

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

Preferred products: generic everolimus, Torpenz

Pre - PA Allowance

None

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. Lymphangioliomyomatosis
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

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- 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 OR
5 mg	180 tablets per 90 days OR
7.5 mg	90 tablets per 90 days OR
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 OR
3 mg	168 dispersible tablets per 84 days OR
5 mg	168 dispersible tablets per 84 days

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

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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- 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