

Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number:

If Applicable: Pharmacy Name: _____
Pharmacy Phone: _____

Complete the Clinical Assessment:

Please attach all relevant medical records and test results.

STEP
2

Diagnosis	<input type="checkbox"/> Chronic Lymphoid Leukemia, refractory <input type="checkbox"/> Other (please state): _____ _____
Clinical Consideration	Patient has had documented failure of both of the following (check below and give date): <input type="checkbox"/> fludarabine: date (mo/year) _____ and <input type="checkbox"/> Campath (alemtuzumab): date (mo/year) _____
Physician Specialty	Diagnosis made by: <input type="checkbox"/> Oncology <input type="checkbox"/> Other (please state): _____
Supporting Documentation	Diagnosis: ICD-9 Code #/ Description / J Code (required):
	Please attach a copy of the prescription or provide ALL of the information below: Arzerra [®] (ofatumumab) Strength _____ Sig _____ Qty _____ Refills _____
	<p align="center">We will not process incomplete forms. If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.</p>

STEP
3

I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)

Prescriber Signature

Date

STEP
4

Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:

970-248-5034

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 01/09/12

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Arzerra® (ofatumumab)

CLASSIFICATION

- Antineoplastic, monoclonal antibody

DESCRIPTION

- Ofatumumab is a human IgG1-kappa monoclonal antibody that specifically binds to the small and large extracellular loops of the CD20 molecule on normal B lymphocytes and on B-cell chronic lymphocytic leukemia, resulting in B-cell lysis.
- Efficacy was based on a 42% durable objective tumor response rate seen in ofatumumab-treated adults with refractory chronic lymphocytic leukemia (CLL) (n=59), according to a single-arm study of patients with relapsed or refractory CLL (n=154). No data demonstrate an improvement in disease-related symptoms or increased survival.
- Progressive multifocal leukoencephalopathy (PML), including fatal PML, has been observed with ofatumumab.

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	Tier 6 (Medical benefit)
Commercial Formulary:	Tier 6 (Medical benefit)
Medicare Part D coverage:	Tier 5; Part B if incident to a physician's service, Part D if obtained at a pharmacy

COVERAGE CRITERIA

Arzerra® (ofatumumab) meets the definition of **medical necessity** for the following:

- Chronic lymphoid leukemia, Refractory to fludarabine and alemtuzumab

Arzerra® (ofatumumab) is considered **experimental** for the following:

- Any condition or diagnosis that is not FDA approved or Compendia supported.

Required Provider Specialty:

- Approval is limited to Oncology

DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy in pediatric patients has not been established)

- Chronic lymphoid leukemia, Refractory: 300 mg IV, followed 1 week later by 2000 mg IV weekly for 7 doses (dose 2 to 8), followed 4 weeks later by 2000 mg every 4 weeks for 4 doses (dose 9 to 12);

- Dose 1: Initiate at an initial rate of 12 mL/hr (3.6 mg/hr), if infusion is well-tolerated, rate may be escalated in 2-fold increments at 30 min intervals to a maximum of 200 mL/hr
- Dose 2: Initiate at an initial rate of 12 mL/hr (24 mg/hr), if infusion is well-tolerated, rate may be escalated in 2-fold increments at 30 min intervals to a maximum of 200 mL/hr
- Dose 3 through 12: Initiate at an initial rate of 25 mL/hr (50 mg/hr), if infusion is well-tolerated, rate may be escalated in 2-fold increments at 30 min intervals to a maximum of 400 mL/hr
- Premedication: 30 min to 2 hr before each dose with acetaminophen (1000 mg or equivalent), oral or IV antihistamine (cetirizine 10 mg or equivalent), and IV corticosteroid (prednisolone 100 mg or equivalent)
 - Corticosteroid premedication dose may be gradually reduced for doses 3 through 8, if grade 3 or greater infusion reaction did not occur with the preceding dose
 - Corticosteroid premedication dose may be reduced to prednisolone 50 to 100 mg or equivalent for doses 10 through 12, if grade 3 or greater infusion reaction did not occur with dose 9

Dosing adjustments:

- Body weight: no dose adjustment is recommended
- Gender: no dose adjustment is recommended
- Infusion reaction, grade 1 or 2: interrupt infusion and if reaction resolves or remains less than or equal to grade 2, resume at one-half the previous infusion rate; resume infusion at normal infusion rate as tolerated
- Infusion reaction, grade 3: interrupt infusion and if reaction resolves or remains less than or equal to grade 2, resume infusion at a rate of 12 mL/hr; resume infusion at normal infusion rate as tolerated
- Infusion reaction, grade 4: discontinue the infusion and do not resume

PRECAUTIONS:

- Chronic obstructive pulmonary disease, moderate to severe (unapproved use); risk of grade 3 bronchospasm during infusion
- Cytopenias, including prolonged severe neutropenia and thrombocytopenia may occur; monitoring recommended
- Hepatitis B infection, carriers or at risk of infection; risk of hepatitis B reactivation with fulminant hepatitis, hepatic failure, and death; evaluate for evidence of infection before beginning treatment and closely monitor for reactivation for 6 to 12 months following therapy; discontinue therapy if viral hepatitis occurs
- Infusion reactions, some serious (eg. bronchospasm, dyspnea, laryngeal edema, pulmonary edema, angioedema, cardiac ischemia/infarction) have been reported; especially during first 2 infusions; premedication is recommended; depending on the severity of the reaction, adjustment in infusion rate, interruption, and/or discontinuation of therapy is recommended
- Obstruction of small intestinal may occur
- Progressive multifocal leukoencephalopathy (PML) including fatalities, may occur; new onset or changes in preexisting neurological signs and symptoms may be indicative of PML; discontinue therapy if PML occurs
- Viral vaccination, live; do not use in patients who recently received ofatumumab therapy

Billing/Coding information

Associated HCPCS Codes:

J9302	Injection, ofatumumab, 10mg (For billing prior to 1/1/11 use C9260)
J9999	Not otherwise classified, antineoplastic drugs (Refer to manual for billing instructions)

Associated CPT Coding:

Associated ICD-9 Coding:

204.1	Chronic lymphoid leukemia

COST

- AWP (April 2010): Arzerra 100mg/5ml vial: \$528.00
- AWP (January 2012): Arzerra 100mg/5ml vial: \$528.00

COMMITTEE APPROVAL:

- January 26, 2011

GUIDELINE UPDATE INFORMATION:

April 2010	Policy created
January 2012	Policy updated

REFERENCES:

- DRUGDEX®, accessed 04/06/2010, 1/4/2012
- Product Information: ARZERRA™ intravenous injection, solution, ofatumumab intravenous injection, solution. GlaxoSmithKline, Research Triangle Park, NC, 2009.