

**AFINITOR and, AFINITOR DISPERZ, **TORPENZ (everolimus)****

Preferred products: generic everolimus, Torpenz

**Pre - PA Allowance**

None

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**Prior-Approval Requirements****Afinitor and Torpenz only****Age** 18 years of age or older**Diagnoses**Patient must have **ONE** of the following:

1. **Renal Cell Carcinoma with ONE of the following:**
  - a. Disease is of non-clear cell histology
  - b. Disease is of predominantly clear cell histology and has progressed on prior antiangiogenic therapy
2. **Advanced HR-positive, HER2 negative breast cancer**
  - a. Patient has previously been treated with letrozole or anastrozole
  - b. Used in combination with an endocrine agent (e.g., exemestane, fulvestrant, or tamoxifen)
3. Hodgkin's lymphoma
4. Lung neuroendocrine tumors
5. Soft tissue sarcoma that expresses **ONE** of the following histologies:
  - a. PEComa/Recurrent
  - b. Angiomyolipoma
  - c. Lymphangi leiomyomatosis
6. **Pancreatic neuroendocrine tumors**
7. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma
8. Renal angiomyolipoma with Tuberous Sclerosis Complex (TSC)
  - a. Patient does **NOT** require immediate surgery
9. Gastrointestinal (GI) neuroendocrine tumors
  - a. Metastatic or unresectable progressive disease
10. Thymus neuroendocrine tumors
  - a. Metastatic or unresectable progressive disease
11. Osteosarcoma
  - a. Patient has previously been treated with a first-line therapy agent
  - b. Used in combination with sorafenib
12. Thymomas / Thymic carcinomas
13. Thyroid carcinoma that expresses **ONE** of the following histologies:

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- a. Papillary
- b. Hürthle cell
- c. Follicular thyroid carcinoma
- 14. Gastrointestinal Stromal Tumors (GIST)
  - d. Used in combination with either imatinib, sunitinib, or regorafenib
  - e. Disease progression after single-agent therapy with imatinib, sunitinib, or regorafenib
- 15. Endometrial carcinoma
  - f. Used in combination with letrozole

**AND the following for **Brand Afinitor only**:**

- a. Patient **MUST** have tried **ONE** of the preferred products (generic Afinitor: everolimus or Torpenz) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

**Afinitor Disperz only**

**Age** 2 years of age or older

**Diagnosis**

Patient must have the following:

- 1. TSC associated partial-onset seizures.
  - a. Used as adjunctive therapy
  - b. **Brand Afinitor Disperz only:** Patient **MUST** have tried the preferred product (generic Afinitor Disperz: everolimus) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

**Afinitor, Afinitor Disperz, and Torpenz**

**Age** 1 year of age or older

**Diagnosis**

Patient must have the following:

- 1. Subependymal Giant Cell Astrocytoma (SEGA) with TSC
  - a. **NOT** a candidate for curative surgical resection

**AFINITOR and, AFINITOR DISPERZ, TORPENZ (everolimus)**

Preferred products: generic everolimus, Torpenz

- b. **NOT** being used to prevent kidney transplant rejection
- c. **Brand Afinitor/Afinitor Disperz only:** Patient **MUST** have tried **ONE** of the preferred products (generic Afinitor/Afinitor Disperz: everolimus or Torpenz) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

**Prior - Approval Limits****Quantity****Afinitor/Torpenz**

Strength	Quantity
2.5 mg	180 tablets per 90 days <b>OR</b>
5 mg	180 tablets per 90 days <b>OR</b>
7.5 mg	90 tablets per 90 days <b>OR</b>
10 mg	90 tablets per 90 days

**Maximum daily limit of any combination: 10 mg****OR****Afinitor Disperz**

Strength	Quantity
2 mg	168 dispersible tablets per 84 days <b>OR</b>
3 mg	168 dispersible tablets per 84 days <b>OR</b>
5 mg	168 dispersible tablets per 84 days

**Maximum daily limit of any combination: 10 mg****Duration** 12 months

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**Prior – Approval *Renewal* Requirements****Afinitor and Torpenz only****Age** 18 years of age or older**Diagnoses**Patient must have **ONE** of the following

1. **Renal cell carcinoma**
2. **Advanced HR-positive, HER2 negative breast cancer**

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Preferred products: generic everolimus, Torpenz

- a. Used in combination with an endocrine agent (e.g., exemestane, fulvestrant, or tamoxifen)
3. Hodgkin's lymphoma
4. Lung neuroendocrine tumors
5. Soft tissue sarcoma that expresses **ONE** of the following histologies:
  - a. PEComa/Recurrent
  - b. Angiomyolipoma
  - c. Lymphangioleiomyomatosis
6. **Pancreatic neuroendocrine tumors**
7. Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma
8. Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC)
9. Gastrointestinal (GI) neuroendocrine tumors
10. Thymus neuroendocrine tumors
11. Osteosarcoma
  - a. Used in combination with sorafenib
12. Thymomas / Thymic carcinomas
13. Thyroid carcinoma that expresses **ONE** of the following histologies:
  - a. Papillary
  - b. Hürthle cell
  - c. Follicular thyroid carcinoma
14. Gastrointestinal Stromal Tumors (GIST)
  - a. Used in combination with either imatinib, sunitinib, or regorafenib
15. Endometrial carcinoma
  - a. Used in combination with letrozole

**AND the following for **Brand Afinitor** only:**

- a. Patient **MUST** have tried **ONE** of the preferred products (generic Afinitor: everolimus or Torpenz) unless the patient has a valid medical exception (e.g., inadequate response, intolerance, contraindication)

**Afinitor Disperz only**

**Age**      2 years of age or older

**Diagnosis**

Patient must have the following:

1. TSC associated partial-onset seizures.

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- a. Used as adjunctive therapy
- b. **Brand Afinitor Disperz only:** Patient **MUST** have tried the preferred product (generic Afinitor Disperz: everolimus) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

**Afinitor, Afinitor Disperz, and Torpenz**

**Age**      1 year of age or older

**Diagnosis**

Patient must have the following:

1. Subependymal Giant Cell Astrocytoma (SEGA) with TSC
  - a. **NOT** being used to prevent kidney transplant rejection
  - b. **Brand Afinitor/Afinitor Disperz only:** Patient **MUST** have tried **ONE** of the preferred products (generic Afinitor/Afinitor Disperz: everolimus or Torpenz) unless the patient has a valid medical exception (e.g., inadequate response, intolerance, contraindication)

**Prior - Approval *Renewal* Limits**

Same as above