GEORGIA DEPARTMENT OF COMMUNITY HEALTH

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

Preferred	Non-Preferred
Ibrance capsules (palbociclib) Kisqali (ribociclib) Kisqali Femara Co-Pack (ribociclib/letrozole) Nerlynx (neratinib) Orserdu (elacestrant) Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf) Piqray (alpelisib) Talzenna (talazoparib) Truqap (capivasertib) Tukysa (tucatinib) Verzenio (abemaciclib)	N/A

LENGTH OF AUTHORIZATION: 1 year

NOTES:

- Special consideration given for members who have stage IV advanced metastatic cancer.

PA CRITERIA:

Ibrance Capsules

- Approvable for members with a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative recurrent, advanced or metastatic breast cancer when used in combination with an aromatase inhibitor or with fulvestrant (Faslodex). In addition, male and pre/perimenopausal members must be receiving a luteinizing hormone-releasing hormone (LHRH) agonist unless a LHRH agonist is not appropriate for the member.

Kisqali

- Approvable for members with a diagnosis of HR-positive, HER2-negative recurrent, advanced or metastatic breast cancer when used in combination with an aromatase inhibitor or with fulvestrant (Faslodex). In addition, male and pre/perimenopausal members must be receiving a luteinizing hormone-releasing hormone (LHRH) agonist unless a LHRH agonist is not appropriate for the member.

Kisqali Femara Co-Pack

- Approvable for members with a diagnosis of postmenopausal HR-positive, HER2-negative recurrent, advanced or metastatic breast cancer. In addition, male and pre/perimenopausal members must be receiving a luteinizing hormone-releasing hormone (LHRH) agonist unless a LHRH agonist is not appropriate for the member.

Nerlynx

- Approvable for members with a diagnosis of early-stage (Stage I, II or III) HER2-positive breast cancer when the member has completed adjuvant trastuzumab (Herceptin)-based therapy.
- Approvable for member with a diagnosis of late-stage (Stage IV) advanced, metastatic or recurrent HER2-positive breast cancer when used in combination with capecitabine (Xeloda) when the member has received two or more prior anti-HER2 based regimens.

Orserdu

- Approvable for male or postmenopausal female members with a diagnosis of estrogen receptor (ER)-positive, HER2-negative recurrent, advanced or metastatic breast cancer with an ESR1 mutation who has disease progression following at least one line of endocrine therapy.

Phesgo

- Approvable for members with a diagnosis of HER2-positive breast cancer when used in combination with chemotherapy.
- Approvable for members with a diagnosis of HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease when used in combination with docetaxel.

Piqray

- Approvable for members with a diagnosis of PIK3CA-mutated, HR-positive, HER2-negative recurrent, advanced or metastatic breast cancer when used in combination with fulvestrant (Faslodex) and who have experienced disease progression while on or after an endocrine-based regimen.

Talzenna

- Approvable for members with a diagnosis of BRCA-mutated recurrent, HER2-negative recurrent, advanced or metastatic breast cancer.
- Approvable for members with a diagnosis of homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) when used in combination with enzalutamide (Xtandi) and when used concurrently with a gonadotropin-releasing hormone (GnRH) analog or the member has had bilateral orchiectomy.

Truqap

- Approvable for members with a diagnosis of HR-positive, HER2-negative recurrent, advanced or metastatic breast cancer with a PIK3CA/AKT1/PTEN alteration who have experienced disease progression following at least one endocrine-based regimen or who have experienced recurrence on or within 12 months of completing adjuvant therapy when used in combination with fulvestrant (Faslodex). In addition, male and pre/perimenopausal members must be receiving a luteinizing hormone-releasing hormone (LHRH) agonist unless a LHRH agonist is not appropriate for the member.

Tukysa

- Approvable for members with a diagnosis of HER2-positive unresectable, recurrent, advanced or metastatic breast cancer when used in combination with trastuzumab (Herceptin) and capecitabine (Xeloda) and who have received one or more prior anti-HER2-based regimens.

- ❖ Approvable for members with a diagnosis with RAS wild-type, HER2-positive advanced, metastatic or unresectable colorectal cancer who have progressed following treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy.

Verzenio

- ❖ Approvable for members with a diagnosis of HR-positive, HER2-negative breast cancer who have node-positive, early breast cancer at high risk of recurrence when used in combination with tamoxifen or an aromatase inhibitor.
- ❖ Approvable for members with a diagnosis of HR-positive, HER2-negative recurrent, advanced or metastatic breast cancer when used in combination with an aromatase inhibitor.
- ❖ Approvable for members with a diagnosis of HR-positive, HER2-negative recurrent, advanced or metastatic breast cancer when used in combination with fulvestrant (Faslodex).
- ❖ Approvable for members with a diagnosis of HR-positive, HER2-negative recurrent, advanced or metastatic breast cancer who have experienced disease progression following endocrine therapy and prior chemotherapy.
- ❖ In addition, male and pre/perimenopausal members must be receiving a luteinizing hormone-releasing hormone (LHRH) agonist unless a LHRH agonist is not appropriate for the member.

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.