

## Prior Authorization Drug Guidelines

### **THYMOGLOBULIN (anti-thymocyte globulin)**

Effective Date: 10/20/214

Date Developed: 10/14/214

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

**Description:** **Thymoglobulin** is a purified, pasteurized gamma immune globulin obtained by immunizing rabbits with human thymocytes resulting in several clones of antilymphocytes capable of inhibiting the proliferative responses to several mitogens.

**Authorization Criteria:** Treatment of acute rejection in renal transplants in conjunction with other immunosuppressants

**Unlabeled Uses:** Induction therapy in renal transplant; treatment of myelodysplastic syndrome

**Note:** Per VCHCP policy, unlabeled uses are not covered unless specific information is submitted. See VCHCP Policy on Coverage for Prescription Medication for Off-Label Use.

**Dosing:** 1.5 mg/kg daily for 7-10 days (infused over a minimum 6 hours for the first infusion and at least 4 hours on subsequent days) reduce dose by one-half if the WBC count is between 2,000 and 3,000 cells/mm<sup>3</sup> or if the platelet count is between 50,000 and 75,000 cells/mm<sup>3</sup>; stopping treatment should be considered if the WBC count falls below 2,000 cells/mm<sup>3</sup> or platelets below 50,000 cells/mm<sup>3</sup>

**How Supplied:** Lyophilized: 25mg/10 mL vial (reconstitute with sterile water)

#### **Contraindications/Warnings:**

**Major Adverse Reactions:** Acute infections; reactivation of latent infectious agents; sepsis; increased risk of malignancy; inflammatory reaction at the infusion site; lymphopenia; thrombocytopenia; Serious immune-mediated reactions, e.g. anaphylaxis or severe cytokine release syndrome (CRS); should be used under strict medical supervision in a hospital setting, and patients should be carefully monitored during the infusion.

## REFERENCES

1. Bonnefoy-Bérard N, et al. Antibodies against functional leukocyte surface molecules in polyclonal antilymphocyte and antithymocyte globulins. *Transplantation* (1991)**51**:669-673.
2. Bonnefoy-Bérard N, et al. Inhibition of CD25 (IL-2R $\alpha$ ) expression and Tcell proliferation by polyclonal anti-thymocyte globulins. *Immunology* (1992)**77**:61-67.
3. Bourdage J, et al. Comparative polyclonal antithymocyte globulin and antilymphocyte/antilymphoblast globulin anti-CD antigen analysis by flow cytometry. *Transplantation* (1995)**59**:1194-1200.
4. Gaber AO, et al. Results of the double-blind, randomized, multicenter, phase III clinical trial of Thymoglobulin versus Atgam in the treatment of acute graft rejection episodes after renal transplantation. *Transplantation* (1998)**66**:29-37.
5. Hardinger KL, “Rabbit Antithymocyte Globulin Induction Therapy in Adult Renal Transplantation,” *Pharmacotherapy*, 2006, 26(12):1771-83.
6. [www.uptodate.com](http://www.uptodate.com): Antithymocyte Globulin: Drug Guidelines

### Revision History:

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