Rapamune (sirolimus)
Policy Number: C4725-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
9/1/2012	9/9/2020	9/9/2021
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
J7520-sirolimus, oral, 1mg	RxPA	Q4 2020 20201028C4725-A

PRODUCTS AFFECTED:
Rapamune (sirolimus)

DRUG CLASS:
Macrolide Immunosuppressants

ROUTE OF ADMINISTRATION:
Oral

PLACE OF SERVICE:
Retail Pharmacy
The recommendation is that medications in this policy will be for pharmacy benefit coverage and Member self- administered

AVAILABLE DOSAGE FORMS:
Rapamune TABS 0.5MG, 1MG Rapamune TABS 2MG Rapamune SOLN 1MG/ML

FDA-APPROVED USES:
Indicated for: Prophylaxis of organ rejection in patients age 13 years or older receiving renal transplants, Treatment of patients with lymphangioleiomyomatosis (LAM)

COMPENDIAL APPROVED OFF-LABELED USES:

COVERAGE CRITERIA: INITIAL

DIAGNOSIS:
Prophylaxis of organ rejection, lymphangioleiomyomatosis (LAM)

REQUIRED MEDICAL INFORMATION:
A. PROPHYLAXIS OF ORGAN REJECTION:
1. Documentation of solid organ transplant NOTE TO REVIEWER: PER FDA LABEL BLACK BOX WARNING- RAPAMUNE IS NOT recommended in liver or lung transplant patients- SHOULD THIS BE REQUESTED PLEASE USE THE OFF-LABEL MCP POLICY FOR REVIEW
   AND
2. (a) Documentation of trial and failure (toxicity or signs of rejection) of an anti-rejection regimen containing TWO of the following: cyclosporine, tacrolimus, azathioprine, mycophenolate, Corticosteroids
   OR
   (b) Member has renal dysfunction

OR
(c) Member has coronary allograft vasculopathy following hearttransplant
AND
3. Prescriber attests that if member is: (a) low to moderate immunologic risk: Rapamune (sirolimus) will be used initially with cyclosporine and corticosteroids OR (b) high-immunologic risk: Rapamune (sirolimus) will be used combination with cyclosporine and corticosteroids for the first 12 months following transplantation

B. LYMPHANGIOLEIOMYOMATOSIS (LAM):
1. Documentation of diagnosis of LAM confirmed by a lung biopsy or HRCT(high-resolution computerized tomography) showing cystic lung disease
AND
2. Documentation of one of the following conditions: Diagnosis of Tuberous sclerosis complex (TSC), Chylous pleural effusion, Angioleiomyomas

DURATION OF APPROVAL:
Initial authorization: 12 months, Continuation of therapy: 12 months

QUANTITY:
no requirements

PRESCRIBER REQUIREMENTS:
PROPHYLAXIS OF ORGAN REJECTION: Prescribed by or in consultation with a transplant specialist. Consultation notes required. LYMPHANGIOLEIOMYOMATOSIS (LAM): Prescribed by or in consultation with a pulmonologist or oncologist

AGE RESTRICTIONS:
PROPHYLAXIS OF ORGAN REJECTION: 13 years of age or older
LYMPHANGIOLEIOMYOMATOSIS (LAM): 18 years of age and older

CONTINUATION OF THERAPY:
A. PROPHYLAXIS OF ORGAN REJECTION:
1. Documentation Member is responsive to therapy demonstrated by no signs or symptoms of acute/chronic kidney rejection

B. LYMPHANGIOLEIOMYOMATOSIS (LAM):
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation (documentation required) AND
2. Documentation of no intolerable adverse effects or drugtoxicity
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms. [NOTE TO REVIEWER: These could include: Reduction in the rate of decline in spirometric values (FEV1 and FVC) relative to those measured prior to treatment and/or chest CT scan and/orVEGF-D levels

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Rapamune (sirolimus) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.

OTHER SPECIAL CONSIDERATIONS:
None

BACKGROUND:

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

APPENDIX:

None

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, Member records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES:

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10. Bilbao I, Sapisochin G, Dopazo C, et al. Indications and Management of Everolimus after Liver Transplantation. Trans Proceedings. 2009;41:2172-76