

Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number:

If Applicable: Pharmacy Name: _____
 Pharmacy Phone: _____

Complete the Clinical Assessment:

STEP
2

Diagnosis	<input type="checkbox"/> Advanced Renal Cell Carcinoma (RCC) <input type="checkbox"/> Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS) – and not a candidate for surgical resection <input type="checkbox"/> Progressive neuroendocrine tumor of pancreatic origin (PNET)	<input type="checkbox"/> Other (please state): _____ _____ _____
Clinical Consideration	For RCC: Patient has had documented failure of (check below and give date): <input type="checkbox"/> Sutent (sunitinib): date (mo/year) _____ <i>or</i> <input type="checkbox"/> Nexavar (sorafenib): date (mo/year) _____	
Physician Specialty	Diagnosis made by: <input type="checkbox"/> Oncology <input type="checkbox"/> Other (please state): _____	
Supporting Documentation	Diagnosis: ICD-9 Code #/ Description / J Code (required): Please attach a copy of the prescription or provide ALL of the information below: Afinitor [®] (everolimus) Strength _____ Sig _____ Qty _____ Refills _____	
	Please attach all relevant medical records and test results. We will not process incomplete forms. If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.	

STEP
3

I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)

 Prescriber Signature

 Date

STEP
4

Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk: 970-248-5034

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 01/14/11

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Afinitor (everolimus)

CLASSIFICATION

- Antineoplastic

DESCRIPTION

- Inhibits mammalian target of rapamycin kinase activity which reduces the activity of S6 ribosomal protein kinase, eukaryotic elongation factor 4E-binding protein, inhibits the expression of hypoxia-inducible factor, and reduces vascular endothelial growth factor expression
- Everolimus was superior to placebo for progression-free survival in 410 adults with metastatic renal cell carcinoma whose disease had progressed despite prior treatment with sunitinib, sorafenib, or both sequentially, according to a randomized, double-blind, phase 3 trial
- Everolimus is an analogue of rapamycin (sirolimus) with immunosuppressive and antiproliferative activity. It was developed to improve upon the wide inter-individual variation in pharmacokinetic parameters observed with oral sirolimus in animal and human studies. Everolimus is not a prodrug of sirolimus; it exhibits metabolic stability in that hydrolytic cleavage of the side chain does not occur to a significant extent in vivo.
- In renal transplantation: Similar to sirolimus (rapamycin), everolimus has been studied for use with cyclosporine/steroids to prevent acute rejection episodes in renal transplant recipients. Everolimus is available under the brand name Zortress for this purpose.
- Everolimus is indicated for the treatment of subependymal giant cell astrocytoma associated with tuberous sclerosis in patients 3 years of age or older with a body surface area 0.5 m² or greater who are not candidates for curative surgical resection. Treatment with everolimus for 6 months resulted in a significant decrease in the volume of the primary subependymal giant cell astrocytoma compared with baseline in patients with tuberous sclerosis, according to a phase 1-2, prospective, open-label study (n=28).

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	T4
Commercial Formulary:	T4
Medicare Part D coverage:	T5 (Part D)

COVERAGE CRITERIA

Afinitor (everolimus) meets the definition of **medical necessity** for the following:

- Renal cell carcinoma, advanced disease after failure of treatment with sunitinib or sorafenib
- Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS) – and not a candidate for surgical resection
- Progressive neuroendocrine tumors of pancreatic origin in patients with unresectable, locally advanced, or metastatic disease

Afinitor (everolimus) is considered **experimental** for the following (requests will be individually reviewed for medical necessity):

- Cardiac transplant rejection; Prophylaxis
- Renal transplant rejection; Prophylaxis

Required Provider Specialty:

- Approval is limited to Oncology

DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy in pediatric patients has not been established)

- Renal cell carcinoma, advanced disease after failure of treatment with sunitinib or sorafenib: 10 mg ORALLY once daily
- Advanced progressive neuroendocrine tumors of pancreatic origin: 10 mg ORALLY once daily

Dosing adjustments:

- Concomitant use of strong CYP3A4 inducer; increase everolimus in 5 mg increments, up to 20 mg orally once daily; concomitant use should be avoided when possible; if strong CYP3A4 inducer is discontinued, return everolimus to the dose used prior to CYP3A4 inducer initiation
- Geriatric: no dose adjustments recommended
- Hepatic impairment: moderate hepatic impairment (Child-Pugh class B), reduce dose to 5 mg; use in severe impairment (Child-Pugh C) is not recommended
- Renal impairment: no dose adjustments recommended
- Severe or intolerable adverse events (including noninfectious pneumonitis): reduce to 5 mg once daily; if interruption of therapy is necessary, reintroduce at a reduced dose of 5 mg orally daily

PRECAUTIONS:

- Adverse reactions, severe and/or intolerable; may require dose adjustment or interruption of therapy
- CBC aberrations (decreases in hemoglobin, lymphocytes, neutrophils, platelets); has been reported; monitoring recommended
- Concomitant use of P-glycoprotein (PgP) or strong or moderate CYP3A4 inhibitors; use should be avoided
- Hepatic impairment, preexisting moderate (Child-Pugh class B); dose adjustment recommended
- Hepatic impairment, preexisting severe (Child-Pugh class C); use not recommended
- Hyperglycemia has been reported; monitoring recommended
- Dyslipidemia (hyperlipidemia and hypertriglyceridemia) has been reported; monitoring recommended
- Hypersensitivity reactions, including anaphylaxis have been reported
- Live vaccine use and/or close contact with live vaccine recipients should be avoided
- Localized or systemic opportunistic infections, sometimes severe including fatalities have been reported; monitoring recommended; discontinuation of therapy may be required
- Mouth ulcers, oral mucositis, and stomatitis have been reported
- Noninfectious pneumonitis has been reported; monitoring and dose adjustments recommended; discontinuation of therapy may be required in severe cases
- Serum creatinine, elevation has been reported; monitoring of renal function is recommended

Billing/Coding information

- n/a

COST

- AWP (April 2010): Afinitor 10mg tablets (1): \$247.58

COMMITTEE APPROVAL:

- January 26, 2011

GUIDELINE UPDATE INFORMATION:

April 2010	Policy created
December 2011	Updated with new indication (SEGA)

REFERENCES:

- DRUGDEX®, accessed 04/06/2010
- Product Information: AFINITOR(R) oral tablets, everolimus oral tablets. Novartis Pharmaceutical Corporation, East Hanover, NJ, 2009.