Breast Cancer Therapies
Effective 08/01/2022

Plan	☐ MassHealth ☒ MH UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		

Contact Information			
	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882

Exceptions	N/A

Overview

Approval Diagnosis:	• Advanced or metastatic HER2-positive breast cancer (Nerlynx®) • Extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer (Nerlynx®) • HER2-negative, HR-positive early breast cancer (Verzenio®) • HER2-negative HR-positive breast cancer in women (Ibrance®, Kisqali®, Kisqali-Femara® Co-Pack) • HER2-negative HR-positive breast cancer in men (Ibrance®) • HER2-negative, HR-positive, PIK3CA-mutated breast cancer in men and postmenopausal women (Piqray®) • HER2 positive breast cancer (advanced unresectable or metastatic) (Tukysa®) • HR-positive, HER2-negative advanced or metastatic breast cancer (Verzenio®)

Reference Table:

No PA	Drugs that require PA
	Ibrance® (palbociclib)[PD]
	Kisqali® (ribociclib)
	Kisqali-Femara® Co-Pack (ribociclib/letrozole)
	Nerlynx® (neratinib)
	Piqray® (alpelisib)
	Tukysa® (tucatinib)
	Verzenio® (abemaciclib)

[PD] Preferred Drug. In general, a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Please note, for Breast Cancer therapies, a trial with a preferred agent is not required prior to approval of a non-preferred agent.
§ Brand Preferred over generic equivalents. In general, a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Ibrance® (palbociclib)
Prescriber provides documentation of **ALL** of the following:
1. Member has a diagnosis of HER2-negative, HR-positive breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. **ONE** of the following:
    a. Concomitant drug therapy with an aromatase inhibitor (anastrazole, letrazole, exemestane)
    b. Concomitant drug therapy with fulvestrant
5. Quantity requested of ≤1 unit/day

Kisqali® (ribociclib)
Prescriber provides documentation of **ALL** of the following:
1. Member has a diagnosis of HR-positive, HER2-negative advanced or metastatic breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. **ONE** of the following:
    a. Concomitant drug therapy with an aromatase inhibitor (anastrazole, letrazole, exemestane)
    b. Concomitant drug therapy with fulvestrant

Kisqali-Femara® Co-Pack (ribociclib/letrozole)
Prescriber provides documentation of **ALL** of the following:
1. Member has a diagnosis of HR-positive, HER2 negative advanced or metastatic breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing

Nerlynx® (neratinib)
<u>Adjuvant Therapy for Early Stage Breast Cancer*</u>
Prescriber provides documentation of **ALL** of the following:
1. Member is using Nerlynx as extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing

4. Member received trastuzumab therapy within the past two years
5. Quantity requested is ≤ 6 units/day

**Member is limited to one year total therapy with neratinib for adjuvant treatment.*

Treatment of Advanced or Metastatic Breast Cancer
Prescriber provides documentation of **ALL** of the following:

1. Member has a diagnosis of advanced or metastatic HER2-positive breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Paid claims or physician attestation of inadequate response or adverse reaction to two anti-HER2-based regimens *(e.g., Herceptin® [trastuzumab], Kadcyla® [ado-trastuzumab emtansine], and Perjeta® [pertuzumab])*
5. Requested agent will be used in combination with capecitabine
6. Quantity requested is ≤ 6 units/day

Piqray® (alpelisib)
Prescriber provides documentation of **ALL** of the following:

1. Member has a diagnosis of HER2-negative, HR-positive, PIK3CA-mutated breast cancer in men and postmenopausal women (See Appendix A)
2. Prescriber is an oncologist
3. Appropriate dosing
4. Member has disease that progressed following treatment with endocrine-based therapy†
5. Requested agent will be used in combination with fulvestrant

†*Endocrine therapy may include aromatase inhibitor (e.g. letrozole, anastrazole), tamoxifen, fulvestrant.*

Tukysa® (tucatinib)
HER2 positive breast cancer (advanced unresectable or metastatic)
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Requested agent will be used in combination with trastuzumab and capecitabine
5. Paid claims or physician attestation of inadequate response or adverse reaction to ONE anti-HER2-based regimen *(e.g., Herceptin® [trastuzumab], Kadcyla® [ado-trastuzumab emtansine], and Perjeta® [pertuzumab])*
6. Quantity requested is ≤ 4 tablets/day

Verzenio® (abemaciclib)
HR-positive, HER2-negative breast cancer (advanced or metastatic)
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. **ONE** of the following:
    a. Paid claims or physician documentation of concomitant treatment with an aromatase inhibitor *(e.g., letrozole, anastrazole, exemestane)*
    b. Paid claims or physician documentation of concomitant drug therapy with fulvestrant

c. Requested agent will be used as monotherapy when disease has progressed after both hormonal therapy and chemotherapy

5. Quantity requested is ≤ 2 tablets/day

HR-positive, HER2-negative **early** breast cancer
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. **ONE** of the following:
   a. Paid claims or physician documentation of concomitant treatment with an aromatase inhibitor *(e.g., letrozole, anastrazole, exemestane)*
   b. Paid claims or physician documentation of concomitant drug therapy with tamoxifen
5. Quantity requested is ≤ 2 tablets/day

Continuation of Therapy
Reauthorization will be granted when physician provides attestation of positive response to therapy.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months
2. Requests for Nerlynx® (neratinib) for adjuvant treatment may be approved for a **maximum total duration of 1 year only**.
3. Requests for Verzenio® (abemaciclib) for adjuvant treatment of early breast cancer may be approved for a **maximum total duration of 2 years only**.
4. The following quantity limits apply:

Ibrance tablets	30 tablets per 30 days
Nerlynx tablets	180 tablets per 30 days
Tukysa tablets	120 tablets per 30 days
Verzenio tablets	60 tablets per 30 days

Appendix

Appendix A: Requests Which Do Not Clearly Document Postmenopausal Status
The NCCN Guideline for the Treatment of Breast Cancer defines menopause as one of the following:

- Prior bilateral oophorectomy
- Age ≥60 years
- Age <60 years and amenorrheic for 12 or more months in the absence of chemotherapy, tamoxifen, toremifene, or ovarian suppression and FSH and estradiol in the postmenopausal range
- If taking tamoxifen or toremifene, and age <60 years, then FSH and plasma estradiol level in the postmenopausal range

References

1. Tykerb (lapatinib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2021.
2. Ibrance (palbociclib) [prescribing information]. New York, NY: Pfizer Labs; November 2019.
3. Kisqali (ribociclib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; September 2021.

4. Kisqali Femara Co-Pack (ribociclib and letrozole) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2021.
5. Piqray (alpelisib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2021.
6. Nerlynx (neratinib) [prescribing information]. Los Angeles, CA: Puma Biotechnology Inc; June 2021.
7. Tukysa (tucatinib) [prescribing information]. Bothell, WA: Seattle Genetics Inc; April 2020.
8. Verzenio (abemaciclib) [prescribing information]. Indianapolis, IN: Lilly USA, LLC; October 2021.

Review History

11/17/2021 – Created and Reviewed for Nov P&T. matched with MH UPPL. Effective 01/01/2022
06/22/2022 - Reviewed and updated for June P&T; matched MH UPPL. Criteria update for expanded indication of Verzenio for adjuvant treatment (with endocrine therapy: tamoxifen or an aromatase inhibitor) of adults patients with HR+, HER2-, node-positive, early breast cancer as high risk of recurrence and a Ki-67 score of 20% or higher. Criteria stating "Member is postmenopausal or has received ovarian ablation or suppression" was removed throughout guideline where appropriate. Effective 08/01/22.

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