



**Chemotherapy: Lymphoid Leukemia Drugs**  
**Arzerra/Kesimpta (ofatumumab) J9302,**  
**Bendeka/Treanda (bendamustine HCl) J9034/J9033,**  
**Erwinaze (asparaginase erwinia chrysanthemi)**  
**J9019, Gazyva (obinutuzumab) J9301, Oncaspar**  
**(pegaspargase) J9266, Rylaze (asparaginase) J9021**  
**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"/>	<b>NEW START - Start Date:</b> _____	<input type="checkbox"/>	<b>Continuation</b> (within 365 days): Date of last treatment _____
<input type="checkbox"/>	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 <input type="checkbox"/> Self-administered	Dose (Wt: _____ kg Ht: _____ )	Frequency	End Date if known

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: NSCLC Meds PA

### Drug Name(s):

ARZERRA  
BENDEKA  
ERWINAZE  
GAZYVA

KESIMPTA  
ONCASPAR  
TREANDA  
RYLAZE

### 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

### Coverage Duration:

**New Start: Approval will be for 6 months**

**Continuation: Approval will be for 12 months**

### FDA Indications:

#### Arzerra, Kesimpta

- Chronic lymphoid leukemia, Extended treatment for patients in complete or partial response after at least 2 lines of therapy for recurrent or progressive disease
- Chronic lymphoid leukemia, Previously untreated, in combination with chlorambucil
- Chronic lymphoid leukemia, Refractory to fludarabine and alemtuzumab
- Chronic lymphoid leukemia, Relapsed, in combination with fludarabine and cyclophosphamide
- Relapsing remitting multiple sclerosis

#### Bendeka, Treanda

- Chronic lymphoid leukemia
- Non-Hodgkin's lymphoma, Indolent B-cell, refractory to rituximab or rituximab-containing regimens

#### Gazyva

- Chronic lymphoid leukemia, Previously untreated, in combination with chlorambucil
- Follicular lymphoma, After relapse, or those who are refractory to a rituximab-containing regimen, in combination with bendamustine followed by obinutuzumab monotherapy
- Follicular lymphoma, In combination with chemotherapy followed by obinutuzumab monotherapy, in previously untreated stage II bulky, III, or IV disease in those with at least a partial response to combination therapy

**Erwinaze**

- Acute lymphoid leukemia, In combination with other chemotherapeutic agents in patients with hypersensitivity to E coli-derived asparaginase

**Oncaspar**

- Acute lymphoid leukemia, First-line, in combination with other agents
- Acute lymphoid leukemia, In combination with other agents in patients with hypersensitivity to L-asparaginase

**Rylaze**

- Acute lymphoid leukemia, In combination with other chemotherapy agents; in patients who have developed E. coli-derived asparaginase hypersensitivity
- Lymphoblastic lymphoma, In combination with other chemotherapy agents; in patients who have developed E. coli-derived asparaginase hypersensitivity

**Off-Label Uses:**

**Arzerra, Kesimpta**

- Waldenstrom macroglobulinemia

**Bendeka, Treanda**

- Metastatic breast cancer
- Multiple myeloma
- Non-Hodgkin's lymphoma
- Waldenstrom macroglobulinemia, In combination with rituximab
- Amyloidosis, relapsed or refractory, combination with dexamethasone
- Mantle cell lymphoma, previously untreated, transplant ineligible, in combination with rituximab

**Oncaspar**

- Acute lymphoid leukemia
- Extranodal NK/T-cell lymphoma, nasal type

**Age Restrictions:**

**Azerra, Bendeka, Gazyva, Kesimpta, Treanda:** Safety and effectiveness not established in pediatric patients

**Rylaze:** 1 month or older

**Other Clinical Considerations:**

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

**Resources:**

[https://www.micromedexsolutions.com/micromedex2/librarian/CS/14AD71/ND\\_PR/evidencexpert/ND\\_P/evidencexpert/DUPLICATIONSHIELDSYN/C/659BD9/ND\\_PG/evidencexpert/ND\\_B/evidencexpert/ND\\_AppProduct/evidencexpert/ND\\_T/evidencexpert/PFActionId/evidencexpert.DoIntegrat edSearch?SearchTerm=OFATUMUMAB%20&UserSearchTerm=OFATUMUMAB%20&SearchFilter=filterNone&navitem=searchGlobal#](https://www.micromedexsolutions.com/micromedex2/librarian/CS/14AD71/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYN/C/659BD9/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegrat edSearch?SearchTerm=OFATUMUMAB%20&UserSearchTerm=OFATUMUMAB%20&SearchFilter=filterNone&navitem=searchGlobal#)

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## Part B Prior Authorization Guidelines

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CLINICAL / CMS  
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