

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## Afinitor (everolimus)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Afinitor tablets(everolimus)
Afinitor Disperz (everolimus)

### APPROVAL CRITERIA

Requests for **Afinitor Disperz (everolimus)** tablets may be approved if the following criteria are met:

- I. Individual is 1 year of age or older; **AND**
- II. Individual has a diagnosis of Tuberous sclerosis complex (TSC); **AND**
- III. Individual is using for the treatment of subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected (e.g., treated with surgery);

#### **OR**

- IV. Individual is 2 years of age or older; **AND**
- V. Individual has a diagnosis for TSC-associated partial-onset seizures; **AND**
- VI. Individual is using as adjunctive treatment.

**Note:** Tablets (Afinitor) and tablets for oral suspension (Afinitor Disperz) are NOT interchangeable; Afinitor Disperz is only indicated for the treatment of subependymal giant cell astrocytoma (SEGA), in conjunction with therapeutic monitoring. Do NOT combine formulations to achieve desired dose.

Requests for **Afinitor (everolimus)** tablets may be approved if the following criteria are met:

- I. Individual has a diagnosis of advanced hormone receptor positive (HR+), HER2 negative breast cancer disease; **AND**
- II. Individual is taking in combination with exemestane after failure with either letrozole or anastrozole;

#### **OR**

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- III. Individual has a diagnosis of recurrent or stage IV metastatic HR+ HER2 negative breast cancer in postmenopausal women or men with breast cancer (NCCN 2A);  
**OR**
- IV. Individual is premenopausal and has had prior ovarian ablation/suppression therapy (NCCN 2A);  
**AND**
- V. Individual has been treated with prior endocrine therapy within the last 12 months (NCCN 2A);  
**AND**
- VI. Individual is using in combination with exemestane, fulvestrant, or tamoxifen (NCCN 2A);
- OR**
- VII. Individual has a diagnosis of advanced renal cell cancer (RCC); **AND**
- VIII. Individual has failed either sunitinib or sorafenib therapy;  
**OR**
- IX. Individual is using as monotherapy or in combination with lenvatinib in subsequent therapy for predominant clear cell histology (NCCN 1);  
**OR**
- X. Individual is using as monotherapy or in combination with lenvatinib or bevacizumab in systemic therapy for non-clear cell histology (NCCN 2A); **OR**
- XI. Individual is using as monotherapy as systemic therapy for non-clear cell histology (NCCN 2A);
- OR**
- XII. Individual has a diagnosis of advanced papillary RCC including hereditary leiomyomatosis and renal cell cancer (HLRCC); **AND**
- XIII. Individual is using in combination with bevacizumab (NCCN 2A);
- OR**
- XIV. Individual has a diagnosis of Tuberous sclerosis complex (TSC) with subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected (e.g., treated with surgery) (Label, NCCN 2A);
- OR**
- XV. Individual has a diagnosis of renal angiomyolipoma with TSC not requiring immediate surgery;
- OR**
- XVI. Individual has a diagnosis of relapsed or refractory Hodgkin Lymphoma (NCCN 2A);  
**AND**
- XVII. Individual is using as monotherapy;

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**OR**

XVIII. Individual has a diagnosis of progressive Neuroendocrine tumors of pancreatic origin (PNET) with unresectable, locally advanced, or metastatic disease (Label, NCCN 2A);

**OR**

XIX. Individual has a diagnosis of progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal tract, thymus or lung origin (also known as carcinoid) with unresectable, locally advanced, or metastatic disease (Label, NCCN 2A);

**OR**

XX. Individual has a diagnosis of progressive or relapsed Waldenstrom's macroglobulinemia (lymphoplasmacytic lymphoma) (NCCN 2A);

**OR**

XXI. Individual has a diagnosis of Soft Tissue Sarcoma including, Gastrointestinal Stromal Tumors (GIST), PEComa, recurrent angiomyolipoma, or lymphangioleiomyomatosis (NCCN 2A);

**OR**

XXII. Individual has a diagnosis of Thymomas and Thymic Carcinomas and using as second-line therapy (NCCN 2A);

**OR**

XXIII. Individual has a diagnosis of progressive and/or symptomatic iodine-refractory Thyroid Carcinomas, including papillary, follicular, and Hürthle Cell (NCCN 2A);

**OR**

XXIV. Individual has a diagnosis of Uterine Neoplasm-Endometrial carcinoma; **AND**

XXV. Individual is using in combination with letrozole (NCCN 2A);

Requests for Afinitor Tablets (everolimus) may not be approved for the following:

I. Individual is using for the treatment of functional carcinoid tumors.

**Note:** Tablets (Afinitor) and tablets for oral suspension (Afinitor Disperz) are NOT interchangeable; Afinitor Disperz is only indicated for the treatment of subependymal giant cell

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astrocytoma (SEGA), in conjunction with therapeutic monitoring. Do NOT combine formulations to achieve desired dose.

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: October 14, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on October 14, 2019.
  - a. Breast Cancer. V3.2019. Revised September 6, 2019.
  - b. Central Nervous System Cancer. V2.2019. Revised September 16, 2019.
  - c. Hodgkin Lymphoma. V2.2019. Revised July 15, 2019.
  - d. Kidney Cancer. V.2020. Revised August 5, 2019.
  - e. Neuroendocrine and Adrenal Tumors. V1.2019. Revised March 5, 2019.
  - f. Soft Tissue Sarcoma. V4.2019. Revised September 12, 2019.
  - g. Thymomas and Thymic Carcinomas. V2.2019. Revised March 11, 2019.
  - h. Thyroid Carcinoma. V2.2019. Revised September 16, 2019.
  - i. Uterine Neoplasms. V4.2019. Revised September 16, 2019.

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