VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization Drug Guidelines

THYMOGLOBULIN (anti-thymocyte globulin)

Effective Date: 10/20/214
Date Developed: 10/14/214
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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. It does this by acting on T-cell surface antigens and depleting CD4 lymphocytes

Authorization Criteria: Prophylaxis and treatment of acute rejection in renal transplants in conjunction with other immunosuppressants

Off-Label:

Chronic graft-versus-host disease, prevention (in hematopoietic cell transplantation); Heart transplant, acute cellular rejection, treatment; Heart transplant, induction therapy; Intestinal and multivisceral transplantation, induction therapy; Intestinal transplant, acute cellular rejection, treatment; Liver transplant, induction therapy; Liver transplant, severe acute cellular rejection, treatment; Lung transplant, induction therapy; Lung transplant, persistent acute cellular rejection, treatment; Pancreas transplant, induction therapy; Pancreas transplant, severe acute cellular rejection, treatmen

NOTE: Should only be used by physicians experienced in immunosuppressive therapy in transplantation. Should be used under strict medical supervision in a hospital setting, and patients should be carefully monitored during the infusion.

Dosing:

Renal transplant acute rejection:1.5 mg/kg daily for 7-14 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

Renal transplant induction therapy: IV: 1.5 mg/kg/day for 4 to 7 days; the first dose should be administered prior to reperfusion of the donor kidney

Note: Refer to product literature for other disease- specific dosing schedules.

NOTE: Significant drug interactions exist, requiring dose/frequency adjustment or avoidance. Consult drug interactions database for more information.

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

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; "cytokine storm");

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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 authorization criteria and added “Note: Refer to product literature for other disease- specific dosing schedules” in the Dosing section. Added Off Label, and references were updated.