

Specialty Pharmacy Program

Afinitor® (everolimus)

CLINICAL BACKGROUND

Afinitor (everolimus) is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) after failure of treatment with Sutent (sunitinib) or Nexavar (sorafenib).

Afinitor is classified as a kinase inhibitor and acts by inhibiting mammalian target of rapamycin (mTOR), a protein in the cancer cell that controls tumor cell division and blood vessel growth. Afinitor is intended as second-line treatment for those patients with advanced RCC who have been treated with another kinase inhibitor, Sutent or Nexavar. Sutent and Nexavar are considered as first-line therapies for advanced RCC. Advanced RCC is defined as disease that has relapsed or is medically unresectable stage IV RCC.

Hypersensitivity reactions have been observed in patients taking Afinitor or other mTOR derivatives (e.g., Torisel). Afinitor is classified as pregnancy category D and women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment with Afinitor.

APPROVAL DURATION

Approval duration: 12 months

APPROVAL CRITERIA

FDA-Approved Indication(s)

1. Treatment of patients with advanced renal cell carcinoma (RCC) after failure of treatment with Sutent (sunitinib) or Nexavar (sorafenib).