EVEROLIMUS

Generic	Brand	HICL	GCN	Exception/Other
EVEROLIMUS	AFINITOR		20784 20844 28783 31396	
EVEROLIMUS	AFINITOR DISPERZ		34589 34590 34592	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

AFINITOR DISPERZ

1. Does the patient have **ONE** of the following diagnoses and associated criteria?
   - Subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC) AND meet the following:
     - The patient is 1 year of age or older
     - The patient's diagnosis requires therapeutic intervention but cannot be curatively resected
   - Tuberous sclerosis complex (TSC)-associated partial-onset seizures AND meet the following:
     - The patient is 2 years of age or older
     - The medication will be used as adjunctive treatment

   If yes, **approve for 12 months by GPID.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **EVEROLIMUS (Afinitor Disperz)** requires a diagnosis of subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC) or tuberous sclerosis complex (TSC)-associated partial-onset seizures. In addition, the following criteria must be met:
   For diagnosis of subependymal giant cell astrocytoma (SEGA) in tuberous sclerosis complex (TSC), approval requires:
   - The patient is 1 year of age or older
   - The patient's diagnosis requires therapeutic intervention but cannot be curatively resected

   For diagnosis of TSC-associated partial-onset seizures, approval requires:
   - The patient is 2 year of age or older
   - The medication will be used as adjunctive treatment

CONTINUED ON NEXT PAGE

EVEROLIMUS

GUIDELINES FOR USE (CONTINUED)

AFINITOR

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has failed or is contraindicated to treatment with Sutent (sunitinib) **OR** Nexavar (sorafenib)

   If yes, **approve for 12 months by GPID with the following quantity limits:**
   - **Afinitor 2.5mg (GPID 28783): #1 tablet per day.**
   - **Afinitor 5mg (GPID 20784): #1 tablet per day.**
   - **Afinitor 7.5mg (GPID 31396): #2 tablets per day.**
   - **Afinitor 10mg (GPID 20844): #2 tablets per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's diagnosis requires therapeutic intervention but cannot be curatively resected

   If yes, **approve for 12 months by GPID.**
   If no, continue to #3.

3. Is the patient 18 years of age or older and have a diagnosis of progressive neuroendocrine tumor (NET) with unresectable, locally advanced or metastatic disease and meet **ONE** of the following criteria?
   - Neuroendocrine tumor (NET) of pancreatic origin (PNET)
   - Well-differentiated, non-functional neuroendocrine tumor (NET) of gastrointestinal (GI) or lung origin

   If yes, **approve for 12 months by GPID with the following quantity limits:**
   - **Afinitor 2.5mg (GPID 28783): #1 tablet per day.**
   - **Afinitor 5mg (GPID 20784): #1 tablet per day.**
   - **Afinitor 7.5mg (GPID 31396): #2 tablets per day.**
   - **Afinitor 10mg (GPID 20844): #2 tablets per day.**

   If no, continue to #4.

CONTINUED ON NEXT PAGE

EVEROLIMUS

GUIDELINES FOR USE - AFINITOR (CONTINUED)

4. Does the patient have a diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC) that does not require immediate surgery **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID with the following quantity limits:**
   - **Afinitor 2.5mg (GPID 28783): #1 tablet per day.**
   - **Afinitor 5mg (GPID 20784): #1 tablet per day.**
   - **Afinitor 7.5mg (GPID 31396): #2 tablets per day.**
   - **Afinitor 10mg (GPID 20844): #2 tablets per day.**

   If no, continue to #5.

5. Is the patient a postmenopausal woman with a diagnosis of advanced hormone receptor (HR)-positive, HER2-negative breast cancer (defined as IHC less than or equal to 3+ or FISH amplification ratio less than or equal to 2.0) and meet **ALL** of the following criteria?
   - The patient has failed or is contraindicated to treatment with Femara (letrozole) or Arimidex (anastrozole)
   - Afinitor will be used in combination with Aromasin (exemestane).

   If yes, **approve for 12 months by GPID with the following quantity limits:**
   - **Afinitor 2.5mg (GPID 28783): #1 tablet per day.**
   - **Afinitor 5mg (GPID 20784): #1 tablet per day.**
   - **Afinitor 7.5mg (GPID 31396): #2 tablets per day.**
   - **Afinitor 10mg (GPID 20844): #2 tablets per day.**

   If no, do not approve.
   DENIAL TEXT: See AFINITOR denial text on the next page.

CONTINUED ON NEXT PAGE

EVEROLIMUS

GUIDELINES FOR USE - AFINITOR (CONTINUED)

AFINITOR DENIAL TEXT: The guideline named **EVEROLIMUS (Afinitor)** requires ONE of the following FDA approved indications:

- Advanced renal cell carcinoma (RCC) after failure of or contraindication to treatment with sunitinib (Sutent) or sorafenib (Nexavar), which may also require prior authorization AND the patient is 18 years of age or older
- Subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC) that requires therapeutic intervention but cannot be curatively resected AND the patient is 1 year of age or older
- Progressive neuroendocrine tumor (NET) with unresectable, locally advanced or metastatic disease, either neuroendocrine tumor (NET) of pancreatic origin (PNET) or well-differentiated, non-functional neuroendocrine tumor (NET) of gastrointestinal or lung origin AND the patient must also be 18 years of age or older
- Renal angiomyolipoma, and tuberous sclerosis complex (TSC) that does not require immediate surgery AND the patient is 18 years of age or older
- For postmenopausal women with a diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer (defined as IHC less than or equal to 3+ or FISH amplification ratio less than or equal to 2.0) in combination with Aromasin (exemestane) after failure of or contraindication to treatment with Femara (letrozole) or Arimidex (anastrozole).

RATIONALE

Ensure appropriate utilization of everolimus based on FDA approved indication and NCCN guidelines.

DOSAGE AND ADMINISTRATION

Afinitor and Afinitor Disperz are two different dosage forms. Select the recommended dosage form based on the indication. Do not combine Afinitor and Afinitor disperz to achieve the total dose. Modify the dosage for patients with hepatic impairment or for patients taking drugs that inhibit or induce pglycoprotein (P-gp) and CYP3A4.

Advanced HR+ BC, advanced NET, advanced RCC, or renal angiomyolipoma with TSC:

- Afinitor 10 mg once daily orally until disease progression or unacceptable toxicity.

SEGA with TSC:

- Afinitor/Afinitor Disperz 4.5 mg/m^2 once daily orally until disease progression or unacceptable toxicity.
- Titrate the dose to attain trough concentrations of 5-15 ng/mL.

TSC-Associated Partial-Onset Seizures

- Afinitor Disperz 5 mg/m^2 once daily orally until disease progression or unacceptable toxicity.
- Titrate the dose to attain trough concentrations of 5-15 ng/mL.

CONTINUED ON NEXT PAGE

EVEROLIMUS

FDA APPROVED INDICATIONS

AFINITOR is a kinase inhibitor indicated for the treatment of:

- Postmenopausal women with advanced hormone receptor-positive, HER2negative breast cancer (advanced HR+ BC) in combination with exemestane after failure of treatment with letrozole or anastrozole.
- Adults with progressive neuroendocrine tumors of pancreatic origin (PNET) and adults with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) or gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic. Afinitor is not indicated for the treatment of patients with functional carcinoid tumors.
- Adults with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib.
- Adults with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery.

Afinitor and Afinitor Disperz are kinase inhibitors indicated for the treatment of:

- Adult and pediatric patients aged 1 year and older with tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected.

Afinitor Disperz is a kinase inhibitor indicated for:

- Adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC associated partial-onset seizures.

REFERENCES

- Afinitor [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. April 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/25/18

Created: 05/11
Client Approval: 05/18

P&T Approval: 04/18