UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Afinitor

Program	Prior Authorization
Medication	Afinitor (everolimus)
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	7/2017
Effective Date	9/2017

1. Background:

Afinitor® (everolimus) is a kinase inhibitor indicated for the treatment of advanced renal cell carcinoma after treatment with Sutent® (sunitinib) or Nexavar® (sorafenib); for the treatment of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) in those patients who require therapeutic intervention but are not a candidate for curative surgical resection; for the treatment of progressive neuroendocrine tumors of pancreatic origin (PNET) that are well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic; for treatment of renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery; and in postmenopausal women with advanced hormone receptor-positive, HER2- negative breast cancer (advanced HR+ BC) in combination with Aromasin® (exemestane) after failure of treatment with Femara® (letrozole) or Arimidex® (anastrozole).[1]. The National Cancer Comprehensive Network (NCCN) also recommends use of Afinitor in Waldenström's macroglobulinemia / lymphoplasmacytic lymphoma, lung 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.[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

-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:

(a) Patient with predominantly *clear cell* histology

-AND-

(b) History of failure, contraindication, or intolerance to at least **one** prior tyrosine kinase inhibitor therapy [e.g., Nexavar (sorafenib), Sutent (sunitinib)]

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 (TSC)

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

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 (off-label)

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

-AND-

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

-AND-

(5) Patient is a postmenopausal woman

-AND-

(6) **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
(b) Patients was treated with tamoxifen at any time

-AND-

(7) Used in combination with Aromasin (exemestane)

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 (off-label)

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 (off-label)

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

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. Bone Cancer (off-label)

1. Initial Authorization

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

(1) One of the following

(a) Diagnosis of osteosarcoma
(b) Diagnosis of dedifferentiated chondrosarcoma
(c) Diagnosis of high-grade undifferentiated pleomorphic sarcoma (UPS)

-AND-

(2) History of failure, contraindication, or intolerance to at least **one** prior first-line chemotherapy regimen

-AND-

(3) Used in combination with Nexavar (sorafenib)

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. Thymomas and Thymic Carcinomas (off-label)

1. Initial Authorization

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

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

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

-AND-

(2) History of failure, contraindication, or intolerance to at least **one** prior first-line chemotherapy regimen.

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.

K. Thyroid Carcinoma (off-label)

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 recurrent disease
(b) Persistent locoregional 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.

3. References:

1. Afinitor [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2016.

2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. June 6, 2017.

Program	Prior Authorization –Afinitor (everolimus)
Change Control	
Sept 2013	New guideline.
Sept 2014	Annual Review
Dec 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)
July 2016	Clinical criteria updated to align with Employer and Individual notification policy; updated policy to new template
July 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.