GEORGIA DEPARTMENT OF COMMUNITY HEALTH

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

Preferred	Non-Preferred
Alecensa (alectinib) Alunbrig (brigatinib) Erlotinib generic Gavreto (pralsetinib) Gilotrif (afatinib) Iressa (gefitinib) Krazati (adagrasib) Lorbrena (lorlatinib) Lumakras (sotorasib) Retevmo (selpercatinib) Rozlytrek (entrectinib) Tabrecta (capmatinib) Tagrisso (osimertinib) Tepmetko (tepotinib) Vizimpro (dacomitinib) Xalkori (crizotinib) Zykadia (ceritinib)	N/A

LENGTH OF AUTHORIZATION: 1 year

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

PA CRITERIA:

Alecensa

- Approvable for members with a diagnosis of advanced or metastatic non-small cell lung cancer (NSCLC) when the member has positive for anaplastic lymphoma kinase (ALK) rearrangement.

Alunbrig

- Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for ALK rearrangement.

Erlotinib Generic

- Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for EGFR exon 19 deletion or exon 21 (L858R) substitution mutation.
- Approvable for members with a diagnosis of locally advanced, unresectable or metastatic pancreatic cancer when used in combination with gemcitabine.
- Approvable for members with progressive leptomeningeal disease.

Gavreto

- Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for RET fusion.
- Approvable for members with a diagnosis of recurrent, advanced or metastatic thyroid cancer when the member has tested positive for RET fusion, when the member requires systemic therapy and when the member is refractory or not amenable to radioactive iodine therapy.

Gilotrif

- Approvable for members with a diagnosis of advanced or metastatic non-squamous NSCLC when the member has tested positive for epidermal growth factor receptor (EGFR) mutation, such as S768I, L861Q, G719X, exon 19 deletion or exon 21 (L858R) substitution, and when the medication is being used as first-line tyrosine kinase inhibitor (TKI) therapy.
- Approvable for members with a diagnosis of advanced or metastatic squamous NSCLC when member has disease progression on or after platinum-based chemotherapy.
- Approvable for members with a diagnosis of recurrent, unresectable or metastatic squamous cell carcinoma of head or neck when member has disease progression on or after platinum-based chemotherapy.

Iressa

- Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for EGFR exon 19 deletion or exon 21 (L858R) substitution mutation and when the medication is being used as first-line TKI therapy.

Krazati and Lumakras

- Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for KRAS G12C mutation who have received at least one prior systemic therapy.

Lorbrena

- Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for ALK rearrangement.
- Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for ROS1 rearrangement and when the member has disease progression on or is intolerant to other ROS1 inhibitor therapy.

Retevmo

- Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for RET fusion.
- Approvable for members with a diagnosis of recurrent, persistent, advanced or metastatic MTC when the member has tested positive for RET fusion and when the member requires systemic therapy.
- Approvable for members with a diagnosis of recurrent, advanced or metastatic thyroid cancer when the member has tested positive for RET fusion, when the member requires systemic therapy and when the member is refractory or not amenable to radioactive iodine therapy.
- Approvable for members with a diagnosis of advanced or metastatic solid tumors when the member has tested positive for RET fusion and when the member has progressed on or following treatment or the member has no satisfactory alternative treatment options.

Rozlytrek

- Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for ROS1 rearrangement or neurotrophic tyrosine receptor kinase (NTRK) gene fusion.
- Approvable for members with a diagnosis of solid tumors when the member has tested positive for NTRK gene fusion when the member's tumor is metastatic or surgical resection is likely to result in severe morbidity and when the member has progressed following treatment or the member has no satisfactory alternative therapy.

Tabrecto

- Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for mesenchymal-to-epithelial transition (MET) exon 14 skipping mutation.

Tagrisso

- Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for EGFR T790M mutation and when the member has disease progression on or after other EGFR inhibitor therapy.
- Approvable for members with a diagnosis of early stage NSCLC after tumor resection when the member has tested positive for EGFR exon 19 deletions or exon 21 (L858R) substitution mutation and when the medication is being used as adjuvant therapy.
- Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for EGFR exon 19 deletions or exon 21 (L858R) substitution mutation and when the medication is being used as first-line TKI therapy.
- Approvable for members with progressive leptomeningeal disease.

Tepmetko

- Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for MET exon 14 skipping mutation.

Vizimpro

- Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for EGFR exon 19 deletion or exon 21 (L858R) substitution mutation and when the medication is being used as first-line TKI therapy.

Xalkori

- Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for ALK rearrangement, MET exon 14 skipping mutation or ROS1 rearrangement.
- Approvable for members with a diagnosis of relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) when the member has tested positive for ALK rearrangement.
- Approvable for members with a diagnosis of unresectable, recurrent or refractory inflammatory myofibroblastic tumor (IMT) when the member has tested positive for ALK rearrangement.

Zykadia

- ❖ Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for ALK rearrangement.
- ❖ Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for ROS1 rearrangement and when the medication is being used as first-line TKI therapy.

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 Pharmacy and click on Other Documents, then select the most recent quarters QLL List.