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

**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/mm³ or if the platelet count is between 50,000 and 75,000 cells/mm³; stopping treatment should be considered if the WBC count falls below 2,000 cells/mm³ or platelets below 50,000 cells/mm³

**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


Revision History:

Date Approved by P&T Committee: 10/28/14; QAC 11/25/14
Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD
Date Approved by P&T Committee: 1/27/15
Date Reviewed/No Updates: 1/26/16 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/26/16
Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/24/17
Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/23/18
Date Reviewed/No Updates: 1/22/19 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/22/19

<table>
<thead>
<tr>
<th>Revision Date</th>
<th>Content Revised (Yes/No)</th>
<th>Contributors</th>
<th>Review/Revision Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/24/17</td>
<td>No</td>
<td>Catherine Sanders, MD; Robert Sterling, MD</td>
<td>Annual review</td>
</tr>
<tr>
<td>1/23/18</td>
<td>No</td>
<td>Catherine Sanders, MD; Robert Sterling, MD</td>
<td>Annual review</td>
</tr>
<tr>
<td>1/22/19</td>
<td>No</td>
<td>Catherine Sanders, MD; Robert Sterling, MD</td>
<td>Annual review</td>
</tr>
</tbody>
</table>