VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

Arranon (nelarabine)

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

Effective Date: 10/22/13

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20

Pharmacologic Category: Antineoplastic Agent, Antimetabolite;

authorization Criteria:

relapsed or refractory T-cell acute lymphoblastic leukemia (ALL) and T-cell lymphoblastic lymphoma

Dosage: **Adult**

T-cell acute lymphoblastic leukemia (ALL), T-cell lymphoblastic lymphoma: I.V.: 1500 mg/m^2/dose on days 1, 3, and 5; repeat every 21 days until transplant, disease progression, or unacceptable toxicity.

Administration:

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

Children: Infuse over 1 hour daily for 5 consecutive days

Adults: Infuse over 2 hours on days 1, 3, and 5

Major adverse reactions and Black Box Warnings:

>10%:

Cardiovascular: Peripheral edema (15%), edema (11%)

Central nervous system: Fatigue (50%), fever (23%), somnolence (7% to 23%; grades 2-4: 1% to 6%), dizziness (21%; grade 2: 8% adults), headache (15% to 17%; grades 2-4: 4% to 8%), hypoesthesia (6% to 17%; grades 2/3: children 5%, adults 12%), pain (11%)

Dermatologic: Petechiae (12%)

Endocrine & metabolic: Hypokalemia (11%)

Gastrointestinal: Nausea (41%), diarrhea (22%), vomiting (10% to 22%), constipation (21%)

Hematologic: Anemia (95% to 99%; grade 4: 10% to 14%), neutropenia (81% to 94%; grade 4: children 62%, adults 49%), thrombocytopenia (86% to 88%; grade 4: 22% to 32%), leukopenia (38%; grade 4: 7%), neutropenic fever (12%; grade 4: 1%)

Hepatic: Transaminases increased (12%; grade 3: 4%)

Neuromuscular & skeletal: Peripheral neuropathy (12% to 21%; grades 2/3: 11% to 14%), weakness (6% to 17%; grade 4: 1%), paresthesia (4% to 15%; grades 2/3: 3% to 4%), myalgia (13%)

Respiratory: Cough (25%), dyspnea (7% to 20%)

1% to 10%:

Cardiovascular: Hypotension (8%), sinus tachycardia (8%), chest pain (5%)

Central nervous system: Ataxia (2% to 9%; grades 2/3: children 1%, adults 8%), confusion (8%), insomnia (7%), depressed level of consciousness (6%; grades 2-4: 2%), depression (6%), seizure (grade 3: 1% adults; grade 4: 6% children), motor dysfunction (4%; grades 2/3: 2%), amnesia (3%; grade 2: 1%), balance disorder (2%; grade 2: 1%), sensory loss (1% to 2%), aphasia (grade 3: 1%), attention disturbance (1%), cerebral hemorrhage (grade 4: 1%), coma (grade 4: 1%), encephalopathy (grade 4: 1%), hemiparesis (grade 3: 1%), hydrocephalus (1%), intracranial hemorrhage (grade 4: 1%), lethargy (1%), leukoencephalopathy (grade 4: 1%), loss of consciousness (grade 3: 1%), mental impairment (1%), nerve paralysis (1%), neuropathic pain (1%), nerve palsy (1%), paralysis (1%), sciatica (1%), sensory disturbance (1%), speech disorder (1%)

Endocrine & Metabolic: Hypocalcemia (8%), dehydration (7%), hyper-/hypoglycemia (6%), hypomagnesemia (6%)

Gastrointestinal: Abdominal pain (9%), anorexia (9%), stomatitis (8%), abdominal distension (6%), taste perversion (3%)

Hepatic: Albumin decreased (10%), bilirubin increased (10%; grade 3: 7%, grade 4: 2%), AST increased (6%)

Neuromuscular & skeletal: Arthralgia (9%), back pain (8%), muscle weakness (8%), rigors (8%), limb pain (7%), abnormal gait (6%), noncardiac chest pain (5%), tremor (4% to 5%; grade 2: 2% to 3%), dysarthria (1%), hyporeflexia (1%), hypertonia (1%), incoordination (1%)

Ocular: Blurred vision (4%), nystagmus (1%)

Renal: Creatinine increased (6%)

Respiratory: Pleural effusion (10%), epistaxis (8%), pneumonia (8%), sinusitis (7%), wheezing (5%), sinus headache (1%)

Miscellaneous: Infection (5% to 9%)

<1% (Limited to important or life-threatening): Craniospinal demyelination, neuropathy (peripheral) (similar to Guillain-Barré syndrome), opportunistic infection, pneumothorax, progressive

multifocal leukoencephalopathy (PML), respiratory arrest, rhabdomyolysis, tumor lysis syndrome

Contraindications

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

Neurotoxicity: **[U.S. Boxed Warning]: Severe neurotoxicity, including mental status changes, severe somnolence, seizure, and peripheral neuropathy (ranging from numbness to motor weakness or paralysis), has been reported. Observe closely for signs and symptoms of neurotoxicity; discontinue if ≥ grade 2. Adverse effects associated with demyelination or similar to Guillain-Barré syndrome (ascending peripheral neuropathies) have also been reported. Neurologic toxicities may not fully return to baseline after treatment cessation.** Neurologic toxicity is dose-limiting. Risk of neurotoxicity may increase in patients with concurrent or previous intrathecal chemotherapy or history of craniospinal irradiation.

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VENTURA COUNTY
HEALTH CARE PLAN

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