Everolimus (Afinitor, Torpenz)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Afinitor tablets(everolimus) – brand and generic Torpenz tablets (everolimus) – generic
Afinitor Disperz (everolimus) – brand and generic

APPROVAL CRITERIA

Requests for **Afinitor Disperz (everolimus) – brand and generic** 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, 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) - brand and generic** tablets **or Torpenz (everolimus) - generic** 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 (Label); **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 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 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

VIII. Individual has a diagnosis for Tuberous sclerosis complex-associated (TSC) associated renal cell carcinoma;

OR

IX. 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

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

XI. Individual has low-grade (WHO grade 1 or 2) glioma; **AND**

XII. Individual is unlikely to require surgery with no critical hydrocephalus or imminent cerebral herniation; **AND**

XIII. Individual is using as monotherapy

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

XVIII. 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);

OR

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

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

OR

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

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

OR

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

OR

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

OR

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

XXIX. Individual is using in combination with letrozole;

OR

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

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

OR

XXXII. Individual has a diagnosis of Langerhans cell histiocytosis, Erdheim-Chester disease, or Rosai-Dorfman disease (NCCN 2A); **AND**

XXXIII. Individual is using as a single agent therapy.

Requests for everolimus tablets (Afinitor, Torpenz) may not be approved for the following:

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

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.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. 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.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed September 9, 2024..
    a. Bone Cancer. V1.2025. Revised August 20, 2024.
    b. Breast Cancer. V4.2024. Revised July 3, 2024.
    c. Central Nervous System Cancer. V2.2024. Revised July 25, 2024.
    d. Gastrointestinal Stromal Tumors (GIST). V2.2024. Revised July 31, 2024.
    e. Histiocytic Neoplasms. V2.2024. Revised July 19, 2024.
    f. Hodgkin Lymphoma. V3.2024. Revised March 18, 2024.
    g. Kidney Cancer. V2.2025. Revised September 6, 2024.
    h. Neuroendocrine and Adrenal Tumors. V2.2024. Revised August 1, 2024.
    i. Soft Tissue Sarcoma. V2.2024. Revised July 31, 2024.
    j. Thymomas and Thymic Carcinomas. V1.2024. Revised November 21, 2023.
    k. Thyroid Carcinoma. V4.2024. Revised August 19, 2024.
    l. Uterine Neoplasms. V2.2024. Revised March 6, 2024.
    m. Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma. V2.2024. Revised December 5, 2023.