HEALTH PLANS
UNIVERSITY OF UTAH

MEDICAL PHARMACY PRIOR AUTHORIZATION REQUEST FORM
TECARTUS®

For authorization, please answer each question and fax this form PLUS chart notes back to the U of U Health Plans Prior Authorization Department at 801-213-1547.

Failure to submit clinical documentation to support this request will result in a dismissal of the request.

If you have medical pharmacy prior authorization questions, please call for assistance: Individual Exchange: 833-981-0214, Commercial Groups: 833-981-0213

Disclaimer: Prior authorization request forms are subject to change in accordance with Federal and State notice requirements.

Date:	Member Name:	ID#:
DOB:	Gender:	Physician:
Office Phone:	Office Fax:	Office Contact:
Height/Weight:		HCPCS Code:

Member must try formulary preferred drugs before a request for a non-preferred drug may be considered. If treatment with preferred products has not been successful, you must submit which preferred products have been tried, dates of treatment, and reason for failure. Reasons for failure must meet the Health Plan medical necessity criteria.

Product being requested: ☐ Tecartus® (brexucabtagene autoleucel)

Dosing/Frequency:_____

If the request is for reauthorization, proceed to reauthorization section.

Questions	Yes	No	Comments/Notes
MANTLE CELL LYMPHOMA			
1. Is the member 18 years of age or older?	☐	☐	
2. Does the member have a diagnosis of relapse or refractory mantle cell lymphoma?	☐	☐	**Please provide documentation**
3. Was the member refractory, or had no response, to all of the following: • Anthracycline or bendamustine-containing regimen • Anti-CD20 therapy, such as rituximab • Bruton's Tyrosine Kinase (BTK) inhibitors, such as ibrutinib or acalabrutinib?	☐	☐	**Please provide documentation**
4. Does the member have a histological confirmation of cyclin D1 overexpression or presence of the translocation t(11;14)?	☐	☐	**Please provide documentation**
5. Does the member have at least one measurable lesion per the Lugano Classification? • Lymph nodes: the longest diameter in axial plane is >1.5 cm • Extranodal lesions: the longest diameter in axial plane is > 1.0 cm	☐	☐	**Please provide documentation**
6. Does the member have adequate bone marrow reserve with all of the following: • Platelet count ≥ 75,000/µL	☐	☐	**Please provide documentation**

• Absolute neutrophil count (ANC) ≥ 1,000 cells/µL • Absolute lymphocyte count (ALC) ≥ 100 cells/µL			
7. Does the member have a Karnofski score ≥ 70 or Eastern Cooperative Oncology Group (ECOG) score < 2?	☐	☐	**Please provide documentation**
8. Does the member have a documented ability to tolerate a lymphodepleting chemotherapy regimen of cyclophosphamide 500mg/m^2 intravenously and fludarabine 30mg/m^2 intravenously on the fifth, fourth, and third days before Tecartus™ infusion?	☐	☐	**Please provide documentation**
9. Does the member have adequate and stable renal, cardiac, and pulmonary function with all of the following: • Creatinine clearance ≥ 60mL/min • Cardiac ejection fraction ≥ 50% and no evidence of pericardial effusion determined by an echocardiogram • Baseline oxygen saturation > 92% on room air?	☐	☐	**Please provide documentation**
10. Dose the member have any of the following: • Previous allogeneic hematopoietic cell transplant (HSCT) • Prior treatment with chimeric antigen receptor therapy or other genetically modified T-cell therapy; or is being considered for treatment with any other gene therapy • Presence of fungal, bacterial, viral, or other infection that is uncontrolled requiring IV antimicrobials for management prior to Tecartus™ infusion • Active inflammatory disorders • Active hepatitis B (HBsAG positive) or hepatitis C (anti-HCV positive) virus, if viral load is detectable • History of central nervous system lymphoma • Active central nervous system (CNS) lymphoma or CNS disorders by imaging • Detectable malignant cells in the cerebrospinal fluid or brain metastases?	☐	☐	
11. Has the member received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy?	☐	☐	
12. Will Tecartus™ be given at a certified center to administer Tecartus™?	☐	☐	
13. Has the member and the requesting provider enrolled in the Yescarta® and Tecartus™ REMS program?	☐	☐	
B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)			
1. Has the member received a previous treatment course of the requested medication or another CD19-directed chimeric antigen receptor (CAR-T) therapy, or any prior CD19 directed therapy other than blinatumomab?	☐	☐	**Please provide documentation**

2. Does the member have Philadelphia chromosome-negative disease that is relapsed or refractory as defined as one of the following: • Primary refractory disease; *or* • First relapse with remission of 12 months or less; *or* • Relapsed or refractory disease after at least 2 previous lines of systemic therapy; *or* • Relapsed or refractory disease after allogeneic stem cell transplant (allo-SCT)	☐	☐	**Please provide documentation**
3. Does the member have Philadelphia chromosome-positive disease and meets either of the following: • Relapsed or refractory disease despite treatment with at least 2 different tyrosine kinase inhibitors (TKIs) (e.g., bosutinib, dasatinib, imatinib, nilotinib, ponatinib); or • The member is intolerant to TKI therapy	☐	☐	**Please provide documentation**
4. Does the member have morphological disease in the bone marrow?	☐	☐	**Please provide documentation**
5. Does the member have an ECOG performance status of 0 to 2?	☐	☐	**Please provide documentation**
6. Does the member have adequate and stable kidney, liver, pulmonary, and cardiac function?	☐	☐	**Please provide documentation**
7. Does the member have active hepatitis B, active hepatitis C, or any active uncontrolled infection?	☐	☐	**Please provide documentation**
8. Does the member have active graft versus host disease?	☐	☐	
9. Does the member have an active inflammatory disorder?	☐	☐	
What medications and/or treatment modalities have been tried in the past for this condition? Please document name of treatment, reason for failure, treatment dates, etc.			
Additional information:			
Physician Signature:			

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Policy: PHARM-M031
Origination Date: 10/21/2020
Reviewed/Revised Date: 01/19/2022
Next Review Date: 01/19/2023
Current Effective Date: 02/01/2022