Drug Policy:

Afinitor™ (everolimus)

POLICY NUMBER UM ONC_1192	**SUBJECT** Afinitor™ (everolimus)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 01/04/12, 04/11/12, 12/12/12, 01/02/13, 01/03/14, 06/09/15, 04/12/16, 02/06/17, 01/02/17, 01/10/18, 01/08/19, 12/11/19, 01/08/20, 11/11/20, 10/13/21	**APPROVAL DATE** October 13, 2021	**EFFECTIVE DATE** October 29, 2021	**COMMITTEE APPROVAL DATES** 01/04/12, 04/11/12, 12/12/12, 01/02/13, 01/03/14, 06/09/15, 04/12/16, 02/06/17, 01/02/17, 01/10/18, 01/08/19, 12/11/19, 01/08/20, 11/11/20, 10/13/21	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Afinitor (everolimus) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When applicable, generic alternatives are preferred over brand-name drugs.

B. Breast Cancer

1. Afinitor (everolimus) may be used as subsequent therapy in combination with Aromasin (exemestane), Faslodex (fulvestrant), or tamoxifen for hormone receptor-positive, human epidermal growth factor receptor 2-negative, and in post-menopausal women/premenopausal women with ovarian ablation or suppression, and with recurrent or metastatic disease previously treated with a nonsteroidal aromatase inhibitor or tamoxifen.

C. Renal Cell Carcinoma (RCC)

1. Afinitor (everolimus) may be used as monotherapy as third line therapy for relapse or stage IV renal cell carcinoma. This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to show overall survival outcomes compared to other available therapies on NCH L1 pathway for first and second-line settings.

D. Advanced or Metastatic Neuroendocrine Tumors

1. Afinitor (everolimus) is indicated for the treatment of progressive neuroendocrine tumors, regardless of origin, in members with unresectable locally advanced or metastatic disease.

III. EXCLUSION CRITERIA

A. Member has disease progression while taking Afinitor (everolimus).

B. Dosing exceeds single dose limit of Afinitor (everolimus) 10 mg.

C. Do not exceed 120 (2.5 mg) tablets/month, 60 (5 mg) tablets/month, 30 (7.5 mg) tablets/month, or 30 (10 mg) tablets/month.

D. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Afinitor prescribing information. Novartis Pharmaceutical Corporation. East Hanover, NJ. 2021.

B. Clinical Pharmacology Elsevier Gold Standard 2021.

C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.

D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.

E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2021.