

PREFERRED SPECIALTY MANAGEMENT POLICY

- POLICY:** Oncology – Everolimus Products Preferred Specialty Management Policy
- Afinitor® (everolimus tablets – Novartis, generic)
 - Afinitor Disperz® (everolimus tablets for oral suspension – Novartis, generic)

REVIEW DATE: 06/26/2024

OVERVIEW

Everolimus, a kinase inhibitor, is indicated for the following conditions:¹

- **Breast cancer**, treatment of postmenopausal women with advanced hormone receptor-positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative disease in combination with exemestane, after failure of treatment with letrozole or anastrozole.
- **Neuroendocrine tumors**, treatment of progressive disease of pancreatic origin and progressive, well-differentiated, non-functional neuroendocrine tumors of gastrointestinal or lung origin that are unresectable, locally advanced, or metastatic in adults. Limitation of Use: Afinitor is not indicated for the treatment of patients with functional carcinoid tumors.
- **Renal cell carcinoma**, treatment of advanced disease after failure of treatment with sunitinib or sorafenib in adults.
- **Tuberous sclerosis complex (TSC)-associated renal angiomyolipoma**, not requiring immediate surgery in adults.
- **TSC-associated subependymal giant cell astrocytoma (SEGA)**, that requires therapeutic intervention but cannot be curatively resected in patients ≥ 1 year of age. Afinitor Disperz is also FDA-approved for this indication.
- **TSC-associated partial-onset seizures**, adjunctive treatment of patients ≥ 2 years of age. Only Afinitor Disperz is FDA-approved for this indication.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of Preferred Products. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Oncology – Everolimus Products Prior Authorization Policy* criteria. The program also directs the patient to try one Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). If the patient meets the standard *Oncology – Everolimus Products Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for a Preferred Product will be authorized. All approvals are provided for 1 year in duration.

Automation: None.

Afinitor (Brand) Preferred Specialty Management Program

Preferred Product: generic everolimus tablets
Non-Preferred Product: Afinitor tablets (brand)

Afinitor Disperz (Brand) Preferred Specialty Management Program

Preferred Product: generic everolimus tablets for oral suspension
Non-Preferred Product: Afinitor Disperz tablets for oral suspension (brand)

RECOMMENDED EXCEPTION CRITERIA

06/26/2024

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REFERENCES

1. Afinitor® tablets, Afinitor Disperz® tablets for oral suspension [prescribing information]. East Hanover, NJ: Novartis; February 2022.