Prior Authorization DRUG Guidelines

RAPAMUNE (sirolimus)

Effective Date: 10/20/2014
Date Developed: 10/14/2014
Last Approval Date: 01.26.16, 01.24.17

Description: RAPAMUNE inhibits T-lymphocyte activation and proliferation and antibody production that occurs in response to cytokines (e.g. IL-2, IL-4, IL-15) by a mechanism that is distinct from other immunosuppressants.*

Authorization Criteria: Prophylaxis of organ rejection in renal transplantation

Unlabeled Uses: Prophylaxis of organ rejection and allograft vasculopathy in heart transplant recipients; prevention acute graft-versus-host disease (GVHD) in allogeneic stem cell transplantation; treatment of refractory acute or chronic GVHD; treatment of chordoma, renal angiomyolipoma, or lymphangioleiomyomatosis.

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

Dosing: 2mg orally once a day after a loading dose of 6mg in patients aged 13 years or older, in conjunction with cyclosporine and corticosteroids, administered as soon as possible after transplantation, adjusted according to therapeutic monitoring (i.e. trough concentrations)

How Supplied: Tablets 0.5,1,2 mg; oral solution 60 mg/60 mL

Contraindications/Warnings: not recommended for liver or lung transplants; increased susceptibility to infection and possible development of lymphoma or skin cancer; angioedema; delayed wound healing; fluid accumulation (e.g. peripheral edema, lymyedema, pleural effusion, ascites, and pericardial effusions); increased serum cholesterol and triglycerides; deterioration of renal function with prolonged use; proteinuria

NOTE: Only physicians experienced in immunosuppressive therapy and management of renal transplant patients should use Rapamune®.

Major Adverse Reactions: Pericardial tamponade, anaphylaxis, renal failure, TTP

Major Drug Interactions: Use of ACEI may enhance chance of angioedema; enhanced side effects of other immunosuppressives; decreased metabolism of CYP3A4 substrates, diminished
effect of inactivated vaccine; enhanced adverse effects of live vaccines; grapefruit juice decreases clearance

REFERENCES

5. National Institute for Occupational Safety and Health (NIOSH), "NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012

*for those interested, the chemical name of sirolimus is:


Revision History:
Date Approved by P&T Committee: 10/28/14; QAC 11/25/14
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<td>Catherine Sanders, MD; Robert Sterling, MD</td>
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