

Breast Cancer Therapies
Datroway (datopotamab deruxtecan-dlnk)
Enhertu (fam-trastuzumab deruxtecan-nxki)
Faslodex (fulvestrant)
Halaven (eribulin)
Kadcyla (ado-trastuzumab)
Margenza (margetuximab-cmkb)
Perjeta (pertuzumab)
Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf)
Trodelvy (sacituzumab govitecan-hziy)
Effective 07/01/2025

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
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
Notes	Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview

Datroway (datopotamab deruxtecan-dlnk) is indicated for the treatment of adult patients with unresectable or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.

Enhertu (fam-trastuzumab deruxtecan-nxki) is a HER2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of:

- Adult members with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen either:
 - in the metastatic setting, or
 - in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within six months of completing therapy
- Adult members with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen .
- Adult members with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.

- Adult members with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating human epidermal growth factor receptor 2 HER2 (ERBB2) mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy.

Faslodex (fulvestrant) is Food and Drug Administration (FDA)-approved for the treatment of:

- Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2) negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy.
- HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy.
- HR-positive, HER2-negative advanced or mBC in postmenopausal women in combination with ribociclib, as initial endocrine-based therapy or following disease progression on endocrine therapy.
- HR-positive, HER2-negative advanced or mBC in combination with palbociclib or abemaciclib in women with disease progression after endocrine therapy.

Halaven (eribulin) is classified as a non-taxane microtubule inhibitor and is believed to work by inhibiting cancer cell growth. It is indicated for:

- the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease.
- the treatment of patients with unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.

Kadcyla (ado-trastuzumab emtansine), also known as T-DM1, is FDA-approved as single agent therapy for the treatment of patients with HER2-positive mBC who previously received trastuzumab and a taxane, separately or in combination.

Margenza (margetuximab-cmkb) is indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

Perjeta (pertuzumab) is a HER2/neu receptor antagonist that is FDA-approved for use in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive mBC who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) is indicated for use in combination with chemotherapy as neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer (EBC) and adjuvant treatment of adult patients with HER2-positive EBC at high risk of recurrence.

Trodelyv (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior therapies, at least one of them for metastatic disease.

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:

Datroway (datopotamab deruxtecan-dlnk)

1. Diagnosis of HR-positive, HER2-negative unresectable locally advanced or metastatic breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Inadequate response or adverse reaction to ONE or contraindication to ALL endocrine-based therapies
5. Inadequate response or adverse reaction to TWO prior non-endocrine-based systemic therapies in the metastatic setting
6. If HER2 IHC 0+, 1+, or 2+/ISH negative (HER2-low) breast cancer, inadequate response, adverse reaction, or contraindication to Enhertu (fam-trastuzumab deruxtecan-nxki)

Enhertu (fam-trastuzumab deruxtecan-nxki)

HER2-Positive Metastatic Breast Cancer

1. Diagnosis of unresectable or metastatic HER2-positive breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing (weight required)
4. 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)

Metastatic Gastric or GEJ Adenocarcinoma

1. Diagnosis of locally advanced or metastatic HER2-positive gastric or GEJ adenocarcinoma
2. Prescriber is an oncologist
3. Appropriate dosing (weight required)
4. Inadequate response or adverse reaction to a trastuzumab-based regimen

HER2-Low Metastatic Breast Cancer

1. Diagnosis of unresectable or metastatic HER2-low (IHC 1+ or IHC2+/ISH-) breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing (weight required)
4. 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])

Non-Small Cell Lung Cancer (NSCLC)

1. Diagnosis of unresectable or metastatic NSCLC whose tumors have activating HER2 (ERBB2) mutations
2. Prescriber is an oncologist
3. Appropriate dosing (weight required)
4. Inadequate response or adverse reaction to ONE prior systemic therapy



Solid Tumors

1. Diagnosis of unresectable or metastatic HER2-positive (IHC 3+) solid tumor
2. Prescriber is an oncologist
3. Appropriate dosing (weight required)
4. ONE of the following:
 - a. Inadequate response or adverse reaction to ONE prior systemic therapy (refer to latest NCCN guidelines for guidance of prior systemic therapy options)
 - b. Member has no satisfactory alternative treatment options

Faslodex (fulvestrant)

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, anastrozole, letrozole, exemestane)
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 anastrozole 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

Halaven (eribulin)

Metastatic or Recurrent Breast Cancer

1. Diagnosis of metastatic or recurrent breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing (height and weight or BSA is required)
4. Inadequate response or adverse reaction to TWO prior chemotherapy regimens that included a taxane and an anthracycline
5. Inadequate response, adverse reaction or contraindication to vinorelbine (may have been part of the previous chemotherapy regimens)

Unresectable or Metastatic Liposarcoma

1. Diagnosis of unresectable or metastatic liposarcoma
2. Prescriber is an oncologist
3. Appropriate dosing (height and weight or BSA is required)
4. Inadequate response, adverse reaction or contraindication to an anthracycline-containing regimen

Kadcyla (ado-trastuzumab)

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 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

Margenza (margetuximab-cmkb)

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. 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)

Perjeta (pertuzumab)

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. Use is for adjuvant or neoadjuvant chemotherapy, requested agent will be used in combination with trastuzumab AND chemotherapy

Phesgo (pertuzumab/trastuzumab/ hyaluronidase-zzxf)

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)

Trodelvy (sacituzumab govitecan-hziy)

Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer

1. Diagnosis of unresectable locally advanced or metastatic triple negative breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Inadequate response or adverse reaction to at least TWO prior systemic therapies, at least one for metastatic disease (See Appendix for previous therapies)

HR-Positive, HER2-Negative Unresectable Locally Advanced or Metastatic Breast Cancer

1. Diagnosis of HR-positive, HER2-negative unresectable locally advanced or metastatic breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing



4. Inadequate response or adverse reaction to ONE or contraindication to ALL endocrine-based therapies (See Appendix for previous therapies)
5. Inadequate response or adverse reaction to TWO prior non-endocrine-based systemic therapies in the metastatic setting (See Appendix for previous therapies)
6. If HER2 IHC 0+, 1+, or 2+/ISH negative (HER2-low) breast cancer, inadequate response, adverse reaction, or contraindication to Enhertu (fam-trastuzumab deruxtecan-nxki)

Continuation of Therapy

Reauthorization by prescriber will infer a positive response to therapy.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.

References

1. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Version 4.2024 [guideline on the internet]. 2024 Jul 3 [cited 2024 Aug 8]. Available from: http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf.
2. Enhertu [prescribing information]. Basking Ridge (NJ): Daiichi Sanko, Inc; 2024 Apr.
3. NCCN. Clinical Practice Guidelines in Oncology for Gastric Cancer. Version 3.2024; 2024 Jul 30 [cited 2024 Aug 8]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf.
4. NCCN. Clinical Practice Guidelines in Oncology for Esophageal and Esophagogastric Junction Cancers. Version 4.2024; 2024 Jul 30 [cited 2024 Aug 8]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf.
5. NCCN. Clinical Practice Guidelines in Oncology for Non-Small Cell Lung Cancer. Version 7.2024; 2024 Jun 26 [cited 2024 Aug 8]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf.
6. Faslodex [package insert]. Wilmington (De): AstraZeneca Pharmaceuticals, Inc; 2020 Sep.
7. Halaven [package insert on the Internet]. Woodcliff Lake (NJ): Eisai Inc; 2022 Sep.
8. NCCN Practice Guidelines in Oncology. Soft Tissue Sarcoma [guideline on the Internet]. Version 2.2024. 2024 Jul 31 [cited 2024 Aug 8]. Available from: http://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf.
9. Kadcyla [package insert]. South San Francisco (CA): Genentech, Inc.; 2024 Jul.
10. Verma S, Gianni Luca, Krop IE, Welslau M, Baselga J, Pegram M, et al. Trastuzumab Emtansine for HER2-Positive Advanced Breast Cancer. *N Engl J Med*. 2012;367:1783-91.
11. Margenza (margetuximab-cmkb) [prescribing information]. Rockville (MD): MacroGenics, Inc.; 2023 May
12. Perjeta [package insert]. South San Francisco (CA): Genentech, Inc.; 2020 Oct. 17. Baselga J, Cortés J, Kim SB, Im SA, Hegg R, Im YH, et al. Pertuzumab plus trastuzumab plus docetaxel for metastatic breast cancer. *N Engl J Med*. 2012 Jan 12;366(2):109-19.
13. Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) [prescribing information]. South San Francisco (CA): Genentech, Inc.; 2022 Nov.
14. Trodelvy (sacituzumab govitecan-hziy) [prescribing information]. Morris Plains (NJ): Immunomedics, Inc.; 2024 Apr.
15. National Comprehensive Cancer Network. NCCN Practice Guidelines in Oncology Bladder Cancer. Version 4.2024. 2024 May 9 [cited 2024 Aug 8]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf.

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

12/11/24 – Reviewed and updated for P&T. Separated criteria Rx vs MB drugs. Added expanded indication for Enhertu in adults with unresectable or metastatic HER2-positive (IHC 3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options. Effective 1/6/25

06/11/25 – Reviewed and updated for P&T. Removed diagnosis of adults with locally advanced or metastatic urothelial cancer from Trodelvy due to indication withdrawal. Datroway added to criteria. Added another step-through with Enhertu for requests for Trodelvy if HER2 IHC 0+, 1+, or 2+/ISH negative (HER2-low) breast cancer. Updated reauth criteria to align with MH. Removed Appendix as info can be found on NCCN. Effective 7/1/25

