



Prior Authorization Approval Criteria

Afinitor (everolimus)

Generic name:	Everolimus
Brand name:	Afinitor
Medication class:	antineoplastic agent
FDA-approved uses:	Advanced renal cell carcinoma after failure of treatment with sunitinib (Sutent) or sorafenib (Nexavar) Subependymal giant cell astrocytoma tumors associated with tuberous sclerosis
Available dosage forms:	5 mg and 10mg tablets
Usual dose:	10 mg once daily 5 mg once daily for patients with Child-Pugh class B hepatic impairment Maximum is 20 mg once daily for patients who are strong inducers of CYP3A4.
Approximate monthly cost:	10 mg \$6755.00 (based on AWP 2009) 5 mg \$6405.00

Duration of therapy: As long as benefits are observed or until unacceptable toxicity occurs.

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
 - Clinically diagnosed advanced renal cell carcinoma.
 - Must be prescribed by an oncologist or hematologist.
 - Must have tried and failed or intolerant to Sutent.
 - Must have tried and failed or intolerant to Nexavar.
- OR
- Clinically diagnosed sub-ependymal giant cell astrocytoma (SEGA) tumors associated with tuberous sclerosis
 - Tumors must be inoperable

Criteria for continuation of therapy:

- Disease stable without tumor progression

Contraindication:

- Hypersensitivity to everolimus, to other rapamycin derivatives, or to any of the excipients.

Not approved if:

- Patient does not meet the above stated criteria.
- Patient has any contraindications to the use of Afinitor

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 09/09/09

Revised: 12/08/10