



Anti-Neoplastic: B-Cell Lymphoma Drugs
Besponsa (inotuzumab ozogam) J9229, Columvi (glofitamab-gxbr) J9286, Blincyto (blinatumomab) J9039,
Campath/Lemtrada (alemtuzumab) J0202, Polivy (polatuzumab) J9309, Epkinly (epocoritamab-bysp) J9321, Zynlonta (loncastuximab tesirine-lpyl) J9359, Yescarta (Axicabtagene ciloleucel) Q2041

**Prior Authorization Request
 Medicare Part B Form**

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone _____ / Fax _____		

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Self-administered Provider-administered Home Infusion

Chart notes attached. **Other important information:** _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)
 Provider has reviewed the attached “Criteria for Approval” and attests the member meets ALL required PA criteria.
 If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)
 Provider has reviewed the attached “Criteria for Continuation” and attests the member meets ALL required PA Continuation criteria.
 Patient had an adequate response or significant improvement while on this medication.
 If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Oncology: B-Cell Lymphoma Drugs PA

Drug Name(s):

BESPONSA	BLINCYTO
CAMPATH	LEMTRADA
POLIVY	ZYNLONTA
YESCARTA	AXICABTAGENE CILOLEUCEL
COLUMVI	EPKINLY

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

Cannot be prescribed for experimental or investigational use.

Prescriber Restrictions:

Oncologist or other cancer specialist

Lemtrada: Neurologist, Oncologist or other relevant specialist

Coverage Duration:

New Start: Approval will be for 6 months

Continuation: Approval will be for 12 months

FDA Indications:

Besponsa

- Precursor B-cell acute lymphoblastic leukemia, relapsed or refractory

Blinicyto

- B-cell acute lymphoblastic leukemia, CD19-positive disease in first or second complete remission with minimal residual disease-positive (0.1% or greater)
- B-cell acute lymphoblastic leukemia, relapsed or refractory, CD19-positive disease

Campath

- B-cell chronic lymphocytic leukemia, Monotherapy

Lemtrada

- B-cell chronic lymphocytic leukemia variant, Monotherapy
- Relapsing remitting multiple sclerosis (inadequate response to two or more drugs indicated for treatment of MS)

Polivy

- Diffuse large B-cell lymphoma, relapsed or refractory, in combination with bendamustine and a rituximab product, after at least 2 prior therapies

Columvi

- Diffuse large B-cell lymphoma, Relapsed or refractory, not otherwise specified or large B-cell lymphoma arising from follicular lymphoma, after 2 or more lines of systemic therapy

Epkinly

- Diffuse large B-cell lymphoma, Relapsed or refractory, not otherwise specified, including diffuse large B-cell lymphoma arising from indolent lymphoma, and high-grade B-cell lymphoma after 2 or more lines of systemic therapy

Off-Label Uses:

Campath/Lemtrada

- Autoimmune disease - Cytopenia
- Cardiac transplant rejection; prophylaxis
- Chronic lymphoid leukemia
- Graft versus host disease, In patients receiving allogeneic stem cell transplant for hematologic malignancies, steroid-refractory
- Malignant tumor of lymphoid hemopoietic and related tissue
- Primary cutaneous T-cell lymphoma, Relapsed or refractory
- Rejection of intestine transplant; prophylaxis
- Rejection of pancreas transplant; prophylaxis
- Renal transplant rejection, Induction therapy; Prophylaxis
- T-cell prolymphocytic leukemia

Polivy

- Diffuse large B-cell lymphoma, Intermediate- or high-risk, previously untreated, in combination with cyclophosphamide, DOXOrubicin, predniSONE, and rituximab

Yescarta

- B-cell lymphoma, Large, relapsed or refractory, after 2 or more lines of systemic therapy
- B-cell lymphoma, Large, relapse within 12 months or refractory to first-line chemoimmunotherapy
- Follicular lymphoma, Relapsed or refractory after 2 or more lines of systemic therapy

Zynlonta

- B-cell lymphoma, Large, relapsed or refractory, after 2 or more lines of systemic therapy

Age Restrictions:

Besponsa, Polivy: Safety and effectiveness not established in pediatric patients

Other Clinical Considerations:

Cancer diagnoses: Criteria as per NCCN or other FDA-approved cancer related guidelines.

Black Box Warning:

Columvi: Cytokine Release Syndrome (CRS), including serious or fatal reactions, can occur in patients receiving glofitamab-gxbl. Premedicate before each dose, and initiate treatment with the glofitamab-gxbl step-up dosing schedule to reduce the risk of CRS. Withhold glofitamab-gxbl until CRS resolves or permanently discontinue based on severity.

Black Box Warning:

Epkinly:

- Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving epcoritamab-bysp. Initiate treatment with the epcoritamab-bysp step-up dosing schedule to reduce the incidence and severity of CRS. Withhold epcoritamab-bysp until CRS resolves or permanently discontinue based on severity.
- Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), including life threatening and fatal reactions, can occur with epcoritamab-bysp. Monitor patients for neurological signs or symptoms of ICANS during treatment. Withhold epcoritamab-bysp until ICANS resolves or permanently discontinue based on severity

Resources:

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