

Prior Authorization DRUG Guidelines

Arranon (nelarabine)

Date Developed: 9/3/13 by Albert Reeves MD

Effective Date: 10/22/13

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1/31/23, 2/13/24, 2/18/25

Pharmacologic Category: Antineoplastic Agent, Antimetabolite;

Authorization Criteria: Treatment of relapsed or refractory T-cell acute lymphoblastic leukemia/lymphoma in patients ≥ 1 year of age following at least 2 chemotherapy regimens

Dosage:

Adult

I.V.: 1500 mg/m²/dose on days 1, 3, and 5; repeat every 21 days until transplant, disease progression, or unacceptable toxicity.

Children and Adolescents:

Dosing and frequency vary by protocol and/or treatment phase; refer to specific protocol.

NOTE: Adequate I.V. hydration recommended to prevent tumor lysis syndrome; allopurinol may be used if hyperuricemia is anticipated.

Major adverse reactions and Black Box Warnings:

Neurotoxicity: [US Boxed Warning]: Severe neurotoxicities, including mental status changes, severe somnolence, seizures, and peripheral neuropathy (ranging from numbness and paresthesias to motor weakness and paralysis), have been reported. Adverse reactions associated with demyelination and ascending peripheral neuropathies similar in appearance to Guillain-Barré syndrome have also been reported. Neurologic toxicities may not fully return to baseline after treatment cessation.

Other: Bone marrow suppression; CNS depression; Tumor lysis syndrome; Renal and/or Hepatic impairment [NOTE: Detection of chronic or past HBV infection

requires a risk assessment to determine antiviral prophylaxis requirements, monitoring, and follow-up. Hepatitis B virus screening recommended

Contraindications

There are no contraindications listed within the manufacturer's labeling.

References:

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7. Gökbüget N, Basara N, Baurmann H, et al, "High Single-Drug Activity of Nelarabine in Relapsed T-Lymphoblastic Leukemia/Lymphoma Offers Curative Option With Subsequent Stem Cell Transplantation," *Blood*, 2011, 118(13):3504-11. [PubMed 21715318]
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10. Kisor DF, Plunkett W, Kurtzberg J, et al, "Pharmacokinetics of Nelarabine and 9-beta-D-Arabinofuranosyl Guanine in Pediatric and Adult Patients During a Phase I Study of Nelarabine for the Treatment of Refractory Hematologic Malignancies," *J Clin Oncol*, 2000, 18(5):995-1003. [PubMed 10694549]
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12. National Institute for Occupational Safety and Health (NIOSH), "NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012." Available at <http://www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf>. Accessed January 21, 2013.
13. Kisor DF, Plunkett W, Kurtzberg J, et al, "Pharmacokinetics of Nelarabine and 9-beta-D-Arabinofuranosyl Guanine in Pediatric and Adult Patients During a Phase I Study of Nelarabine for the Treatment of Refractory Hematologic Malignancies," *J Clin Oncol*, 2000, 18(5):995-1003.
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15. Winter SS, Dunsmore KP, Devidas M, et al. Safe integration of nelarabine into intensive chemotherapy in newly diagnosed T-cell acute lymphoblastic leukemia: Children's Oncology Group Study AALL0434. *Pediatr Blood Cancer*. 2015;62(7):1176-1183.

Revision History:

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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
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2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Modified dosage for children and adolescents, Updated the Major

			adverse reactions and Black Box Warnings sections. Removed the adverse effect section
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