Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	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

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

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**
   D. Individual is using in combination with bevacizumab as 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 renal angiomyolipoma with TSC not requiring immediate surgery;

OR

X. Individual has a diagnosis of relapsed or refractory Hodgkin Lymphoma (NCCN 2A); **AND**

XI. Individual is using as monotherapy; **AND**

XII. Individual is using as third-line or subsequent systemic therapy;

OR

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

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

OR

XIV. 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

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

OR

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

XVII. Using for unresectable or metastatic disease progressive after single-agent therapy with imatinib, sunitinib, and regorafenib;

OR

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

XIX. Using as a single-agent therapy in recurrent disease;

OR

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

OR

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

OR

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

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

XXIV. Not using for isolated metastases disease.

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

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

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

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.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. 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, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 14, 2020.
    a. Breast Cancer. V6.2020. Revised September 8, 2020.
    b. Central Nervous System Cancer. V3.2020. Revised September 11, 2020.
    c. Hodgkin Lymphoma. V5.2020. Revised August 4, 2020.
    d. Kidney Cancer. V1.2021. Revised July 15, 2020.
    e. Neuroendocrine and Adrenal Tumors. V2.2020. Revised July 24, 2020.
    f. Soft Tissue Sarcoma. V2.2020. Revised May 28, 2020.
    g. Thymomas and Thymic Carcinomas. V1.2020. Revised November 27, 2019.
    h. Thyroid Carcinoma. V2.2020. Revised July 15, 2020.
    i. Uterine Neoplasms. V2.2020. Revised July 24, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.