



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 3/17/2016
LAST REVIEW DATE: 2/18/2021
LAST CRITERIA REVISION DATE: 2/18/2021
ARCHIVE DATE:

AFINITOR® (everolimus) oral tablet AFINITOR® DISPERZ (everolimus) oral tablet for suspension

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy:** Afinitor (everolimus) and Afinitor Disperz (everolimus) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist, Nephrologist, Gastroenterologist, Neurologist, or Gynecologist depending upon indication or use
 2. A confirmed diagnosis of **ONE** of the following:
 - a. **For Afinitor:**
 - i. Postmenopausal woman with advanced hormone receptor positive, HER2-negative breast cancer in combination with exemestane, after failure of treatment with letrozole or anastrozole.
 - ii. Individual 18 years of age or older with progressive neuroendocrine tumors of pancreatic origin (PNET) with unresectable, locally advanced or metastatic disease
 - iii. Individual 18 years of age or older with progressive, well-differentiated, nonfunctional NET of gastrointestinal (GI) or lung origin with unresectable, locally advanced or metastatic disease
 - iv. Individual 18 years of age or older with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib
 - v. Individual 18 years of age or older with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery
 - vi. Individual 18 years of age or older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected
 - vii. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
 - b. **For Afinitor Disperz:**
 - i. Individual 1 year of age or older with tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected
 - ii. Individual 2 years of age or older who have partial-onset seizures associated with TSC used as adjuvant treatment
 - iii. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
 3. **ALL** of the following baseline tests have been completed before initiation of treatment:
 - a. Comprehensive metabolic panel
 - b. Lipid profile
 - c. Complete blood count

Initial approval duration: 6 months



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- **Criteria for continuation of coverage (renewal request):** Afinitor (everolimus) or Afinitor Disperz (everolimus) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist, Nephrologist, Gastroenterologist, Neurologist, or Gynecologist depending upon indication or use
 2. Individual's cancer has not progressed while on therapy
 3. Individual has been adherent with the medication
 4. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
 - a. Significant adverse effect such as:
 - i. Life-threatening non-infectious pneumonitis that has not recovered or has recurred and is in need of urgent intervention
 - ii. Invasive fungal infection needing antifungal treatment
 - iii. Life-threatening stomatitis needing urgent intervention
 - iv. Life-threatening febrile neutropenia needing urgent intervention
 5. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Afinitor (everolimus) tab is indicated for the treatment of postmenopausal women with advanced hormone receptor positive, HER2-negative breast cancer (advanced HR+ BC) in combination with exemestane, after failure of treatment with letrozole or anastrozole; for the treatment of adult patients with progressive neuroendocrine tumors of pancreatic origin (PNET) with unresectable, locally advanced or metastatic disease and treatment of adult patients with progressive, well-differentiated, nonfunctional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin with unresectable, locally advanced or metastatic disease (everolimus is not indicated for the treatment of patients with functional carcinoid tumors); for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib; and for the treatment of adult patients with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery.

Afinitor (everolimus) tab and Afinitor (everolimus) Disperz tab for suspension are indicated for the treatment of pediatric (1 year of age or older) and adult patients with tuberous sclerosis complex (TSC) for the treatment of subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected.



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Afinitor (everolimus) is an inhibitor of mammalian target of rapamycin (mTOR), a serine-threonine kinase, downstream of the PI3K/AKT pathway. The mTOR pathway is dysregulated in several human cancers. Everolimus binds to an intracellular protein, FKBP-12, resulting in an inhibitory complex formation with mTOR complex 1 (mTORC1) and thus inhibition of mTOR kinase activity. Inhibition of mTOR by everolimus has been shown to reduce cell proliferation, angiogenesis, and glucose uptake in *in vitro* and/or *in vivo* studies.

Resources:

Afinitor (everolimus) tablet and Afinitor Disperz (everolimus) tablet for oral suspension product information, revised by Novartis Pharmaceuticals Corporation 03-2020, at DailyMed <http://dailymed.nlm.nih.gov> accessed January 30, 2021.

Afinitor (everolimus). National Comprehensive Cancer Network (NCCN). NCCN Drugs & Biologics Compendium. 2021; Available at: <http://www.nccn.org>. Accessed January 30, 2021.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.
