UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Afinitor

Program	Prior Authorization
Medication	Afinitor (everolimus)
Markets in Scope	Arizona, Hawaii, New York, New York EPP, California, Nevada, Maryland, New Jersey, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	5/2020
Effective Date	7/2020

1. Background:

Afinitor® (everolimus) is a kinase inhibitor indicated for the treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer in combination with exemestane after failure of treatment with letrozole or anastrozole; in adults with progressive neuroendocrine tumors of pancreatic origin (PNET) and adults with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic; adults with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib; adults with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery; treatment of adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected; and for the adjunctive treatment of TSC associated partial-onset seizures.[1]

The National Cancer Comprehensive Network (NCCN) also recommends use of Afinitor in invasive breast cancer, Waldenström's macroglobulinemia / lymphoplasmacytic lymphoma, neuroendocrine tumors with carcinoid histology, non-clear cell kidney cancer, soft tissue sarcomas, osteosarcomas, dedifferentiated chondrosarcoma, high-grade undifferentiated pleomorphic sarcoma (UPS), thymomas and thymic carcinomas, Hodgkin lymphoma, follicular, Hürthle cell and papillary thyroid carcinomas, meningioma, and endometrial carcinoma.[2]

2. Coverage Criteria:

A. <u>Neuroendocrine Tumors</u>

1. <u>Initial Authorization</u>

a. **Afinitor** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of **<u>one</u>** of the following:

(a) Neuroendocrine tumors of pancreatic origin
(b) Neuroendocrine tumors of gastrointestinal origin
(c) Neuroendocrine tumors of lung origin
(d) Neuroendocrine tumors of thymic origin

-AND-

(2) Disease is progressive

-AND-

(3) **One** of the following:

(a) Disease is unresectable
(b) Disease is locally advanced
(c) Disease is metastatic

Authorization will be issued for 12 months.

2. Reauthorization

a. **Afinitor** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Afinitor therapy

Authorization will be issued for 12 months.

B. Advanced Renal Cell Carcinoma

1. Initial Authorization

a. **Afinitor** will be approved based on **all** of the following criteria:

(1) Diagnosis of renal cell cancer

-AND-

(2) **One** of the following:

(a) Disease has relapsed

-OR-

(b) **Both** of the following:

i. Medically or surgically unresectable tumor
ii. Diagnosis of Stage IV disease

-AND-

(3) **One** of the following:

(a) Patient with non- clear cell histology

-OR-

(b) **Both** of the following:

i. Patient with predominantly clear cell histology

-AND-

ii. History of failure, contraindication, or intolerance to at least **one** prior systemic therapy [e.g., Nexavar (sorafenib), Sutent (sunitinib), Opdivo (nivolumab), Cabometyx (cabozantinib)]

Authorization will be issued for 12 months.

2. Reauthorization

a. **Afinitor** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Afinitor therapy

Authorization will be issued for 12 months.

C. Renal Angiomyolipoma with Tuberous Sclerosis Complex

1. Initial Authorization

a. **Afinitor** will be approved based on the following criterion:

(1) Diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery

Authorization will be issued for 12 months.

2. Reauthorization

a. **Afinitor** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Afinitor therapy

Authorization will be issued for 12 months.

D. Subependymal Giant Cell Astrocytoma with Tuberous Sclerosis Complex

1. Initial Authorization

a. **Afinitor** will be approved based on **both** of the following criteria:

(1) Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS)

-AND-

(2) Patient is not a candidate for curative surgical resection

Authorization will be issued for 12 months.

2. Reauthorization Criteria

a. **Afinitor** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Afinitor therapy

Authorization will be issued for 12 months.

E. Waldenströms Macroglobulinemia or Lymphoplasmacytic Lymphoma

1. Initial Authorization

a. **Afinitor** will be approved based on **both** the following criteria:

(1) Diagnosis of **one** of the following:

(a) Waldenströms macroglobulinemia
(b) Lymphoplasmacytic lymphoma

-AND-

(2) **One** of the following:

(a) Disease is non-responsive to primary treatment
(b) Disease is progressive
(c) Disease has relapsed

Authorization will be issued for 12 months.

2. Reauthorization Criteria

a. **Afinitor** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Afinitor therapy

Authorization will be issued for 12 months.

F. Breast Cancer

1. Initial Authorization

a. **Afinitor** will be approved based on **all** of the following criteria:

(1) Diagnosis of breast cancer

-AND-

(2) **One** of the following:

(a) Disease is recurrent

-OR-

(b) Disease is metastatic

-AND-

(3) **One** of the following:

(a) Disease is hormone receptor positive (HR+) [i.e., estrogen-receptor-positive (ER+) or progesterone-receptor-positive (PR+)]

-OR-

(b) **Both** of the following:

i. Disease is hormone receptor negative (HR-)
ii. Disease has clinical characteristics that predict a HR+ tumor

-AND-

(4) Disease is human epidermal growth factor receptor 2 (HER2)-negative

-AND-

(5) **One** of the following:

(a) Patient is a postmenopausal woman

-OR-

(b) **Both** of the following:

i. Patient is a premenopausal woman
ii. Patient is being treated with ovarian ablation/suppression

-OR-

(c) Patient is male

-AND-

(6) **One** of the following:

(a) **Both** of the following:

i. Used in combination with Aromasin (exemestane)

-AND-

ii. **One** of the following:

a. Disease progressed while on or within 12 months of non-steroidal aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole)] therapy

-OR-

b. Patient was treated with tamoxifen at any time

-OR-

(b) Used in combination with **one** of the following:

i. Fulvestrant
ii. Tamoxifen

Authorization will be issued for 12 months.

2. Reauthorization Criteria

a. **Afinitor** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Afinitor therapy

Authorization will be issued for 12 months.

G. Hodgkin Lymphoma

1. Initial Authorization

a. **Afinitor** will be approved based on **both** of the following criteria:

(1) Diagnosis of classical Hodgkin lymphoma

-AND-

(2) **One** of the following:

(a) Disease is refractory
(b) Disease has relapsed

Authorization will be issued for 12 months.

2. Reauthorization Criteria

a. **Afinitor** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Afinitor therapy

Authorization will be issued for 12 months.

H. Soft Tissue Sarcoma

1. Initial Authorization

a. **Afinitor** will be approved based on **one** of the following criteria:

(1) Diagnosis of PEComa (perivascular epitheliod cell tumor)
(2) Diagnosis of recurrent angiomyolipoma
(3) Diagnosis of lymphangioleiomyomatosis
(4) **All** of the following:

(a) Diagnosis of Gastrointestinal Stromal Tumor (GIST)

-AND-

(b) Disease has progressed after single agent therapy with one of the following: Gleevec (imatinib), Sutent (sunitinib), or Stivarga (regorafenib)

-AND-

(c) Used in combination with **one** of the following:

i. Gleevec (imatinib)
ii. Sutent (sunitinib)
iii. Stivarga (regorafenib)

Authorization will be issued for 12 months.

2. Reauthorization Criteria

a. **Afinitor** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Afinitor therapy

Authorization will be issued for 12 months.

I. Thymomas and Thymic Carcinomas

1. Initial Authorization

a. **Afinitor** will be approved based on **both** of the following criteria:

(1) **One** of the following:

(a) Diagnosis of thymic carcinoma
(b) Diagnosis of thymoma

-AND-

(2) **One** of the following:

(a) History of failure, contraindication, or intolerance to at least **one** prior first-line chemotherapy regimen
(b) Patient has extrathoracic metastatic disease

Authorization will be issued for 12 months.

2. Reauthorization Criteria

a. **Afinitor** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Afinitor therapy

Authorization will be issued for 12 months.

J. Thyroid Carcinoma

1. Initial Authorization

a. **Afinitor** will be approved based on **all** of the following criteria:

(1) Diagnosis of **one** of the following:

(a) Follicular carcinoma
(b) Hürthle cell carcinoma
(c) Papillary carcinoma

-AND-

(2) **One** of the following:

(a) Unresectable locoregional recurrent disease
(b) Persistent disease
(c) Metastatic disease

-AND-

(3) **One** of the following:

(a) Patient has symptomatic disease
(b) Patient has progressive disease

-AND-

(4) Disease is refractory to radioactive iodine treatment

Authorization will be issued for 12 months.

2. Reauthorization

a. **Afinitor** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Afinitor therapy

Authorization will be issued for 12 months.

K. Meningioma

1. Initial Authorization

a. **Afinitor** will be approved based on **all** of the following criteria:

(1) Diagnosis of meningioma

-AND-

(2) Disease is recurrent or progressive

-AND-

(3) Surgery and/or radiation is not possible

-AND-

(3) Used in combination with bevacizumab (e.g., Avastin, Mvasi)

Authorization will be issued for 12 months.

2. Reauthorization Criteria

a. **Afinitor** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Afinitor therapy

Authorization will be issued for 12 months.

L. Endometrial Carcinoma

1. Initial Authorization

a. **Afinitor** will be approved based on **both** of the following criteria:

(1) Diagnosis of endometrial carcinoma

-AND-

(2) Used in combination with letrozole

Authorization will be issued for 12 months.

2. Reauthorization

a. **Afinitor** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Afinitor therapy

Authorization will be issued for 12 months.

M. Tuberous Sclerosis Complex associated Partial-Onset Seizures

1. Initial Authorization

a. **Afinitor** will be approved based on **both** of the following criteria:

(1) Diagnosis of tuberous sclerosis complex associated partial-onset seizures

-AND-

(2) Used as adjunctive therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. Afinitor will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Afinitor therapy

Authorization will be issued for 12 months.

N. NCCN Recommended Regimens

1. Initial Authorization

a. **Afinitor** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Afinitor** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Afinitor therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Afinitor [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. April 14, 2020.

Change Control	
9/2013	New guideline.
9/2014	Annual Review
12/2015	Advanced renal cell carcinoma indication: Criteria revised to specify that pts with" relapsed or medically unresectable stage IV kidney cancer with predominant clear cell histology" must try one prior tyrosine kinase inhibitor; however, pts with "relapsed or medically unresectable stage IV kidney cancer with predominant non-clear cell histology" have no prior therapy requirement Breast cancer indication: Prior therapy criterion revised to include tamoxifen as an option (previously only included a non-steroidal aromatase inhibitor)
7/2016	Clinical criteria updated to align with Employer and Individual notification policy; updated policy to new template
7/2017	Updated background and added criteria for thyroid carcinoma and the bone cancers, dedifferentiated chondrosarcoma, high-grade undifferentiated pleomorphic sarcoma (UPS) per NCCN guidelines. Updated references.
5/2018	Updated background. Added criteria for meningioma, gastrointestinal stromal tumors, endometrial carcinoma, thymic neuroendocrine tumors, and updated breast cancer criteria per NCCN guidelines. Added criteria for new indication of tuberous sclerosis complex associated partial-onset seizures. Added NCCN Recommended review criteria. Updated references.
5/2019	Removed criteria for bone cancer since it is no longer NCCN recommended. Updated background and references.
5/2020	Annual review. Updated background. Updated coverage criteria for soft tissue sarcoma, thymomas and thymic carcinomas, and meningiomas per NCCN guidelines. Updated references.