CareFirst Family of health care plans

CVS caremark™

# SPECIALTY GUIDELINE MANAGEMENT

## AFINITOR (everolimus)

## POLICY

### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Postmenopausal women with advanced hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer, in combination with exemestane, after failure of treatment with letrozole or anastrozole
2. Adults with progressive neuroendocrine tumors of pancreatic origin (pNETs) that are unresectable, locally advanced or metastatic
3. Adults with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib
4. Adults with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery
5. Adults with progressive, well-differentiated, non-functional neuroendocrine tumors of gastrointestinal or lung origin that are unresectable, locally advanced or metastatic
6. Adults and pediatric patients with tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected
7. Adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC-associated partial-onset seizures

B. Compendial Uses
1. Relapse or stage IV RCC:
   a. Systemic therapy for non-clear cell histology
   b. Subsequent therapy for predominant clear cell histology
2. Soft tissue sarcoma subtypes:
   a. Perivascular epithelioid cell tumors (PEComa)
   b. Recurrent angiomyolipoma
   c. Lymphangioleiomyomatosis
3. Neuroendocrine tumor of the thymus
4. Thymomas and thymic carcinomas
5. Osteosarcoma
6. Classical Hodgkin lymphoma
7. Papillary, Hürthle cell, and follicular thyroid carcinoma
8. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma

All other indications are considered experimental/investigational and are not a covered benefit.

## II. CRITERIA FOR INITIAL APPROVAL

**A. Breast Cancer**
Authorization of 12 months may be granted for treatment of HR-positive, HER2-negative recurrent or metastatic breast cancer when prescribed in combination with exemestane and any of the following criteria are met:
1. Member has been previously treated with tamoxifen
2. Disease has progressed while on or within 12 months of therapy with a nonsteroidal aromatase inhibitor

**B. Renal Cell Carcinoma**
Authorization of 12 months may be granted for treatment of relapsed, metastatic, or unresectable RCC when either of the following criteria are met:
1. Disease is of non-clear cell histology
2. Disease is of predominantly clear cell histology and has progressed on prior antiangiogenic therapy (e.g., Avastin, Sutent, Votrient).

**C. Neuroendocrine Tumors**
Authorization of 12 months may be granted for treatment of neuroendocrine tumors of pancreatic gastrointestinal, lung, or thymic origin.

**D. Renal Angiomyolipoma Associated With Tuberous Sclerosis Complex (TSC)**
Authorization of 12 months may be granted for treatment of renal angiomyolipoma associated with TSC.

**E. Subependymal Giant Cell Astrocytoma (SEGA) Associated With Tuberous Sclerosis Complex (TSC)**
Authorization of 12 months may be granted for treatment of SEGA associated with TSC.

**F. Partial-Onset Seizures Associated With Tuberous Sclerosis Complex (TSC)**
Authorization of 12 months may be granted for treatment of partial-onset seizures associated with TSC.

**G. Soft Tissue Sarcoma**
Authorization of 12 months may be granted for treatment of any of the following subtypes of soft tissue sarcoma: perivascular epithelioid cell (PEComa), angiomyolipoma, or lymphangioleiomyomatosis.

**H. Thymomas and Thymic Carcinomas**
Authorization of 12 months may be granted for treatment of thymomas and thymic carcinomas.

**I. Osteosarcoma**
Authorization of 12 months may be granted for treatment of osteosarcoma.

**J. Classical Hodgkin Lymphoma**
Authorization of 12 months may be granted for treatment of classical Hodgkin lymphoma.

**K. Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma**
Authorization of 12 months may be granted for treatment of Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma.

**L. Thyroid Carcinoma**

Authorization of 12 months may be granted for treatment of thyroid carcinoma with any of the following histologies: papillary, Hurthle cell, follicular.

## III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

## IV. REFERENCES


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