STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EVEROLIMUS-AFINITOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EVEROLIMUS	AFINITOR, EVEROLIMUS		20784 20844 28783 31396	GPI-14 (21532530000330 21532530000310 21532530000320 21532530000325)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced hormone receptor (HR)-positive, HER2-negative breast cancer and meet **ALL** of the following criteria?
   - The patient is a postmenopausal woman
   - Afinitor will be used in combination with exemestane
   - The patient has failed or has a contraindication to treatment with Femara (letrozole) or Arimidex (anastrozole)

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   - **2.5mg: #1 per day.**
   - **5mg: #1 per day.**
   - **7.5mg: #2 per day.**
   - **10mg: #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of progressive, neuroendocrine tumors (NET) with unresectable, locally advanced or metastatic disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following?
   - The patient has a neuroendocrine tumors of pancreatic origin (PNET)
   - The patient has well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows**
   - **2.5mg: #1 per day.**
   - **5mg: #1 per day.**
   - **7.5mg: #2 per day.**
   - **10mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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EVEROLIMUS-AFINITOR

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   - **2.5mg: #1 per day.**
   - **5mg: #1 per day.**
   - **7.5mg: #2 per day.**
   - **10mg: #2 per day.**

   If no, continue to #5.

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

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   - **2.5mg: #1 per day.**
   - **5mg: #1 per day.**
   - **7.5mg: #2 per day.**
   - **10mg: #2 per day.**

   If no, continue to #6.

6. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma (SEGA) 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 or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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EVEROLIMUS-AFINITOR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EVEROLIMUS (Afinitor)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Advanced hormone receptor-positive (HR: a type of protein), human epidermal growth factor receptor 2 (HER2: a type of protein)-negative breast cancer
   2. Progressive, neuroendocrine tumors (NET: a rare type of tumor) with unresectable (unable to remove by surgery), locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) or metastatic disease (cancer that has spread to other parts of the body)
   3. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   4. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated renal angiomyolipoma (type of kidney tumor)
   5. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated subependymal giant cell astrocytoma (SEGA: a type of brain tumor)

B. **If you have advanced hormone receptor-positive, HER2-negative breast cancer, approval also requires:**
   1. You are a postmenopausal woman
   2. Afinitor will be used in combination with Aromasin (exemestane)
   3. You have failed or have a contraindication (harmful for) to treatment with Femara (letrozole) or Arimidex (anastrozole)

C. **If you have progressive, neuroendocrine tumors (NET) with unresectable, locally advanced or metastatic disease, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have neuroendocrine tumors of pancreatic origin (PNET: tumor in the pancreas)
      b. You have well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI: relates to the digestive system) or lung origin

D. **If you have advanced renal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older

E. **If you have tuberous sclerosis complex (TSC)-associated renal angiomyolipoma, approval also requires:**
   1. You are 18 years of age or older
   2. You do not require immediate surgery

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EVEROLIMUS-AFINITOR

GUIDELINES FOR USE (CONTINUED)

F. **If you have tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma, approval also requires:**
   1. You are 1 year of age or older
   2. Your diagnosis requires therapeutic intervention but cannot be curatively resected (completely remove with surgery)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Afinitor.

REFERENCES

- Afinitor/Afinitor Disperz [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. February 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/23
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Client Approval: 10/21
P&T Approval: 04/18