



## Prior Authorization Approval Criteria

### *Afinitor (everolimus)*

<b>Generic name:</b>	Everolimus
<b>Brand name:</b>	Afinitor
<b>Medication class:</b>	antineoplastic agent
<b>FDA-approved uses:</b>	Advanced renal cell carcinoma after failure of treatment with sunitinib (Sutent) or sorafenib (Nexavar)
<b>Available dosage forms:</b>	5 mg and 10mg tablets
<b>Usual dose:</b>	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.
<b>Approximate monthly cost:</b> (based on AWP 2009)	10 mg \$6755.00 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*):

- 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.

**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