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: 10/19/2022

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 adults with progressive disease of pancreatic origin and adults with progressive, well-differentiated, non-functional neuroendocrine tumors of gastrointestinal 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.
- **Renal cell carcinoma**, treatment of adults with advanced disease after failure of treatment with Sutent® (sunitinib capsules) or sorafenib.
- **Tuberous sclerosis complex (TSC)-associated renal angiomyolipoma,** treatment of adults with this disease not requiring immediate surgery.
- **TSC-associated subependymal giant cell astrocytoma (SEGA)**, treatment of patients ≥ 1 year of age that requires therapeutic intervention but cannot be curatively resected. Afinitor Disperz is also FDA-approved for this indication.
- **TSC-associated partial-onset seizures**, adjunctive treatment of patients ≥ 2 years of age. 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

Non-Preferred Product	Exception Criteria
Afinitor	**1.** Approve for 1 year if the patient meets ALL of the following (A, B, and C): **A)** Patient meets the standard *Oncology – Everolimus Products Prior Authorization Policy* criteria; AND **B)** Patient has tried generic everolimus tablets; AND **C)** Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] which, per the prescriber, would result in a significant allergy or serious adverse reaction. **2.** If the patient has met the standard *Oncology – Everolimus Products Prior Authorization Policy* criteria (1A), but has not met exception criteria (1B) and/or (1C) above for brand Afinitor: approve generic everolimus tablets.
Afinitor Disperz	**1.** Approve for 1 year if the patient meets ALL of the following (A, B, and C): **A)** Patient meets the standard *Oncology – Everolimus Products Prior Authorization Policy* criteria; AND **B)** Patient has tried generic everolimus tablets for oral suspension; AND **C)** Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] which, per the prescriber, would result in a significant allergy or serious adverse reaction. **2.** If the patient has met the standard *Oncology –Everolimus Products Prior Authorization Policy* criteria (1A), but has not met exception criteria (1B) and/or (1C) above for brand Afinitor Disperz: approve generic everolimus tablets for oral suspension.

REFERENCES

1. Afinitor® tablets, Afinitor Disperz® tablets for oral suspension [prescribing information]. East Hanover, NJ: Novartis; April 2021.