



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: Bendamustine

Brand Name: Treanda®

Medication Class: Antineoplastic agent, Alkylating agent

FDA Approved Uses:

- Treatment of chronic lymphocytic leukemia (CLL)

Available Dosage Forms:

- 100 mg powder for reconstitution; must be further diluted before infusion

Usual Dose:

- 100 mg/m² on day 1 and 2 of a 28 days treatment cycle (for up to 6 cycles)
- Delay treatment for Grade 4 hematologic toxicity or for clinically significant \geq Grade 2 non-hematologic toxicity
- Dosage adjustments are required for both hematologic and clinically significant non-hematologic toxicities of Grade 3 or greater: reduce dose to 50mg/m² on days 1 and 2. If Grade 3 or greater toxicity recurs, reduce dose to 25mg/m² on days 1 and 2. Dose re-escalation may be considered.
- Consider using allopurinol as prevention for patients at high risk of tumor lysis syndrome for the first few weeks of treatment

Duration of Therapy: Up to 6 months

Approximate monthly cost (based on AWP 3/20/08): Approximately \$4,500 per month (approx. \$27,000 per year)

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

- Adult with CLL (efficacy vs. first-line therapies other than chlorambucil is unknown)

Criteria for Continuation of Therapy:

- Decrease in or elimination of CLL cells

Cautions:

- Tumor Lysis syndrome – may cause acute renal failure and death
- Bone marrow suppression
- Dermatologic toxicity
- Hypersensitivity/infusion reaction
- Infection



Monitoring:

- Hepatic function
- Renal function
- CBC with differential

Contraindications:

- Hypersensitive to bendamustine, mannitol or any component of the formulation.
- Do not use in patients with CrCl < 40ml/min. and use with caution in patients with mild or moderate renal impairment
- Do not use in patients with moderate hepatic impairment (AST or ALT 2.5–10 x ULN and total bilirubin 1.5–3 x ULN) or severe hepatic impairment (total bilirubin >3 x ULN) and use with caution in patients with mild hepatic impairment.

Not Approved if:

- Patient does not meet the above listed criteria
- Being used to treat conditions other than FDA indicated uses
- Patient has any contraindications

Special Considerations:

- hazardous agent – must use appropriate precautions for handling and disposal
- safety and efficacy have not been studied in children
- Maintain adequate hydration
- Prophylactic treatment with allopurinol may be need in patients at risk for tumor lysis syndrome.
- Consider pre-medication with antihistamine, antipyretics, and/or corticosteroids for patients with previous grade 1 or 2 infusion reaction to bendamustine.

P&T Approval: _____ Date: _____