

Everolimus (Afinitor, Torpenz)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Afinitor tablets(everolimus)
Torpenz 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 under 19 years of age;

OR

- 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;

OR

- IV. Individual has a diagnosis for TSC-associated partial-onset seizures; **AND**
- V. Individual is using as adjunctive treatment.

Note: Tablets (Afinitor, Torpenz) 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 or **Torpenz (everolimus)** tablets may be approved if the following criteria are met:

- I. Individual is under 19 years of age;

OR

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

OR

- IV. 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**
- V. Individual is premenopausal and has had prior ovarian ablation/suppression therapy (NCCN 2A);

AND

- VI. 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

- VII. Individual has a diagnosis of advanced renal cell cancer (RCC); **AND**
- VIII. 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 2A); **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

- IX. Individual has a diagnosis for Tuberous sclerosis complex-associated (TSC) associated renal cell carcinoma (NCCN 2A);

OR

- X. Individual has a diagnosis of Tuberous sclerosis complex (TSC) subependymal giant cell astrocytoma (SEGA);

AND

- XI. Individual requires therapeutic intervention but cannot be curatively resected (label); **OR**
- XII. Individual is using as adjuvant treatment if symptomatic or grow (NCCN 2A);

AND

- XIII. Individual is using as a single agent;

OR

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

OR

- XV. Individual has a diagnosis of relapsed or refractory Hodgkin Lymphoma (NCCN 2A);

AND

- XVI. Individual is using as monotherapy; **AND**
- XVII. Individual has used 3 prior lines of therapy;

OR

XXVIII. Individual has a diagnosis of Neuroendocrine tumors of pancreatic origin (PNET) with unresectable, locally advanced, recurrent, or metastatic disease (Label, NCCN 1, 2A);

OR

XIX. Individual has a diagnosis of neuroendocrine tumors (NET) of gastrointestinal tract, thymus or lung origin (also known as carcinoid) with unresectable, locally advanced, recurrent, or metastatic disease (Label, NCCN 1, 2A);

OR

XX. Individual has a diagnosis of well-differentiated grade 3 neuroendocrine tumor with locally advanced, or metastatic disease (NCCN 2A);

OR

XXI. Individual has a diagnosis of Waldenstrom's macroglobulinemia (lymphoplasmacytic lymphoma) (NCCN 2A); **AND**

XXII. Individual is using as a single agent for previously treated disease;

OR

XXIII. Individual has a diagnosis of Gastrointestinal Stromal Tumors (GIST) (NCCN 2A); **AND**

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

OR

XXV. Individual has a diagnosis of Soft Tissue Sarcoma, perivascular epithelioid cell tumor (PEComa), Angiomyolipoma or lymphangiomyomatosis; **AND**

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

OR

XXVII. Individual has a diagnosis of Thymomas and Thymic Carcinomas (NCCN 2A);

OR

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

OR

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

XXX. Individual is using in combination with letrozole;

OR

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

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

OR

- XXXIII. Individual has a diagnosis of Langerhans cell histiocytosis, Erdheim-Chester disease, or Rosai-Dorfman disease (NCCN 2A); **AND**
- XXXIV. Individual is using as a single agent therapy.

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Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed October 12, 2025.
 - a. Bone Cancer. V1.2026. Revised October 6, 2025.
 - b. Breast Cancer. V4.2025. Revised April 17, 2025.
 - c. Central Nervous System Cancer. V2.2025. Revised August 28, 2025.
 - d. Gastrointestinal Stromal Tumors (GIST). V1.2025. Revised April 17, 2025.
 - e. Histiocytic Neoplasms. V2.2024. V1.2025. Revised June 20, 2025.
 - f. Hodgkin Lymphoma. V2.2025. Revised January 30, 2025.
 - g. Kidney Cancer. V1.2026. Revised July 24, 2025.
 - h. Neuroendocrine and Adrenal Tumors. V3.2025. Revised October 1, 2025.
 - i. Soft Tissue Sarcoma. V1.2025. Revised May 2, 2025.
 - j. Thymomas and Thymic Carcinomas. V2.2025. Revised May 19, 2025.
 - k. Thyroid Carcinoma. V1.2025. Revised March 27, 2025.
 - l. Uterine Neoplasms. V3.2025. Revised March 7, 2025.
 - m. Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma. V1.2026. Revised June 24, 2025.

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