

# 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**

- 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. One of the following:
- A. Individual is using in combination with exemestane if progressed within 12 months or on a nonsteroidal aromatase inhibitor (NCCN 2A); **OR**
  - B. Individual is using in combination with fulvestrant (NCCN 2A); **OR**
  - C. Individual is using in combination with tamoxifen (NCCN 2A);

**OR**

- VI. Individual has a diagnosis of advanced renal cell cancer (RCC); **AND**
- VII. One of the following:
- A. Individual has failed either sunitinib or sorafenib therapy; **OR**
  - B. Individual is using as monotherapy or in combination with lenvatinib in subsequent therapy for predominant clear cell histology (NCCN 1); **OR**
  - C. Individual is using as monotherapy or in combination with lenvatinib or bevacizumab in systemic therapy for non-clear cell histology (NCCN 2A);

**OR**

- VIII. 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);

**OR**

- IX. Individual has a diagnosis of Tuberous sclerosis complex-associated (TSC) subependymal giant cell astrocytoma (SEGA); **AND**
- X. Individual has low-grade (WHO grade 1 or 2) glioma; **AND**
- XI. Individual is unlikely to require surgery with no critical hydrocephalus or imminent cerebral herniation; **AND**
- XII. Individual is using as monotherapy

**OR**

- XIII. Individual has a diagnosis of renal angiomyolipoma with TSC not requiring immediate surgery;

**OR**

- XIV. Individual has a diagnosis of relapsed or refractory Hodgkin Lymphoma (NCCN 2A); **AND**
- XV. Individual is using as monotherapy; **AND**
- XVI. Individual has used 3 prior lines of therapy;

**OR**

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

**OR**

- XVIII. 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**

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

**OR**

XX. Individual has a diagnosis of Soft Tissue Sarcoma, Gastrointestinal Stromal Tumors (GIST) (NCCN 2A); **AND**

XXI. Individual has disease progression after single-agent therapy with imatinib, sunitinib, ripretinib, and regorafenib;

**OR**

XXII. Individual has a diagnosis of Soft Tissue Sarcoma, PEComa/Recurrent Angiomyolipoma or lymphangiomyomatosis; **AND**

XXIII. Using as a single-agent therapy in recurrent disease, advanced, metastatic, or inoperable disease (NCCN 2A);

**OR**

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

**OR**

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

**OR**

XXVI. Individual has a diagnosis of Uterine Neoplasm-Endometrial carcinoma (NCCN 2A); **AND**

XXVII. Individual is using in combination with letrozole; **AND**

XXVIII. Not using for isolated metastases disease;

**OR**

XXIX. Individual has a diagnosis of recurrent or progressive meningioma (NCCN 2A); **AND**

XXX. Individual is using in combination with octreotide acetate LAR (Sandostatin LAR Depot).

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

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

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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.: 2023. 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>. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Updated periodically..
  - a. Bone Cancer. V1.2024. Revised August 7, 2023.
  - b. Breast Cancer. V4.2023. Revised March 23, 2023.
  - c. Central Nervous System Cancer. V1.2023. Revised March 24, 2023.
  - d. Gastrointestinal Stromal Tumors (GIST). V1.2023. Revised March 13, 2023.
  - e. Histiocytic Neoplasms. V1.2023. Revised August 11, 2023.
  - f. Hodgkin Lymphoma. V2.2023. Revised November 8, 2022.
  - g. Kidney Cancer. V1.2024. Revised June 21, 2023.
  - h. Neuroendocrine and Adrenal Tumors. V1.2023. Revised August 2, 2023.
  - i. Soft Tissue Sarcoma. V2.2023. Revised April 25, 2023.
  - j. Thymomas and Thymic Carcinomas. V1.2023. Revised December 15, 2022.
  - k. Thyroid Carcinoma. V4.2023. Revised August 16, 2023.
  - l. Uterine Neoplasms. V2.2023. Revised April 28, 2023.
  - m. Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma. V1.2023. Revised July 6, 2022.

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