



Prior Authorization Approval Criteria

Arzerra (ofatumumab)

Generic name:	ofatumumab
Brand name:	Arzerra
Medication class:	monoclonal antibody
FDA-approved uses:	treatment of patients with chronic lymphocytic leukemia (CLL) refractory to fludarabine and alemtuzumab.
Available dosage forms:	100mg/5ml single use vial
Usual dose:	Administered as an intravenous infusion. 12 doses administered as follows: 300mg as the initial dose followed 1 week later by 2,000mg weekly for 7 doses (dose 2-8), followed 4 weeks later by 2,000mg every 4 weeks for 4 doses (dose 9-12).
Approximate cost: (based on AWP 2010)	\$117,744.00 for total treatment cycle of 12 doses.
Duration of therapy:	indefinite

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Patient must have clinically diagnosed CLL.
- Must have failed fludarabine and alemtuzumab.
- Must be prescribed by an oncologist.
- Must be reviewed by a medical director.

Monitoring:

- Monitor blood counts for neutropenia and thrombocytopenia.
- Neurologic function and discontinue therapy if suspected.
- Screen high risk patients for reactivation of Hepatitis B

Contraindication:

- None listed at this time.

Not approved if:

- Patient does not meet the above stated criteria

Special Considerations:

- Experience with this agent is extremely limited and its use outside of clinical trials should be limited to the FDA-approved indication.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 06/09/10