



Prior Authorization Approval Criteria

Arranon (nelarabine)

Generic name:	Nelarabine
Brand name:	Arranon
Medication class:	Antineoplastic; antimetabolite
FDA-approved uses:	Treatment of patients with T-cell acute lymphoblastic leukemia (T-ALL) and T- cell lymphoblastic lymphoma (T-LBL) that has not responded to, or has relapsed following, treatment with at least two chemotherapy regimens
Available dosage form:	250 mg vial (5 mg/ml)
Usual dose range:	Adult: 1500 mg/m ² intravenously over 2 hours on days 1, 3, and 5, repeated every 21 days. Pediatric: 650 mg/m ² intravenously over 1 hour daily for 5 consecutive days, also repeated every 21 days.
Duration of therapy:	Until there is evidence of disease progression, the patient experiences unacceptable toxicity or, the patient becomes a candidate for bone marrow transplant.
Cost (based on AWP 2006):	\$4,000.00 for one day's treatment for an adult with a BSA of 1.7 m ²

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

- Must be prescribed by an oncologist or a hematologist.
- Must have clinically documented T-cell acute lymphoblastic leukemia (T-ALL)

OR

- Must have clinically documented T- cell lymphoblastic lymphoma (T-LBL)
- Patient has been intolerant to or relapsed following treatment with at least two chemotherapy regimens.

Criteria for continuation of therapy (*bullet points below are all inclusive unless otherwise noted*):

- Not a candidate for bone marrow therapy
- Disease is stable, not progressing
- Patient tolerates treatment without any unacceptable toxicity

Caution:

- Severe neurologic events have been reported including mental status changes, somnolence, convulsions and peripheral neuropathy ranging from numbness and paresthesias to motor weakness and paralysis
- Some reports of demyelination and ascending peripheral neuropathies similar in appearance to Guillain-Barre syndrome
- Leukopenia, thrombocytopenia and neutropenia
- Hydration, urine alkalinization, and allopurinol prophylaxis are recommended to prevent hyperuricemia associated with the tumor lysis syndrome

Monitoring:

- Complete blood counts
- Neurologic toxicity

Contraindications:

- Patient has a history of hypersensitivity to any of the product ingredients.

Not approved if:

- Patient does not meet the above-stated criteria.
- Patient has any contraindications to the use of nelarabine.

Special considerations:

- Similar drugs: cytarabine, fludarabine.
- Usual treatment can include vincristine, prednisone, an anthracycline, asparaginase, cyclophosphamide and cytarabine.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 06/14/06