Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Afinitor (everolimus)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Afinitor tablets(everolimus)
Afinitor Disperz (everolimus)

APPROVAL CRITERIA

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

A. Individual is 1 year of age or older: **AND**
B. Individual has a diagnosis of Tuberous sclerosis complex (TSC); **AND**
C. 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

D. Individual is 2 years of age or older; **AND**
E. Individual has a diagnosis for TSC-associated partial-onset seizures; **AND**
F. 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.

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

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

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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OR

C. 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

D. Individual is premenopausal and has had prior ovarian ablation/suppression therapy (NCCN 2A);

AND

E. Individual has been treated with prior endocrine therapy within the last 12 months (NCCN 2A);

AND

F. Individual is using in combination with exemestane, fulvestrant, or tamoxifen (NCCN 2A);

OR

G. Individual has a diagnosis of advanced renal cell cancer (RCC); **AND**

H. Individual has failed either sunitinib or sorafenib therapy;

OR

I. Individual is using as monotherapy or in combination with lenvatinib in subsequent therapy for predominant clear cell histology(NCCN 1);

OR

J. Individual is using as monotherapy or in combination with lenvatinib in systemic therapy for non-clear cell histology (NCCN 2A);

OR

K. Individual has a diagnosis of advanced papillary RCC including hereditary leiomyomatosis and renal cell cancer (HLRCC); **AND**

L. Individual is using in combination with bevacizumab (NCCN 2A);

OR

M. 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

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

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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OR

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

P. Individual is using as monotherapy (NCCN 2A);

OR

Q. Individual has a diagnosis of progressive Neuroendocrine tumors of pancreatic origin (PNET) with unresectable, locally advanced, or metastatic disease;

OR

R. 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

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

OR

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

OR

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

OR

V. Individual has a diagnosis for relapsed/refractory or metastatic Osteosarcoma (NCCN 2A); **AND**

W. Individual is using in combination with sorafenib;

OR

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

OR

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

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

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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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.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

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Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

The NCCN Drugs & Biologics Compendium (NCCN Compendium™) © 2018 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically.