

GEORGIA MEDICAID FEE-FOR-SERVICE AFINITOR PA SUMMARY

Preferred	Non-Preferred
Afinitor (everolimus) Afinitor Disperz (everolimus)	N/A

LENGTH OF AUTHORIZATION: 1 Year

NOTE: Special consideration taken for members with stage IV advanced metastatic cancer.

PA CRITERIA:

<u>Afinitor</u>

- Approvable for members with a diagnosis of progressive neuroendocrine tumors of pancreatic origin (PNET) that are unresectable, locally advanced or metastatic.
- ❖ Approvable for members with a diagnosis of progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI), lung or thymus origin (carcinoid tumors) that are unresectable, locally advance, or metastatic.
- ❖ Approvable for members with a diagnosis of advanced, relapsed, stage IV or surgically unresectable renal cell carcinoma (RCC, kidney cancer) who have a predominantly clear histology and have failed therapy with cabozantinib (Cabometyx) and nivolumab (Opdivo) or who have a predominantly non-clear histology and have failed therapy with sunitinib (Sutent).
- ❖ Approvable for members with a diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tubular sclerosis complex (TSC) who are not candidates for curative surgical resection.
- Approvable for members with a diagnosis of renal angiomyolipomas associated with tubular sclerosis complex (TSC) who do not require immediate surgery.
- Approvable for postmenopausal members with a diagnosis of advanced, recurrent or stage IV hormone receptor-positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative breast cancer when used in combination with exemestane (Aromasin) after failure of treatment with letrozole (Femara) or anastrozole (Arimidex) or when used in combination with fulvestrant (Faslodex) or tamoxifen (Nolvadex, Soltamox).
- Approvable for members with a diagnosis of refractory or relapsed Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma.

Afinitor Disperz

- Approvable for members with a diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tubular sclerosis complex (TSC) who are not candidates for curative surgical resection. Members older than 10 years of age must be unable to swallow solid dosage forms (tablets) in order for the Disperz formulation to be approved.
- ❖ Approvable for members with a diagnosis of partial-onset seizure associated with tubular sclerosis complex (TSC) when used in combination with other antiepileptic medication(s) after failure to achieve adequate seizure control with at least 2 antiepileptic medications.



QLL CRITERIA:

Afinitor

❖ An authorization to exceed the QLL may be granted for the 7.5mg or 10mg strength if member is receiving a concomitant strong CYP 3A4 inducer.

Afinitor Disperz

- ❖ An authorization to exceed the QLL may be granted for the 3mg or 5mg strength if member is receiving a concomitant strong CYP 3A4 inducer.
- ❖ An authorization to exceed the QLL may be granted for the 2mg strength based on whole blood trough levels of everolimus.

EXCEPTIONS:

- Exceptions to these conditions of coverage are considered through the prior authorization process.
- The Prior Authorization process may be initiated by calling **OptumRx at 1-866-525-5827.**

PREFERRED DRUG LIST:

• For online access to the Preferred Drug List (PDL), please go to http://dch.georgia.gov/preferred-drug-lists.

PA AND APPEAL PROCESS:

 For online access to the PA process, please go to <u>www.dch.georgia.gov/prior-authorization-process-and-criteria</u> and click on Prior Authorization (PA) Request Process Guide.

QUANTITY LEVEL LIMITATIONS:

 For online access to the current Quantity Level Limits (QLL), please go to <u>www.mmis.georgia.gov/portal</u>, highlight Pharmacy and click on <u>Other Documents</u>, then select the most recent quarters QLL List.