SENTARA COMMUNITY PLAN (MEDICAID)

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; fax to 1-844-305-2331. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. If information provided is not complete, correct, or legible, authorization can be delayed.

The Sentara Health Plans Oncology Program is administered by OncoHealth

For any oncology indications, the most efficient way to submit a prior authorization request is through the OncoHealth OneUM Provider Portal at https://oneum.oncohealth.us. Fax to 1-800-264-6128. OncoHealth can also be contacted by Phone: 1-888-916-2616.

Drug Requested: Tecartus® (brexucabtagene autoleucel) IV (Q2053) (Medical)

Member Name:	
Member Sentara #:	
Prescriber Name:	
Prescriber Signature:	
Office Contact Name:	
Phone Number: Fax Number:	
DRUG INFORMATION: Authoriz	zation may be delayed if incomplete.
DRUG INFORMATION: Authoriz	zation may be delayed if incomplete. Length of Therapy:
DRUG INFORMATION: Authoriz Drug Form/Strength: Dosing Schedule:	zation may be delayed if incomplete.

- the member's ability to regain maximum function and would not subject the member to severe pain.
 - A. Quantity Limit (max daily dose) [NDC Unit]:
 - 1 infusion of Tecartus[®] 200 million autologous anti-cd19 CAR -positive viable T cells only
 - B. Max Units (per dose and over time) [HCPCS Unit]:
 - 1 infusion of Tecartus® 200 million autologous anti-cd19 CAR -positive viable T cells only

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

A

 □ Member is 18 years of age or older AND □ Healthcare facility has enrolled in the YESCARTA® & TECARTUS® REMS and training has been give to providers on the management of cytokine release syndrome (CRS) and neurological toxicities AND □ Member does NOT have a clinically significant active systemic infection or inflammatory disorder AND □ Prophylaxis for infection has been followed according to local guidelines AND □ Member has NOT received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during brexucabtagene autoleucel treatment, and will not receive live vaccines until immune recovery following treatment AND □ Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis)
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AND
☐ Medication will be used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture)
AND
☐ Member has an ECOG performance status of 0-1
AND
☐ Member has <u>NOT</u> received prior CAR-T therapy
AND
□ Provider attests to all applicable clinical criteria for at least <u>ONE</u> of the diagnoses below:
Mantle Cell Lymphoma

☐ Member did <u>NOT</u> receive prior allogeneic hematopoietic stem cell transplantation (HSCT)

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	AND
	Member does <u>NOT</u> have central nervous system lymphoma, detectable cerebrospinal fluid malignant cells or brain metastases
	AND
	Member has a confirmed diagnosis of Mantle Cell Lymphoma, determined to be relapsed or refractory
	AND
	Member must have received previous systemic therapy which included at least ONE agent from EACH of the following categories:
	☐ Bruton tyrosine kinase (BTK) inhibitor (e.g., ibrutinib, acalabrutinib, zanubrutinib)
	☐ Anti-CD20 monoclonal antibody (e.g., rituximab)
	☐ Anthracycline- OR bendamustine-containing chemotherapy
□ B	B-Cell Precursor Acute Lymphoblastic Leukemia
	Member has relapsed or refractory disease
	AND
	<u>ONE</u> of the following must be met:
	☐ Member has <u>NOT</u> received prior anti-CD19 therapy (e.g., blinatumomab)
	☐ Member previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease
	AND
	Member does NOT have CNS-3 disease or CNS-2 disease with neurological changes
	AND
	Member's current disease state satisfies ONE of the following:
	☐ Member has Philadelphia chromosome (Ph)-positive disease [MUST be tyrosine kinase inhibitor (TKI) intolerant OR refractory to at least two (2) different TKIs]
	☐ Member has Philadelphia chromosome (Ph)-negative disease

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Reauthorization	Criteria –	Coverage	cannot be	renewed
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Medication being provided by: Please check applicable box below.
□ Location/site of drug administration:
NPI or DEA # of administering location:
<u>OR</u>
□ Specialty Pharmacy
For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health's definition of argent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

^{**}Use of samples to initiate therapy does not meet step edit/preauthorization criteria. **

^{*}Previous therapies will be verified through pharmacy paid claims or submitted chart notes. *