VENTURA COUNTY
HEALTH CARE PLAN

CARE VALUE POLICY

POLICY: Oncology – Afinitor Care Value Policy

DATE REVIEWED: 01/08/2020

DRUGS AFFECTED:

- Afinitor® 2.5 mg, 5 mg, and 7.5 mg (everolimus tablets – Novartis)
- Everolimus 2.5 mg, 5 mg, and 7.5 mg tablets (generics – multiple manufacturers)

OVERVIEW

Afinitor, a kinase inhibitor, is indicated for the following conditions:[1]

1) treatment of postmenopausal women with advanced hormone receptor-positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative breast cancer (advanced HR+ breast cancer) in combination with exemestane, after failure of treatment with letrozole or anastrozole;
2) treatment of adult patients with progressive neuroendocrine tumors (NETS) of pancreatic origin (PNET) and adults with progressive, well-differentiated, non-functional NETS of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic. Limitation of Use: Afinitor is not indicated for the treatment of patients with functional carcinoid tumors;
3) treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of treatment with Sutent® (sunitinib capsules) or Nexavar® (sorafenib tablets);
4) treatment of adult patients with renal angiomyolipoma and tuberous sclerosis complex (TSC) not requiring immediate surgery; and
5) treatment of adult patients with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected.[1]
6) adjunctive treatment of adult and pediatric patients ≥ 2 years of age with TSC-associated partial-onset seizures.

Afinitor 2.5 mg, 5 mg and 7.5 mg are available as generic tablets. Afinitor 10 mg tablets and Afinitor Disperz are only available as brand products and are not targeted in this care value policy. For more information on criteria for these agents within a Prior Authorization (PA) program by specific condition, refer to the respective PA policy.

POLICY STATEMENT

This Care Value program requires the patient to meet the ESI Standard *Oncology – Afinitor* Prior Authorization criteria and requires the patient to try generic everolimus tablets and meet the Exception Criteria prior to the approval of brand Afinitor. All approvals are for 1 year in duration, unless otherwise noted below.

Automation: None

Documentation: Documentation will be required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, and prescription receipts.

Preferred: generic everolimus 2.5 mg, 5 mg, and 7.5 mg tablets
Non-Preferred: Afinitor 2.5 mg, 5 mg, and 7.5 mg tablets

RECOMMENDED EXCEPTION CRITERIA

Trade Name	Exception
Afinitor	**1.** The patient must meet ALL of the following (A, B, and C): **A)** The patient meets the ESI Standard *Oncology – Afinitor Prior Authorization Policy*; AND **B)** The patient has tried generic everolimus tablets; AND **C)** The Brand product is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. **2.** For patients who have met the Afinitor prior authorization criteria, but have not met exception criteria **B)** or **C)** above for brand Afinitor: approve generic everolimus tablets.

REFERENCES

1. Afinitor tablets [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2018.
2. Everolimus tablets [prescribing information]. Chestnut Ridge, NY: Par Pharmaceutical; May 2019.

HISTORY

Type of Revision	Summary of Changes*	Date Reviewed
New policy	--	01/08/2020