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: 10/18/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 adults with 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. 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.

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)

Oncology – Everolimus non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Targeting was added for brand and generic Afinitor 10 mg tablet strength. As a result, the policy now targets all strengths of Afinitor so reference to the various strengths of the drug were removed.	09/22/2021
Selected Revision	The name of the policy was changed from "Oncology – Afinitor PSM Policy" to "Oncology – Everolimus Products PSM Policy." Targeting was added for Afinitor Disperz, including all strengths of brand and generic. Generic everolimus tablets for suspension was added as a Preferred Product and Afinitor Disperz was added as a Non-Preferred Product. **Afinitor:** The requirement that patient meets the "Oncology – Afinitor Prior Authorization Policy" was reworded to "Oncology – Everolimus Products Prior Authorization Policy" criteria. **Afinitor Disperz:** This drug was added as a Non-Preferred Product and exception criteria were added.	11/03/2021
Annual Revision	No criteria changes.	10/19/2022
Annual Revision	No criteria changes.	10/18/2023