GEORGIA DEPARTMENT OF COMMUNITY HEALTH

GEORGIA MEDICAID FEE-FOR-SERVICE
ONCOLOGY, ORAL - RENAL PA SUMMARY

Preferred	Non-Preferred
Afinitor Disperz (everolimus tablets for oral suspension) Cabometyx (cabozantinib) Everolimus tablets generic Fotivda (tivozanib) Inlyta (axitinib) Lenvima (lenvatinib) Sutent (sunitinib) Votrient (pazopanib) Welireg (belzutifan)	n/a

LENGTH OF AUTHORIZATION: 1 year

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

PA CRITERIA:

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 11 years of age or older must be unable to swallow solid oral dosage formulations (i.e., tablets).
- 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.

Cabometyx

- Approvable for members with a diagnosis of advanced, relapsed, refractory, stage IV or unresectable renal cell carcinoma (RCC).
- Approvable for members with a diagnosis of hepatocellular carcinoma (HCC) with Child Pugh A or B liver impairment who have been previously treated with sorafenib (Nexavar).
- Approvable for members with a diagnosis of locally advanced or metastatic differentiated thyroid cancer (DTC) who are refractory to or ineligible for radioactive iodine therapy and have progressed following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy.
- Approvable for members with a diagnosis of recurrent or persistent medullary thyroid cancer (MTC) that is unresectable.

Everolimus Tablets Generic

- Approvable for members with a diagnosis of advanced, relapsed, refractory, stage IV or unresectable renal cell carcinoma (RCC) who have failed therapy with sunitinib (Sutent) or sorafenib (Nexavar).
- 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 progressive pancreatic neuroendocrine tumors (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 advanced or metastatic.
- 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 angiomyolipoma associated with tubular sclerosis complex (TSC) who do not require immediate surgery.
- Approvable for members with a diagnosis of refractory or relapsed Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma.

Fotivda

- Approvable for members with a diagnosis of advanced, relapsed, refractory, stage IV or unresectable renal cell carcinoma (RCC) who have been previously treated with at least two prior systemic therapies.

Inlyta

- Approvable for members with a diagnosis of advanced, relapsed, refractory, stage IV or unresectable renal cell carcinoma (RCC).

Lenvima

- Approvable for members with a diagnosis of advanced, relapsed, refractory, stage IV or unresectable renal cell carcinoma (RCC) when used in combination with pembrolizumab (Keytruda) or when used in combination with everolimus (Afinitor) who have received at least one prior antiangiogenic therapy.
- Approvable for members with a diagnosis of unresectable, locally advanced, recurrent, persistent or metastatic differentiated thyroid cancer (DTC) that is progressive or symptomatic and refractory to radioactive iodine therapy.
- Approvable for members with a diagnosis of unresectable hepatocellular carcinoma (HCC).

- Approvable for members with a diagnosis of advanced or recurrent endometrial carcinoma (EC) that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), when used in combination with pembrolizumab (Keytruda), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation.

Sutent

- Approvable for members with a diagnosis of advanced, relapsed, refractory, stage IV or unresectable renal cell carcinoma (RCC).
- Approvable as adjunct therapy for members at high risk of recurrent RCC following nephrectomy.
- Approvable for members with a diagnosis of progressive pancreatic neuroendocrine tumors (pNET) when the tumors are well-differentiated and unresectable locally advanced or metastatic.
- Approvable for members with a diagnosis of gastrointestinal stromal tumor (GIST) who have succinate dehydrogenase (SDH)-deficient disease or who have experienced disease progression or intolerance with imatinib (Gleevec).

Votrient

- Approvable for members with a diagnosis of advanced, relapsed, refractory, stage IV or unresectable renal cell carcinoma (RCC).
- Approvable for members with a diagnosis of advanced soft tissue sarcoma who have received prior chemotherapy.

Welireg

- Approvable for members with a diagnosis of von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas or pancreatic neuroendocrine tumors (pNET) and who do not require immediate surgery.
- Approvable for members with a diagnosis of advanced, relapsed, refractory, stage IV or unresectable renal cell carcinoma (RCC) who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI).

QLL CRITERIA:

Everolimus Tablets Generic

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

Afinitor Disperz

- An authorization to exceed the QLL may be granted for the 3 mg or 5 mg strength if member is receiving a concomitant strong CYP 3A4 inducer.
- An authorization to exceed the QLL may be granted for the 2 mg 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 www.dch.georgia.gov/prior-authorization-process-and-criteria 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 www.mmis.georgia.gov/portal, highlight Provider Information and click on Provider Manuals. Scroll to the page with Pharmacy Services and select that manual.