Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Rapaume® (Sirolimus) and Zortress® (Everolimus)***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***March 2015 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *May 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Rapamune® (sirolimus) and Zortress® (everolimus).

Rapamune® (sirolimus) is an oral immunosuppressive agent indicated for:

- Prophylaxis of organ rejection in patients age 13 years or older receiving renal transplants
- Treatment of patients with lymphangioleiomyomatosis (LAM)

Zortress® (everolimus) is an oral immunosuppressive agent indicated for the prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving kidney transplants.

Rapamune® (sirolimus) and Zortress® (everolimus) are both indicated for use in combination with cyclosporine and a corticosteroid following transplantation. Therapeutic drug level monitoring should be performed for all patients on Rapamune® (sirolimus) or Zortress® (everolimus).

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DEFINITIONS

Coronary Allograft Vasculopathy – a complication following heart transplant involving the narrowing and occlusion of the coronary arteries

Cytomegalovirus (CMV) – a virus that commonly results in no symptoms or minimally symptomatic acute illness in immunocompetent patients, but can cause a wide range of clinical presentations, including retinitis, pneumonia, encephalitis, hepatitis, and gastrointestinal ulceration in patients with immune systems that are suppressed due to disease or medications

Lymphangioleiomyomatosis (LAM) – an uncommon multisystem disease that affects primarily women and is characterized by proliferation of abnormal smooth muscle-like cells (LAM cells) that lead to cystic lung destruction, chylous pleural effusions, lymphatic masses (lymphanioleiomyomas), and abdominal angiomyolipomas

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drugs, Rapamune® (sirolimus) and Zortress® (everolimus), are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective product:

1. **Rapamune (sirolimus)**
   - **Prophylaxis of organ rejection:**
     - Must be prescribed by or in consultation with a transplant specialist
     - Must have undergone a solid organ transplant
     - Must meet at least ONE of the following criteria:

        - Must have tried and failed an anti-rejection regimen containing at least TWO of the following drugs (trial and failure is defined as an intolerance to the anti-rejection regimen, or the inability of the regimen to prevent rejection at appropriate therapeutic dosing):
            - Cyclosporine
            - Tacrolimus
            - Azathioprine
            - Mycophenolate mofetil
            - Mycophenolate sodium
        - Must have renal dysfunction
        - Must have coronary allograft vasculopathy following heart transplant

- **Lymphangioleiomyomatosis (LAM):**
    - Must be prescribed by or in consultation with a pulmonologist or oncologist
    - Must be age 18 years or older
    - Must have a diagnosis of LAM confirmed by a lung biopsy or HRCT showing cystic lung disease
    - Must have ONE of the following conditions:
        - Diagnosis of Tuberous sclerosis complex (TSC)
        - Chylous pleural effusion
        - Angioleiomyomas
- **Graft vs. Host Disease (GVHD) prophylaxis:**
    - Must be used in the setting of stem cell/bone marrow transplant
    - Must be prescribed by or in consultation with a transplant specialist

2. Zortress (everolimus)

- Must be prescribed by or in consultation with a transplant specialist
- Must have undergone a solid organ transplant
- Must meet at least ONE of the following criteria:
    - Must have tried and failed an anti-rejection regimen containing at least TWO of the following drugs (trial and failure is defined as an intolerance to the anti-rejection regimen, or the inability of the regimen to prevent rejection at appropriate therapeutic dosing):
        - Cyclosporine
        - Tacrolimus
        - Azathioprine
        - Mycophenolate mofetil

        - Mycophenolate sodium
    - Must have renal dysfunction
    - Must have coronary allograft vasculopathy following heart transplant
    - Must be seronegative for Cytomegalovirus (CMV) with donor organ seropositive for CMV
    - Must have symptomatic CMV Disease

Reauthorization Criteria (Applies to LAM diagnosis only):

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• LAM: Up to 1 year • All other indications: Up to duration of member's membership with plan
Reauthorization	• LAM: Up to 1 year • All other indications: N/A

If the established criteria are not met, the request is referred to a Medical Director for review.

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RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/16, 02/17, 02/18*
Criteria Update	*05/18*