



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Afinitor®

Common Name: Everolimus

PDL Category: Antineoplastics-Protein-Tyrosine Kinase Inhibitors

<u>Comparable Products</u>	<u>Preferred Drug List Status</u>
Nexavar®	Non-Recommended
Sutent®	Recommended

Summary

Indications and Usage: Treatment of patients with advanced renal cell carcinoma after failure of treatment with sunitinib or sorafenib.¹

Mechanism of Action: Inhibits mTOR, a protein in the cancer cell, resulting in a reduction of cell proliferation, angiogenesis, and glucose uptake.¹

Dosage Forms: Tablets: 5mg and 10mg

Recommended Dosage: 10 mg once daily. Dose reduction to 5 mg once daily may be needed to manage adverse drug reactions and for patients with Child-Pugh class B hepatic impairment. If strong inducers of CYP3A4 are required, increase dose in 5 mg increments to a maximum of 20 mg once daily.¹

Common Adverse Drug Reactions: Stomatitis, infections, asthenia, fatigue, cough, and diarrhea.¹

Contraindications: Hypersensitivity to other rapamycin derivatives.¹

Manufacturer: Novartis Pharma Stein AG

Analysis: Afinitor® is a once daily oral cancer treatment for patients with advanced renal cell carcinoma after failure of treatment with sunitinib or sorafenib. FDA approval was based on a Phase III trial indicating that Afinitor more than doubled time without tumor growth and reduced the risk of disease progression by 67% compared with placebo. Trials are currently underway to evaluate its usefulness in the treatment of other cancers. It is recommended that Afinitor® be added to the Preferred Drug List as a recommended drug as it provides an effective therapeutic alternative for the treatment of advanced renal cell carcinoma after standard therapies have failed.

IME Recommendation:

<input type="checkbox"/> Preferred Drug	<input checked="" type="checkbox"/> Recommended Drug
<input type="checkbox"/> Non-Preferred Drug	<input type="checkbox"/> Non-Recommended Drug
<input type="checkbox"/> Preferred Drug with Conditions	

1. Afinitor® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2009.