Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

catamaran

AFINITOR (Everolimus)

GPI CODING:

215325300003**

DESCRIPTION:

AFINITOR (Everolimus) is a macrolide immunosuppressant and analog of sirolimus classified as a proliferation signal inhibitor (PSI). Everolimus is an inhibitor of the mammalian target of rapamycin (mTOR), a serine-threonine kinase, downstream of the PI3K/AKT pathway. The mTOR pathway has been shown to be dysregulated in many human cancers, causing cell proliferation, angiogenesis, and glucose uptake by the tumor. Everolimus inhibits mTOR by forming a complex with the intracellular protein FK506 binding protein-12 (FKBP-12) which then binds to the FKBP-12-rapamycin binding domain on mTOR, to effectively inhibit its kinase activity, reducing protein synthesis and causing cell arrest in the G1-phase. In addition, in clear-cell renal cell carcinoma, loss of the von-Hippel Landau tumor suppressor gene leads to an accumulation of hypoxia-inducible factor 1 (HIF-1) and over expression of HIF-1 target gene products. HIF-1 target gene products include vascular endothelial growth factor (VEGF), platelet-derived growth factor (PDGF), and glucose transporter 1 (GLUT 1). These products cause an increase in angiogenesis, cell proliferation, and glucose metabolism. Everolimus has been shown to inhibit the expression of HIF-1 and subsequently reduce the expression of the HIF-1 target gene products.

APPROVAL DURATION:

Initial approvals and renewals: 12 months

Quantity Limits
2.5-mg tablets: 8 tablets/day
5-mg tablets: 4 tablets/day
7.5-mg tablets: 2 tablets/day
10-mg tablets: 2 tablets/day
2-mg oral suspension: 10 tablets/day
3-mg oral suspension: 7 tablets/day
5-mg oral suspension: 4 tablets/day

CRITERIA FOR AFINITOR

Renal Cell Carcinoma

I. Patient is ≥18 years of age **AND**
II. Patient has a diagnosis of advanced/metastatic renal cell carcinoma (RCC) **AND**
III. Patient has failed therapy (disease progressed) with sunitinib [SUTENT] or sorafenib [NEXAVAR]

OR

Progressive Pancreatic Neuroendocrine Tumors

I. Patient is ≥18 years of age **AND**
II. Patient has a diagnosis of progressive neuroendocrine tumors of pancreatic origin (pNET) that are unresectable, locally advanced, or metastatic

OR

Renal angiomyolipoma with TSC

I. Patient is ≥18 years of age **AND**
II. Patient has a diagnosis of renal angiomyolipoma and TSC **AND**
III. Patient does not require immediate surgery

OR

Breast Cancer

I. Patient is a postmenopausal woman **AND**
II. Patient has a diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer **AND**
III. Patient has failed treatment with letrozole [Femara] or anastrozole [Arimidex] **AND**
IV. Afinitor will be used in combination with exemestane [Aromasin]

OR

Subependymal Giant Cell Astrocytoma (SEGA)

I. Patient is ≥1 year of age **AND**
II. Patient has SEGA associated with tuberous sclerosis complex (TSC) that requires therapeutic intervention but is not a candidate for curative surgical resection
III. Patient may use everolimus tablets and tablets for oral suspension

OR

Off Label Uses for Oncology Drug

I. Off label uses for oncology drugs if considered medically acceptable in one or more of the following compendia (i.e., Micromedex DrugDex, AHFS, Clinical Pharmacology, and NCCN.) A use is identified by a compendium as medically accepted if the:
   A. Indication is a Category 1 or 2A in NCCN,
   B. Indication is a Class I, Class IIa or Class IIb in DrugDex,
   C. Narrative text in AHFS or Clinical Pharmacology is supportive; or
   D. The use is supported by clinical research in 2 or more peer-reviewed medical journals

Authorization for continued use will be considered when the following criteria are met: patient has an objective response to therapy.