Breast Cancer Therapies
Effective 01/01/2022

<table>
<thead>
<tr>
<th>Plan</th>
<th>Program Type</th>
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<tbody>
<tr>
<td>☐ MassHealth</td>
<td>☒ Prior Authorization</td>
</tr>
<tr>
<td>☒ MH UPPL</td>
<td>☒ Quantity Limit</td>
</tr>
<tr>
<td>☐ Commercial/Exchange</td>
<td>☐ Step Therapy</td>
</tr>
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<table>
<thead>
<tr>
<th>Benefit</th>
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<tbody>
<tr>
<td>☒ Pharmacy Benefit</td>
<td></td>
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<tr>
<td>☐ Medical Benefit (NLX)</td>
<td></td>
</tr>
</tbody>
</table>

| Specialty Limitations| This medication has been designated specialty and must be filled at a contracted specialty pharmacy. |

<table>
<thead>
<tr>
<th>Contact Information</th>
<th>Specialty Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Plans</td>
<td>Phone: 866-814-5506</td>
</tr>
<tr>
<td></td>
<td>Fax: 866-249-6155</td>
</tr>
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<table>
<thead>
<tr>
<th>Non-Specialty Medications</th>
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<tbody>
<tr>
<td>MassHealth</td>
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<tr>
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<tr>
<td>Commercial</td>
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<tr>
<td>Exchange</td>
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<tr>
<th>Medical Specialty Medications (NLX)</th>
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<tbody>
<tr>
<td>All Plans</td>
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| 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 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:

<table>
<thead>
<tr>
<th>No PA</th>
<th>Drugs that require PA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tykerb® (lapatinib)</td>
<td>Ibrance® (palbociclib)\textsuperscript{PD}</td>
</tr>
<tr>
<td></td>
<td>Kisqali® (ribociclib)</td>
</tr>
<tr>
<td></td>
<td>Kisqali-Femara® Co-Pack (ribociclib/letrozole)</td>
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<tr>
<td></td>
<td>Nerlynx® (neratinib)</td>
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<tr>
<td></td>
<td>Piqray® (alpelisib)</td>
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<tr>
<td></td>
<td>Tukysa® (tucatinib)</td>
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<tr>
<td></td>
<td>Verzenio® (abemaciclib)</td>
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</tbody>
</table>
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. If applicable, member is postmenopausal or has received ovarian ablation or suppression (See Appendix A)
5. **ONE** of the following:
   a. Concomitant drug therapy with an aromatase inhibitor (anastrazole, letrozole, exemestane)
   b. Concomitant drug therapy with fulvestrant
6. Quantity requested of ≤1 unit/day

**Kisqali® (ribociclib)**
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, letrozole, 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 HER2-negative, HR-positive breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Member is postmenopausal or has received ovarian ablation or suppression (See Appendix A)

**Nerlynx® (neratinib)**
Adjuvant Therapy for Early Stage Disease*
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
   Prescriber is an oncologist
2. Appropriate dosing
3. Member received trastuzumab therapy within the past two years
4. Quantity requested is $\leq 6$ units/day

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

Treatment of Metastatic Disease
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 (*Herceptin*, *Kadcyla*, *Perjeta*)
5. Requested agent will be used in combination with capecitabine
6. Quantity requested is $\leq 6$ 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. Inadequate response or adverse reaction to one anti-HER2-based regimen (*Herceptin*, *Kadcyla*, *Perjeta*)
6. Quantity requested is $\leq 4$ tablets/day

**Verzenio® (abemaciclib)**
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. Member is postmenopausal or has received ovarian suppression or ablation (See Appendix A)
5. ONE of the following:
   a. Pharmacy claims or physician documentation of concomitant treatment with an aromatase inhibitor (e.g. *letrozole*, *anastrozole*, *tamoxifen*, *fulvestrant*)
b. Pharmacy 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

6. Quantity requested is ≤ 2 tablets/day

**Continuation of Therapy**
Reauthorization will be granted when physician provides attestation of positive response to therapy.
- Requests for Nerlynx® (neratinib) for adjuvant treatment may be approved for a **maximum total duration of 1 year only**.

**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. The following quantity limits apply:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibrance tablets</td>
<td>30 tablets per 30 days</td>
</tr>
<tr>
<td>Nerlynx tablets</td>
<td>180 tablets per 30 days</td>
</tr>
<tr>
<td>Tukysa tablets</td>
<td>120 tablets per 30 days</td>
</tr>
<tr>
<td>Verzenio tablets</td>
<td>60 tablets per 30 days</td>
</tr>
</tbody>
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**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.
3. Kisqali (ribociclib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; September 2021.
5. Piqray (alpelisib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2021.
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
Disclaimer
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