Mass General Brigham
Health Plan

Breast Cancer Therapies
Effective 03/04/2024

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	Some medications have been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	Enhertu, Faslodex, Halaven, Kadcyla, Margenza, Perjeta, Phesgo, and Trodelvy are only available through the medical benefit. All other drugs will be available through the pharmacy benefit.		

Overview

No PA	Drugs that require PA
Arimidex® # (anastrozole)	Afinitor®(everolimus2.5 mg, 5 mg, 7.5 mg, 10 mg)†
Aromasin®# (exemestane)	Afinitor Disperz®(everolimus tablets for oral suspension) †
Fareston®# (toremifene)	Enhertu®(fam-trastuzumab deruxtecan-nxki) MB
Femara®# (letrozole)	Faslodex®(fulvestrant) *MB
Navelbine® # (vinorelbine)	Halaven®(eribulin) MB
Soltamox®(tamoxifen solution)	Ibrance® (palbociclib)PD
tamoxifen tablet	Kadcyla® (ado-trastuzumab) MB
Tykerb®# (lapatinib)	Kisqali® (ribociclib)
	Kisqali-Femara® Co-Pack (ribociclib/letrozole)
	Margenza®(margetuximab-cmkb) MB
	Nerlynx® (neratinib)
	Orserdu® (elacestrant)
	Perjeta® (pertuzumab) MB
	Phesgo®(pertuzumab/trastuzumab/hyaluronidase-zzxf) MB
	Piqray® (alpelisib)
	Trodelvy®(sacituzumab govitecan-hziy) MB
	Tukysa® (tucatinib)
	Verzenio® (abemaciclib)

#This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
†Afinitor®(everolimus) products are reviewed in the Kinase Inhibitors guideline.
*A-rated generic available. Both brand and A-rated generic require PA.

[PD] Preferred Drug. In general, requires 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
MB - Medical Benefit

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members new to the plan 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:

Enhertu® (fam-trastuzumab deruxtecan-nxki)
ONE of the following:
1. Diagnosis of unresectable or metastatic HER2-positive breast cancer
    a. Prescriber is an oncologist
    b. Appropriate dosing (weight required)
    c. 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), agents that are used in combination would count as one regimen)
2. Diagnosis of locally advanced or metastatic HER2-postive gastric or GEJ adenocarcinoma
    a. Prescriber is an oncologist
    b. Appropriate dosing (weight required)
    c. Paid claims or physician attestation of inadequate response or adverse reaction to a trastuzumab-based regimen
3. Diagnosis of unresectable or metastatic HER2-low (IHC 1+ or ICH2+/ISH-) breast cancer
    a. Prescriber is an oncologist
    b. Appropriate dosing (weight required)
    c. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** prior chemotherapy regimen *(e.g. anthracyclines [doxorubicin, liposomal doxorubicin], taxanes [paclitaxel], anti-metabolites [capecitabine, gemcitabine], microtubule inhibitors [vinorelbine, eribulin])*
4. Diagnosis of unresctable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating HER2 (ERBB2) mutations
    a. Prescriber is an oncologist
    b. Appropriate dosing (weight required)
    c. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** prior systemic therapy

Faslodex® (fulvestrant)
ALL of the following:
1. Diagnosis of **ONE** of the following:
    a. HR-positive advanced or metastatic breast cancer
    b. Advanced or metastatic breast cancer with past trials of antiestrogen therapy *(e.g., tamoxifen, anastrazole, letrozole, exemestaine)*
2. Prescriber is an oncologist
3. Appropriate dosing

4. **ONE** of the following:
    a. Member is HER2-negative and **ONE** of the following:
        i. Requested agent will be used as monotherapy
        ii. Requested agent will be used in combination with a CDK inhibitor *(e.g. abemaciclib, palbociclib or ribociclib)*
        iii. Concomitant therapy with anastrazole or letrozole
    b. Member is HER2-positive and **ONE** of the following:
        i. Requested agent will be used as monotherapy
        ii. Requested agent will be used in combination with trastuzumab
5. If request is for Brand Name Faslodex®, prescriber must also provide medical records documenting an inadequate response or adverse reaction to generic fulvestrant (as per the Brand Name and Non-Preferred Generic Drugs guideline)

Halaven® (eribulin)
ONE of the following:
1. Diagnosis of metastatic or recurrent breast cancer
    a. Prescriber is an oncologist
    b. Appropriate dosing (height and weight or BSA is required)
    c. Two prior chemotherapy regimens that included a taxane and an anthracycline
    d. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to vinorelbine (may have been part of the previous chemotherapy regimens)
2. Diagnosis of unresectable or metastatic liposarcoma
    a. Prescriber is an oncologist
    b. Appropriate dosing (height and weight or BSA is required)
    c. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to an anthracycline-containing regimen

Ibrance® (palbociclib)
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. Requested agent will be used in combination with an aromatase inhibitor (anastrazole, letrazole, exemestane)
    b. Requested agent will be used in combination with fulvestrant
5. Quantity requested of ≤1 unit/day

Kadcyla® (ado-trastuzumab)
ALL of the following:
1. Diagnosis of HER2-positive breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. **ONE** of the following:
    a. Member has recurrent or metastatic breast cancer AND paid claims or physician attestation of inadequate response or adverse reaction to trastuzumab and a taxane, separately or in combination

b. Member has early breast cancer (EBC) and residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment

Kisqali® (ribociclib)
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. Requested agent will be used in combination with an aromatase inhibitor (anastrazole, letrazole, exemestane)
    b. Requested agent will be used in combination with fulvestrant

Kisqali-Femara® Co-Pack (ribociclib/letrozole)
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

Margenza® (margetuximab-cmkb)
ALL of the following:
1. Diagnosis of HER2-positive metastatic breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Requested agent will be used in combination with chemotherapy (capecitabine, eribulin, gemcitabine or vinorelbine)
5. Paid claims or physician attestation of inadequate response or adverse reaction to at least **TWO** anti-HER2-based regimens (e.g., Herceptin®(trastuzumab), Kadcyla®(ado-trastuzumab emtansine), and Perjeta®(pertuzumab), agents that are used in combination would count as one regimen)

Nerlynx® (neratinib)
ONE of the following:
1. Member is using Nerlynx as extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer (*Member is limited to one year total therapy with neratinib for adjuvant treatment*)
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Member received trastuzumab therapy within the past two years
    d. Quantity requested is ≤ 6 units/day
2. Member has a diagnosis of advanced or metastatic HER2-positive breast cancer
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. 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), agents that are used in combination would count as one regimen)
    d. Requested agent will be used in combination with capecitabine
    e. Quantity requested is ≤ 6 units/day

Orserdu® (elacestrant)
ALL of the following:
1. Diagnosis of ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Paid claims or physician attestation of inadequate response or adverse reaction to ONE line of endocrine therapy containing a CDK4/6 inhibitor **
5. **ONE** of the following:
    a. For Orserdu 86 mg tablets, requested quantity is ≤ 3 tablets/day
    b. For Orserdu 345 mg tablets, requested quantity is ≤ 1 tablet/day

**Examples include: aromatase inhibitor (letrozole, anastrazole, exemestane) + CDK4/6 inhibitor (ribociclib, abemaciclib or palbociclib), fulvestrant + CDK4/6 inhibitor (ribociclib, abemaciclib or palbociclib)

Perjeta® (pertuzumab)
ALL of the following:
1. Diagnosis of HER2-positive breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. **ONE** of the following:
    a. For recurrent or stage IV disease, requested agent will be used in combination with trastuzumab **AND** docetaxel or paclitaxel
    b. For use is for adjuvant or neoadjuvant chemotherapy, requested agent will be used in combination with trastuzumab **AND** chemotherapy

Phesgo® (pertuzumab/trastuzumab/ hyaluronidase-zzxf)
ALL of the following:
1. Diagnosis of HER2-positive breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. **ONE** of the following:
    a. For early breast cancer, requested agent will be used in combination with chemotherapy
    b. For metastatic breast cancer, requested agent will be used in combination with docetaxel as a first line treatment in a metastatic setting *(e.g., members should not have received prior anti-HER2 therapy)*

Piqray® (alpelisib)
ALL of the following:
1. Member has a diagnosis of HER2-negative, HR-positive, PIK3CA-mutated breast cancer
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.*

Trodelvy® (sacituzumab govitecan-hziy)
ONE of the following:
1. Diagnosis of unresectable locally advanced or metastatic triple negative breast cancer

a. Prescriber is an oncologist
b. Appropriate dosing
c. Paid claims or physician attestation of inadequate response or adverse reaction to at least **TWO** prior systemic therapies, at least one for metastatic disease *(See Appendix for previous therapies)*

2. Diagnosis of locally advanced or metastatic urothelial cancer
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Inadequate response or adverse reaction to a platinum containing regimen **AND** a PD-1 or PD-L1 inhibitor
3. Diagnosis of HR-positive, HER2-negative unresectable locally advanced or metastatic breast cancer
    a. Prescriber is an oncologist
    b. Appropriate dosing
    a. Inadequate response, adverse reaction to **ONE** or contraindication to **ALL** endocrine-based therapies *(See Appendix for previous therapies)*
    c. Inadequate response or adverse reaction to **TWO** prior non-endocrine-based systemic therapies in the metastatic setting *(See Appendix for previous therapies)*

Tukysa® (tucatinib)
ALL of the following:

1. Diagnosis of HER2-positive, advanced unresectable or metastatic breast cancer
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Requested agent will be used in combination with trastuzumab and capecitabine
    d. 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), agents that are used in combination would count as one regimen)
    e. Quantity requested is ≤ 4 tablets/day
2. Diagnosis of RAS wild-type (WT), HER2-positive unresectable or metastatic colorectal cancer
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following regimens (see Appendix):
        i. CAPEOX
        ii. FOLFOX
        iii. FOLFIRI
        iv. FOLFOXIRI
        v. FOLFIRINOX
        vi. irinotecan-based therapy
        vii. oxaliplatin-based therapy
    d. Requested agent will be used in combination with trastuzumab
    e. Requested quantity is ≤ 4 tablets/day

Verzenio® (abemaciclib)
ONE of the following:

1. Diagnosis of HR-positive, HER2-negative, advanced, or metastatic breast cancer
    a. Prescriber is an oncologist
    b. Appropriate dosing

c. **ONE** of the following:
    i. Requested agent will be used in combination with an aromatase inhibitor *(e.g., letrozole, anastrazole, exemestane)*
    ii. Requested agent will be used in combination with fulvestrant
    iii. Requested agent will be used as monotherapy when disease has progressed after both hormonal therapy and chemotherapy
d. Quantity requested is ≤ 2 tablets/day

2. Diagnosis of HR-positive, HER2-negative **early** breast cancer
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. **ONE** of the following:
        i. Requested agent will be used in combination with an aromatase inhibitor *(e.g., letrozole, anastrazole, exemestane)*
        ii. Requested agent will be used in combination with tamoxifen
    d. 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. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
5. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.
6. 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
Orserdu tablets	90 tablets per 30 days (86mg) 30 tablets per 30 days (345mg)

Appendix

Previous Trials for Trodelvy® (sacituzumab govitecan-hziy) in triple negative breast cancer (TNBC)

- Anthracyclines: doxorubicin, liposomal doxorubicin
- Anti-metabolites: capecitabine, gemcitabine
- Cyclophosphamide
- Epirubicin
- Ixabepilone
- Microtubule inhibitors: vinorelbine, eribulin
- Platinum: carboplatin, cisplatin
- Taxanes: paclitaxel, docetaxel, albumin-bound paclitaxel
- For germline BRCA1/BRCA2 mutations: olaparib or talazoparib
- For PD-L-1-positive TNBC: pembrolizumab + chemotherapy (albumin-bound paclitaxel, paclitaxel, or gemcitabine and carboplatin)

The following agents are considered useful under certain circumstances per the NCCN guidelines. Each regimen should be considered as one trial.

- Carboplatin + paclitaxel or albumin-bound paclitaxel
- Cyclophosphamide/methotrexate/fluorouracil
- Docetaxel/capecitabine
- Doxorubicin/cyclophosphamide
- Epirubicin/cyclophosphamide
- Gemcitabine/carboplatin
- Gemcitabine/paclitaxel
  Gemcitabine/paclitaxel

Previous Trials for Trodelvy® (8acituzumab govitecan-hziy) (locally advanced or metastatic, HR-positive HER2-negative breast cancer

Endocrine-based therapy:

Preferred Regimens

First-line

- Aromatase inhibitor + CDK 4/6 inhibitor
  - Aromatase inhibitor + ribociclib
  - Aromatase inhibitor + abemaciclib
  - Aromatase inhibitor + palbociclib
- Fulvestrant + CDK 4/6 inhibitor
  - Fulvestrant+ ribociclib
  - Fulvestrant+ abemaciclib
  - Fulvestrant+ palbociclib

Second- and Subsequent-Line Therapy

- Fulvestrant + CDK 4/6 inhibitor (if CDK 4/6 inhibitor was not previously used)
- Everolimus + endocrine therapy (exemestane, fulvestrant, tamoxifen)

Other Recommended Regimens

- Selective ER down-regulator
  - Fulvestrant
- Selective ER down-regulator
  - Fulvestrant + anastrazole
  - Fulvestrant + letrozole
- Non-steroidal aromatase inhibitor
  - anastrozole

    - Letrozole
- Selective ER modulator
    - tamoxifen
- Steroidal aromatase inactivator
    - Exemestane

Useful in Certain Circumstances

- Megestrol
- Estradiol
- Additional targeted therapy options

Systemic Chemotherapy:

Preferred

- Anthracycline (doxorubicin, liposomal doxorubicin)
- Taxanes: (paclitaxel, docetaxel, albumin-bound paclitaxel)
- Anti-metabolites (capecitabine, gemcitabine)
- Microtubule inhibitors (vinorelbine, eribulin)

Other Recommended

- Cyclophosphamide
- Docetaxel
- Albumin-bound paclitaxel
- Epirubicin
- Ixabepilone

Useful in Certain Circumstances

- AC (doxorubicin/cyclophosphamide)
- EC (epirubicin/cyclophosphamide)
- CMF (cyclophosphamide/ methotrexate/fluorouracil)
- Docetaxel/capecitabine
- GT (gemcitabine/paclitaxel)
- Gemcitabine/carboplatin
- Carboplatin + paclitaxel or albumin-bound paclitaxel
- For germline BRCA1/BRCA2 mutations: olaparib or talazoparib

Components of Commonly Used Regimens for Treatment of Colorectal Cancer

Regimen Abbreviation	Drug Components
5-FU	fluorouracil
CAPEOX	capecitabine/oxaliplatin
FOLFIRI	leucovorin calcium (folinic acid)/fluorouracil/irinotecan
FOLFOX	leucovorin calcium (folinic acid)/fluorouracil/oxaliplatin
FOLFOXIRI/FOLFIRINOX	leucovorin calcium (folinic acid)/5-fluorouracil/oxaliplatin/irinotecan

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.
9. Orserdu® (elacestrant) [package insert]. New York (NY): Stemline Therapeutics, Inc; 2023 Feb.

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.
01/11/2023 – Reviewed and updated for Jan P&T. Updated PA table to include Tykerb, Afinitor, Afinitor Disperz. Updated verbiage of combination therapy throughout. Listed out indications within criteria."Requests which do not clearly document postmenopausal status" appendix was removed. Effective 3/1/23.
03/15/23 - Reviewed and updated for Mar P&T. Matched MH UPPL criteria. Added criteria for the following: Enhertu, Faslodex, Halaven, Kadcyla, Margenza, Perjeta, Phesgo, Trodelvy. Added Appendix "Previous Trials for Trodelvy." Effective 4/1/23.
05/10/23 – Reviewed and updated for P&T. Orserdu (elacestrant) was added to policy for the treatment of postmenopausal women or adult men with ER-positive, HER2-negative, ESR1- mutated advanced or metastatic breast cancer (mBC) with disease progression following at least one line of endocrine therapy. Effective 6/5/23.
06/30/23 – Reviewed and updated for P&T. Admin update: Clarified that Trodelvy is available through pharmacy and medical benefits (dual). Effective 6/30/23
7/12/23 – Reviewed and updated for P&T. Added expanded indication for Tukysa in combination with trastuzumab for RAS WT, HER2-positive unresectable or metastatic colorectal cancer. Added expanded indication for Trodelvy for HR-positive, HER2-negative unresectable locally advanced or metastatic breast cancer. A MH decision was made to have Trodelvy be available under medical benefit only. Effective 7/31/23
02/14/24 – Reviewed and updated for P&T. Updated Trodelvy criteria (MB) to be more in line with FDA-labeled indications. Updated Appendix for Trodelvy acceptable previous trials. Enhertu is removed from pharmacy benefit and will only be available on Medical benefit with PA. Effective 3/4/24