BlueCross BlueShield of Arizona
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| **PHARMACY COVERAGE GUIDELINES** | **ORIGINAL EFFECTIVE DATE: 03/17/16** |
| **SECTION: DRUGS** | **LAST REVIEW DATE: 02/21/19** |
| | **LAST CRITERIA REVISION DATE: 02/21/19** |
| | **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.**

## AFINITOR® (everolimus) oral tablet
## AFINITOR® DISPERZ (everolimus) oral tablet for suspension (cont.)

**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 an Oncologist

  2. A confirmed diagnosis of **ONE** of the following:

     **For Afinitor:**
     - Invasive breast cancer for recurrent or stage IV (M1) hormone receptor (HR)-positive, non-visceral or asymptomatic visceral human epidermal growth factor receptor 2 (HER2)-negative disease for postmenopausal women who have been treated with prior endocrine therapy within 1 year **or** in premenopausal women treated with ovarian ablation/suppression who have had prior endocrine therapy within 1 year in combination with exemestane, or fulvestrant, or tamoxifen
     - Invasive breast cancer in combination with an aromatase inhibitor (anastrozole, letrozole, or exemestane) or fulvestrant with a drug for suppression of testicular steroidogenesis for recurrent or stage IV (M1) hormone receptor (HR)-positive, non-visceral or asymptomatic visceral human epidermal growth factor receptor 2 (HER2)-negative disease for the treatment of males
     - Classic Hodgkin lymphoma (≥ 18 year of age), as a single agent for relapsed or refractory disease
     - Kidney cancer (clear cell, non-clear cell), for relapse or stage IV disease as a single agent or in combination with lenvatinib or in combination with bevacizumab as systemic therapy for non-clear cell histology
     - Neuroendocrine tumors of the gastrointestinal tract, lung and thymus (Carcinoid Tumors) for management of locoregional bronchopulmonary/thymic/gastrointestinal tract disease or disease
     - Neuroendocrine tumors of the pancreas for the management of progressive loco-regional advanced disease and/or distant metastatic disease
     - Gastrointestinal stromal tumors (GIST) in combination with either imatinib, sunitinib, or regorafenib for disease progression after single-agent therapy with imatinib, sunitinib, and regorafenib
     - PEComa/recurrent angiomyolipoma/Lymphangioleiomyomatosis, single agent therapy for the treatment of PEComa, recurrent angiomyolipoma, and lymphangioleiomyomatosis
     - Thymomas and Thymic carcinomas, second-line therapy as a single agent

## AFINITOR® (everolimus) oral tablet
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- Thyroid carcinoma (papillary, follicular, Hürthle cell), for treatment of progressive and/or symptomatic iodine-refractory unresectable locoregional recurrent or persistent disease or distant metastatic disease if clinical trials or other systemic therapies are not available or appropriate

- Endometrial carcinoma/Endometrioid adenocarcinoma, in combination with letrozole

- Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma, single agent therapy for previously treated disease that does not respond to primary therapy or for progressive or relapsed disease

- Individual is an adult with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery

- 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

**For Afinitor and Afinitor Disperz:**

- Individual (pediatric or adult) with tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected

- Adjuvant treatment of partial-onset seizures associated with TSC in an individual 2 years of age or older

- 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:
   - Comprehensive metabolic panel
   - Lipid profile
   - Complete blood count

4. There are **NO** contraindications
   - Contraindications include:
     - Hypersensitivity to everolimus, to other rapamycin derivatives, or to any of the excipients

**Initial approval duration**: 6 months

## AFINITOR® (everolimus) oral tablet
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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 an Oncologist
  2. Individual's cancer has not progressed while on therapy
  3. Individual has been adherent with the medication
  4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
     - Contraindications as listed in the criteria for initial therapy section
     - Significant adverse effect such as:
       - Life-threatening non-infectious pneumonitis that has not recovered or has recurred and is in need of urgent intervention
       - Invasive fungal infection needing antifungal treatment
       - Life-threatening stomatitis needing urgent intervention
       - Life-threatening febrile neutropenia needing urgent intervention
  5. There are no significant interacting drugs

  **Renewal duration**: 6 months

## AFINITOR® (everolimus) oral tablet
## AFINITOR® DISPERZ (everolimus) oral tablet for suspension (cont.)

**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.

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:**

NCCN Drugs & Biologics Compendium Afinitor accessed 02-06-19

Afinitor and Afinitor Disperz. Package Insert. Revised by manufacturer 9/2017. Accessed 02-26-2018.

Afinitor and Afinitor Disperz. Package Insert. Revised by manufacturer 6/2016. Accessed 02-14-2017.

Afinitor and Afinitor Disperz. Package Insert. Revised by manufacturer 2/2016. Accessed 03-17-2016.

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.

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**Fax completed prior authorization request form to 602-864-3126** or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

# Pharmacy Prior Authorization Request Form

**Do not copy for future use. Forms are updated frequently.**
**REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.**

## Member Information

| Member Name (first & last): | Date of Birth: | Gender: | BCBSAZ ID#: |
|---|---|---|---|
| Address: | City: | State: | Zip Code: |

## Prescribing Provider Information

| Provider Name (first & last): | Specialty: | NPI#: | DEA#: |
|---|---|---|---|
| Office Address: | City: | State: | Zip Code: |
| Office Contact: | Office Phone: | Office Fax: | |

## Dispensing Pharmacy Information

| Pharmacy Name: | Pharmacy Phone: | Pharmacy Fax: |
|---|---|---|

## Requested Medication Information

| Medication Name: | Strength: | | Dosage Form: |
|---|---|---|---|
| Directions for Use: | Quantity: | Refills: | Duration of Therapy/Use: |

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

## Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

## Clinical Information

1. **What is the diagnosis? Please specify below.**

   **ICD-10 Code:** _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

| Medication Name, Strength, Frequency | Dates started and stopped or Approximate Duration | Describe response, reason for failure, or allergy |
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5. **Are there any supporting labs or test results? Please specify below.**

| Date | Test | Value |
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# Pharmacy Prior Authorization Request Form

**6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.**
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

**Signature affirms that information given on this form is true and accurate and reflects office notes**

Prescribing Provider's Signature: Date:

**Please note**: Some medications may require completion of a drug-specific request form.

**Incomplete forms or forms without the chart notes will be returned.**

Office notes, labs, and medical testing relevant to the request that show medical justification are required.