



Prior Authorization Approval Criteria

Clolar (clofarabine)

Generic name:	Clofarabine
Brand name:	Clolar
Medication class:	Antineoplastic agent
FDA-approved use:	Patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens
Available dosage form:	1 mg/ml (20 ml) solution for injection
Usual dose range:	52 mg/m ² /day IV over 2 hours on days 1 through 5; repeat every 2-6 weeks
Duration of therapy:	Indeterminate; dependent upon clinical responses with treatment cycles repeated following recovery or return to baseline organ function
Cost (based on ASP 7/20/06):	\$270,780 per year

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

- Patient must be age 1-21 years old
- Clinically diagnosed with refractory acute lymphoblastic leukemia (ALL)
- Failed/intolerant to at least 2 prior regimens

Criteria for continuation of therapy: Must be approved for ensuing cycles of relapsed acute lymphoblastic leukemia.

Cautions:

- Dosing is based on BMI and physicians should give continuous IV fluids over the course of 5 days to reduce the effects of tumor lyses and adverse effects.
- Possibility of bone marrow suppression
- Dehydration and hypotension due to nausea, vomiting, and diarrhea
- Safety and efficacy have not been established in adults

Monitoring: BP, respiratory status, liver and renal functions, CBC

Contraindications: Hypersensitivity to clofarabine.

Not approved if:

- Above-stated criteria are not met.
- Patient is hypersensitive to clofarabine.

Special considerations: Stop treatment if hypotension develops for any reason during the 5 days of administration. Reinitiate at a lower dose if the hypotension is transient or resolves without pharmacological intervention.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 11/14/08