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

Preferred	Non-Preferred
Ayvakit (avapritinib) Balversa (erdafitinib) Cometriq (cabozantinib) Koselugo (selumetinib) Lonsurf (trifluridine and tipiracil) Lytgobi (futibatinib) Nexavar (sorafenib) Pemazyre (pemigatinib) Qinlock (ripretinib) Stivarga (regorafenib) Tazverik (tazemetostat) Temozolomide generic Turalio (pexidartinib) Vitrakvi (larotrectinib)	Caprelsa (vandetanib)

LENGTH OF AUTHORIZATION: 1 year

NOTES:

- Preferred and non-preferred agents require prior authorization (PA).
- Special consideration taken for members with stage IV advanced metastatic cancer.

PA CRITERIA:

Ayvakit

- Approvable for members with a diagnosis of unresectable or metastatic gastrointestinal stromal tumor (GIST) whose tumor is harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.
- Approvable for members with a diagnosis of advanced systemic mastocytosis (AdvSM) or indolent systemic mastocytosis (ISM) who have a platelet count $\geq 50 \times 10^9/L$.
- Approvable for members with a diagnosis of myeloid/lymphoid neoplasm with eosinophilia who are positive for *FIP1L1-PDGFRA*, are harboring *PDGFRA D842 V* mutation and are resistant to imatinib (Gleevec).

Balversa

- Approvable for members with a diagnosis of locally advanced or metastatic urothelial bladder carcinoma with a susceptible FGFR3 or FGFR2 genetic alteration who have progressed with at least one line of platinum-containing chemotherapy.

Caprelsa

- Approvable for members with a diagnosis of symptomatic or progressive medullary thyroid cancer (MTC) that is unresectable locally advanced or metastatic.
- Approvable for members with advanced or metastatic non-small cell lung cancer (NSCLC) whose tumor has tested positive for RET fusion rearrangement.
- Prescriber and pharmacy must be enrolled in the Caprelsa Risk Evaluation and Mitigation Strategy (REMS) program.

Cometriq

- Approvable for members with a diagnosis of symptomatic or progressive medullary thyroid cancer (MTC) that is unresectable locally advanced or metastatic.
- Approvable for members with advanced or metastatic non-small cell lung cancer (NSCLC) whose tumor has tested positive for RET fusion rearrangement.

Koselugo

- Approvable for members with a diagnosis of neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas.

Lonsurf

- Approvable for members with a diagnosis of advanced or metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy as well as with an anti-vascular endothelial growth factor (anti-VEGF) therapy. If the member's metastatic colorectal cancer is classified as RAS wild-type, the member must have also been previously treated with an anti-epidermal growth factor receptor (anti-EGFR) therapy.
- Approvable for members with a diagnosis of unresectable advanced, recurrent or metastatic gastric or gastroesophageal junction adenocarcinoma who have been previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.

Lytgobi

- Approvable for members with a diagnosis of locally advanced or metastatic intrahepatic cholangiocarcinoma whose tumor is positive for a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, is unresectable and has been previously treated.

Nexavar

- Approvable for members with a diagnosis of locally recurrent, advanced or metastatic differentiated thyroid carcinoma (DTC) that is progressive or symptomatic and refractory to radioactive iodine (RAI) therapy.

- Approvable for members with a diagnosis of recurrent or persistent, unresectable medullary thyroid carcinoma (MTC) who have experienced disease progression on vandetanib (Caprelsa) or cabozantinib (Cometriq), or who are not candidates for vandetanib or cabozantinib therapy.
- Approvable for members with a diagnosis of anaplastic thyroid carcinoma.
- Approvable for members with a diagnosis of relapsed, advanced or stage IV renal cell carcinoma (RCC).
- Approvable for members with a diagnosis of unresectable hepatocellular carcinoma (HCC).
- Approvable for members with a diagnosis of gastrointestinal stromal tumor (GIST) who have experienced disease progression after imatinib (Gleevec), sunitinib (Sutent) and regorafenib (Stivarga).
- Approvable for members with a diagnosis of desmoid tumors (aggressive fibromatosis), angiosarcoma, solitary fibrous tumor or hemangiopericytoma.

Pemazyre

- Approvable for members with a diagnosis of locally advanced or metastatic cholangiocarcinoma whose tumor is positive for a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, is unresectable and has been previously treated.
- Approvable for members with a diagnosis of relapsed or refractory myeloid/lymphoid neoplasms (MLNs) whose tumor is positive for a fibroblast growth factor receptor 1 (FGFR1) rearrangement.

Qinlock

- Approvable for members with a diagnosis of advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have experienced disease progression with 3 or more kinase inhibitors, including imatinib (Gleevec).

Stivarga

- Approvable for members with a diagnosis of advanced or metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy as well as an antivascular endothelial growth factor (anti-VEGF) therapy. If the metastatic CRC is classified as RAS wild-type, member must have been previously treated with an antiepidermal growth factor receptor (anti-EGFR) therapy.
- Approvable for members with a diagnosis of unresectable, locally advanced or metastatic gastrointestinal stromal tumors (GIST) who are resistant or intolerant to imatinib (Gleevec) and sunitinib (Sutent).
- Approvable for members with a diagnosis of hepatocellular carcinoma (HCC) who have been previously treated with sorafenib (Nexavar).

Tazverik

- Approvable for members with a diagnosis of locally advanced or metastatic epithelioid sarcoma who are not eligible for complete resection.

- Approvable for members with a diagnosis of relapsed or refractory follicular lymphoma whose tumor is positive for an EZH2 mutation and have received at least 2 prior systemic therapies or who have no satisfactory alternative treatment options.

Temozolomide Generic

- Approvable for members with a diagnosis of anaplastic astrocytoma, oligodendoglioma, oligoastrocytoma, glioma, glioblastoma, metastatic malignant melanoma or brain metastases.

Turalio

- Approvable for members with a diagnosis of tenosynovial giant cell tumor (TGCT)/pigmented villonodular synovitis who are symptomatic, have severe morbidity or functional limitation, and are not a candidate for surgery.
- Prescriber, member and pharmacy must be enrolled in the Turalio Risk Evaluation and Mitigation Strategy (REMS) program.

Vitrakvi

- Approvable for members with a diagnosis of non-small cell lung cancer (NSCLC) who have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation.
- Approvable for members with a diagnosis of salivary gland cancer, congenital/infantile fibrosarcoma, soft tissue sarcoma (other than angiosarcoma or pleomorphic rhabdomyosarcoma), thyroid cancer or other solid tumor who have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, who have a tumor that is recurrent, metastatic or who surgical resection is likely to result in severe morbidity, and who have no satisfactory alternative treatment options or who have progressed following treatment.

QLL CRITERIA:

Temozolomide Generic

- An authorization to exceed the QLL may be approved for members requiring increased dosage based on the member's body surface area (BSA).

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 http://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 Quantity Level Limits (QLL), please go to https://www.mmis.georgia.gov/portal, highlight Provider Information and click on Provider Manuals. Scroll to the page with Pharmacy Services and select that manual.