lymphoblastic leukemia (ie, white blood cell count ≥5 cells/µL		blood after the attainment of a complete remission with chemotherapy and/or allogeneic cell transplant; OR	
<ul> <li>4. At least 18 years of age at the time of infusion; AND</li> <li>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</li> <li>6. Have adequate organ function with no significant deterioration in organ function expected within 4 weeks after apheresis; AND</li> <li>7. Do not have any of the following: <ul> <li>a. Burkitt lymphoma.</li> <li>b. Active hepatitis B, C, or any uncontrolled infection.</li> <li>c. Grade 2 to 4 graft-versus-host disease.</li> <li>d. Concomitant genetic syndrome associated with bone marrow failure with the exception of Down syndrome.</li> <li>e. Received allogeneic cellular therapy, such as donor lymphocyte infusion, within 6 weeks prior to brexucabtagene autoleucel infusion.</li> <li>f. Active central nervous system acute lymphoblastic leukemia (ie, white blood cell count ≥5 cells/µL</li> </ul> </li> </ul>		eradicate all detectable leukemia cells [<5% blasts] from the bone marrow and blood with subsequent	
<ol> <li>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</li> <li>Have adequate organ function with no significant deterioration in organ function expected within 4 weeks after apheresis; AND</li> <li>Do not have any of the following:         <ul> <li>a. Burkitt lymphoma.</li> <li>b. Active hepatitis B, C, or any uncontrolled infection.</li> <li>c. Grade 2 to 4 graft-versus-host disease.</li> <li>d. Concomitant genetic syndrome associated with bone marrow failure with the exception of Down syndrome.</li> <li>e. Received allogeneic cellular therapy, such as donor lymphocyte infusion, within 6 weeks prior to brexucabtagene autoleucel infusion.</li> <li>f. Active central nervous system acute lymphoblastic leukemia (ie, white blood cell count ≥5 cells/µL</li> </ul> </li> </ol>	3.	When Philadelphia chromosome-positive: failure of tyrosine kinase inhibitors; AND	
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 brexucabtagene autoleucel infusion. f. Active central nervous system acute lymphoblastic leukemia (ie, white blood cell count ≥5 cells/µL	4.	At least 18 years of age at the time of infusion; AND	
<ul> <li>weeks after apheresis; AND</li> <li>7. Do not have any of the following: <ul> <li>a. Burkitt lymphoma.</li> <li>b. Active hepatitis B, C, or any uncontrolled infection.</li> <li>c. Grade 2 to 4 graft-versus-host disease.</li> <li>d. Concomitant genetic syndrome associated with bone marrow failure with the exception of Down syndrome.</li> <li>e. Received allogeneic cellular therapy, such as donor lymphocyte infusion, within 6 weeks prior to brexucabtagene autoleucel infusion.</li> <li>f. Active central nervous system acute lymphoblastic leukemia (ie, white blood cell count ≥5 cells/μL</li> </ul> </li> </ul>	5.	therapy, or any gene therapy or are being considered for treatment with any other cell therapy or any	
<ul> <li>a. Burkitt lymphoma.</li> <li>b. Active hepatitis B, C, or any uncontrolled infection.</li> <li>c. Grade 2 to 4 graft-versus-host disease.</li> <li>d. Concomitant genetic syndrome associated with bone marrow failure with the exception of Down syndrome.</li> <li>e. Received allogeneic cellular therapy, such as donor lymphocyte infusion, within 6 weeks prior to brexucabtagene autoleucel infusion.</li> <li>f. Active central nervous system acute lymphoblastic leukemia (ie, white blood cell count ≥5 cells/µL</li> </ul>	6.		
<ul> <li>b. Active hepatitis B, C, or any uncontrolled infection.</li> <li>c. Grade 2 to 4 graft-versus-host disease.</li> <li>d. Concomitant genetic syndrome associated with bone marrow failure with the exception of Down syndrome.</li> <li>e. Received allogeneic cellular therapy, such as donor lymphocyte infusion, within 6 weeks prior to brexucabtagene autoleucel infusion.</li> <li>f. Active central nervous system acute lymphoblastic leukemia (ie, white blood cell count ≥5 cells/μL</li> </ul>	7.	, e	
<ul> <li>c. Grade 2 to 4 graft-versus-host disease.</li> <li>d. Concomitant genetic syndrome associated with bone marrow failure with the exception of Down syndrome.</li> <li>e. Received allogeneic cellular therapy, such as donor lymphocyte infusion, within 6 weeks prior to brexucabtagene autoleucel infusion.</li> <li>f. Active central nervous system acute lymphoblastic leukemia (ie, white blood cell count ≥5 cells/µL</li> </ul>			
<ul> <li>syndrome.</li> <li>e. Received allogeneic cellular therapy, such as donor lymphocyte infusion, within 6 weeks prior to brexucabtagene autoleucel infusion.</li> <li>f. Active central nervous system acute lymphoblastic leukemia (ie, white blood cell count ≥5 cells/µL</li> </ul>		·	
brexucabtagene autoleucel infusion.  f. Active central nervous system acute lymphoblastic leukemia (ie, white blood cell count ≥5 cells/µL			

### **CPT CODES/ HCPCS CODES/ ICD CODES**

Clinical Trial #

HCPCS codes:	Code Description	
C9399	Unclassified drugs or biologicals	
J3490	Unclassified drugs	
J3590	Unclassified biologics	
J9999	Not otherwise classified, antineoplastic drugs	
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	
XW23346	Transfusion of Brexucabtagene Autoleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 6	

<sup>&</sup>lt;sup>a</sup> 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.

<sup>&</sup>lt;sup>b</sup>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).

Code	Description

Providers should enter other relevant code(s) below:

Code	Description