



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

| Preferred  | Non-Preferred |
|--|---------------|
| Ibrance capsules (palbociclib)<br>Itovebi (inavolisib)<br>KISQALI (ribociclib)<br>KISQALI Femara Co-Pack (ribociclib/letrozole)<br>Nerlynx (neratinib)<br>Orserdu (elacestrant)<br>Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf)<br>Piqray (alpelisib)<br>Talzenna (talazoparib)<br>Truqap (capivasertib)<br>Tukysa (tucatinib)<br>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.

Itovebi

- ❖ 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 palbociclib (Ibrance) in members who are endocrine-resistant and thus have experienced disease recurrence while on or after completing adjuvant endocrine therapy. 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 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 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](http://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](http://www.mmis.georgia.gov/portal), highlight Pharmacy and click on [Other Documents](#), then select the most recent quarters QLL List.